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Patents Bill gets RS approval

By Our Special Correspondent

NEW DELHI, Dec. 22.

With a determined shove from the Congress (I), the Vajpayee Government late tonight secured the Rajya Sabha's approval for the Patents Bill, the first step towards meeting the April 1999 deadline of fulfilling commitments to the WTO. The victory for the Treasury Benches did not come before the Congress(I) was able to underscore the Vajpayee Government's precariousness and the coalition regime's dependence upon the Congress(I) goodwill. At the same time, some incidents at the time of protracted clause by clause voting exposed the unease nursed by some in BJP and Congress(I) ranks.

The Rajya Sabha's approval became imminent once the Government agreed to accept a Congress(I) amendment to Section 24 (A)(3) to read: "provided that an exclusive right to sell or distribute will not be granted for an article or substance which is based on Indian system of medicine and already in the public domain."

Under pressure from a determined non-Congress(I) Opposition, the Bill and earlier a few amendments were put to vote. For the Bill proper, the voting machine recorded 43 votes against and 83 in favour. Some votes were unaccounted for because of the members' unfamiliarity with the procedure. But the die was cast earlier, as soon as the first amendment by the Left for sending the Bill to a select committee was put to vote. In this case voting slips were also counted and the total read 47 in favour of moving the amendment and 99 against.

The passage of the Bill was not without a few embarrassing moments for both the Congress (I) and the BJP. Apprehending a break in ranks, Mr. Pranab Mukherjee interrupted his party colleague, Mr. Vyalar Ravi, who was in the process of withdrawing his amendments. "You are not moving anything," he curtly ordered. After the inevitable protests by the Left, Mr. Ravi later explained that all he was saying that since the Union Industry Minister, Mr. Sikandar Bakht, had acquiesced, he was withdrawing a certain amendment.

Similarly the BJP's Mr. K. R. Malkani was undecided till the last moment and sought Mr. Bakht's direction on the issue. With Mr. Bakht declining to get involved, Mr. Malkani read the writing on the wall and withdrew the proposed change. At the end, the only change allowed was the one which secured Congress(I) support for the Patents Bill.

In the morning, under the explicit "direction and initiative" of the Congress(I) president, Mrs. Sonia Gandhi, the party found a way of making an omelette without breaking the egg in the matter of the controversial Patents Bill. It made its support conditional upon the Vajpayee Government agreeing to incorporate an amendment that would protect the "Indian system of medicine", thereby denying the Sangh Parivar even the satisfaction of claiming credit for doing its swadeshi USP.

The Congress(I) hit upon the "Indian system of medicine" prescription after a 90-minute discussion this morning by the party's Legislative Affairs Committee, with Mrs. Sonia Gandhi presiding over.

The two seniormost members of the last Congress(I) government — Dr. Manmohan Singh and Mr. Pranab Mukherjee — were most vocal in asserting that the party had no option but to help carry the process they began during the P.V.Narasimha Rao regime to its logical conclusion: the two were dismissive of the dissenters and their argument of protecting the "Indian interests".

However, the two gentlemen fell in line with the "Indian system of medicine" prescription once it dawned upon them that the party president was inclined to steal the Sangh Parivar's "swadeshi clothes". Promptly Mr. P.J.Kurien was asked to draft an appropriate amendment, and he along with Dr. Manmohan Singh were asked to present a kind of demarche to the Industries Minister, Mr. Sikander Bakht. Mr. Bakht promptly agreed to incorporate the Congress(I) amendment as his amendment.

After committing himself to incorporating the Congress(I) amendment, Mr. Bakht informed the BJP's parliamentary wing of his commitment; the Prime Minister who was presiding over the meeting was relieved to be presented with a fait accompli. Later, the Minister for Parliamentary Affairs, Mr. Madan Lal Khurana, also supported Mr. Bakht's commitment, paving the way for the eventual passage of the Patents Bill — courtesy the Congress(I).

The Congress(I) spokesman, Mr. Ajit Jogi, explained that the party was guided by two principles: first, it wanted to uphold India's "long, glorious" tradition of honouring international commitments; and second, the present bill is "almost the same" as was drafted by the Congress(I) government in 1994-95.

The proceedings began with the non-Congress Opposition, chiefly the Left, protesting vehemently that its member had not received copies of the proposed amendments to the Bill while the Congress(I) and the BJP members on the other hand claimed to have received copies of the amendments. Some order could be restored only after the Chairman of the House promised to investigate the matter.

The debate could begin only in the post-lunch session which saw amendments being moved by the non-Congress(I) members. The Opposition's case was summed up by the veteran CPI(M) leader, Dr. Ashok Mitra, who appealed for a consensus particularly in view of the letter to the Prime Minister written by six Chief Ministers requesting for a discussion on the issue as it impinged upon the states' jurisdiction.

Debate details on Page 5

Wider public debate on Patents Bill sought

NEW DELHI, Dec. 22.

Uproar and acrimony preceded debate on the controversial but crucial Patent Amendment Bill in the Rajya Sabha today with the ruling BJP and main Opposition Congress backing it and the Left parties pressing for amendments to refer the measure to a select committee.

Discussion on the Bill had to wait for over 150 minutes which was lost in numerous points of order and lengthy procedural wrangles over members' right to speak on their amendments first.

The Bill, which was moved by the Industry Minister, Mr. Sikander Bakht, after the question hour, soon ran into rough weather when the Left members joined by some JD, RJD and Congress members quoted rules and conventions to demand that amendment movers could make brief observations before start of discussion.

During the heated exchanges, a remark by a ruling party member sparked off an uproar with the Left party members claiming it was directed against a particular State. The matter was finally set to rest when the Chairman, Mr. Krishan Kant, said he apologised as custodian of the House for any "unfortunate" remark and adjourned the House for lunch.

Five amendments were moved suggesting the Bill be referred to a joint parliament select committee as there was time till April to fulfil the WTO obligations. The amendments, moved by Mr. Gurudas Dasgupta (CPI), Mr. Biplab Dasgupta, Mr. Ashok Mitra (CPI-M), Ms. Kamala Sinha (JD) and Mr. Ramashankar Kaushik (SP) also suggested a wider public debate on the Bill.

The Chairman turned down the Left parties' demand for a vote on referring the legislation to a select committee after a 90-minute polemics on the amendments in the post-Lunch session.

Earlier, he also rejected the contention that the Bill could not be taken up for discussion as it had once been referred to a select committee of the House. He ruled it was an old Bill of 1995 which automatically lapsed with the dissolution of the Lok Sabha. Initiating the discussion, Mr. Kapil Sibal (Cong) said contrary to the Left parties' campaign, the Bill provided for adequate safeguards for national interest and security. It would be better for the country to be inside the WTO and negotiate to derive benefits. However, he said his party was opposed to either patent or EMRs for Indian system of medicines.

Mr. Arun Shourie (BJP) said Trips prohibited patenting of animals and plants and pointed out that even in the case of a patent derived by a U.S. company on "healing properties of turmeric" India had succeeded in getting the patent cancelled. Referring to the Basmati patent got by Rice Tec Inc of the U.S., he said it was on a germplasm taken from Pakistan and crossed with a long grain Texan variety. None of the 250 essential drugs shortlisted by WHO would come under the Patents Act amendment, he said and charged those opposing the amendment with being "irrational".

Mr. Ashok Mitra (CPI-M) said, "Even if we do not meet the April 19, 1999 deadline on allowing EMRs there is no question of somebody throwing India out of WTO." The purpose of the Bill was to demolish the safeguards in the Patents Act of 1970.

Stating that the Chief Ministers of Andhra Pradesh, Tamil Nadu, Kerala, Assam, West Bengal and Tripura had written to the Centre not to pass the Patents Bill in a hurry, he said, "You cannot ignore the States." Dr. Raja Ramanna (nominated), supporting the Bill, said there was no need to be afraid of multinational corporations. He regretted that efforts made by Indian scientists were not being appreciated by policymakers. Mr. Vayalar Ravi (Congress) said it would have been better if the Bill had been moved after getting public opinion. — PTI

'People should be informed of global treaties'

EXPRESS NEWS SERVICE

Bangalore, March 13: The National Law School Director Dr N L Mitra said that the Constitution has to be suitably amended, so that people are informed about the International treaties signed by the Government.

Delivering a lecture on 'Post-GATT Situation and Constitutional Governance in India' at Chinmaya Hall here on Saturday, Mitra said India had signed many International treaties for the last 50 years, but the people were kept in the dark. The Constitution also had made provisions so that the treaties were to be made public in Parliament, only if there was a necessity to amend the law.

"For the last 43 years there were seven rounds of talks on GATT, but none of them have been made public. What is in store for the Indians in the latest 'Patent Bill' is also not made public. While a set of burueaucrats signed these treaties, no information was passed to Parliament. It is sad that during the last 43 years, there was not even one page debate on various issues of GATT," Mitra regretted.

Stating that Indian Government always followed a dual policy on economic issues, Mitra said "the Government retained the National policies and suitably amended whenever international policies demanded for a change. During the negotiations also, India never had a proper bargaining. While India succeeded in many political diplomatic issues, it failed miserably in guarding the economic interests," Mitra lamented.

Coming down heavily on the Intelligence Property Protection, Mitra said it was 'Investment Property Protection'. "The monopoly for 20 years over any invention is not given to the scientist, but it is given to the investor who wants to commercially exploit the scientist's invention. So it is not the protection to intelligent property but it is protection for investor's property," Mitra said.

Terming that Indian economy was on cross roads during post-GATT scenario, Mitra said the Indian Government has failed in tackling many of the international economic issues. "The Parliament has passed the 'Process Patent Bill', while there is time till the year 2005 to pass the 'Product Patent Bill'. However, the Parliament has passed 'Exclusive Marketing Rights' (EMR) Bill, which will be effective from April 19, this year. This would shoot up the prices of at least 27 drugs, including life saving drugs used to treat heart patients," he said.

"India also is not ready with the 'Sui-Generi' laws, though the last date to present the law is Dec 31, 1999. Some NGOs have taken interest in this regard. Over 270 Indian medicine herbs are in US and most of them are getting patented. However, India is just watching as a mute spectator," Mitra lamented.

Lok Sabha okays Patents Bill

11-3-99
ET EX

ENS Economic Bureau

New Delhi, Mar 10: The Patents (Amendment) Bill to allow exclusive marketing rights (EMRs) for foreign pharmaceuticals and agro-chemicals firms was passed in the Lok Sabha on Wednesday with the Congress support. The Bill was passed by a voice vote after the Left parties, Janata Dal and Loktantrik Morcha walked out in protest.

The Bill's passage puts the Government in the clear with the World Trade Organisation's (WTO) April 19 deadline for amending the patents legislation to allow EMRs in pharmaceuticals and agro-chemicals.

Industries Minister Sikhandar Bakht, who piloted the Bill through the Lower House, assured members that all necessary safeguards had been incorporated and the Bill would not harm the national interest in any way.

The Rajya Sabha had passed the Patents Bill during the last Parliament session, but the Government could not move the Bill in the Lok Sabha due to a last-minute flip-flop by the Congress which suddenly changed its stance on the Bill.

The Government then decided not to take any chances and issued an Ordinance instead to meet the WTO deadline of April 19, lest the Bill failed to be passed even in the Budget (current) session of Parliament.

The Government has been heavily criticised in the last two days for issuing an Ordinance when the Rajya Sabha had already passed the Bill.

Parliament approves Patents Bill

New Delhi, March 13: The controversial Patents (Amendment) Bill was on Saturday approved by Parliament after it was passed by the Rajya Sabha through a voice vote amidst protest walk out by the non-Congress Opposition.

The Bill was approved after rejecting the statutory resolution moved by senior CPI member Gurudas Dasgupta seeking disapproval of the Presidential Ordinance of January 8. The Bill replacing the Presidential Ordinance was passed by the Lok Sabha on Sunday.

The Bill amending the Patents Act was earlier passed by the Rajya Sabha on December 22 last year. However, it could not be passed in the Lok Sabha. In the meantime, the government amended the Bill further through an Ordinance.

Replying to a four-hour discussion, Industry Minister Sikander Bakht rejected the Opposition charge that the Bill was against national interest and said it was mandatory to get it passed before the April 19 deadline to fulfill the World Trade Organisation commitment.

He discounted the Opposition contention that government had not taken into consideration recommendations of the Law Commission report saying they pertained mostly to product patents while this Bill was on bio-diversity.

The Opposition alleged that the government had kept the House in dark about the recommendations of the Law Commission which said that the provisions of the Bill were detrimental to national interests.

In his reply, Bakht said the government had to secure the passage of the Bill to meet its obligations under the World Trade Organisation. However, he made it clear that the Government was committed to protecting national interests.

"We know we may have to face problems but we have to meet our international obligations," he added.

Bakht said Indian pharmaceutical companies would have to restructure themselves but they have time till 2005 when a new legislation would have to be brought forward to give effect to the country's international obligations in the pharmaceutical sector.

He said he had received the objections of the Law Commission to the Bill from the Prime Minister and had already written to the Commission, replying to doubts raised by it • UNI

Do Drugs Cost Less in India?

Amit Sen Gupta

A comparative analysis of drug prices in India and other countries shows that the average cost of older drugs is highest in India, while newer pharmaceutical products still under patent protection globally, or recently out of its purview, are cheapest in India.

A MAJOR element of the campaign against changing India's patent laws, in order to comply with requirements of the GATT agreement, has focused on the alleged fact that existing prices are lower in India than other countries. Hence, it has been argued that a change in India's patent system would lead to a massive increase in the prices of drugs. This claim has been voiced both by Indian industry associations as well as public interest groups campaigning against the GATT agreement.

While a lot of rhetoric has been used by both sides in this debate, the claims and counter-claims have not always been based on hard facts. In order to put this debate in its proper perspective, an analysis of comparative prices of drugs in different countries is presented here. The countries chosen include four developing countries from South Asia – India, Bangladesh, Pakistan and Sri Lanka, and two countries from the developed world – Canada and the UK. The countries of South Asia were chosen as they, broadly, are at similar stages of development and their economies function under familiar constraints. The two countries in the developed market economies are similar to the extent that both retain strong state support to health care and have mechanisms to regulate cost of health care including those of drugs. India with its liberal process patenting system as regard to pharmaceuticals (now under suspended animation) is the only country in this study not to have a product patent regime as yet (if one discounts the recent amendment which could not be bypassed by parliament).

Drugs chosen for analysis fall under two groups. The first group comprises of six drugs – amoxycillin, co-trimoxazole, diazepam, erythromycin, frusemide and propanolol – which have been in the market for a long time and are not under patent protection (process or product) in the countries analysed. While an analysis based on these six drugs cannot be termed as exhaustive, they are fairly representative of the drugs in the Indian market. Of the five top selling products in the Indian market, formulations of these drugs account for three, and of the top 20 these account for seven, viz, Althrocin, Septran, Roscillin, Novamox, Mox, Ampoxin and Voveran. Althrocin, a formulation of erythromycin, is the top selling brand with an annual turnover of Rs 4.24 crore. The second group comprises three newer drugs, Ranitidine, Diclofenac and Nifedipin, which are still under product patent outside India or have come off patents only recently. These drugs too are fairly representative with formulations based on two of them, Zinetac containing ranitidine and Voveran containing diclofenac, being listed at the sixth and 20th places respectively among top selling products (*ORG Retail Audit*, December 1994).

The retail prices of these drugs have been compared in the six countries. Where different brands have varying prices, the lowest price has been taken for purposes of comparison. In order to show the relative position in different countries, average cost of each basket of drugs (comprising six drugs in the basket of older drugs and three drugs in the case of newer drugs) has been computed. This

TABLE 2: COMPARATIVE COSTS OF NEWER DRUGS
(Patent Protected or Recently Off Patents)

	Cost in $ of 100 Units (Tablets/Capsules)			Average Cost for Basket of Three Drugs Where Cost in India=1	Real GPD Per Capita in Dollars (1991)	Adjusted Cost of Basket of Three Drugs (According to GPD Per Capita)
	Ranitidine	Diclofenac	Nifedipin			
India	3.00	2.00	2.00	1.00	1510.00	1.00
Bangladesh	5.00	2.00	20.00	4.22	1160.00	5.49
Pakistan	14.00	7.00	2.00	3.06	1970.00	2.35
Sri Lanka	63.00	2.00	9.00	8.83	2650.00	5.03
Canada	31.00	30.00	28.00	13.11	19320.00	1.02
UK	73.00	16.00	11.00	12.61	16340.00	1.17

Source: Same as in Table 1.

TABLE 1: COMPARATIVE COSTS OF OLDER DRUGS
(Not Patent Protected)

	Cost in $ of 100 Units (Tablets/Capsules)						Average Cost for Basket of Six Drugs Where Cost in India=1*	Real GDP Per Capita in Dollars (1991)	Adjusted Cost of Basket of Six Drugs (According to GPD Per Capita)**
	Amoxycillin	Cotrimoxazole	Diazepam	Erythromycin	Frusemide	Propanolol			
India	9.00	3.00	3.00	12.00	1.00	3.00	1.00	1510.00	1.00
Bangladesh	6.00	3.00	–	10.00	1.00	1.00	0.77	1160.00	1.00
Pakistan	5.00	3.00	3.00	5.00	0.60	1.00	0.65	1970.00	0.50
Sri Lanka	4.00	1.00	0.14	5.00	0.60	0.60	0.34	2650.00	0.19
Canada	8.00	6.00	0.50	6.00	0.50	–	0.81	19320.00	0.06
UK	7.00	5.00	1.00	6.00	–	–	0.82	16340.00	0.08

* Calculated by taking cost of each drug in India as 1 unit and computing the relative cost in other countries. Then the average of the basket of drugs has been taken. Where data for all drugs not available, average computed on the basis of number of drugs on which data is available.

** Calculated by multiplying average cost with the ratio of GDP per capita in India, with the corresponding figure for each country. This gives a rough measure of the financial impact of buying drugs in each country.

Source: K Balasubramaniam, 'Retail Drug Prices in Asia-Pacific Region', *HAI News*, December 1995.

computation was done by taking the price of each drug as one unit in the case of India. Based on this the relative cost of each of the drugs in the countries studied have then been calculated, and a mean value for each basket calculated from this. To show the real impact of drug prices the relative cost and mean cost adjusted against the GDP per capita has also been shown.

The analysis is shown in Tables 1 and 2. We see from Table 1 that the average cost of older drugs is the highest in India. The cost is three times that in Sri Lanka and even higher than in UK and Canada. Adjusted against GDP per capita, cost of these drugs works out to be five times that in Sri Lanka and 12 to 16 times that in UK and Canada. The position is the complete reverse in the case of newer (patent protected) drugs. Table 2 shows that in the case of these drugs, prices are lowest in India. These drugs are three to 13 times more expensive in the other countries studied. Even when adjusted against GDP per capita the costs of these drugs work out to be the cheapest in India.

This interesting outcome lays bare the half-truths and lies resorted to by the two contending industry associations in the pharmaceutical sector in India, the Indian Drug Manufacturers Association (IDMA) (representing Indian companies) and the Organisation of Pharmaceutical Producers of India (OPPI) (representing multinational companies). The IDMA has consistently argued that drug prices are the lowest in India and a change in patent laws would reverse this position. The above analysis clearly shows that drug prices are lower in India only in the case of patent protected drugs. We find from our study that in the case of other drugs, prices are higher in India than even developed industrialised countries. Given the fact that drugs in the Indian market, which are under product patents globally, account for only 10-12 per cent of total pharmaceutical sales, this means that by and large Indian drugs are costlier.

This is indeed a strange situation as logically India should have an edge over almost any country in the world in this respect. Unlike Pakistan, Bangladesh and Sri Lanka, India has the indigenous capability to manufacture most drugs. Further economies of scale should favour Indian manufacturers in comparison to these south Asian countries, given the larger size of the Indian market. Compared to UK and Canada, Indian manufacturers enjoy the advantage of lower infrastructural and labour costs. A conclusion one can draw is that the industry in India is either unwilling or incapable of passing on the results of these gratuitous circumstances to the consumer. In fact, to the contrary, companies in India (both Indian and MNC) have received a further bonus in 1995 in the form of the new Drug Price Control Order, where price control mechanisms have been further relaxed by drastically reducing the span of control and by increasing the profitability allowed in drugs still under price control. If the industry still wishes to claim that the new DPCO is fair, it would lay itself open to the charge that Indian industry is not globally competitive. This is a factor worth exploring and would point to a high degree of technology obsolescence in the industry.

Table 2 exposes the claims of the OPPI, which argues that a change in Indian patent laws will not affect drug prices significantly. The OPPI has consistently claimed that drug prices for patent protected drugs will be kept in check by India's drug price control system. What our study shows is that in fact India's price control system has been incapable of pegging drug prices even at the level of prices in some developed countries. The comparatively low prices of newer drugs have been in spite of the lax control mechanisms, solely as a result of India's liberal patent laws. Scrapping of the 1970 Indian Patent Act would do away with whatever little relief Indian consumers could avail.

In conclusion, the above study raises some important fundamental issues. It shows that India's drug pricing mechanism has proved to be ineffective in keeping down drug prices. The benefits of the advantage that the Indian pharmaceutical industry enjoys over all other third world nations, in terms of the availability of indigenous technology and a large domestic market, have not been passed on to the consumers. The second point of concern is the tacit support that the industry has received, regarding its claim that drug prices in India are comparatively lower, from some public interest groups opposing any change in India's patent laws. While the tactical necessity of aligning with Indian industry associations like the IDMA is clear, the reasons for adopting their rhetoric in this measure are obscure. It probably points to the need for exercising proper vigilance when such short-term alliances are worked out, lest the charge of co-option be laid at the door of public interest bodies. It also points to the need for such bodies to critically examine arguments put forward by the industry, before putting the stamp of approval in joint platforms.

Drug Prices: Sharp Rise after Decontrol

Wishvas Rane

The sharp rise in drug prices has been facilitated by the new policy adopted by the government on drug pricing.

UNDER the 1995 DPCO, drug units are entitled for 18 per cent post-tax return on net worth if bulk drugs are manufactured from the basic stages, as against 16 per cent in the 1987 DPCO. This rise the drug manufacturers can claim justifiably. The bulk drug units making 6-APA and 7-ADCA intermediates for synthetic penicillin will now have to source penicillin G from local manufacturers to the extent of 70 per cent of their requirement. This government policy shows a clear shift in favour of domestic penicillin G manufacturers. An inevitable outcome of this is likely to be a price increase of semi-synthetic penicillins like ampicillin, amoxycillin and cephalexin.

The drug industry and trade had come to an agreement to increase the trade margins for decontrolled drugs in phases, starting from July 1. The government has decontrolled a total of 67 bulk drugs and their formulations under DPCO 1995 and chemists are entitled to a higher margin for these products. The agreement provides for a 2 per cent increase in trade margins at 18 per cent to retailers from July 1 for all formulations of drugs which are outside the price control under DPCO 1995. The wholesale trade will get a margin of 9 per cent for the decontrolled drugs. A further 2 per cent increase in the retail trade margin and a 1 per cent hike in wholesale margin will be effected from January 1996 in the second phase. With these increases the retail margin will be 20 per cent and wholesalers' margin will be 10 per cent for all decontrolled drugs. This makes a total of 30 per cent for drug retailing and wholeselling.

According to a comment in *Express Pharma Pulse* (June 29, 1995), "A 30 to 40 per cent rise in the prices of most of the decontrolled drugs is expected from July 1995, with the agreement between the drug industry associations and pharmaceutical trade to hike trade margins taking effect. A further 60 per cent increase in prices of these drugs is likely from next year. An estimated Rs 25 crore is expected to be collected by the All India Organisations of Chemists and Druggists (AIOCD) from the drug units." In short the drug industry and the trade decide amongst themselves how much should be extracted from the consumers, and the government takes the position of a silent spectator.

Normally 10 per cent free scheme is offered by many drug companies throughout the year, but Table 1 shows the additional free schemes offered.

From Table 2 we find that the prices of nearly 20 per cent of the products and 28 per cent of the products and packs have gone up. The break-up of the price rise shows that 11.17 per cent have shown a rise of less than 10 per cent, 5.32 per cent a rise of 10 to 20 per cent, 3.83 per cent a rise of 20 to 30 per cent, 2.30 per cent a rise of 30 to 40 per cent and 1.28 per cent a rise of 40 to 50 per cent. But strangely enough 3.80 per cent show a rise of over 50 per cent. Some of this rise may be of bigger packings. This has been the usual practice of the drug companies to increase the prices of different packings of products at different times. (See Appendix Table for full list of products which have registered a price rise over December 1994 prices in September 1995.)

Over 100 per cent rise is recorded in 41 products and 11 of these are ophthalmic products of Bell Pharma. The top position is taken by Gesicaine, a local anaesthetic of S G Pharma with a rise of 221 per cent and followed by Glucagon (for hypoglycemic attack), Torrent, 200 per cent; Hematrine (iron preparation), Sandoz, 148 per cent; Daktacort (antifungal), Ethnor, 147 per cent; Epsolin (anticonvulsant), Cadila, 145 per cent; Depsonil (antidepressant), S G Ph, 144 per cent; Septopal (antibiotic), Merck, 139 per cent; Nutrisan (nutrition supplement), Sandoz, 121 per cent; Alludrox Gel (antacid), Wyeth, 114 per cent; Myambutol (antitubercular), Cyanamide, 114 per cent; Corex (cough mixture), Pfizer, 108 per cent; Testanol-25 (hormone), Infar, 108 per cent; Lanoxin (cardiac drug), B Wellcome, 105 per cent; Dilantin (anticonvulsant), Parke Davis, 105 per cent; and Endrine (nasal decongestant), Wyeth, 104 per cent.

Ten products show a rise between 90 and 100 per cent, 7 products between 80 and 90 per cent, 17 products between 70 and 80 per cent, 10 products between 60 and 70 per cent, and 33 products between 50 and 60 per cent. In this group the most commonly used products are Arovit (vitamin), Neosporin (skin ointment), Incidal (antiallergic), Zcet (cough mixture), Prenatal

TABLE 1. FREE SCHEMES

Manufacturer	Brand Name	Scheme	Per Cent Free
Amazon	Coldin Tab	10 + 6	60
	Zolgin Tab	10 + 5	50
	Ibunova Tab	10 + 6	60
Brown and Burk	Eldopar Cap	10 + 5	50
Micro Labs	Renitab 150	10 + 4	40
	Microflox 250/500	10 + 4	40
	Microdine Oint	10 + 5	50
Plethico	Gentamycin 10 ml	7 + 5	71.43
Mac Labs	Genman 2 ml	10 + 5	50

TABLE 2. PRODUCTWISE PRICE RISE

Category System	No of Products Showing Per Cent Price Rise of					
	0-10	10-20	20-30	30-40	40-50	Over 50
Alimentary	28	10	4	1	2	2
Cardiovascular	27	23	12	10	3	9
Central nervous	49	30	11	13	4	20
Musculo-skeletal	17	5	7	4	6	3
Hormones	31	13	13	4	2	9
Genito-urinary	13	9	6	1	2	3
Infections	110	22	22	12	5	17
Nutrition	65	29	19	12	7	18
Respiratory	20	12	9	5	–	9
Ear-Nose-Throat	1	5	2	2	2	6
Eye	10	6	4	3	5	17
Allergic	4	2	4	3	4	2
Skin	27	12	15	11	2	11
Others	1	14	10	2	2	11
Total Products (3,607)	403	192	138	83	46	137
Per cent	11.17	5.32	3.83	2.30	1.28	3.80

(nutritional supplement), Gardinal (anticonvulsant), Sodium antimony gluconate (for Kala azar), Algipan (pain balm), Xylocaine (anaesthetic), Efcorlin (nasal drops), Diabinase (diabetes), Paraxin (antibiotic), Nebasulph (antiseptic), Triaminic (cough mixture), Arovit (vitamin). Pfizer has hiked the price of its tetracycline by going generic. The price of Gardinal, the most effective and the cheapest of anticonvulsants, has gone up by 50 per cent.

In June 1993, the prices were marginally reduced, but were increased in December 1993 reaching a maximum by June 1995. The comparative figures presented here are from *Monthly Index of Medical Specialities* (MIMS) December 1993 to September 1995: 5.32 per cent of the products have shown marginal decline in prices and the maximum decline is for norfloxacin, ciprofloxacin, famotidine, omeprazol, rifampicin, etc. The real price rise began from June 1995 and henceforth more and more products will raise the prices.

In September 1994, the government of India, ministry of chemicals and fertilisers, department of chemicals and petrochemicals announced modifications in the Drug Policy, 1986. Under clause 22.7.2(iv) 'Span of Control' it says "Government will keep a close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, the government would take appropriate measures, including reclamping of price control." Now that 67 drugs have been decontrolled, it becomes the responsibility of voluntary organisations to keep track of price rise and force the government to take appropriate action.

Under clause 22.7.3 'Ceiling Prices' it says "Ceiling prices would be fixed for commonly marketed standard pack sizes of price-controlled formulations and it would be obligatory for all, including small scale units, to follow the price so fixed." Now in this category we will look at the prices of two most commonly used drugs, paracetamol and aspirin. The ceiling prices fixed and notified by the government of India under DPCO 1987 and continued to be in operation under DPCO 1995 are as follows (Order No 672(E), September 14, 1992).

Paracetamol 500 mg/tab strip (10 T) @ Rs 2.74; 125 mg/5 ml syrup (60 ml) @ Rs 7.04; 150 mg/ml drops (15 ml) @ Rs 6.58.

The actual prices prevalent today are:

Calpol (Burroughs Wellcome) 500 mg tab (10 T) Rs 4.12 +50.36 per cent; 125 mg/5 ml (60 ml) Rs 11.67 +65.77 per cent. Crocin (Duphar) 500 mg tab (10 T) Rs 3.98 + 45.26 per cent; 125 mg/5 ml syrup (60 ml) Rs 10.78 +53.13 per cent; 150 mg/ml drops (15 ml) Rs 7.34 +11.55 per cent. Metacin (Themis) 500 mg tab (10 T) Rs 3.13

APPENDIX TABLE: PRODUCTS SHOWING PRICE RISE MORE THAN 50 PER CENT

Product	Company	Packing	Rate on		Per Cent Rise
			December 1993	September 1995	
Gesicaine (1 per cent)	S G Pharma	30 ml	3.48	11.17	220.98
Fristina	MAC	110 ml	6.10	19.52	220.00
Kenalog S	Sarabhai	2.5 gm	2.53	8.03	217.39
Otoflour	Bell Pharma	10 T	4.00	12.00	200.00
Glucagon	Torrent	vial	114.98	330.00	187.01
Stadmed Entrozyme	Stadmed	45 ml	7.51	21.30	183.62
Mycoderm	FDC	100 gm	15.25	22.40	181.67
Fungizone IV	Sarabhai	50 mg	55.51	150.00	170.22
Midarine	Burroughs Wellcome	2 ml	3.42	6.93	181.58
Bell Homatropine (2 per cent)	Bell Pharma	10 ml	5.62	14.90	165.12
Capsovit forte	Pharmed	30 C	9.20	24.00	160.87
Mac Soralen	Mac	15 ml	6.80	17.66	159.71
Walavin FP	Wallace	10 T	8.80	22.77	158.75
Bell Diono Resolvant	Bell	3 gm	5.90	15.00	154.24
Bell Resolvant	Bell	3 gm	5.05	12.80	153.47
Hematrine	Sandoz	40 C	16.16	40.00	147.52
Daktacort	Ethnor	5 gm	7.93	19.60	147.16
Epsolin	Cadila	2 ml	1.01	2.47	144.55
Depsonil PM	S G Pharma	10 C	6.58	16.05	143.92
Bell Homa (1 per cent)		10 ml	4.20	10.15	141.67
Septopal	Merck		1534.41	3672.46	139.37
Algipan	Wyeth	20 gm	7.43	17.70	138.22
Broacil dry syp	IDPL	40 ml	9.61	22.61	135.28
Copamide	Dey's	10 T	1.73	4.00	131.21
Capto Miotic (2 per cent)	Bell	10 ml	13.80	31.80	130.43
Marax Unimed		20 T	12.83	28.81	124.55
Nutrisan	Sandoz	30 C	13.55	30.00	121.40
Bellpino Artmna	Bell	5 ml	4.65	10.00	115.05
Allodrex Gel	Wyeth	350 ml	13.49	28.93	114.46
Myambutol	Cyanamide 400 mg	10 T	5.92	12.64	113.51
Gesicaine (1 per cent)	S G Pharma	30 ml	4.16	8.83	113.22
Biomiotic	Bell	10 ml	18.80	40.00	112.77
Tivision	Bell	10 ml	4.70	10.00	112.77
Corex	Pfizer	60 ml	9.39	19.55	108.20
Testanon-25	Infar	1 ml	5.00	10.40	108.00
Lanoxin	Burroughs Wellcome	10 T	1.95	4.00	105.13
Dilantin	Parke Davis	100 T	21.65	44.41	105.13
Albudac	Cadila	50 ml	695.00	1420.00	104.32
Endrine	Wyeth	30 ml	9.42	19.22	104.03
Pincort	Bell	5 ml	6.25	12.75	104.00
Citravite	Pharmed	10 T	6.90	14.00	102.90
Thromycin	IDPL	45 ml	9.68	19.25	98.86
Kinetone	Boots	300 ml	211.14	42.00	98.68
Calmod	IDPL 5 mg	10 T	3.35	6.65	98.51
Lanixin	Burroughs Wellcome	2 ml	2.70	5.31	96.67
Arovit	Roche drops	7.5 ml	10.76	21.15	96.56
Zinco Sulpha	Bell	10 ml	5.09	10.00	96.46
Neosporin Skin	Burroughs Wellcome	20 mg	11.86	22.94	93.42
Ridinox	Bell	10 ml	5.20	10.00	92.31
Lorvas	Torrent	10 T	11.70	22.50	92.31
Pupilleto Forte	Bell	5 ml	5.00	9.50	90.00
Incidal	Bayer	10 T	2.91	5.50	89.00
Vanmycetin	Opticaps	100	15.01	28.29	88.47
Zeet	Alembic	110 ml	10.44	19.58	87.55
Prenatal	Cyanamide	150 C	36.43	67.99	86.63
Gardinal	Rhone Poulenc	2 ml	6.80	12.69	86.62
Betenin	Boots	450 ml	23.19	43.17	86.16
Licab	Torrent 300 mg	10 T	5.90	10.90	84.75
Sodium Antimony Gluconate	Alb Dav	30 ml	43.75	78.65	79.77
Oricitral	Pharm Research	450 ml	30.65	55.00	79.45
Algipan	Wyeth	40 g	14.25	25.50	78.95
Bronkotab 4	Biddle Sawyer	10 T	2.93	5.18	76.79
Xylocaine (2 per cent)	Astra IDL	30 ml	7.30	9.05	76.76
Hemocid	Biddle Sawyer	20 ml	32.00	56.36	76.13
Benocide	Burroughs Wellcome	10 T	11.18	2.01	75.42

(*Continued*)

APPENDIX TABLE: PRODUCTS SHOWING PRICE RISE MORE THAN 50 PER CENT (Continued)

Product	Company	Packing	Rate on		Per Cent Rise
			December 1993	September 1995	
Efcorlin	Glaxo	15 ml	4.82	8.40	74.27
Hexavit	IDPL	500 T	64.00	111.53	74.24
Bidurate-L	Croydon	10 T	3.90	6.71	73.59
Methazil	Bell	10 ml	6.35	8.50	73.47
Diabinase (100 mg)	Pfizer	10 T	2.66	4.60	72.93
Cnotorax HC	S G Pharma	10 g	7.45	12.84	72.35
Paraxin (250 mg)	Boerrhinger-M	10 C	11.67	20.00	71.38
Depsonil forte	S G Pharma	10 T	3.13	5.35	70.93
Nebas sulph powder	Pfizer	10 g	7.46	12.71	70.38
Beetrion	Francho Indian	10 T	4.06	6.91	70.20
Triaminic	Wander	10 T	6.22	10.55	69.61
Kenacomb	Sarabhai	5 g	4.46	7.56	69.51
Sarotena	CFL Pharma	10 T	3.25	5.41	66.46
Arovit	Roche	10 T	6.72	11.11	65.33
Catobell	Bell	10 ml	6.10	10.00	63.93
Brexic	Wockhardt	6 C	4.50	7.32	62.67
Dexona	Cadila	5 ml	40.71	65.44	50.75
Salinex	IDPL	10 T	1.68	2.70	60.71
Maxinox	Max	10 ml	8.25	13.24	60.48
Perfocyn	Bell	5 ml	6.55	10.50	60.31
Terramycin (generic)	Pfizer	4 C	3.82	6.11	59.95
Nebasulph skin	Omni protec	15 G	9.44	15.07	59.64
Hexidol plus	Torrent	10 T	11.91	18.90	58.69
Derobin	Glaxo	25 g	11.39	18.07	58.65
Altol	Induco	10 T	10.61	16.80	58.34
Glynase	USV	10 T	5.50	8.69	58.00
Oxytetracyclin skin	Pfizer	5 g	5.07	8.01	57.99
Hamycin vag (6 ovules)	HAL		10.00	15.76	57.60
Tavist	Wander	50 ml	20.77	32.67	57.29
Sedonal	East India	12 T	2.61	4.09	56.70
Gravol	Wallace	10 T	6.35	9.95	56.69
Depsonil DZ	Burroughs Wellcome	10 T	3.08	4.82	56.49
Kay-Ciel	Stadmed	228 ml	15.01	23.50	56.56
Hycibex	Pharmed	110 ml	9.07	14.12	56.45
Lynoral	Infar	10 T	6.00	9.35	55.83
Testanon-50	Infar	1 ml	12.00	18.70	55.83
Calpol	Burroughs Wellcome	60 ml	7.49	11.67	55.81
Wockadine	Wockhardt	500 ml	122.45	189.48	54.74
Arachitol (3 lack)	Duphar	3x1 ml	8.00	12.36	54.50
Sarotena	CFL Pharma	10 T	6.25	9.65	54.40
Aquasol	USV	30 C	23.05	35.50	54.01
Subamycin	Dey's	10 C	7.60	11.69	53.82
Tonoferon	East India	450 ml	27.41	41.94	53.01
PZA	Ciba	10 T	17.12	23.10	52.45
Paracin	Stadmed	60 ml	5.25	8.00	52.38
Dexosyn ZN	Bell	5 ml	5.29	8.05	52.17
Eptoin	Boots	100 T	27.85	42.25	51.71
Gardinal (60 ml)	Rhone Poulenc	10 T	3.28	4.97	51.52
Gardinal (30 ml)	Rhone Poulenc	10 T	2.39	3.62	51.46
Synertab	Pharmed	10 T	6.48	9.80	51.23
Astelong	Torrent	60 ml	15.83	23.90	50.78
Neosporin	Burroughs Wellcome	10 ml	8.90	12.97	50.81
Arlidin	USV	10 T	8.36	12.60	50.72

+14.23 per cent; 125 mg/5 ml syrup (60 ml) Rs 8.21 +16.62 per cent, 150 mg/ml drops (15 ml) Rs 7.42 + 12.77 per cent (Metacin prices have not gone up yet).

The popular brands of paracetamol prices are 65.77 to 11.55 per cent more than the ceiling price fixed by the government. The price of Calpol tablet has gone up by 40 per cent and syrup by 56 per cent and Crocin tablet has gone up by 35 per cent and syrup by 31 per cent.

Another way of circumventing the rules and regulations is to make drug combinations. One such example is Fortagesic of Win-Medicare. It contains paracetamol 500 mg and pentazocin 15 mg per tablet. Fortwin 25 mg pentazocin costs Rs 2.73 per tablet and Crocin 500 mg paracetamol tablets costs Rs 0.40. So 500 mg paracetamol and 25 mg pentazocin should cost Rs 3.13. But Fortagesic with 15 mg pentazocin and 500 mg paracetamol costs Rs 4.95 per tablet. Similarly Win-Medicare has another overpriced combination product of paracetamol 450 mg + chlormezanone 100 mg costing Rs 2.50 per tablet.

The ceiling price of aspirin formulation (per order No 12(E) of January 4, 1988) is as follows: Aspirin 300 mg/tablet strip (10 tabs) @ Rs 0.64; Actual prices are as follows (for 10 tablet strips): Apidin (IDPL) Aspirin 200 mg +++ (10 T) Rs 2.42; Colsprin (Reckits) Aspirin 325 mg (10 T) Rs 1.92; Disprin (Reckits) 350 mg +++ (10 T) Rs 2.00; Micropyrin (Nicholas) 350 mg + (10 T) Rs 2.37; and Winsprin (Win-Medicare) 324 mg (10 T) Rs 3.73.

The brand prices are more than the ceiling prices from 483 per cent to 200 per cent. Besides none of these products confirm to the standard formulation of 300 mg aspirin. This shows the inefficiency of FDA in allowing irrational formulations.

To top all this the drug companies have marketed small dose aspirin as anti-coagulants for prophylaxis in cases of increased risks of blood clotting. The government notified ceiling price of 300 mg aspirin/tab (10 T) is Rs 0.64, ASA 50 (German Remedies) 50 mg aspirin/tab (10 T), 6; and Aspicot (Concept) 80 mg aspirin/tab (10 T), 2.20. How can the government allow 9.38 times (938 per cent) the ceiling price to ASA 50 and a price rise of 24.08 per cent as well? If we can compare all the ceiling prices and find wide discrepancies this can be reported to the government.

Most of the expectorants (Benadryl, Brozedex, Cinaryl, Corex, Deacos, Lupihist, Mit's linctus, Protussa plus, Solvin, Soothex, Sovental, Triaminic, Tristina, Zedex and Zeet) show increase in price, ranging from 20 per cent to 220 per cent. Likewise vitamin formulations (Aquasol-A, Arachitol, Arovit, Becosules, Beetrion, Beplex, Betonin, Bivinal forte, Citravite, Cobadex forte, Hexavit, Hovite, Hycibex, Macroberin, Pedic, Polybion, Stresscaps, Sukcee, Viseneral, Vitneuron, etc); minerals (Calcium-Sandoz, Cital, Citralka, Coslyte, Electral, Electrobiob, Filibon, Macalvit, Nutrisan, Ostocalcium, etc); iron preparations (Dexorange plus, Fefol, Fessovite, Hematrine, Hepatoglobin, Imferon, Phosphomin, Tonoferon, etc); and nutritional products (Bayer's tonic, Hemiphos, Kinetone, Livogen, Neogadine elixir, etc) show rise in price.

In the antituberculous products, the prices of ethambutol, and pyrazinamide have gone up. Among antibiotics tetracycline and chloramphenicol rates have gone up. Prices of hormones have consistently been raised and this time, we see the price of Aquaviron (without B12) has gone up by 41.36 per cent, Lynoral by 56 per cent, Orgalutin by 47 per cent and Testanon by 108 per cent. Most of the anticonvulsants like Dilantin, Epilex,

Epsolin, Eptoin, Garoin, Mysolin, Valparan alkalets, and Gardinal have also shown a price rise. Prices of sedatives and antidepressants continue to rise.

Some of the newer entrants in the drug industry have become intelligent enough to market only tablets – so that capital investment is less or one can get the tablets compounded on a loan licence – for vague indications, where doctors cannot complain that there are no results, and at very high prices so that there is no need to ask for an increase in rates. One such example is Serdia which has introduced the following products.

	Rates (Rs)
Conversyl (antihypertensive) 10 T	201.47 (1 od)
Daflon-500 (cardiac) 10 T	158.64 (1 bd)
Diamicron (antidiabetic) 10 T	90.40 (1 bd)
Flavedon-20 (cardiac) 10 T	90.40 (1 tds)
Isomeride (antiobesity) 10 C	88.81 (1 bd)
Natrilix (antihypertensive) 10 T	37.10 (1 od)
Ponderax (antiobesity) 10 C	77.22 (1 od)
Survector (antidepressant) 10 T	119.96 (1 bd)
Trivastal LA (anti-parkinson) 10 T	141.55 (1-4 d)

(Od is once daily; bd is twice daily; and tds thrice daily.)

Are such high introductory rates for such products justified?

Plight of Child Labourers

Pankaj

Though immediate intervention to alleviate the misery of child labourers is necessary, any attempt to render them jobless is equally uncalled for.

DELHI, where maximum number of organisations work for the welfare of child labourers and where laws for abolishing child labour throughout the country are formulated, has 18 per cent of its 25 lakh child population employed in various types of physical labour.

A report by the UNICEF says, the working conditions for child labourers are harsh in India. About 45,000 children work for almost ten hours a day in the various industries. In Delhi, a majority of the child labour is engaged as domestic servants. Vehicle repair shops and garages employ a sizeable number of the child labourers. Children can also be found working in dhabas, tea stalls and in small hotels to a large extent.

In UP, carpets industries in Mirzapur and Bhadoi and glass industry of Firozabad, and various other industries have 7-8 million child labourers. UP accounts for 20 per cent of the entire child labour force in the country. It is shameful that after 47 years of independence India has more than 5.5 crore child labourers. No serious attempt has been made to liberate them except the Child Labour (Prohibition and Regulation) Act, 1986 and the Factories Act in 1948.

According to the Centre of Concern for the Child Labour, at present 10,000 children are engaged in rag picking in Delhi, with last 15 years registering a rapid increase in their presence. The centre also mentions that girls constitute 30 per cent of the child labour. A large number of child labourers live on streets and this makes them more vulnerable to sexual and drug abuse.

A few months ago India found herself in an embarrassing situation when Germany refused to attend an international conference of carpet manufacturers organised by India on the grounds that the Indian carpets were made by the children. To abolish child labour, the European Community has passed the social clause to apply selective import restrictions on the countries who are denying minimum labour standard to their workers. The Indian carpet industry, which has a turnover of approximately Rs 1,400 crore, will suffer.

In Mirzapur-Bhadoi carpet belt 40 per cent of the carpet weavers are children below 14 years. Knitting, weaving and pre-processing in these carpet industries adversely affect their back and their eye sight and in a very short period they lose their fingers. Another 10,000 children work in the lock industry of Aligarh where they slog for 12-15 hours in dim light and amidst highly poisonous chemicals which make them prone to asthma and various skin problems. It has been estimated that 45,000 children below 15 years are engaged in brass industries in Moradabad and 50,000 children in the bangle industries of Firozabad. In Lucknow, zari industry employs at least 45,000 children. Child labour is a feature of almost all the states. In diamond cutting and polishing industry of Surat at least 50,000 children do drilling and polishing in highly polluted environment for long hours which exposes them to several health hazards due to lack of basic facilities at the workplace.

The world conference in Vienna in 1993 recognised the important role the governments can play in improving the lot of children. It urged nations to mobilise maximum resources to reduce child mortality rate and provide nutritious food to all children. Unfortunately, no political party ever took to abolish child labour as children do not constitute vote banks. According to South Asian Coalition on Child Servitude, only voluntary organisations are doing the work of emancipating child labour. Non-government organisations can more effectively implement policies for revival, protection and development of children. But most of the NGOs end up rendering the child labourers unemployed.

The NGOs always demand high priority to be given to the literacy of these children. Now, how can a child afford education after giving up his low waged job? If he goes to school he has to spend on his studies, while working not only was he earning but also contributing to family income.

Child labourers are paid low wages ranging from one-third to one-half of that paid to adult labourers, even if the output of the former is more. Some demand equal wages for child labourers. But laws hardly transform the society. Last year (till June 1994) 309 child labourers were 'released'. But now it has become a common feature to find one lot of child labourers being 'released' only to be replaced by other group of children. The inspectors upon whom lies the responsibility to enforce laws are often bribed by the employers. Of course, industrialists who exploit child labour on a large scale and get high profits, will not pay enough to the children till government exerts pressure.

Child labour is common in developing countries like Nepal, India, Pakistan and Turkey, etc. In these countries poverty and child exploitation go hand in hand. Instead of industrialisation which deprives the children of income earning opportunities, schemes for poverty alleviation and rehabilitation of child labourers are a better alternative.

Muslim Women's Voices

Expanding Gender Justice under Muslim Law

Sabeeha Bano

An opinion survey among Muslim women in a section of Delhi indicates that while the enactment of a Uniform Civil Code is a difficult proposition, the objectives sought to be promoted through the enactment can be achieved equally well by a process of reform of personal laws through the internal initiatives of different communities.

EVEN though there has been a spate of research on women in India since the UN declared the International Women's Year two decades ago, little corresponding research exists in respect of Muslim women in India. The few studies that have appeared during the last two decades have been undertaken either with the commonly prevalent prejudice against Muslims in mind or were otherwise methodologically deficient in that they employed indices of measurement of women's status which had little relevance to the realities of their existence within the Indian environment. Therefore, studies on Muslim women are called for if a realistic assessment of the issues of concern to them and their community is to be formed.

Since little empirical research exists on Muslim women, the impression somehow exists that they have no voice and no feelings about the issues which concern them. This is particularly the case when it comes to the issue of gender justice. On this important issue, which has been highlighted time and again during the past several decades through the demand for enactment of a Uniform Civil Code applicable to all Indians, the debate has usually taken place among men. Even when women have raised the issue, their reasons for demanding a Uniform Civil Code have been taken over by men and equally, contested by men. What are women's sensibilities on this question has never appeared on the surface, and this has distorted an understanding of the problem in proper perspective.

Enactment of a Uniform Civil Code enjoined upon the state in terms of Article 44 of the Directive Principles of State Policy in the Constitution of India has proved to be an extremely contentious issue. The protagonists of the Uniform Civil Code do not as a whole belong to a common category in terms of the arguments which they use in order to buttress their demand for enactment of a Uniform Civil Code. Among them, there are a good many people who are strongly committed to democratic and liberal values and feel that the concept of a common citizenship enshrined in the Indian Constitution demands that there should also be a common law for all citizens. Others are motivated by very narrow nationalist or chauvinist ideas to demand a common civil code for all Indians. For them, a Uniform Civil Code is a necessary condition for the promotion of a strong national feeling. Others still demand a Uniform Civil Code because they feel that the personal laws of the different communities, including Muslim Personal Law, are gender unjust, and gender justice may be easier to ensure through a Uniform Civil Code. On the other hand, those opposing the enactment of a Uniform Civil Code have couched their arguments in the democratic right of cultural minorities to continue to follow their distinct cultural traditions and personal laws.

This is not an appropriate place to undertake an examination of the rationale of the different arguments advanced to demand or oppose the enactment of a Uniform Civil Code. It is sufficient to indicate that the manner in which the debate on this controversial question has gone on, there has emerged a fair degree of consensus that enactment of a Uniform Civil Code in the present situation is not going to be easy. For one thing, the legal diversity which exists in this country is far too complex and bewildering and any attempt to force uniformity of legal practice will be generative of a great deal of social strife. Secondly, there also exists diversity with respect to jurisprudence or what might be considered the philosophy of law. Enactment of a Uniform Civil Code will entail reconciling these different principles of jurisprudence which is not going to be easy. Finally, personal laws of several tribal communities are sanctified by the Constitution and overruling them can lead to constitutional difficulties.

On the whole, consensus among large sections of opinion, except some hardcore liberals and nationalists, is tending towards the position that enactment of a Uniform Civil Code is not possible, but the question of ensuring gender justice remains. This should be ensured through the different communities taking the initiative on their own to reform their personal laws to give effect to considerations of gender justice without coercion from the state or any other agency. Such reform is also called for in the face of the emerging tension between the constitutional civil law as it has developed through the decisions of the Supreme Court and the personal laws of the different communities. If the final enactment of a Uniform Civil Code is not to be made an eventual contingency in the face of the growing chasm between the constitutional law and the provisions of the personal laws, internal reform through rationalising the personal laws would appear to be a good strategy for those groups and communities which do not want to submit under pressure of either the liberals or the Hindu chauvinists to the tyranny of a Uniform Civil Code.

Our aim here is to articulate Muslim women's voice on this question by focusing on the response offered by women respondents on aspects of social practice and law which are the core of the issue of gender justice and the principal reason for the demand of a Uniform Civil Code on the part of those who feel that gender justice cannot be assured under traditional personal laws of the different communities in general and Muslim Personal Law in particular. Our analysis is based on the assumption that eventually consensus on the question of internal reform would be a suitable strategy to withstand pressure for the enactment of a Uniform Civil Code and in the process of that reform what Muslim women themselves think should be of critical relevance.

The data presented here was collected from a sample of 200 respondents drawn from the Muslim localities in and around the Jamia Millia Islamia in Delhi as part of a larger study designed to find out women's understanding of the Koranic and Muslim Personal Law provisions relating to divorce, marriage and inheritance, etc. From this study, we have isolated a set of questions for this discussion. Of the total respondents covered by this study, 194 (97 per cent) were Sunnis and 6 (3 per cent) were Shias. Most of them belong to the Ashraf category of social groups such as Saiyed, Pathan and Sheikh. The Saiyed women account for 30 (15 per cent), Khan for 37 (18 per cent), and Sheikh for 72 (36 per cent). Others belonged to intermediate or lower social groups of Muslims: Ansaris account for 15 (6 per cent), Sulaimani, Saifi and Dhobi for 22 (11 per cent), and Meo for 5 (3 per cent). The large majority of them, 142 (71 per cent) were between 26 and 45 years old, 28 (14 per cent) were below 25 years of age and 30 per cent (15 per cent) were above 46 years of age.

In terms of educational background, 37 (19 per cent) were informally educated, 125 (63 per cent) had received formal education and 38 (19 per cent) were illiterate. Of the formally educated respondents, 15 (8 per cent) were educated up to the fifth standard, 40 (20 per cent) were educated up to sixth to 12th standard, and 70 (35 per cent) were educated up to the degree level. Whether educated or not, most of the respondents, 147 (74 per cent) were housewives, two (1 per cent) were working in house-based economic activity, 10 (5 per cent) were self-employed, 40 (20 per cent) were in service, and one (.5 per cent) is in business. Of those

engaged in gainful economic activity, 11 (6 per cent) were earning up to Rs 500, six (3 per cent) were earning between Rs 500 and Rs 1,500, 10 (5 per cent) were earning between Rs 1,500 and Rs 3,000 and 26 (30 per cent) were earning more than 3,000 a month.

Since women enjoy limited autonomy in terms of what they do with their earnings and their access to the economic resources of their families, the respondents were asked a set of questions with respect to those aspects as well. Of those having an independent earning, seven (4 per cent) spend their earnings the way they want, and 46 (23 per cent) hand over their earnings to the husband to be spent on the family. Again, 87 (44 per cent) respondents said they were free to open and operate their own bank account, and 113 (57 per cent) admitted that they did not enjoy this freedom. On the whole, it would appear that the respondents are by and large living within a traditional family setting and are dependent on their husbands and families in terms of their daily course of life.

Their personal lifestyles further confirm this. Of all the respondents, only one is unmarried but lives within a family setting; 175 (88 per cent) are married, four (2 per cent) are divorced, 17 (9 per cent) are widowed and three (2 per cent) are separated, but they too are living with their paternal families. Of those married, 198 (99 per cent) had a traditional religious marriage and only one had a civil marriage. As many as 138 (69 per cent) pray daily (which does not mean that they pray five times daily; it only means that they perform at least one prayer daily), 40 (20 per cent) pray at least on Friday, and 19 (10 per cent) pray occasionally. One respondent said she prayed only during personal crises and two said they did not pray at all. Again, 156 (78 per cent) observe fast for all 30 days during Ramazan, 40 (20 per cent) observe fast on some days, and four do not observe fasts at all. As far as engaging in a reading of the Koran as a religious duty is concerned, 63 (32 per cent) read the Koran daily, 85 (43 per cent) read only sometimes, five (3 per cent) read only on special occasions and 47 (24 per cent) do not read the Koran as a religious duty. Of those who read the Koran, 70 (35 per cent) admitted that they understand the Koran and 83 (42 per cent) admitted that they did not understand what was there in the Koran even though they read it from time to time.

Since observance of purdah is considered a characteristics of Muslim women, the respondents were asked if they believed in the purdah and what was the precise form in which they themselves observed purdah. Of all the respondents 182 (91 per cent) said they believed in purdah and 18 (9 per cent) denied believing in purdah. Of those who said they believed in purdah, 65 (33 per cent) believed in wearing the burqa, 68 (34 per cent) believe in covering the head with the end of the sari or a dupatta, and 49 (25 per cent) believe in observing purdah through proper behaviour without engaging in any adherence to form of dress. On the whole, therefore, the large majority of the women respondents covered are fairly typical Muslim women.

Since one of the areas at the centre of the controversy over the enactment of Uniform Civil Code is that of marriage and divorce, the respondents were asked a series of questions about marriage and divorce. Of all the respondents, 86 (43 per cent) reported that their formal consent to the marriage was sought by their parents, and as many as 113 (57 per cent) said that no formal consent to their marriage was sought from them. Again, 198 (99 per cent) were married through a 'nikah' ceremony. The payment of mehr promised by their husbands at the time of marriage ranged as low as Rs 100 and as high as Rs 40,000. Three respondents (2 per cent) entered marriage on a 'mehr' of less than Rs 100, 35 (18 per cent) on Fatmi mehr which is an amount equivalent to that fixed by Prophet Muhammad while marrying his daughter, seven (4 per cent) on an amount between Rs 100 and Rs 1,000, 25 (13 per cent) on an amount between Rs 1,000 and Rs 5,000 and 92 on an amount above Rs 50,000. This last category includes one respondent whose mehr was of the order of Rs 1,25,000. Interestingly, as many as 37 (19 per cent) respondents reported that they did not know what was the mehr fixed at the time of their marriage.

For all the respondents except one, their present marriage was their first marriage. It is often believed that the ease of divorce in the case of Muslims results in frequent casting away of the wife. If our data is to be relied upon, it would seem that divorce is not very common among Muslims. This is as true of men as much as women as our question with respect to the marriage of the respondents' husband shows that in the case of 187 (94 per cent) respondents their marriage to their present husband was also the first marriage for the husband. Only in eight (4 per cent) cases the present marriage of the husband was his second marriage and in one case the present marriage was a fourth marriage. Of those husbands whose present marriage is not their first marriage, only eight (4 per cent) had divorced their wife and three (2 per cent) had married a second time after having been widowed earlier.

Even though the overwhelming majority of the respondents have never been divorced and only eight (4 per cent) have married husbands who had been widowed or divorced earlier, the large majority of them are of the view that the practice of triple divorce is iniquitous to women. As many as 164 (82 per cent) felt that the practice of triple divorce should be abolished completely, while 20 (10 per cent) thought otherwise and another 16 (8 per cent) did not show a firm opinion on this matter. On the question of polygamy as many as 173 (88 per cent) want the provision for polygamous marries to be abolished completely, 14 (7 per cent) think otherwise and 13 (7 per cent) are undecided. Accordingly, on an overall assessment, as many as 76 (38 per cent) respondents felt that Muslim personal law discriminates against women, 70 (35 per cent) thought otherwise and another 54 (27 per cent) were undecided.

If such a large proportion of women feel that the provisions of Muslim personal law relating to triple divorce and polygamy are iniquitous to women and should be abolished or that Muslim personal law discriminates against women, the question naturally follows what they feel about how the reform of the law should be effected. Of all the respondents 76 (38 per cent) felt that Muslim personal law should remain unaltered which, in other words, means that in their opinion the personal law needs no reforms. The remaining respondents thought that changes or reforms in specific areas were called for. As many as 73 (37 per cent) felt that reform in respect of polygamy was called for, 62 (31 per cent) felt that reform in respect of custody of the child in the event of separation or divorce was called for, and 58 (29 per cent) said that the provisions regarding maintenance to a divorced or separated wife needed reform. Only one respondent also said that reform in respect to a woman's right in paternal property was required.

The broad consensus which seems to be emerging in Indian society with respect to the enactment of Uniform Civil Code is that such an enactment is a difficult proposition, but the objectives sought to be promoted through the enactment of Uniform Civil Code can be achieved equally well by a process of reform of the different personal laws through internal initiative of the communities themselves. Our discussion of the data from the respondents shows that there is a clear understanding of the need for this kind of reform as well as a clear understanding of the areas where such reforms are called for. Our respondents' specific answers also go to show this broad consensus. The respondents were asked to indicate whether a Uniform Civil Code should be enacted, or Muslim Personal Law should be retained as it is, or it should be reformed. Only 29 (14 per cent) respondents said that Muslim Personal Law should be replaced with a gender-just Uniform Civil Code, and a roughly equal number 30 (15 per cent) felt that Muslim Personal Law should be retained as it is. Of the remaining respondents, 35 (28 per cent) felt that Muslim Personal Law should be retained with minor changes and another 57 (29 per cent) said that Muslim Personal Law needs drastic reforms, but that these changes should be brought about within an Islamic framework. There cannot be clearer indication for the leaders of the community and greater reason for them to initiate the process of reform than this testimony.

as suggested by the chief ministers' conference and thereafter it should be stepped up each year in a phased manner to reduce the burden of subsidy to agriculture substantially. The committee had also emphasised the importance of discontinuing the horsepower-based tariff and had urged that the board should install meters on the premises of all agricultural consumers within three years at the latest.

The move to provide free electricity to all farmers needs to be reconsidered against this background. How can the MSEB ever become financially viable if it is to provide one-third of its total electricity supply free of charge? The state government is apparently considering the question of setting up a state electricity regulatory commission (SERC). The central government, under political pressure from its allies in Punjab and Tamil Nadu, has done a national disservice by diluting the provisions of the central act on the subject insofar as laying down a time-limit for upward revision of agricultural tariffs and reduction of cross-subsidisation of this sector are concerned. It will be futile to appoint a SERC if irrational policies of supplying free electricity are to be pursued by the state government.

The tariff for various categories of consumers was stepped up by MSEB by 10 to 15 percent just a couple of months ago. This tariff increase in much lower than what had been recommended by the board to the state government. Any additional burden of subsidising the agricultural sector will require further increase in tariff. The situation will be further exacerbated once power from Enron starts flowing in the grid of MSEB by the end of 1998. This high cost power will increase the average cost of power to the board. This problem will get further aggravated as more and more high cost power supply becomes available to the board from private sector power projects in the next three years. These large implications should not be lost sight of in taking a final decision on this subject.

The national implications of the proposed move in Maharashtra also need to be appreciated. As the draft Ninth Five-Year Plan formulated by the erstwhile Gujral government (March 1998) has rightly emphasised, rationalisation of electricity tariff is perhaps a pre-requisite for carrying out reforms in the power sector. The Plan brings out that, nationally, agriculture and domestic sectors are presently subsidised to the tune of nearly Rs 20,000 crore each year. There is a limit to which the burden of subsidised sales of electricity to the agriculture and domestic sectors can be passed on to the industrial and commercial sectors. The Plan has underlined that unless corrective steps are taken, the electricity boards will face difficulties in attracting financial resources. Private sector investment is also likely to suffer. By now all this is well known. But is anybody listening?

Andhra Pradesh and Haryana have learnt a lesson on this score the hard way. Both these states had to go back on their decision to supply free electricity to agriculture due to the large and unsustainable implications for the state government finances. One would have expected the other states to learn from this experience. But Maharashtra has shown that all that matters is to retain political power at any cost. With elections round the corner, one should not be surprised if some other states follow suit and rush headlong towards the precipice. Indeed the world of lemmings is difficult to understand.

Price Control on Drugs Is Essential

Wishvas Rane

The drug industry has done its best to sabotage the price control order. But even in its present form it serves a useful purpose and cannot be allowed to be scrapped.

IN most countries including developed countries in Europe and America regulation of drug prices is prevalent in one form or the other. Twelve out of the 16 west European countries control drug prices directly. All the countries have schemes for reimbursing health care cost. The manufacturers are forced to keep prices low so that the drug is kept on a high reimbursement list and this is prescribed more frequently. In UK, the Department of Health's Pharmaceuticals Price Regulation Scheme determines target profit levels individually for each company based on its contribution to the UK economy. Excessive profit gain is corrected either by a reduction in prices or by directly reimbursing the excess profit to the department of health.

Most of these measures are incorporated in our DPCO, but its implementation is not satisfactory. The DPCO was first introduced in 1970 and has been revised thrice since then. In 1970 all the drug prices were controlled, which were then reduced and restricted to 347 drugs in 1978, to 163 drugs in 1987 and to just 73 drugs in 1995. And now the drug industry wants the DPCO to be abolished step by step. The first step is to decontrol 17 bulk drugs, of which cases are pending with the government for past three years. Thereafter, the remaining 57 drugs are to be decontrolled at the rate of 19 drugs every six months (*Economic Times*, September 28).

The government has empowered itself to fix the maximum sale price of bulk drugs, fix retail prices of scheduled formulations, fix ceiling price of scheduled formulations, revise price of bulk drugs and formulations, recover dues accrued under the DPCO 1979, recover overcharge amount, etc. But the government does not seem to use the powers to streamline drug prices. Probably bringing IV fluids under price control will be the first ever case after DPCO 1995. Under section 10b of DPCO the government has been given full power to review the prices of decontrolled products. Most of the newly introduced drugs are highly priced (Wishvas Rane, 'New Drugs at What Cost'?, *EPW*, June 28, 1997) and the government should force manufacturers to fix reasonable rates of these products. This will be one of the ways to make the National Essential Drug List more realistic (Wishvas Rane, 'Is Essential Drug List Becoming Obsolete'? *EPW*, December 6, 1997).

Though regulatory control on post tax return on net worth was imposed on bulk drugs, most companies flouted the control by submitting appropriated data to the Bureau of Industrial Costs and Pricing (BICP). Immediately after the 1986 drug policy, through public interest litigation (PIL) it was revealed that Hoechst, Glaxo, Pfizer, etc, had heavily overcharged on some of their bulk drugs. Thereafter a large number of companies were found to be overcharging for both bulk drugs and formulations. The Supreme Court directed the government to recover excess profit from the drug companies, amounting to Rs 2 crore in 1987. Some of the drug companies started paying up, but others refused to do so. Pfizer, in their balance sheet of 1993, had earmarked nearly Rs 5 crore to pay the government, and had enjoyed the tax benefit, but never paid the amount to the government.

A recent report (*India Today*, July 20) highlighted the fact that flouting of DPCO regulations is rampant in the country and

TABLE 1

Brand	Company	Price Rs
Floxquin-N	Themis Chem	40.00
Meriflox	Merind	20.55
Negaflox	Cadila H	25.75
Norbactin	Ranbaxy	44.78
Norflox	Cipla	47.00
Norilet	Dr Reddy's	38.00
Normax	Ipca	20.84
Norspan	Blue Cross	32.40
Nor-U	Hind Antib	21.20
Obax	Wockhardt	52.28
Quinolox	Kopran	21.15
Uriben	CPL Pharma	20.89
Utibid	Lupin Pinn	42.75

Note: Prices of 10 Tablets norfloxacin, 400 mg

pharmaceutical companies continue to make lakhs and crores of rupees, illegally, abetted by the active connivance of the enforcement authorities. As a single example, 10 tablets of norfloxacin 400 mg has been sold for Rs 52.28, while the actual cost is fixed at Rs 22. The National Pharmaceutical Pricing Authority (NPPA) was established to work out realistic drug prices. But it was not able to comply with this decision. Take the example of norfloxacin and ciprofloxacin, the prices of which have not been accepted by the drug industry and they have obtained stay orders from the courts. Thus these two salts remain out of the purview of DPCO and their varying market prices can be seen from Table 1.

Karnataka has become the first state in the country to start formal large-scale inquiries into the issue of flouting of and circumventing most of the recent set of DPCO regulations. Karnataka accounts for an average annual drug sale of Rs 1,000 crore and investigations by the state drug control authorities have unearthed at least 61 companies making Rs 36 crore in a single year simply through overcharging of drugs that come in the DPCO scheduled category. This includes such large and reputed companies like Ranbaxy and Natco and such drugs as amoxicillin, cloxacillin, metronidazole and a combination of

TABLE 2: CHANGE IN FORMULATION OF COREX

Ingredient	Strength	
	Befor 1995	After 1995
Chlorpheniramine maleate	4 mg	4 mg
Codeine Phosphate	10 mg	10 mg
Ephedrine HCl	5 mg	–
Sodium citrate	150 mg	–
Menthol	0.1 mg	–

Note: Price remains the same.

TABLE 3: PRICES OF ASPIRIN

Brand	Company	mg/tab	Rs/10 tab
ASA-50	German Remedies	50	6.91
Aspicot	Concept	80	2.35
Caspria	Biochem	500*	4.00
Colsprin	Reckit	100*	1.26
		325*	2.16
		650*	2.80
Cotasprin	Batco	50	2.00
Disprin	Reckit Piramal	350*	1.90
Micropyrin	Nicholas	350*	2.14

Note:* inclusion of calcium carbonate, citric acid or caffeine.

norfloxacin and metronidazole.

India Today in its article further says, "The contribution of the pharmaceutical industry to the health sector cannot be doubted, but this does not license them to dupe customers. Upward price revision is never communicated to physicians and consumers, but price reductions are touted in full page advertisements in medical journals and other media. The government on its part does nothing to educate the consumer. Enforcement officials are either ignorant or choose to look the other way. Given the scenario, all responsible consumers must take interest in this issue and bring instances of DPCO violations to the notice of state drug control department or to the NPPA."

There are many ways to hoodwink the DPCO. Changing the composition of a formulation, transferring the brand to one's own subsidiary small-scale industry, and finally discontinuing a product. Pfizer has discontinued its Diabinese (chloropropamide) and Combatrin (pyrantel) because they are not economically viable. The NPPA has further brought down the prices of these products by 26 to 60 per cent, but that does not solve the problem of the consumers. As a monopoly product, the NPPA should make it compulsory to manufacture the products. Change in composition of a formulation has been prompted in some cases because of the government ban orders. Take the example of Corex of Pfizer, wherein ephedrine has been dropped, but the prices have not been reduced.

Another glaring example is of ferrous sulphate, a very commonly required product. Formerly Glaxo had 'Fersolate' that contained ferrous sulphate 195 mg, copper sulphate 2.6 mg and manganese sulphate 2.6 mg per tablet. 500 tablets of 'Fersolate' then costed Rs 40, i e, 8 paise a tablet. This brand was then taken over by Wellcome. They have kept the same composition, but have changed the name as 'Fersolate-CM' and changed the packing to 30 tablets costing Rs 23. The same Fersolate now costs roughly 76 paise a tablet or an increase of 85 per cent.

It is the duty of the Food and Drug Administration to fix the composition of a formulation. Take the example of aspirin which is included in scheduled of the DPCO, and allowed to be marketed in various strengths of 50 mg, 75 mg, 100 mg, 150 mg, 325 mg, 350 mg, 500 mg and 650 mg and the prices varying from Rs 1.26 to Rs 6.91. Table 3 gives the comparative prices of different brands of aspirin. Why should the prices vary from Rs 1.26 to Rs 6.91 and why should 350 mg Disprin cost 19 paise a tablet whereas a 50 mg (one seventh) ASA-50 cost 70 paise a tablet?

OPPI, the MNC organisation have been critical of the price control on bulk drugs. But Knoll, Parke Davis, Rhone Poulenc, Fulford, Franco Indian are among the top 50 formulation companies that do not produce any bulk drug. Glaxo produces only three price-controlled bulk drugs, Pfizer two, HMR three, Wyeth Lab one and German Remedies only two, whereas the big Indian drug companies and medium capital companies like Sol, Kopran, Cross land, Sun Pharma, etc, are concentrating on production of a wide range of essential bulk drugs.

The claim of Indian National sector industry of lowest drug prices in India is not correct (Amitava Guha, 'Price control of Drugs in India: An Overview', *Rational Drug Bulletin*, Vol 8, No 3). It is true that the drug prices in India are lower in comparison to many countries, but is certainly not the lowest as is evident from Table 4. If we compare the prices of drugs procured by international agencies like UNICEF and some international distributing houses, we will observe that in dollar terms their prices are cheaper than the brands available in India. Our government has never tried to negotiate the prices with the manufacturers.

A study done by Delhi Science Forum shows that large drug companies are not interested in producing bulk drugs, but rather prefer to act as mere traders and middlemen by concentrating on formulation market. In such a situation there can be no justification for liberalising production controls, in fact more stringent controls are called for. The study further shows that the prices of drugs under price control have not risen. DPCO, has thus been eminently successful in keeping the price of controlled drugs under control.

Presently the price control through DPCO has not been effective. Proliferation of irrational formulations further compound the problem of drug pricing. Drug companies have been trying to circumvent the DPCO by introducing different strengths (of formulations), and different packs. Standardisation of the strength of a formulation and its pack sizes can be notified based on information available from standard medical literature. A suitable mechanism for fixation of ceiling prices should be worked out with a built-in formula that can take care of the fluctuations in bulk drug prices. In short, instead of abolishing the DPCO, the provisions of the present DPCO be made operative in a more firm and rigorous way.

TABLE 4: COMPARISON OF INTERNATIONAL AND INDIAN DRUG PRICES (1996)

Drug/Strength	Unit	Supplier	Prices US $	
			International	Indian
Amoxicillin 500 mg	100 tab	UNICEF	6.84	28.59
Cephalexin 250 mg	100 cap	KCR	8.60	14.00
Cefuroxime 750 mg	10 vials	ECHO	20.88	36.50
Chloramphenicol 250 mg	100 cap	UNICEF	2.13	5.71
Furosemide 40 mg	100 tab	Cross	0.62	0.95
Nifedipine 10 mg	100 tab	Cross	3.14	21.14

Note: US $ 1 was taken as Rs 35 (1996 rate).
Source: International Drug Prices Indicator Guide, Boston.

INTELLECTUAL PROPERTY RIGHTS AND

THE PHARMACEUTICAL INDUSTRY

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1. PHARMACEUTICAL INDUSTRY - STATUS

During the last 16 years since the Patents Act, 1970 came into force, the Indian Pharmaceutical Industry has achieved diversified growth which has placed it solidly on the world map. UNIDO has classified the Indian Pharmaceutical Industry as having acquired the characteristics of :

- near self-sufficiency in raw materials to start production of Drugs from basic stages;
- wide ranging therapeutic groups of drugs produced;
- using advanced development and process research ;
- possessing an efficient distribution system;
- levels of operation being comparable to international standards in production, technology and quality of products.

The industry has recorded substantial growth during this period as is evident from the following table:

TABLE - A

Year	Production of Bulk Drugs	Production of Formulations
	(RUPEES IN CRORES)	
1975-76	130	560
1987-88	475	2750
GROWTH	3.7 times	4.6 times

The demand for pharmaceutical products has been increasing rapidly and the industry has played a commendable role in anticipating and meeting this demand. The industry is presently producing drugs of various therapeutic groups viz. Antibiotics, Antibacterials, Analgesics, Antipyretics, Anti-T.B., Vitamins, etc. There are currently more than 10,000 manufacturing units in the country of which 250 are in the Organised Sector, including Multinational companies with foreign equity. It is estimated that the total investment of the industry is of the order of Rs.850 crores which has grown from a meagre investment of Rs.24 crores in 1952 as follows:

TABLE - B

CAPITAL INVESTMENT IN PHARMACEUTICAL INDUSTRY

Year	Investment Rs. Crores
1952	24
1961	56
1973	225
1977	450
1982	600
1987	850

FUTURE CHALLENGES BEFORE THE INDUSTRY

Domestic Demand

The per capita annual consumption of drugs in our country is extremely low as compared to other countries, Our per capita consumption is less than Rs.30 (in rural areas, it is less than Rs.10) per annum. Though the per capita consumption during the last one decade has gone up three-fold, we are still far below many developing countries, as is evident from the following data:

TABLE - C

PER CAPITAL CONSUMPTION OF DRUG IN INDIVIDUAL COUNTRIES

	1985 (US $)
Canada	66.2
Argentina	39.6
Mexico	15.7
Egypt	15.0
Brazil	10.3
China	4.4
India	2.2

In our villages, where Health Care system is extremely weak, the requirements of modern drugs should be higher than what is at present. There are, thus, great challenges before the industry to reach drugs to the masses in rural areas to achieve the goal of 'Health for all by 2000 A.D.'. It is anticipated that by the turn of the Century, the demand for pharmaceutical products is projected at over Rs.10,000 Crores against the current level of turnover of Rs.2750 Crores per annum.

Export Potential

In addition to domestic needs, there are vast opportunities for export of drugs to both the developed and developing countries. In fact, the export performance of the industry during the recent past has been excellent. During the last 3 years, exports have risen from Rs.194 crores in 1985-86 to

Rs.290 crores in 1987-88. Well before the turn of the century, it is estimated that the industry's export performance would exceed Rs.1000 crores per annum.

The global drug market during the last one decade has grown from US$ 43.05 billion to US$ 94.1 billion. However, India does not contribute even 2% of the total market. The potential of the industry to generate large exports is now being appreciated and with a pragmatic approach and determined policies, India can certainly do much better in the coming years in substantially raising its level of exports. Already the industry has been able to make its presence felt in the developed countries. The buyers of the Indian drugs percentagewise (%) of total export (1987) are as follows:

TABLE - D

EXPORTS TO DEVELOPED COUNTRIES

	%
USSR	33
USA	14
West Germany	6
France	4
UK	4
Japan	4

PERFORMANCE OF THE INDUSTRY

A Committee of the U.S.Senate (Kefauer Committee) had commented in the early Sixties that "prices of Drugs in India were amongst the highest in the world". This was before the enactment of Patents Act, 1970. It is noteworthy that prices of drugs in India are now amongst the lowest in the world. Internationally, comparative data about prices at which pharmaceutical products are available to the Indian people can be judged from the following Table:

TABLE - E

Sl. No.	Products	Year of Patent Expiry	INDIA		UNITED KINGDOM		Price difference %
			Pack	Price Rs.	Pack	Price Rs.	
1.	2.	3.	4.	5.	6.	7.	8
1.	ALLOPURINOL TAB 100mg	1986	10's	5.84	100's	303.81	+ 420 *
2.	LOPERAMIDE CAPS 2 mg	1990	10's	5,00	30's	81.14	+ 441 *
3.	MEBENDAZOLE TAB 100 mg	1989	6's	4.88	6's	37.92	+ 677 *
4.	PIROXICAM CAPS 20 mg	1986	6's	7.20	30's	184.75	+ 413 *

1.	2.	3.	4.	5.	6.	7.	8.
5.	TIMOLOL MALEATE 25%	1988	5 ml	14.95	5 ml	129.92	+ 742 *
6.	NIFEDIPINE CAPS 10 mg	1986	100's	50.00	100's	296.34	+ 493 *
7.	RANITIDINE TABS 300 mg	N.A.	10's	36.00	30's	666.82	+ 503 *
8.	CLOTRIMOZOLE CREAM	1989	15 gm	6.15	20 gm	44.24	+ 440 *
9.	CIMETIDINE TABS 200 mg	1992	10's	8.97	120's	432.72	+ 302 *
10.	GLIBENCLAMIDE 5 mg	N.A.	100's	8.88	100's	234.35	+2539
11.	STANOZOLOL TABS 5 mg	N.A.	10's	14.48	56's	540.90	+ 567

*Difference worked out on proportionate basis

This price comparison is only one example - in most countries which follow product patents, prices are as high if not even higher.

Further, in the domestic market the price rise of pharmaceutical products has been the lowest as compared to other price-regulated industries in the country. This is evident from the following Table:

TABLE - E

INDUSTRY	WHOLESALE PRICE INDEX (BASE 1970-71 = 100) 1986-87	Annual Increase %
1. Petroleum Products	622	33
2. Coal	716	39
3. Electricity	564	29
4. Cement	469	23
5. Sugar	401	19
6. Paper	392	18
7. Edible Oil	379	17
8. Fertilizers	288	12
9. Drugs & Medicines	203	6

The Pharmaceutical Industry in India has been under Price Control since long. The impact of this control is also evident from a comparison of the All India Consumer Price Index which has been as follows since the beginning of the decade i.e. 1980-81 :-

TABLE-G

	ALL COMMODITIES	DRUGS & MEDICINES
Base 1970 - 71	= 100	100
1980-81	270	137.5
1983-84	321.7	189.2
1986-87	377.8	203.7

RESEARCH ACHIEVEMENTS

The above background indicates that the pharmaceutical industry in India has done well in meeting the national requirements and has now begun to play an important role in foreign trade. This has been mainly possible because of the opportunities which became available to Indian Scientists and to the national companies to develop process technologies for various bulk drugs because of the process patent system enunciated under the Indian Patents Act, 1970. The scientific achievements in introducing new drugs in the country are commendable. The period of introduction of new bulk drugs discovered abroad has already been reduced to 4/5 years than a much longer period in the past as is evident from the following table:

TABLE - H

INTRODUCTION OF NEW DRUGS

	Introduced in		Gap
	World	India	years
Salbutamol (anti-asthmatic)	1973	1977	4
Mebendazole (anthelmintic)	1974	1978	4
Rifampicin (anti-T.B.)	1974	1980	6
Naproxe.. (anti-Rheumatic)	1976	1982	6
Ranitidine (anti-ulcer)	1981	1985	4
Norfloxacin (anti-Bacterial)	1984	1988	4

Production of about 100 bulk drugs has been started in the country through cost effective process technologies developed through indigenous efforts. There

...

are many drugs whose product Patents have yet to expire in the world market. Some of these bulk drugs are already being produced in our country. Production of several other new drugs would also be started each year by national sector companies. The names of bulk drugs whose patents are expiring in the coming years are indicated in the following Table:

TABLE - I

1990	1991	1992	1993
Amikacin	Butorphanol	Becampicillin	Alprazolam
Amiloride	Carbidopa	Cefactor	Atenolol
Bromcriptine	Micanazole	Cyclobenzaprine	Dobutamine
Diflunisal	Nifedipine	Naproxen	Metoprolol
Loperamide	Norgestrel	Probucol	Nadolol
Tolmetin			
Tretinon			

1994	1995	1996
Cimetidine	Captopril	Amcinonide
Mezlocillin	Pentazocine	Cefamandole
Terbutaline	Pipercillin	Cefotaxime
	Prazocin	Ciisplatin
		Moxalactam

Against the above performance, global pressures are being mounted to curtail the freedom presently available not only to the domestic pharmaceutical industry but also to Pesticides, Petro-chemicals and the Food Industries thereby directly affecting the opportunities of self-reliance export performance and availability of products at reasonable prices.

The Indian Patents Act, 1970 And The Pharmaceutical Industry

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National Seminar on Patent Laws

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WAY BACK IN THE EARLY 1940'S, AS THE world was going through the trauma of another war, India experienced a rude shock. The nations it depended on for vital supplies were busy fighting. As a result there was an acute shortage of life-saving drugs. With the national industry still in its infancy, we learnt the hard way that dependence on others could be suicidal. But then at that time we were not independent.

Today, after 40 years of Independence, the national sector pharmaceutical industry has attained an enviable position of technological self-sufficiency. It was the Indian Patents Act, 1970 that laid the foundation for this development.

Unfortunately, today there are pressures to amend this very Act, to sacrifice all our achievements by joining a self-serving cartel and in effect to return to the era of colonisation — this time economic and technological.

The health care of its people has been one of the prime concerns of our government. We are signatories to the Alma Ata declaration of health for all by 2000 AD. By that year our population is likely to exceed one billion. The government is rightly intent on strengthening the infrastructure to make available essential medicines at fair and reasonable prices. This objective would be defeated if the law is amended to provide extended process patent protection and product patents.

To better appreciate the impact of any such amendment, let us study the situation that existed prior to this Act.

Before and after the Act

Even two decades after Independence, the national scene was dominated by foreign-held patents. Their stranglehold was so strong that monopolies and high prices were the order of the day.

It was a period when the Indian consumer was denied the use of several life-saving drugs which were being introduced internationally, as he had no access to these.

Beecham introduced the semi-synthetic penicillin, ampicillin, in Europe in the early 60's. The originators were unwilling to market this drug in our country except on terms and conditions which were totally unacceptable. This was also the case with the cardiac drug, propranolol, introduced by ICI internationally in the mid-60's.

The basic question was, why should India be denied the use of such essential drugs merely because it did not suit the originator. This situation necessitated the promulgation of the Patents Act, 1970. As it happened, propranolol, ampicillin and several life-saving drugs were introduced in India by the national sector only after the Act came into being.

In 1962, when foreign-held patents ruled the Indian pharmaceutical industry, the Kefauver Senate Committee of the USA observed that drug prices in India were among the highest in the world. The situation today is happily the opposite, as is revealed by a comparison of the prices of certain drug formulations (table 1).

TABLE 1

Comparative drug prices

(Wholesale price in rupees; for pack of 10's)

Drug	India	U.K.
Cimetidine 200 mg *(antiulcer)*	6.77	36.40
Ranitidine 150 mg *(antiulcer)*	16.15	121.67
Captopril 25 mg *(antihypertensive)*	15.45	58.56
Nifedipine 10 mg *(cardiovascular drug)*	3.82	29.90
Diltiazem 60 mg *(antihypertensive)*	15.26	40.89
Atenolol 100 mg *(cardiovascular drug)*	11.29	61.15
Haloperidol 5 mg *(cardioprotective drug)*	13.58	41.16
Naproxen 250 mg *(antiarthritic)*	12.76	31.07
Rifampicin 150 mg *(tuberculostatic)*	9.01	46.88

Let us take the example of ranitidine. Its originator is among the 20 companies which market this drug in India. The price in India is just one-eighth of that in Europe. Had there been product patent protection in India, the originator would have used his monopoly advantage to dictate the drug's availability and its price, as is the situation even in neighbouring countries.

The main reason for drug prices being reasonable in India is the absence of monopoly as a consequence of the Patents Act, 1970. Hence, even the transnational corporations here are compelled to market their products at prices that are competitive.

Growth of Indian Industry

The Indian drug industry is today the best organised among all developing countries and is beginning to become a force to reckon with even in the international market. During the 15 years from 1973, the capital investment in the industry has increased by 300 per cent — from Rs 225 crores in 1973 to Rs 850 crores in 1987 (table 2).

As a consequence, there has been a spectacular growth in the ancillary industries as well. Today we are

TABLE 2

Investment in drug industry

Year	Investment *(Rs crores)*
1952	24
1962	56
1973	225
1982	600
1987	850

more or less self-sufficient in basic chemicals, pharmaceutical manufacturing machinery, laboratory testing equipment and packaging equipment.

The drug industry has been providing growth opportunities to a large number of highly qualified, highly skilled managerial and scientific personnel. Moreover, the industry has been eminently complementing the efforts of the scientists in the national research laboratories. The laboratories have developed the technology for a number of new products which have been successfully commercialised by the industry.

The technological development in our country is reflected in the wide range of bulk drugs being produced from the basic stages, through complex multi-stage synthesis and intricate fermentation and extraction technology. Currently India is self-sufficient in a large number of essential drugs (table 3). Anti-TB, anti-infective, anti-cancer, anti-bacterial and anthelmintic drugs are among a host of bulk drugs that are also being exported even to the developed countries.

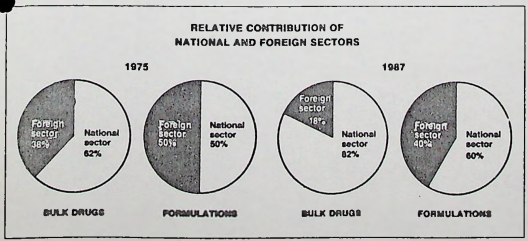
In 1962, India produced bulk drugs worth Rs 15 crores, and formulations worth Rs 100 crores. In 1975, three years after the Patents Act came into effect, bulk drugs production rose to Rs 90 crores, with the national sector accounting for two-thirds. There was a four-fold increase in the production of formulations also, half of it coming from the national sector.

TABLE 3

Major bulk drugs manufactured in India

Albendazole	Insulin
Amoxicillin	Mebendazole
Ampicillin	Methocarbamol
Aspirin	Methyldopa
Atenolol	Metoprolol
Betamethasone	Metronidazole
Cephalexin	Nalidixic Acid
Chloroquin	Nifedipine
Chlorpropamide	Nitrofurantoin
Cisplatin	Norfloxacin
Clonidine	Paracetamol
Cloxacillin	Piroxicam
Codeine	Prednisolone
Danazol	Propranolol
Dextropropoxyphene	Pyrantel Pamoate
Diazepam	Pyrazinamide
Diphenylhydantoin	Quinine
Doxycycline	Rifampicin
Emetine	Salbutamol
Erythromycin	Sodium Valproate
Ethambutol	Sulfamethoxazole
Frusemide	Terbutaline
Furazolidone	Theophylline
Gentamycin	Tinidazole
Glybenclamide	Trimethoprim
Hydrochlorothiazide	Vinblastine
Ibuprofen	Vincristine

In 1987, the national sector contribution was 82 per cent of bulk drugs and 60 per cent of the formulations produced in India (see chart).



Thus, the Indian Patents Act, 1970 has served one of its main purposes. It has enabled the national sector to make an increasingly significant contribution towards self-reliance and self-sufficiency, utilizing innovative and appropriate technology, based essentially on indigenous raw materials and resources.

India is now producing most of the new drugs for which there is a genuine requirement in the country and that too within a short span of their international launch (table 4).

TABLE 4

Introduction of drugs

Drug	Year of launch	
	World	*India*
Ranitidine *(antiulcer)*	1983	1985
Cimetidine *(antiulcer)*	1976	1981
Norfloxacin *(antibacterial)*	1984	1988
Astemizole *(non-sedating antihistamine)*	1986	1988
Acyclovir *(antiviral)*	1985	1988
Salbutamol *(bronchodilator)*	1973	1976
Mebendazole *(anthelmintic)*	1974	1978
Ibuprofen *(antiinflammatory)*	1967	1973
Lorazepam *(anxiolytic)*	1977	1978

It is significant to note that only those drugs which are of proven efficacy and safety are approved by the Ministry of Health. Thanks to this cautious policy, our country has been spared several drugs such as thalidomide, benoxaprofen, zomipirac, isoxicam, etc., which were introduced abroad, later found harmful and subsequently withdrawn.

Each year approximately 40 to 50 new chemical entities are being marketed as new drugs internationally. The claim made by vested interests is that India is being denied the use of these drugs. This is totally baseless. India does not need each and every new drug that is developed abroad. The majority of these, in any case, are me-too drugs produced by molecular manipulation, similar in efficacy to the original, with little or no additional therapeutic benefit.

For example, in the area of anti-bacterials, the quinolones have been a new development. Already well over 40 of these have been developed abroad. We in India are selecting only those that are specifically suited to our requirements. Also from the wide range of cephalosporins, we are currently using the first and second generation cephalosporins. Today we do not need the third and fourth generation cephalosporins as bacterial resistance has not yet been encountered to the earlier ones. At the appropriate time we will consider introducing the later generations of these anti-bacterials.

Thus, the charge that our country is being denied the latest technology is false. As regards getting foreign technology this is what Dr G S Sidhu, former Director General of CSIR, had to say:

"No one will sell you the technology of tomorrow — not even that of today. The moment you purchase technology, you are already in the field of obsolescence by five years or so. By the time you build a plant based on imported technology, your obsolescence has increased from five to may be seven or eight years. No country with technologically advanced knowledge will, in its own interest, give us modern technology."

Vested interests

India is now, by its own efforts, beginning to consolidate its position as a manufacturer of sophisticated bulk drugs and formulations. It appears that the international business and political groups cannot digest our technological advancement.

India is beginning to make a concerted export thrust into the international markets. India does not violate the patent laws of individual countries. We export sophisticated non-patented drugs at competitive prices. Currently, the level of exports of bulk drugs, intermediates, natural products and drug formulations is well over Rs 300 crores annually and is expected to go up significantly. It is this recent growth that the vested interests would like to thwart.

They would like to tie us down in the name of protection of intellectual property rights. Such a principle will be viable only between contracting countries that are on an equal footing. In reality this is not so.

Of the estimated 3.5 million valid patents in the world, less than one per cent belong to the third world countries. Over 85 per cent belong to transnational corporations and 90 per cent of these are not worked on at all. So patents do protect. Not the interests of the developing nations but the monopoly of some of the developed countries.

It should be noted that most of these nations allowed patents only after their domestic industries had attained a state of equality with other leading countries.

Germany provides an interesting example. In 1876, when German industry was in its infancy, Bismarck appointed a committee to study the likely impact of patents. Among the members of the committee were the

founders of Siemens and Hoechst. Their observations make 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 monopolize production abroad. These articles will be imported into this country. Such a danger must be met."

We hold the same view in India today precisely because we are concerned about the future growth of our industry.

Stand of other nations

A more recent example of Japan tells the same story. Till 1976 Japan did not have patents. Only when its domestic industry reached technological parity with Europe and the USA, did they opt for product patents.

The case of Italy holds a lesson for us. Italy is the fifth largest producer of drugs in the world and supplies 40 per cent of the non-patented bulk drug requirements of the USA. It had successfully built up an internationally competitive pharmaceutical industry based on adaptation of technology for new drugs. But the decision to go for product patents spelt doom. Today the share of local firms is nominal, domestic R&D has been slashed and exports have plunged.

Countries in South America have all had flexible patent laws like India. Intense pressure is being mounted on these countries even in the form of trade barriers.

Chile has resisted this as the country is concerned about the welfare of its people. It needs a domestically competitive industry to produce drugs at affordable prices. Patents, Chile has concluded, are hardly healthy.

Costa Rica virtually abolished patents in the late 70's when the country realised the high price difference between patented drugs and similar drugs available from patent-free countries.

Brazil, Argentina and Mexico are all keen to ensure that the poorest sections of their society have access to vital drugs. Therefore their patent laws permit free access to scientific and technological knowledge. But they too are under pressure to change their laws. Brazil is already facing an embargo on exports. The US Pharmaceutical Manufacturers Association (PMA) has filed a petition with their government complaining against Argentina's refusal to grant patent protection.

Countries like Norway and Finland still do not have any pharmaceutical patents. East European countries including the USSR have maintained their independence with regard to patents. One cannot visualise China, with its teeming millions requiring cheaper drugs, to adopt patents. If all countries are not being pressurised, it is only because some are in a position to retaliate.

It is remarkable that in the face of such pressures, Philippines has shown courage in introducing a bill to entirely abolish pharmaceutical patents. What has led a country like Philippines to make this move? The observations made by the initiators of the bill provide the answer:

"(Patents result in higher prices and) diminished welfare for the consumer .... (Patents have) merely served to preserve the domination of the (pharmaceutical) industry by multinational firms and effectively increase the cost of health care in an impoverished society ... since these patents involve the use of trade marks, royalties and licensing agreements, the repatriation of profits by these multinational firms also adversely affects the country's balance of payments position and depletes its dollar reserves."

The bill seeks to exclude from patent protection, inventions related to drugs and medicines, pharmaceutical preparations and products, vitamins and nutritional supplements and other products similarly essential to the maintenance of life and improvement of health.

In India's interest

As these examples indicate, each country has to decide for itself what is best suited to its own needs. External pressures should not override the considerations based on intrinsic logic.

India too, should not succumb and surrender all its achievements that have taken years of painstaking efforts. Patent protection will cripple R&D in the country not only in pharmaceuticals, but also in the areas of biotechnology, agriculture, food, atomic energy, nuclear power and defence. Let us not forsake our future. We have a duty towards the future generations.

The Indian Patents Act, 1970 was born out of a deep concern for the nation's future. It took 12 years to materialize. Probably no other statute was subjected to such protracted debates and deliberations.

It was given shape after marathon debates in both houses of Parliament. Committees headed by eminent jurists like Justice Bakshi Tek Chand and Justice N Rajagopala Ayyangar studied all issues in detail. The National Conference of Scientists and Joint Committee of Parliament on Patents Bill considered all evidence of both Indian and foreign experts and various associations before making their recommendations against patent protection.

We have been under pressure to change the Act earlier too. Whenever the question arose, the government appointed committees to deliberate on the matter. The working group under the chairmanship of L M Thapar, the group led by Dr S Ganguly as well as the recent three-member committee headed by Ashok Ganguly have examined the issue. They have all recommended against any amendment.

Above all, repeated assurances have been given in the Parliament that India will not amend its Patents Act or join the Paris convention. The latest such assurance was given on August 4, 1987 by the Minister of State for Industrial Development.

The Patents Act, 1970 was shaped by Indian necessities in the light of Indian realities. The rationale behind the Act is still valid. The government should not act hastily and amend the Act without recourse to a national debate and referendum. Let the consumer also be involved in this.

Prior to our Independence, there was a burning spirit of patriotism, unity and a sense of purpose in our countrymen. What we now need is another national objective. That of preserving our overall freedom. That of developing our country to the status of a great nation by our own efforts.

The fight is not for the industry nor for a mere piece of legislation. It is a fight for a moral issue. A fight for the right to decide our own destiny.

Drugs and Dunkel

○ *Prakash C. Rao.*

In my medical practice of sixteen years, I have observed an interesting phenomenon. In the beginning of the month, my practice is good, a lot of patients attend my clinic and pay for the treatment promptly. As the end of the month approaches, the practice comes down - few patients attend. This is the experience of my friends too in the profession. Whether people fall ill only in the beginning of the month? No. People do fall ill at the end of the month too. But people attend the clinic when they have money. Towards the end of the month people do not have money to buy the drugs. Prices of the drugs are high for the majority. Although drugs in India are the cheapest in the world, yet the poor find it hard to buy. We have to understand the Dunkel draft in the light of this finding with special reference to the multinationals in the drug industry.

Food, health and education are the basic areas of investment for the development of human resources of any country. These are basically social investments and the benefits too are to be accrued socially. The pattern of historical development of this industry, will enable us to draw some conclusions regarding the impact of the DUNKEL DRAFT TEXT (DDT) and the present government's supporting role of liberalisation and globalisation on the use of drugs in the country and the fate of the indigenous drug industry.

The enterprise of drug manufacture in India is divided into two groups, indigenous and multinationals (MNCs), with their contrasting roles. The Indian industry, with the public sector as its backbone produces a majority of the bulk and essential drugs while the MNCs have flooded the market with the high profit yielding non essential formulations. This fact has been recognized by several authors, particularly since the pioneering findings by the Kefauver and the Hathi Committee reports. Some of these historical details will be brought to focus in the sections that follow.

Beginning of the indigenous drug industry

Prior to the First World War we were importing almost all our drugs. During the first world war, all the import of drug to India was stopped and diverted to the warring countries while India badly needed drugs for her ailing millions. Then the situation in India was that infectious diseases were taking heavy toll of life. With the pioneering efforts of the Indian Scientists, the Indian Pharmaceutical Industry was established around 1920 and it began manufacturing medicines for Malaria, Kala-Azar and many other Infectious diseases.

Soon after the first world war, the MNC's began their business in India. Initially the MNC's collaborated with

the Indian companies to produce drugs. Priority of the drugs brought to India depended on the availability of the drugs with their parent companies abroad and had little connection with the country's own requirements. Later MNCs established their corporate offices in India. They were more active in promoting and selling drugs than in producing drugs. Indian drug companies could not stand the competition by MNCs and gradually the MNCs surpassed the Indian Drug Industry in sales.

Organanisation of Pharmaceutical Producers of India

Meanwhile MNC's joined together and formed the Organisation of Pharmaceutical Producers of India(OPPI), and began influencing the Indian government. As a result, the Industrial Policy Statement(1948) of Government of India recognized the role of foreign companies resulting in the entry of MNC's in a large scale. It was anticipated that MNCs would bring in foreign technology and capital to create an industrial base in India. This hope proved futile, the experiences being too numerous to be enumerated.

Birth of Public Sector

Bulk drugs are utilized in the production of formulation drugs(tablets, capsules, injection). Bulk drug production is essential to produce any formulation that you see in a medical store. In India till 1950, no company produced any bulk drug. Most of the MNCs were formulating drugs out of imported bulk drugs. By this process the parent compamies were benefitted enormously. It was then realized that India should produce bulk drugs as a major step towards self reliance in drugs. The Government of India sought the help of the MNCs in bulk drug production, in terms of technology

transfer but none of them came forward as they were interested in establishing their trade in the country than help India to become self reliant. However, UNICEF and the World Health Organization (WHO) came forward to assist India to establish bulk drug production. As a result, the Hindustan Antibiotics Limited (HAL) was born in 1954. Similarly, the Indian Drugs and Pharmaceuticals Limited (IDPL) was established in 1960 with the assistance of the USSR.

How did the MNCs earn their profits ?

1. They produced only formulations and gave less importance to producing bulk drugs. The major portion of the bulk drug production is by the public sector. Formulation activity is more profitable, less capital intensive. India is the only country in third world which produces bulk drugs, primarily through its public sector and hence drugs in India are cheaper in comparison.

2. It is often asked : What will be the impact on the health programmes in India, if the MNCs leave? None at all. This is because these agencies have in no way helped us in the production of the essential bulk drugs. Some studies, titled: A Decade after the Hathi Committee has brought in this point admirably. The data published in the above mentioned volume show how in the mid 70's to the early 80's the share of the MNCs bulk drug production has progressively gone down while that of the public sector has progressively gone up.

Table 1			
Ratio of Bulk Drug Production / Formulation			
Year	1975	1981	1983
Foreign Sector	1:6	1:12.53	1:12.0
Indian Sector	1:8	1:2.6	1:3.44
Public Sector	1:0.8	1:2.6	1:1.12

Similarly, the MNCs' production of some of the essential drugs also declined, as shown in table 2.

Table 2 (in tonnes)		
Year	1980	1981
Chloramphenicol (Drug to treat typhoid)	46.41	36.16
PAS (Drug to treat TB)	215.16	122.26
INH (Drug to treat TB)	69.18	53.7
Piperzine (Drug to treat worms)	6.3	4.2
Dapsone (Drug to treat Leprosy)	10.28	10.17
DEC (Drug to treat Eosinophilia, filarial worm)	10.58	8.48

Despite the government's direction to produce specific amount of essential drugs, the MNCs produced less of essential drugs and more of non essential drugs, as

table 3 shows.

Table 3		
	1979 Licensed Capacity (tonnes)	*1979 Production (tonnes)*
INH (To treat TB) (essential)	80	52
PAS (To treat TB) (essential)	110	94
Protinex - Pfizer (Health Drink) (non essential)	110	290
Terramycin Injection (Antibiotic Injection) -Pfizer (non essential)	14	54

3. MNC's produced category III and IV drugs and have been making huge profits. Drug Price Control Order, 1979 has fixed the profit margin for category I & II drugs; category III & IV fall under non essential durg category and the drug companies are permitted to fix the prices of drugs according to their wish. Hence all of the MNC's produced mainly the drugs, which belong to category III and IV. Table 4 shows the break up between the different categories, as produced by the MNCs and proves this point.

Table 4			
% Share of the drug produced			
Year	1978	1979	1980
Category I (Essential)	4.5	4.2	3.6
II (Essential)	16.7	14.8	13.2
Category III (Inessential)	67.7	67.8	68.6
Category IV (Inessential)	11.7	12.2	14.6

This is also reflected in the percentage share of the different groups of drugs, as produced by the MNCs in 1985. This is shown in Table 5.

Table 5	
Systemic antibiotics	21.15
Vitamin & Tonics	15.95
Cough & Cold preparation	4.7
Antacids	3.64
Enzymes	2.1
Sex harmones	2.0
Anti T.B. Drugs	2.5

Of the above only the anti T.B. drugs and the systemic antibiotics are the essential ones and the production of these are extremely inadequate compared to the needs.

4. The MNCs'other methods of profit making are: (a) Collaboration with Indian firms to produce drugs and selling them in their brand names at a high price. (b) Transfer pricing - the price of imported chemicals are higher. MNCs get these high priced bulk drugs and formulate instead of using locally available cheaper bulk drug. This leads to drain of foreign exchange in favour of MNC. This is illustrated by some specific cases shown in table 6.

Table 6			
	prices at which bought per/kg	international prices per/kg	% of profit
Doxycycline (antibiotic)	5890	1377	340.5
Ethambutol (Anti T.B. Drug)	620	320	93.8
Frusemide (Diuretic)	1426	450	216.9
Librium (Anti Anxiety Drug)	5555	312	1680.4
Gentamycin (Antibiotic)	35670	3500	919.1

In many cases the import price that the MNCs force us to accept are even higher than the international prices of these bulk drugs. One such interesting case concerns the drug librium.It was available with STC in India at Rs 312 /kg. Roche bought the same drug from the parent company at Rs. 5555 /kg. The reason for refusing to buy from Indian STC was that the product was originally from an East European country.

Some of the other irrational drugs produced by MNCs which have no relevance to our country's needs are:

a Alcohol based tonics

Growth of alcohol based tonic

		1979	1984	growth
Santivini	Sandoz	1.83	3.05	66.67%
Bayers tonic:	Bayer	1.45	2.54	74.17%

b Health drinks - Horlics, Complan etc

c Vitamins There is no rationale for consuming vitimins in excess.

d Enzyme preparation - unienzyme

e Cough expectorant

f Gripe waters

g Sex tonics

h Combination drugs - eg Neurobion

i Hazardous drugs - like clioquinol used for diarrohea,but dangerous because it causes blindness. Analgin - baralgan, novalgin, oxygephenbutazone and many pain killers, which are banned in other countries but are being freely marketed in India.

5. As can only be expected, MNC are using aggressive sales promotion techniques. India has the highest number of medical sales representatives in the world. Doctors are misinformed about the products eg. anabloic steroids (Durabolin, Dianabol) to be used for improving the body's strength and Cyprohaptidine to be used for improving the appetite. Doctors are visited frequently and brainwashed about the products and appeased through lots of gifts and invitations for fivestar dinners.

6. MNC's are promoting drugs in brand names and propagate myths about better quality of the drugs (eg.Calpol of Burroghs Wellcome)and are in fact taking advantage of the inadequacy in our country's drug inspection infrastructure. To this should be added the

double standard that these companies maintain, vis-a-vis drug sale eg. selling those drugs in India, which are banned in the parent country of these companies (eg. Baralgan, Piriton, Osto Calcium B12.).

7. MNC are not spending any money on research in India. Most of the MNCs in developed world will have to spend 10-12 % of their turnover on research. The amount spent in the name of research in India is on market research. Some research is done on drugs for Hypertension and Cancer. Research on drugs to treat diseases of the third world is limited. This exposes the myth that the presence of the MNCs in our country brings to us the rcent advances in medicine

Hathi Committee report

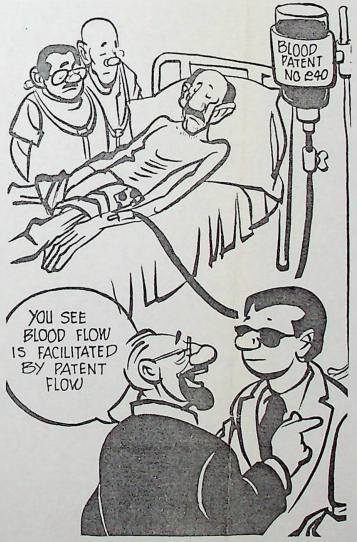
This poor record of the MNC's in India had created furore in the parliament. The Government of India appointed the Jaisukh Lal Hathi committee to go into the details of drug industry in India. Hathi report is one of the most scientific reports on the drug industry since independence. Hathi Committee confirmed that India had the capability to produce all the drugs needed for our country and MNCs blocked the growth of Indian companies.

This report was published in 1975 but was kept in cold storage due to heavy lobbying by the MNCs against the report. Today the government is being accused of not making the contents of the Dunkel Draft public. My experience with the procurement of the Hathi Committee report is quite illustrative of the government's conduct in these affairs. Circulation of this report too was blocked by several agencies. However, I did procure a copy after paying some bribes. If this be the attitude of the

government to its own reports, the present cover up on the contents of the DDT is quite understandable. Three years after the Hathi Committee report a new drug policy was announced in 1978 and it completely ignored Hathi report and gave concession to MNCs. Even today, there is a lot of talk on giving further concessions to the MNCs, though it is known that the drug companies are exploiting a situation characterised by the visible neglect of the primary health centres and open encouragement to the proliferaton of superspeciality hospitals and diagnostic centers.

In contrast, we need a National Drug Authority, who monitors the need and production of drugs in India, as suggested by Hathi Committee report. The NDA must plan the need for essential drugs, their distribution, and quality control. It is necessary to remove inessential, banned and bannable drugs from the market and use the technology available in our country to make the nation self reliant. It is also necessary to bring in a contact between health professionals researchers and planners. This process is yet to gain maturity and even partial collaborative efforts are now threatened due to the World Bank, IMF and GATT conditionalities, that are unified in their demand that our planning process be dismantled. However, if India is to gain self reliance in the field of drugs, it is necessary to defy these conditionalities. Only then can we develop a peoples' drug policy, which will rid us of 70,000 formulation of which 80 % are inessential. As a matter of reinforcement, the contours of this policy have already been worked out through the Hathi Commitee Report.

It is sad to note that even after 45 years of independence we have remained in the cluthces of MNCs.



Medical profession is unaware of DDT and the drug industry is divided in its opinion on the DDT. In view of the above historical background it is possible to create a post DDT scenario, particularly, when enough damage has been done even in the pre-DDT era. It is seen that even though the social requirement vis-a-vis the drug industry are well recorded, the government's pressures on the MNCs to satisfy the social needs of India have at best been feeble. What the DDT aims to achieve is to prepare a legal framework, in which no society can demand that trade has to be subordinated to the societal needs and not the other way round. As far as the Indian drug industry is concerned, the DDT brings pressures through coercive measures like the TRIPS and TRIMS, from which the following conclusions can be derived.

Reversing the Indian Patents Act

1. Inspite of the MNCs, our drugs have remained cheaper comparitively and this is because of the Indian Patents Act of 1970. According to IPA, a drug process can be patented but not the end product-drug. Hence there are many competitors using various processes to produce a drug. which has brought down the price of drugs. The process patent expires in 5-7 years but DDT wants to reverse this, by giving importance to product patents, lasting for 20 years. Since most of the drugs available have been patented in the west earlier than in India, we will lose the patent on these drugs. We may have to buy the drugs from the MNCs, paying a high royalty for 20 yrs. This will force the drugs to become costlier (even 10 times!) and will hit our R&D efforts and industries, resulting in closure of all pharmaceutical laboratories (nearly 8000). This will in turn lead to large scale unemployment.

2. DDT demands that there be no restriction on foreign equity participation. Foreign equity participation allows MNCs to send huge profits to the country of their origin. Hathi committee has observed that MNCs are making huge profits by producing inessential drugs and sending large sums to the parent companies abroad. Hathi report proposes that there should be a gradual reduction of equity participation.The DDT negates this process.

3. DDT demands no restriction in the area of investments. This will enable MNCs to produce drugs which give them more profit. The need of the hour is a National Drug Authority to decide on the issue of priority of drug production and not DDT to dictate us.

4. DDT demands that there should be no licensing. This is one of their major demands. If MNC's are given free hand to do whatever they want(delicencing), it simply means we cannot plan what we need and we cannot exercise any control over them. This will result in a total sell out of our sovereignty to the MNCs.

5. DDT demands that there be no export obligations. Whenever a product is imported there is an export obligation for the company. This will help to keep the balance of payments intact. If DDT is accepted, we will be importing bulk drugs in large quantities at a higher cost. There will be no restrictions on the import of non essential drugs too. Drugs necessary for the elite sections of the people, i.e. those which fetch higher profits will be freely available, while those for the poor will become scarce and prohibitive. In addition, we will be drained of our foreign exchange and will be continuously running short of foreign currency to buy some essential products whenever necessary.

6. DDT wants to remove the obligation to use locally available products and raw materials. Our labour force thus becomes inconsequential. The raw material can be sent by the MNC subsidiary to the parent company abroad and imported back at a high price after value addition.

7. DDT wants foreign investment to be treated at par with domestic companies. This condition will give a severe blow to our sovereignity. If this is accepted our drug companies will not have any preferential treatment even in the country of origin, eg. even the government hospitals cannot declare that they will purchase the drugs from the country's public sector.

In short the DDT wants to scrap the IPA 1970 and to do all the planning globally, through the conditionalities of the TRIMS. Thus the richer nations will be given the freedom to exploit the resources and the markets of the poorer nation.

It is true that the DDT is applicable to all the GATT member countries but given the present historical scenario, one concludes that as a result of globalisation, of which the DDT is a part,

i) America and other developed nations will find even larger markets for their products, mainly by taking advantage of the economic dependence of the developing nations,
ii) the developed nations will find a free access to the sources of raw materials in the developing nations,
iii) cost of the drugs in developing countries will go up adding misery to the lives of the common man,
iv) large scale unemployment and closure of industries will result,
v) developed countries will get huge royalty out of patents as the control on product patents will remain with developed countries.

The process of globalisation has begun. The public sector, the backbone of the Indian drug industry is being dismantled. Protection to it is being gradually removed. The signals are already around. IDPL, the pioneer in bulk drug production is about to close. This is bound to have a crippling effect on the Indian drug industry.

Our dependence is being perpetuated and medical drugs are used as tools in maintaining this dependence. The Hippocratic oath of the doctor will lose its relevance as the doctor now will be forced to serve the demands of the MNCs and not the requirements of his patients' health.

PATENTS - A DESIGN FOR DISASTER

Disease controlled by Amelioration of diseases depends upon medical personnel, health infrastructure and pharmaceutical industry. In India we have a good infrastructure of pharmaceutical industry. Our pharmaceutical industry produces most of the basic drugs in bulk and has brought self reliance in drugs. This is due to the provisions of Indian Patents Act, 1970.

Now, drugs are going to come under a new Patent regime. This patent regime is being forced on many developing countries and India also. Now health aspects of the drugs become secondary to trading aspect of drugs.

Five decades back, it was felt that there is a need for all the countries of the world to have a fair trade in consumer goods, food products, industrial component parts etc. A good intention indeed ! The discussion was initiated and one of its aim was to assist the third world countries to improve their trade and economy. Several rounds of trade negotiations were held in various countries. Eighth round of negotiations was held in Uruguay. The negotiations were dragged on for more than six years. Before the negotiations were concluded, Dunkel, the Director of General Agreement on Tarrifs and Trade (GATT) presented a draft known as Dunkel Draft Treaty (DDT) in 1991 and asked all the partners either to accept or reject and there was no scope for negotiations. The contents of DDT was in favour of developed countries, a definate deviation from the original goal ! The discussion was held in the background of globalisation a warning of disaster to come. The real actors on whose behalf this was done were the MNC's, whose global expansion can take place only by limiting the soverignity of nations.

Meanwhile the third world countries had received a lot of loan from international agencies (IMF, WB) supported by developed countries. It was possible to pressurise because the US became dominant after the collaps of the Soviet Union and East European countries. The developed countries mainly the US used this opportunity to bring pressuse on the third world countries to accept DDT. Remember that India opposed the move in the beginning but later accepted. It can be concluded that there was change in the stage of the play from United Nations to trinity of GATT, IMF & WB. There are various issues in GATT.

Lets discuss the issue of patents in relation to Pharmaceuticals.

Patent issue along with other eight issues are discussed under intellectual property rights.

Patent is a recognition given, right granted by the government to investors for a specific period to exclude other individuals and enterprises from infringing a patented product or process or both. Patents are granted to encourage invention and to secure that invention worked on commercial scale to the fullest extent, to benefit mankind.

In India, the patent regime is there since 1856. A very favourable patent system evolved only after independence, after indepth studies and debates, leading to Indian Patents Act, 1970. It became effective in 1972.

The salient features of IPA 70 are :

Product patent is granted to all except for food, medicines, substances produced by chemical processes.

Process patent is given to food, medicines and substances produced by chemical processess.

Inventions relating to atomic energy, agriculture and horticultural products are not patentable.

Patents last for 10-14 years. For food, drugs and substances produced by chemical processes it lasts for 7 years from the date of application or 5 years from the date of securing a patent, whichever is earlier.

The Indian Patents Act gave boost to Indian Pharmaceutical Industry. As a result, we could achieve self sufficiency in medicine. We could produce 100 basic drugs, 65 - 70 % of the bulk drugs needed for our country were manufactured in India. We entered international market. New drugs were produced in 3-4 years after the drug was released elsewhere, by innovative processes. The prices were once highest in India, before IPA 70 and reduced drastically and were the lowest.

We have exported about 640 crores of drugs to other countries in 1989-90 and today the export is worth 2000 crores.

Exploitation by the MNC's was kept low.
A good achievement indeed !

The IPA 70 protects the interests of both investors and consumers. National interest is given priority, over the interests of the patentee and it helped India develop novel processes in drug production.

The aim of the DDT is to reverse the IPA. DDT demand that there be no restriction on foreign equity participation, no restriction in the area of investment, no licensing system, no export obligation and DDT wants foreign investments to be treated at par with investment of the domestic companies.

This helps global planning through conditionalities of TRIMS.

Richer nations will be given the freedom to exploit the resources and market of poorer nations. The developed nation will find a free access to the resources of raw materials in the developed nationa

As a result, the cost of the drugs in developing countries will go up, adding misery to the lives of common man. it may result in closure of industrial units of Indian origin leading to unemployment. Developed countries will get huge royalty out of patents as the control on product patents will remain with developed countries. Now WTO replaces GATT and India has subscribed to it in 1994. Citing the dangers of WTO "The Tentacles of WTO reach every nook and corner of public life. It regulates industrial products, trade related investment and intelletual property matters. It has complete control over the agricultural services sector and telecommunication and information technology. It is aimed to convert all human life into a big market all human values into exchange commodities".

Twisting of the Patents issue is part of the globalisation, privatisation strategy. The western world with its surpluses is looking towards less developed world and its aim is not only selling their goods but also stop other countries use S & T and become dependent. It is a blueprint for a vicious economic recolonisation of the third world and redivision of the world by the advanced capatalist countries. The proponents of new patents are telling that there is no alternative. Such lies can convince the common man

It is not for promoting development, co-operation and accomodating the entry of developing countries on the world stage. Instead, it aims at establishing insidious control over the decision making process on the countries of the South. The recommendations go far beyond the perview of trade and infact the draft comes as a blatant attach on our economy and political soverignity.

Patents bill was hurriedly presented in the parliament. External compulsion being the main reason - WTO, WB and the pressure of the US government.

The need of the hour is for every Indian to register the protest, otherwise the dangers of neocolonisation will not be far off to see.

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Indian Pharmaceutical Industry: Effect of Proposed Product Patent Regime

Amit Sen Gupta

US statesman Thomas Jefferson remarked, "Ingenuity should receive a liberal encouragement". Jefferson introduced the first patent bill to the US Congress in 1790. It became the Patent Act, upon which US patent and trademark law is built. His comment sums up a popular notion of intellectual property rights, one that is promulgated to a large extent by industries. Discoverers and inventors are thought to deserve special reward or privilege because of the benefit of their discoveries or inventions to society. Benefiting society is not considered a reward in itself, and, true to classical economic theory, certain incentives are needed to encourage invention or innovation.

The strongest proponent of strengthened intellectual property provisions as part of the World Trade Organisation (WTO) is the United States. Not coincidentally, the companies most concerned about intellectual property are U.S.- based. Individual companies, as well as industry groups like the Pharmaceutical Manufacturers Association (PMA) and the Intellectual Property Committee (IPC), a coalition of 13 major U.S. companies, including IBM, DuPont, General Motors, Merck and Co. and Pfizer, had strongly lobbied with the U.S. Govt. on intellectual property issues.

The industrialized and developing countries' conflict over intellectual property protection of pharmaceuticals mirrors the broader conflict over protection for high technology. High technology multinationals claim "imitation goods", many emanating from the Third World, cause them to suffer large losses. The industrial countries do not say, however, that in order for the multinationals' to recover those 'losses' a massive transfer of income from the poor countries to the rich would be required. Third World countries dispute these claims. They point to the historical record of the industrialized countries, most of which did not have strong intellectual property laws when they were developing. For

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example, the United States in the nineteenth century and Japan through most of the twentieth engaged in exactly the sort of activities the United States now labels piracy. More recently, the "four tigers" of East Asia -- Taiwan, South Korea, Hong Kong and Singapore -- industrialized with the help of weak intellectual property protections.

The WTO agreement includes provisions which require changes to be made in the Indian Patents Act of 1970. Such changes would have a direct bearing on the Drug Industry in the country. In fact the Indian Drug Industry has especially been targeted by the Pharmaceutical MNCs for alleged violation of the principles of "free trade", which supposedly provides the philosophical underpinning of the WTO agreement. It is another matter that the principles of free trade in an unequal world are designed almost entirely to benefit those who are more equal than others, namely countries in N.America, Europe and Japan. Moreover a strong Patent regime, as outlined in the WTO agreement is harmful to the interests of not only the Third World but also a large number of people in the developed world.

Intellectual property rights (IPRs) come in five varieties: patents, plant breeders' rights, copyrights, trademarks and trade secrets. This paper seeks to focus on the area of patents, and more specifically on the possible impact of a change in the 1970 Indian Patent Act, in line with the WTO agreement, on the Pharmaceutical Sector in India. The major substantive change being sought by the U.S., European Union and Japan in the Pharmaceutical Sector is a switch to a Product Patent Regime from the present Process Patent Regime. The shift from a process patent regime to the recognition of an exclusive right on production and commercialization, is likely to lead to changes in the market structure and in the conditions for access by consumers to pharmaceutical products. The implications may be examined with regard to drug prices, impact on health care and self reliance in the Indian industry:

Impact on Self Reliance

The Indian Drug Industry has built up a base for production of almost all bulk drugs from basic stage using innovative process technologies. A major role has been played by various CSIR laboratories. This has been possible because of Indian Patent Act of 1970 which allows Process Patents and not Product Patents in the area of vital areas including drug production. One of the proposals in the WTO agreement

Table 1 : CHANGING PATTERN OF RETAIL DRUG SALES -- 1985 TO 1996 (Figures in '000)

	1996		1992		1989		1985		
Therapeutic Group	Value	percent	Value	percent	Value	percent	Value	percent	% change (1985 to 1996
QUINOLINES	3187521	4.72	1744458	4.53	-	-	-		
CEPHALOSPORINS	2576634	3.81	1254401	3.26	477457	2.27	83463	0.71	2987.16
ANTI DIABETIC	1160849	1.72	493109	1.28	213649	1.02	99045	0.84	1072.04
CARDIAC THERAPY	2295296	3.40	1147929	2.98	470153	2.24	212344	1.80	980.93
ANTI EPILEPTICS	706373	1.05	340099	0.88	186716	0.89	65655	0.56	975.89
ANTIEMETIC	922188	1.36	389529	1.01	201848	0.96	91296	0.78	910.11
HYPOTENSIVES	991801	1.47	433982	1.13	175848	0.84	104781	0.89	846.55
ANTACID etc.	3030905	4.48	1790065	4.65	898627	4.27	375779	3.19	706.57
MACROLIDES	1301584	1.93	652952	1.70	384703	1.83	161929	1.38	703.80
SYSTEMIC ANTIHISTAMINE	1163986	1.72	684380	1.78	293214	1.39	149402	1.27	679.10
AMPI/AMOXY/CLOX	4247658	6.28	2515369	6.54	1263622	6.01	551748	4.69	669.85
COUGH & COLD PREP.	3855555	5.70	1857988	4.83	1086320	5.17	525252	4.46	634.04
PSYCHOLEPTICS	1151355	1.70	638270	1.66	278028	1.32	161563	1.37	612.64
ANTI ASTHMATIC	1442635	2.13	775677	2.02	424128	2.02	210292	1.79	586.02
ANTI INFLAM/RHEUM	3748957	5.55	2217417	5.76	1176726	5.60	570355	4.84	557.30
TOP. CORTICOSTEROID	1457866	2.16	794162	2.06	445001	2.12	255329	2.17	470.98
SEX HORMONES	1278522	1.89	766729	1.99	370927	1.76	236159	2.01	441.38
HEPATIC etc.	682436	1.01	365949	0.95	225622	1.07	132601	1.13	414.65
MINERAL SUPPLEMENTS	682512	1.01	392072	1.02	211761	1.01	130393	1.18	389.63
GENERAL NUTRIENTS	1305410	1.93	758531	1.97	519279	2.47	268550	2.28	386.10
VITAMINS	4160010	6.15	2353495	6.12	1486687	7.07	945837	8.03	339.82
ANTI T.B.	2221193	3.29	1493832	3.88	757107	3.60	507538	4.31	337.64
SYS. CORTICOSTEROID	1079769	1.60	554532	1.44	332000	1.58	255455	2.17	322.68
ANTIANAEMIC	1830572	2.71	1038274	2.70	699183	3.32	436898	3.71	318.99
ANTI PARASITIC	1959325	2.90	1166858	3.03	749532	3.56	467818	3.97	318.82
ELECTROLYTES (ORAL & IV)	637097	0.94	449930	1.17	278316	1.32	158792	1.35	301.21
ANALGESICS	1798505	2.66	1144683	2.98	676147	3.22	448946	3.81	300.61
ANTI SPASMOD/CHOLINERGIC	798395	1.18	426096	1.11	306164	1.46	203501	1.73	292.33
ANTI DIARR/ DISINFECT	942429	1.39	551739	1.43	313923	1.49	248497	2.11	279.25
DIGESTIVES INC. ENZYMES	858835	1.27	545152	1.42	357894	1.70	246946	2.10	247.78
TETRACYCLINES	1083589	1.60	737617	1.92	508635	2.42	398557	3.38	171.88
TRIMETHOPRIM COM.	964931	1.43	961144	2.50	751962	3.58	508440	4.32	89.78
TONICS	569014	0.84	460426	1.20	412360	1.96	359902	3.06	58.10
TOTAL	67592595	100	38471053	100	21030743	100	11775823	100	473.99

Source: ORG Retail Audit for relevant periods

The analysis is shown in Tables II and III. We see from Table II that the average cost of older drugs is the highest in India. The cost is 3 times that in Sri Lanka and even higher than in U.K. and Canada. Adjusted against GDP per capita, cost of these drugs works out to be 5 times that in Sri Lanka and 12 to 16 times that in U.K. and Canada. The position is the complete reverse in the case of newer (Patent Protected) drugs. Table III shows that in the case of these drugs, prices are lowest in India. These drugs are 3 to 13 times more expensive in the other countries studied. Even when adjusted against GDP per capita the cost of these drugs work out to be the cheapest in India.

This interesting outcome exposes chinks in the arguments put forward by the two contending Industry Associations in the pharmaceutical sector in India - the Indian Drug Manufacturers Association (representing Indian Companies) and the OPPI (representing Multinational Companies). IDMA has consistently argued that drug prices are the lowest in India and a change in Patent Laws would reverse this position. The above analysis clearly shows that drug prices are lower in India only in the case of Patent protected drugs. We find from our study that in the case of other drugs, prices are higher in India than even developed industrialised countries. Given the fact that drugs in the Indian market, which are under Product Patents globally, account for only 10-12% of total pharmaceutical sales, this means that by and large Indian drugs are costlier.

This is indeed a strange situation as logically India should have an edge over almost any country in the world in this respect. Unlike Pakistan, Bangladesh and Sri Lanka India has the indigenous capability to manufacture most drugs. Further economies of scale should favour Indian manufacturers in comparison to these South Asian countries, given the much larger size of the Indian market. Compared to U.K. and Canada, Indian manufacturers enjoy the advantage of much lower infrastructural and labour costs. A conclusion one can draw is that the Industry in India is either unwilling or incapable of passing on the results of these gratuitous circumstances to the consumer. In fact, to the contrary, companies in India (both Indian and MNC) have receive a further bonus in 1995 in the form of the new Drug Price Control Order, where price control mechanisms have been further relaxed by drastically reducing the span of control and by increasing the profitability allowed

Table 2: Comparative Costs of Older Drugs (Not Patent Protected)

	COST IN $ OF 100 UNITS (Tablets /Capsules)					Av. Cost for basket of 6 Drugs where cost in India=1*	Real GDP Per Capita in Dollars (1991)	Adjusted Cost of basket of 6 Drugs (according to GDP/capita)**
	Amoxy-cillin	Cotrim-oxazole	Diazepam	Erythro-mycin	Fruse-mide	Propal-olol			
INDIA	9.00	3.00	3.00	12.00	1.00	3.00	1.00	1510.00	1.00
BANGLADESH	6.00	3.00	—	10.00	1.00	1.00	0.77	1160.00	1.00
PAKISTAN	5.00	3.00	3.00	5.00	0.60	1.00	0.65	1970.00	0.50
SRI LANKA	4.00	1.00	0.14	5.00	0.60	0.60	0.34	2650.00	0.19
CANADA	8.00	6.00	0.50	6.00	0.50	—	0.81	19320.00	0.06
UK	7.00	5.00	1.00	6.00	—	—	0.82	16340.00	0.08

Source: Retail Drug Prices in the Asia-Pacific region, K.Balasubramanian, HAI News, December 1995 and MIMS, India for relevant period.

* Calculated by taking cost of each drug in India as 1 unit and computing the relative cost in other countries. Then the average of the basket of drugs has been taken. Where data for all drugs not available, average computed on the basis of no. of drugs on which data is available

** Calculated by multiplying average cost with the ratio of GDP per capita in India, with the corresponding figure for each country. This gives a rough measure of the financial impact of buying drugs in each country.

Scheme. The scheme's objectives are to secure the provision of safe and effective medicines to the NHS at reasonable prices. The scheme was renewed in 1993 for five years and is currently under review. The House of Commons Health Committee has now recommended that the criterion of comparative cost effectiveness (as is in vogue in Australia) should be adopted by the NHS before it agrees to pay for new drugs.[3]

Present Trends in Pharmaceutical Industry

In the last two decades, while the Indian Drug Industry has grown considerably, a several disturbing trends are discernible. As these trends would have a bearing on changes within the Industry in case the Indian Patent Law of 1970 is changed to allow Product Patents in Pharmaceutical, a discussion on some of these trends would serve to highlight some relevant concerns.

Emphasis on Expensive Drugs

Most manufacturers are vying for the up-market section of the Indian consumer who can pay heavily to 'buy' health care. Production of expensive drugs outstrip demand while less expensive drugs are in short supply (see Table 4) Thus the indifference shown by companies towards production of low-cost essential drugs. In doing so the Industry is also in danger of falling into a self-destructive loop where 1000 manufacturers fight for the market for drugs among 5% of the population who can pay. This acts as a major constraint to further development of the Industry. With a Product Patent regime, such a trend can only be accentuated, leading to larger sections of the people being "costed out" of the market for drugs.

"Free" Market Ethos of the Reform Process

A study of the production pattern of monitored bulk drugs shows that larger companies are not interested in producing bulk drugs, but rather prefer to act as mere traders and middlemen by concentrating on the formulations market. In such a situation there can be no justification in liberalising production controls, and in fact more stringent production controls are called for.

The logic of the market forces is even less applicable to the Pharmaceutical Industry than other sectors. Unlike consumer goods, drugs are not purchased by the consumer on the basis of his choice or preference. They are purchased/ consumed on the advise of the medical pro-

Table 4 : DIFFERENCES IN PRODUCTION BETWEEN EXPENSIVE AND INEXPENSIVE DRUGS[40]

	INEXPENSIVE DRUGS			EXPENSIVE DRUGS			
DRUG	UNIT	DEMAND	PRODN.	DRUG	UNIT	DEMAND	PRODN.
Antibiotics							
Penicillin	MMU	330.00	304.40	Cephalexin	T	121.00	158.66
Chloramphenicol	T	200.00	80.84	Cloxacillin	T	64.00	127.47
Doxycycline	T	13.00	1.89	Amoxycillin	T	201.00	375.04
Pain Killers							
Aspirin	T	2042.00	1624.37	Ibuprofen	T	241.00	736.64
Anti-Leprosy							
Dapsone	T	64.00	12.00	Clofazimine	T	3.20	6.11

NUTRIENTS & MINERALS	163.6	59.5	52.4	88.06
COUGH & COLD & ANTI ALLERGIC	377.3	160.7	129.2	80.40
ANTI-INFLAM./ANALG., & ANTI SPASMODIC	413.4	226.6	150.0	66.18
RUBS & BALMS	48.0	41.1	26.6	64.96
ANTACID etc.	259.9	143.1	84.5	59.04
ANTI ANAEMIC	145.4	61.6	29.0	47.03
DIABETES, CVS., EPILEPSY, etc.	422.6	134.9	56.3	41.77
ANTI ASTHMATIC	123.5	27.6	11.1	40.22
ANTIBACTERIALS	1254.2	761.8	224.9	29.53
ANTI PARASITIC/ ANTI DIARRHOEAL	236.9	67.6	17.4	25.71
ANTI T.B.	177.7	104.5	18.6	17.84

Source : ORG Retail Survey of top 200 Brands, December 1994.

MNCs Reduce Productive Activities

A recent trend in the Industry would need mention here. Since 1990-91 there has been a discernible trend of a dwindling market share in the case of Multinational companies (see Table 7). Along side this trend there have been a spate of mergers and tie-ups in the Industry in the last few years. Many of these mergers have been a consequence of mergers that have been taking place globally among giant Transnational Pharmaceutical Companies. Bristol-Myers, Sqibb, Hoechst Marion Roussel, Novartis (merger of Ciba and Sandoz) and Pharmacia and Upjohn are all recent products of the trend in mergers. While the above has had its repercussions in the Industry, Indian companies like Piramal (which acquired Nicholas and some other Cos.) have also got into the act in the domestic Industry. Prominent tie ups between Indian firms and foreign Cos. include those between Ranbaxy and Eli Lilly, Cadila and American Herbal Products, Nicholas Piramal and Reckitt & Colman, Cheminor Drugs and Schien, Sarabhai and Magainin Pharma, etc.

Global Trends Towards Increased Monopolies

This global trend towards merger of Drug TNCs has been sparked off due to two kinds of compulsions. Globally, Drug Companies are being forced to reduce the cost of medicines. Pressure is being mounted by Health Insurance Cos., Health Management Organisations (HMOs) and Governments (in countries like U.K. and Canada where the State provides Health Insurance cover) all over Europe and North America.

Table 7 : SALES TURNOVER AND MARKET SHARE OF TOP 20 COS.

	SALES 1990-91	SHARE 1994-95	MARKET SHARE % 1990-91	1994-95
Ranbaxy	285.14	765.85	4.8	7.0
Glaxo	288.93	482.77	4.8	4.4
Lupin	126.52	334.49	2.1	3.0
Cipla	98.05	295.83	1.6	2.7
Hoechst	196.74	281.74	3.3	2.6
Dabur	45.33	260.36	0.8	2.4
Pfizer	111.64	211.99	1.9	1.9
SOL Pharma.	20.65	210.23	0.5	1.9
Sarabhai	118.50	209.92	2.0	1.9
Torrent	--	199.63	N.A	1.8
Dr.Reddy's Lab.	52.96	194.76	0.9	1.8
Alembic	123.25	192.72	2.1	1.7
Knoll	77.80	189.02	1.3	1.7
HAL	103.03	198.00 (est)	1.7	1.7 (est)
Kopran	--	180.01	N.A	1.6
IPCA	60.11	178.49	1.0	1.6
Smithkline Beecham	97.02	178.32	1.6	1.6
Burroughs Wellcome	93.10	175.18	1.6	1.6
Cadila	74.67	175.00 (est)	1.2	1.6
Parke Davis	94.36	148.39	1.6	1.3

Source : Centre for Monitoring of Indian Economy (CMIE)

These pressures have become stronger in recent years with the realisation that spiralling Drug costs are making Health insurance cover (whether state funded or privately managed) unsustainable. In all these countries there is a major move to insist on generic prescription in most cases, thus opening up a huge generics market. The ability of leading Drug TNCs to operate in this market is obviously compromised, as they do not have the advantage of using their Brand Images to corner large chunks of this emerging market. They are thus forced to compete on more or less equal terms which a large number of lesser known Cos. and also sell drugs at relatively cheaper rates. In the U.S., for example, from 1995 through 1997, generic drug prices showed a double-digit rate of decrease. Large Drug TNCs are thus in the process of working out new strategies -- which include greater cartelisation in the form of mergers and tie-ups -- to maintain their suzerainty over the global Pharmaceuticals market. Companies like Rhone-Poulenc and Bayer are already getting into the generics market.

cense and market a drug, respectively, without making available all the evidence about the beneficial and adverse effects of the drug. Pharmaceutical companies claim that clinical-trial reports are commercially valuable intellectual property. In practice, to support the marketing of their new products, most manufacturers make some of their intellectual property generally available by publishing some of the reports upon which their successful licence applications were based. Unfortunately, these reports are not generally representative of all the evidence. A report in 1980 showed that studies submitted in support of applications for new licences for drugs in which side-effects had been shown were less likely than others to be published[6]. There have been innumerable recent instances of suppression of vital information by Drug Companies about their products, even in an environment of strong patent protection. A few of these would merit mention here.

The Journal of the American Medical Association reports that a drug company suppressed research which showed that generic thyroid drugs were as effective as its own branded product for almost seven years. A randomised trial had concluded that two brand name and two generic forms of thyroxine sodium (levothyroxine) were bioequivalent and interchangeable without loss of therapeutic efficacy in most patients for the treatment of hypothyroidism. The two brand name products were Synthroid -- the most commonly used brand in the United States, and Levoxine (now renamed Levoxyl) -- a newer, cheaper product similar in price to generic forms. The authors of the study estimate that using generic or less expensive brand name products in the United States could save $356m a year.

These findings were published in 1997, despite being ready for publication in 1990. In 1987 Betty Dong and colleagues from the department of clinical pharmacy at the University of California Medical Center in San Francisco were asked by Flint Laboratories, the manufacturer of Synthroid, to carry out research comparing their drug with three others. Both sides apparently expected the study to show that Synthroid was superior. By the end of 1990, when the study was complete and it became clear that all four preparations were bioequivalent, the results were sent off to Boots Pharmaceuticals, which had taken over Flint Laboratories.

Dr. Rennie says that over the next four years Boots "waged an energetic campaign to discredit the study and prevent its publication. The study was eventually submitted to JAMA in April 1994, and a publication date was set for 25 January 1995. On 13 January 1995 Dr. Dong suddenly withdrew her manuscript from publication, citing impending legal action by Boots. Apparently, Dr. Dong had signed a restrictive covenant at the beginning of the study stating that all information gathered in the study was confidential and could not be published or released without written consent from Flint Laboratories.

In March 1995 the pharmaceutical branch of Boots was taken over by Knoll Pharmaceuticals. The FDA wrote to the company saying that its assertion that Synthroid was pharmokinetically superior to other preparations was misleading and that the information should not be disseminated. Under pressure from the FDA Knoll agreed on 25 November 1996 to allow the research to be published, but it still insisted that the conclusions were not supported by the data[7].

Drug companies submitting licensing applications to the Food and Drug Administration (FDA) in the United States will now have to reveal whether researchers involved in a drug trial have any financial interest in the company. The new regulations aim to eliminate possible data bias arising from financial considerations. Effective from February 1999, the new rules will require companies to disclose whether clinical investigators have received stock and patent options, payments in the form of research grants, gifts of equipment, consultant fees, and honorariums from lectures.

Drug companies routinely recruit doctors and scientists to study their products and to conduct clinical trials. Clinical investigators may receive substantial compensation for participating in these studies, and these may then be used to support an application to the FDA. A recent article[8] found that doctors who had a financial relationship with manufacturers of calcium channel blockers were more likely to consider them safe and promote them over competing antihypertensive treatments than those who lacked such relationships[9].

The problems that can result from inappropriate concern about intellectual property are illustrated in the case of human albumin solution, a blood product that has been used in the treatment of hypovolaemia and burns since 1941. The licensed indications for albumin are the

ment Foundation International (RAFI), in Canada has shown, if the contribution of Third World peasants and tribals is taken into account, the roles are dramatically reversed: the US owes US$302 million in royalties for agriculture and $5,097 million for pharmaceuticals to Third World countries, according to these latter estimates. In other words, in these two biological industry sectors alone, the US owes $2.7 billion to the Third World.[12]

Conclusion

Finally, an over-arching tendency in the Industry - applicable to both large Indian Cos. and TNCs - needs to be taken note of. Over the years many large Cos. have cut down Bulk Drug production, and are increasingly acting as mere traders. In many therapeutic groups, major production is accounted for by the Small Scale sector. In many cases the latter is depending heavily on imported bulk drugs, i.e. they function as suppliers of imported bulk drugs to large Cos. The trend is discernible, as commented upon earlier, in the sharp rise in the rate of growth of imports. This tendency has been fuelled by liberalisation in the Industry -- making imports easier and also the scrapping of ratio parameters which earlier made it mandatory that a certain percent of a Co's turnover should be made up of by bulk drug production. The Indian industry is thus faced with the twin danger of a resurgent Foreign Sector poised to strike, armed with a strong Patent regime, and an Indian Sector that is increasingly dependant on imported Bulk Drugs. A possible safeguard against such threats -- the Public Sector -- has all but been wound up. The implications for self reliance and Health Security are obvious.

Contrary to the reforms ideology the market does not regulate prices of drugs, as demand primarily depends on prescription habits of doctos, disease profiles, drug resistance etc. Hence the market cannot ever be a proper mediator of prices of drugs. The oligopolistic nature of the Industry, where few companies have monopoly within various therapeutic groups, makes the operation of the market even more infructuous. The present policy of abandoning price and production controls has already led to unjustified rise in prices. The concessions to the Foreign Sector mark a dangerous shift in our policy framework. These concessions and a possible change in the Indian Patents Act will return the Drug Industry to the situation prevailing in the fifties - a situation where TNCs can earn super profits due to their control over technology and brand images.

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Patent System and Pharmaceutical Sector

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ANALYSIS of the impact of changes in patent laws have acquired prominence in the context of the patent regime that the Uruguay Round of GATT is seeking to introduce. The volume of literature produced on the subject has been phenomenal which has contributed to the ongoing debate. But unfortunately there is also a flip side to the debate. Articles have been produced without adequate understanding of the terrain that is sought to be covered. Authors of such articles tend to take a predetermined position and then try to produce masses of data to overawe the uninitiated. The contribution by Prasad and Bhat (1993) forms a part of this category of articles. Right from the manner in which the problem is posed to the methodology adopted, not to speak of the inaccuracies in factual details and interpretations, the article appears to be somewhat contrived. The intent of the authors may have been to express their support for the Dunkel proposals and to convey the message that India should not be afraid of the proposals. But even in doing so they should have made a more competent attempt at handling the complex of issues involved.

The question that arises while arguing for a strengthening of the patent regime of any country is whether it will lead to either better technology transfer or indigenous technology generation. The question whether it will lead to higher prices is essentially a secondary question, and this latter aspect is central to Prasad and Bhat's paper. Unless the first question is answered, the arguments for strengthening the patent system are not valid. The question of the effect of a change in patent regime on technology has been cursorily treated (p 1049), probably because the authors do not understand its importance. There is a surprising lack of acquaintance with the literature and knowledge of how the patent system works, as is evident from the discussion. A good starting point for work on patents is Scherer [1980], at the very least the authors could have referred to this contribution to have some clarity on the subject.

Section II of the paper dealing with the 'Factors behind Emphasis on Strengthening Patents Regime' provides an entirely erroneous interpretation of the dimensions of India's technological dependence. While the fact of India's dependence on imported technology is beyond dispute, the use of patent statistics to arrive at this conclusion is confounding. Patents granted cannot be used as an indicator of transfer of technology under any circumstances. A little awareness about the working of the patent system is all that one requires to avoid such misinterpretations. Moreover, it is a known fact that technology sold to India has an overwhelming share of non-patented know-how. The authors would be well advised to have a look at the Surveys of Foreign Collaborations that the RBI has done in the past.

The discussion on technology gap is equally misleading, particularly in the use of statistics. A crude attempt is made to indicate the technology gap that exists between India and some countries in Table 6 using the Vernon-Hirsch product cycle theory without making any reference to the literature on the subject. The supporting data used in Table 6 have been picked up from Figure 63 of the publication of the Department of Science and Technology referred to as the source. Figure 58 of the same source, on the other hand, tends to suggest that the conclusions sought to be arrived at by the authors about India's technology gap *vis-a-vis* other countries is an exaggeration. 1986, for which data are provided in Table 6, is one of the worst years of India's trade in technology-intensive products. The ratio of exports to imports which had dipped to 0.11 when Congress made its come-back after the Janata rule had increased to 0.26 by 1984-85 and in 1985-86 it had fallen to 0.14. 1985-86 cannot therefore be considered as a normal year as it was defying a trend that was being witnessed in the 80s.

Section III sets out to indicate the 'Impact of Strengthening the Patents Regime on Drugs and Pharmaceuticals' by first indicating what effect the proposed change in patent regime would have on the prices of pharmaceuticals. The question of rise in prices of pharmaceuticals after the introduction of product patents with a longer patent term is inspired by the statements of the then United States Trade Representative (USTR), Carla Hills. This was done, in our view, essentially to divert attention from the more important question of what kind of patent system developing countries should have.

At the outset Prasad and Bhat make a bold statement that "...the arguments of many supporters and opponents of India's present patent regime are not backed by data...". This assertion appears self-contradictory since they do cite various authors who have provided data to bring out the adverse implications of the proposed changes.

In fact, evidences provided by Keayla and others, which the authors have made references to, can be used to contradict their view. They refer to the findings of the Kefauver Committee which had commented that Indian drug prices were "amongst the highest in the world" at a time when India was following the colonial Patents Act, the Patents and Designs Act of 1911, which was a product patent regime. The adoption of the process patent regime following the Patents Act of 1970 has radically changed the price situation in the Indian drugs industry in the decades of the 70s and the 80s—by the authors' own admission, drug prices are now amongst the lowest in the world.

Table 13 purports to give evidence to say that DPCO rather than patents were instrumental in the lower increase in prices of pharmaceuticals. Apart from various methodological problems of using index numbers to illustrate this point, which we shall not discuss here to avoid digression, there is one major lacuna in this analysis. If the DPCO was introduced in 1970 and the new Patent Act in 1972, how does one distinguish the impact of these two measures. The comparison between the two time periods before and after 1972 does not make any sense.

Evidence of the critical role of the patent system in determining the level of prices in the pharmaceutical industry is provided by the authors themselves. Table 15A and 15B indicate that countries in the immediate neighbourhood of India have relatively high drug prices and these countries do not follow a process patent regime. Sri Lanka and Indonesia, being members of Paris Convention, have a product patent regime and Pakistan, though not a member of the Paris Convention, follows the same Patents and Designs Act of 1911 which India had been following before the 1970 Act. The impact of the patent regime on prices is quite conclusive as is borne out by the data the authors provide.

While increase in the price of drugs and pharmaceuticals is inevitable if the process patent regime is changed to a product

patent one, a position which the authors also accept, they have adopted a queer line of reasoning to assuage the fears that much damage would be caused as a result. The first is their excessive emphasis on the use of DPCO to quell the pitch of price rise. The second is that the rise in the price of patented drugs would not affect the poor as they do not consume modern medicines!

Reliance on price controls, particularly after the Dunkel proposals are accepted, would not remain an option as along with the Trade Related Aspects of Intellectual Property Rights (TRIPS) which includes patents, Trade Related Aspects of Investment Measures (TRIMs) would also have to be accepted. The latter provides by any obligations or controls. In view of this the repeated references to DPCO as a controlling mechanism when drug prices do go up after accepting the Dunkel proposals is simply astounding.

The assertions on the impact of increase of drug prices on different sections of the population, particularly its impact on the poor, is very disquieting. Why such concern for the poor after leaving them outside the health system? They do not have entitlement for health services in the existing system (see, for example, the report on three surveys conducted on the health care system—*Business India*, August 17-30, 1992, pp 138ff). The effort should be to expand the health services to all, and more importantly to create entitlements for the poor.

This simplistic analysis is based on two assumptions. First, strengthening the patent system will result in drug inventions in developed countries relevant to their health needs. Such needs may be useful for the rich in developing countries. Second such strengthening will not result in any drug inventions of relevance to the poor. If this argument is valid, and the overwhelming desire is to have product patent regime, then can one come to the policy conclusion that to lessen the effect of any adverse affect of increase in drug prices that is inevitable, the number of people below the poverty line should be increased?

The estimation of what percentage of drugs that are produced in India are still under product patents abroad was an idle question till the former USTR, Carla Hills' statement that only a small percentage of the total pharmaceuticals produced in the country are covered by patents. The situation on the ground is, however, quite different. In some therapeutic groups it has been found that the patented drugs account for more than 90 per cent of the total production. The authors not only take the former USTR's statement uncritically, they also seem to suggest that for a majority of the population, modern medicines, viz, the patented drugs, will remain out of their reach.

In their comments on the drugs scene in India, the authors make contradictory statements. They begin by arguing that "... India is a drug starved country" and then go on to state that "... India is almost self-sufficient in drugs ...".

The handling of the discussion on the GATT negotiations is the lowest point of the paper. One of the most contentious issues in the proposed agreement on TRIPs, viz, treating importation as working of the patent has been discussed without a proper understanding of the proposals. This is clearly reflected in the two statements that are made in the paper. The authors first make an emphatic statement that "in the Dunkel Draft Text nowhere has it been mentioned that imports are tantamount to working..." They go on to say that "though the text says that imports cannot be allowed by others without the consent of the patentee, this necessarily does not mean that the patentee can himself import it".

The confusion that the authors create in this regard can be settled by looking at two articles of the TRIPs agreement, Articles 28 and 31. In Article 28, which lays down the rights of the patentee, imports have been introduced as one of the exclusive rights. Article 31 lays down the conditions for working of the patent and the conditions are so defined that 'working' would now be allowed only under exceptional cases. These two articles taken together indicate that the TRIPs proposals are in fact aimed at virtually taking away the right of the patent granting country to ensure working of the patent granted to a foreign patentee while at the same time they give the patentee the right to exclusively import the product covered by the patent in the country of grant.

In the discussion pertaining to the so-called transitional period provided in the Dunkel Draft Text, the authors commit glaring errors. These are briefly given as under:

(i) All countries would not get a transitional period of five years for changing the patent regime. Developed countries get only one year and all developing countries get four years over the period available to the developed countries, i e, five years.

(ii) The exclusive marketing rights for pharmaceutical and agro-chemical products that the authors indicate is being insisted on by the Americans is in fact a proposal provided in the Dunkel Draft (Article 70.9).

(iii) Providing exclusive marketing rights is not called 'pipeline protection', accepting applications for product patent immediately after the new GATT comes into force is called 'pipeline protection'. This provision has been included as a part of the transitional arrangements.

(iv) The authors indicate that "the question of 'pipeline protection' has not even been mentioned in the original text of Dunkel", a statement that not only contradicts their earlier remarks on 'pipeline protection', but is also confounding! How many texts did the former director general of GATT, Dunkel, prepare, according to the authors?

(v) In the discussion on transitional arrangements the authors use a wrong expression 'pipeline protection granted to developed countries under MFA', used by them to mean the 'transition period' given to the developed countries for removing the quota restrictions under MFA.

It is impossible to list all the other errors that the article is strewn with. Some of these are: (i) "most American drugs are expected to expire in 1990-95", and (ii) "Patents office is the highest office sanctioning transfer of technology to India", and last but not the least, (iii) RCA is expanded as Relative Competitive Advantage.

The authors display surprising ignorance about the status of the Paris Convention when they comment on India's joining it. A reading of the Dunkel proposals would have told them that this issue would automatically get settled once the TRIPs agreement is signed. Article 2 of the draft agreement on TRIPs provides that countries would have to comply with Articles 1-12 and 19 of the Stockholm Act of the Paris Convention (1967).

A word about the source of patent statistics used in the paper. Looking at the comprehensiveness of the data one suspects that the original source lies elsewhere. To our knowledge the Economic Growth Center at Yale University has the only comprehensive database on patents granted in India.

And finally, one cannot gloss over the complete lack of orderliness in the presentation of the references in an academic article. For example, note 42 refers to the Draft Final Act of the Uruguay Round Negotiations, which is known as the Dunkel Draft Text as Dunkel Committee Report! The Trade Negotiations Committee which had tabled the Draft Final Act does not even find a mention.

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Strengthening India's Patent System
Implications for Pharmaceutical Sector

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This paper examines the factors behind the current demand for strengthening the Indian patents system and the effect of such strengthening on the pharmaceutical sector. Against the background of their study of these issues, the authors attempt to arrive at policy conclusions and to answer the following questions: (i) Should India amend its Patents Act, join the Paris Convention or toe the Dunkel line? (ii) If the Patents Act is to be amended, what are the modifications needed? And (iii) what policy changes are needed in the context of the pharmaceutical sector specifically?

I
Introduction

THE issues of Intellectual Property Protection (IPP) is receiving great attention at present and there is great pressure on developing countries in general and India in particular to strengthen their Intellectual Property Rights (IPRs). The purpose of this paper is not to go into the whole gamut of discussions pertaining to IPRs or their evolution in international negotiations.[1] The purpose of this paper is to investigate the following specific issues:

(1) The factors behind the emphasis on strengthening the Indian patent system in India.

(2) The effect of strengthening the Patents Act in the case of India's pharmaceutical sector.

(3) The *modus operandi* for strengthening India's patent regime.

In the light of our study of the above mentioned issues, we have made an attempt to arrive at policy conclusions, which try to answer the following questions: (1) Should India amend its Patent Act, join the Paris Convention or toe the Dunkel line? (2) If India has to amend its Patent Act, what are the modifications needed? (3) What policy changes are needed in the context of patents for the pharmaceutical sector?

The main sources of data for this study are the patents data and company's data at the ISID. The former are available from 1972 to 1989 and the latter from 1974-75 to 1989-90. Besides these data bases, Monthly Index of Medical Specialities (MIMS), Indian Drug Manufacturers Association (IDMA), Organisation of Pharmaceutical Producers of India (OPPI), World Intellectual Property Organisation (WIPO), United Nations Conference on Trade and Development (UNCTAD), Department of Science and Technology (DST), Government of India, etc, have been used wherever necessary.

II
Factors behind Emphasis on Strengthening Patents Regime

In this section, let us examine the important factors behind the new emphasis on strengthening the patents regime in India. This involves the examination of the following factors: (1) The extent of dependence of India on different countries for technology. (2) The situation in developed countries, especially US with respect to their economy, balance of payments position and future growth. (3) The change in the political situation in India, developed countries and world in general.

India's increased dependency on developed countries for technology can be seen by examining three aspects: (1) The importance of different countries in the patents granted by India. (2) The dependency and relative dependency ratio of India with respect to patented technology. (3) The technology gap between India and the developed countries and India and other developing countries and other technology-related indicators of India.

Importance of the Different Countries in the Patents Granted by India

Table 1 shows that the patents granted by India to developed countries forms a major chunk of all patents granted by India and the only important category among the developing countries is the patents granted by India within the country. Among the developed countries, the US (as an individual country) and Europe (as a group of countries) occupy an important place. Since 1982 the percentage of patents granted to Japan is increasing, though it is nowhere near that of the US. Country-wise, the US tops the list of patents granted by India. This is given in the official publication of the government of India[2] which says that the US simply accounted for 40.3 per cent of total applications filed for patents by foreign nationals during 1989-90. This is followed by West Germany, Japan, UK and France. Then comes Switzerland, Russia, Netherlands, Italy and Sweden. Among the developing countries the patents granted by India to Indians is lower than that of the US, individually and Europe in toto. Among the LDCs (other than India), East Europe is very important in 1984-89. Next is Israel and NICs, Malaysia and Thailand. South Asia and Africa are nowhere in the picture.

Table 2 shows the percentage of patents granted by countries and by sectors. Sector-wise, sectors C and B shows the highest percentage of patents granted. Among the countries also C and B sectors are important in the case of the patents granted to developed countries. But in the case of patents granted to Indians all the sectors seem to be well balanced.

Thus, the tables clearly show that India depends on developed countries for technology[3] and that too on a single country like the US or group of countries like European countries. Sector-wise India's dependence is more in C (chemistry, metallurgy) and B (performing operations, transporting) categories. One note of caution is that we have not given weightage to type of patents by the extent of the technology involved.

Dependency and Relative Dependency Ratio of India with Respect to Patents

The dependency ratio (which here, means the total number of patents granted by India to non-Indians as a proportion

of the patents granted by India to Indians) given in Table 3 shows that it has been high till 1978, low from 1979 to 1982 and then again higher since 1983. While the total number of patents (both in force and sealed) has fallen, the dependency ratio has not fallen over the years, except for the initial fall from 1968 to 1970 (i e, before the Patent Act was implemented), indicating that India's increased dependency for technology on developed countries has not been allowed to materialise due to the 1970 Patents Act.

The relative dependency ratio (which, here means the total number of patents granted by India to a particular foreign country (or group of countries) as a proportion of the patents granted by India to Indians) also given in Table 3 shows that India's relative dependency ratio is still absolutely higher with Europe than with the US and India's dependency on the US (as an individual country) and Europe (as a group) is more than India's dependency on itself. The relative dependency ratio of India with the US which has always been at a lower level than with Europe fell from 1976 to 1983 and than regained to the earlier level. But the relative dependency ratio on Europe also fell from 1976 to 1980, then it rose, but never regained its earlier level, thus narrowing the gap between the relative dependency ratios on the US (a single country) and on Europe (a group of countries). The relative dependency ratio on Japan, though lower than both the US and Europe, and has shown a fall during 1976 to 1981, has regained its earlier level and even risen to higher levels. The relative dependency ratio of India with other developing countries which is also at a lower level, has also fallen during 1976 to 1981, and then risen, but has never regained its earlier level. Strangely the relative dependency ratio of India with USSR has been very low and it shows many ups and downs.

Another important fact is that India's dependency ratio in terms of patents in force is higher than in terms of patents sealed as can be seen in Table 4.[4] The table also shows that India's dependency ratios (both in terms of patents sealed and patents in force) before 1972, i e, the period before the 1970 Patents Act was implemented, was very much higher. While during the period 1976-77 to 1980-81 the dependency ratio in terms of patents sealed have shown a fall and then a gradual rise, the dependency ratio in terms of patents in force shows a fall through the entire period after 1976-77. This is possible because of the greater death rate of old patents, though the birth rate of new patents after 1981-82 is rising.

The above analysis brings into focus the following important facts: (1) India's relative dependence on other countries, especially the developed and among them the US and Europe, and among them on the US as a single country has been increasing despite the fact that total number of patents sealed is falling. In today's unipolar world this has far-reaching implications. (2) India's dependency on the west, which fell from 1977 to 1980, coinciding with the Janata Party rule, shows a rise from 1981 during the Congress Party rule. (3) As noted earlier, the fact that total number of patents are falling consequent to the 1970 Patent Act and the fact that dependency on developed countries is not falling, shows that the relative high dependency on western technology has not been allowed to materialise.

Whether a lower dependency ratio is good or bad is a debatable question. But certain inferences can nevertheless be made. For a relatively underdeveloped economy a lower dependency ratio indicates that it is less dependent on foreign countries for technology. This necessarily does not mean that it is good for the economy as technology transfer will be low, while the economy has not yet reached a stage of relative self sufficiency in technology.

However at this stage we are concerned only with showing India's relative dependence on other countries for technology which has put pressure on India to accept the new IPRs and the above analysis clearly shows India's continued dependence and increasing dependence on developed countries for technology in terms of patents in force and patents sealed respectively.

Indicators of Technology Gap and Other Technology-Related Indicators

The technology gap between India and developed countries and India and other developing countries can be judged with the help of comparative indicators of technology like expenditure on R and D as a percentage of GNP, per capita R and D expenditure, number of scientists, engineers and technicians (SET) per thousand population, SET in R and D per thousand population.

The other technology-related indicators of India which show its dependence on technology from other countries, especially the developed countries are the following: (1) India's trade in technology-intensive products; (2) External assistance for S and T programmes received by India; (3) Foreign investments in India; and (4) Royalties, lumpsum amounts, technicians' fees, etc, received and paid by India.

In Table 5, the comparative technology indicators of India and other countries are given. Column I gives the expenditure on R and D as a percentage of GNP for selected countries. This column shows that India invests a very small percentage

Table I: Patents Granted by India: Share of Different Countries (1972-1989)

(In per cent)

Year	Ind	UK	USA	Jap	Fra	WGm	Rus	Can	Aus	Ast	Bel	Den	Net	Nor	Swe	Sws	Italy	DCs	Europe	LDCs
1972	20.18	13.04	26.61	3.88	3.35	10.57	1.94	1.15	0.26	0.18	1.41	0.79	2.20	0.44	1.23	3.44	4.14	75.24	41.32	5.198
1975	20.16	11.31	24.85	4.10	5.80	9.91	2.46	0.59	1.11	0.47	0.70	0.64	2.11	0.23	1.52	4.04	3.87	74.15	40.97	3.458
1976	24.81	11.86	23.42	3.13	4.03	11.30	2.26	1.02	0.75	0.56	0.83	0.83	2.64	0.34	0.98	2.56	3.50	70.33	39.65	3.351
1977	27.88	9.39	22.45	2.81	3.71	12.81	1.98	1.26	0.83	0.47	0.72	0.79	1.87	0.58	1.44	3.13	2.84	67.66	38.31	2.518
1978	26.62	9.24	24.47	2.52	4.12	10.70	3.11	0.55	0.64	1.01	0.14	0.59	2.10	0.59	0.69	3.48	3.93	68.62	37.28	3.934
1979	36.69	7.95	23.14	2.56	3.41	8.80	1.85	0.43	0.92	0.35	0.14	0.14	2.13	0.14	1.14	3.62	2.06	59.76	30.87	7.310
1980	36.50	8.51	20.65	2.45	4.89	9.30	2.64	0.68	0.59	0.78	0.39	0.29	1.96	0.20	0.98	2.74	2.54	60.47	33.46	0.685
1981	32.85	9.00	21.33	1.95	3.89	10.71	2.76	1.38	0.65	0.81	0.32	0.24	1.70	0.24	1.87	4.14	2.35	63.99	35.93	3.650
1982	30.59	7.70	22.00	4.52	3.78	11.63	2.96	0.96	1.04	0.30	0.37	0.15	1.85	0.37	1.04	3.63	2.30	65.41	33.85	2.444
1983	24.87	5.94	24.16	5.62	4.84	13.76	3.23	0.58	0.84	1.23	0.71	0.39	1.81	0.32	0.65	4.91	2.33	72.03	37.53	0.323
1984	21.75	8.59	25.76	4.64	6.16	12.13	2.32	0.77	1.03	0.96	0.70	0.55	2.84	0.37	1.18	3.39	2.73	75.19	40.47	2.912
1985	25.29	8.82	26.26	5.51	4.74	8.98	1.48	0.82	1.12	0.51	0.36	0.76	2.80	0.46	1.27	3.16	3.11	71.65	36.36	2.346
1986	28.95	7.71	27.54	4.16	6.30	9.67	1.10	0.24	1.16	0.86	0.18	0.37	1.53	0.31	1.53	2.08	2.33	67.99	33.72	2.938
1987	27.60	9.17	27.71	4.07	6.66	8.73	1.66	0.68	1.05	0.75	0.48	0.54	1.29	0.20	1.63	3.57	2.17	71.71	36.37	2.309
1988	22.20	6.61	29.27	4.61	5.84	11.39	3.47	1.06	1.76	1.06	0.33	0.20	1.80	0.16	1.18	3.80	1.84	75.18	34.82	2.367
1989	19.70	5.15	29.29	5.98	5.27	12.01	3.14	1.24	2.54	0.65	0.41	0.59	2.43	0.41	1.42	3.43	2.31	77.22	34.91	2.367

Source: Calculated from the data available at the ISID.

of GNP on R and D, 0.9 per cent in 1990, while most of the advanced countries devote more than 2 to 3 per cent of their GNP on R and D. Even Pakistan is ahead of India with 1 per cent expenditure on R and D in 1987. The gap becomes more sharper when we examine the per capita R and D given in column 2. India is at a very low level of the US $ 2.76, while most developed countries are above the US $ 200 level and some even above the US $ 500 level. NICs like Republic of Korea and Singapore show a level of the US $ 75 and 68 respectively. Column 3 shows the number of SET per thousand population which is also at a very low level of 4.50 in 1990 which is lower than the developed countries, NICs and even other developing countries like Brazil, Philippines, etc. This fact should make us realise that though India boasts of being one of the most important nations in the world in terms of SET, in relation to India's population, India is at a very very low level. Similarly SET in R and D per thousand of the population is at a very low level as can be seen in column 4.

Table 6 shows the export and import market shares of some selected technology-intensive products of India and some other countries. This table shows that India's import market shares are higher than export market shares and is also relatively higher than most of the other countries given in the table for almost all the four categories of technology-intensive goods.

Table 7 shows that the share of imports of technology-intensive products are high in India's imports and have risen in the 80s, though it shows some ups and downs as well. More important, is the fact that while the ratio of exports to imports is at the 0.50-0.70 range in the 80s the ratio of technology-intensive exports to technology-intensive imports is still lower at the 0.11 to 0.26 range. This shows that while India is relatively more dependent on other countries in its commodity trade, it is more so in the case of technology-intensive commodity trade. The ratio in the case of trade of others commodities is more than 1 in all the years indicating clearly that India's adverse balance of trade has been due to trade in technology-intensive products. The only point of solace for India is that the ratio is almost constant over the years in the case of technology trade, while it has fallen in the 80s in the case of total trade.

Table 8 shows the external assistance received by India for S and T programmes which is a sizeable amount of US $ 110.35 million in 1987. Among the donors the bilateral sources are more important than multilateral sources, indicating India's greater dependence for technology

TABLE 2: SHARE OF PATENTS IN EACH CATEGORY OF IPC TO TOTAL—COUNTRYWISE (1972-1989)

Category	UK	USA	WGm	Fra	Jap	Ind	Rus	Other DCs	Other LDCs
				1972-74					
A	6.33	7.95	4.17	2.63	27.27	18.34	4.55	6.18	15.38
B	34.81	33.11	16.67	28.95	18.18	19.65	31.82	23.60	23.08
C	18.99	31.46	50.83	44.74	43.18	20.09	18.18	44.38	41.03
D	7.59	4.30	12.50	0.00	0.00	6.11	4.55	7.30	0.00
E	1.27	1.99	2.50	0.00	0.00	6.11	0.00	3.93	7.69
F	13.29	7.28	4.17	10.53	0.00	12.23	13.64	6.74	7.69
G	7.59	3.64	3.33	2.63	6.82	10.92	13.64	1.12	0.00
H	10.13	10.26	5.83	10.53	4.55	6.55	13.64	6.74	5.13
				1975					
	UK	USA	WGm	Fra	Jap	Ind	Rus	Other DCs	Other LDCs
A	5.76	11.79	5.92	4.04	8.57	11.92	0.00	6.08	6.82
B	28.27	19.81	18.34	15.15	22.86	21.80	35.71	17.87	17.05
C	17.80	30.19	38.46	45.45	42.86	26.16	9.52	44.87	43.18
D	5.24	2.83	8.28	6.06	0.00	3.78	0.00	10.27	5.68
E	3.66	2.83	1.18	3.03	4.29	4.65	4.76	3.80	3.41
F	18.85	11.32	9.47	13.13	8.57	7.56	7.14	7.60	6.82
G	3.14	6.60	2.37	9.09	2.86	9.88	2.38	4.18	1.14
H	17.28	14.62	15.98	4.04	10.00	14.24	40.48	5.32	15.91
				1980					
	UK	USA	WGm	Fra	Jap	Ind	Rus	Other DCs	Other LDCs
A	8.05	9.00	5.26	2.00	16.00	12.87	7.41	7.56	6.45
B	28.74	32.70	27.37	20.00	8.00	21.98	22.22	26.05	32.26
C	13.79	27.49	22.11	26.00	48.00	25.74	7.41	28.57	41.94
D	2.30	1.90	11.58	2.00	4.00	4.29	0.00	8.40	0.00
E	6.90	3.32	2.11	16.00	4.00	5.36	3.70	5.88	6.45
F	18.39	12.80	12.63	28.00	12.00	11.80	14.81	8.40	6.45
G	3.45	2.84	5.26	2.00	4.00	8.04	22.22	9.24	0.00
H	18.39	9.95	13.68	4.00	4.00	9.92	22.22	5.88	6.45
				1985					
	UK	USA	WGm	Fra	Jap	Ind	Rus	Other DCs	Other LDCs
A	10.12	13.40	2.84	2.15	9.26	14.31	0.00	11.40	14.29
B	23.81	24.08	21.59	26.88	18.52	18.35	10.34	25.08	19.64
C	23.21	25.83	42.05	32.26	37.96	29.23	31.03	26.06	33.93
D	1.19	2.52	10.80	7.53	4.63	3.83	0.00	9.12	3.57
E	5.95	2.52	1.14	3.23	1.85	5.44	17.24	4.89	8.93
F	21.43	14.76	9.09	16.13	7.41	15.93	24.14	13.36	7.14
G	3.57	5.63	3.98	3.23	3.70	5.85	6.90	3.58	1.79
H	10.71	11.26	8.52	8.60	16.67	7.06	10.34	6.51	10.71
				1989					
	UK	USA	WGm	Fra	Jap	Ind	Rus	Other DCs	Other LDCs
A	4.65	11.11	3.94	7.87	11.88	15.02	11.32	7.66	23.53
B	30.23	16.57	21.18	17.98	13.86	18.02	26.42	27.01	19.61
C	13.95	29.29	29.06	32.58	30.69	30.93	33.96	28.10.	21.57
D	0.00	2.83	8.87	3.37	2.97	3.60	0.00	7.30	0.00
E	10.47	1.21	2.46	3.37	0.00	8.41	1.89	4.01	7.84
F	23.26	16.36	14.29	8.99	18.81	9.61	16.98	14.23	15.69
G	4.65	9.49	4.43	13.48	5.94	8.71	1.89	5.84	3.92
H	12.79	13.13	15.76	12.36	15.84	5.71	7.55	5.84	7.84

Notes: As per International Patent Classification; A = Human Necessities; B = Performing Operations, Transporting; C = Chemistry, Metallurgy; D = Textiles, Paper; E = Fixed Consructions; F = Mechanical Engg. Lighting, Heating, Weapons, Blasting; G = Physics; H = Electricity.

Source: Calculated from the data available at the ISID.

transfer on bilateral than multilateral sources. Here of course, the European countries are the principal donors.

Table 9 shows the foreign investment stocks till 1989 and fresh approvals to India in the 90s. The table shows that the manufacturing sector and in this the technology-intensive products have been important in the foreign investment stocks till 1989. Among the new approvals also (in terms of numbers) technology-intensive sectors have been important till 1990. The total approvals of foreign investments in 1992 is more than the stock of foreign investments till 1989, and the US has a major share in the new approvals. The technology gap between India and the developed countries is cited as the important reason for liberalisation of foreign investment and today India is dependent on the developed countries in general and the US in particular for technology transfer via foreign investments. In fact 60 per cent of foreign direct investment approvals between August 91 to February this year is the US.[5]

Table 10 shows the payments and receipts by India for technology trade in the form of royalties, technical know-how and technicians' fees. Royalties are mainly the payments/receipts of recurring nature related to patented technology; technical know-how payments/receipts are mainly for lumpsum (non-recurring) royalties[6] and technicians' fees are the payments/receipts for technicians. While the receipts are small under all categories, payments are quite substantial, with payments for technical know-how becoming increasingly important in the 80s. This shows the preference in the 80s of the government to purchase technology for lumpsum payments. This of course decreases our dependence on foreign countries to some extent, yet lumpsum payments can be for both patented and non-patented technology and on the whole India's dependence has been increasing. If we see the percentage change in the nine-year period of 80s over 70s (from 1971-72 to 1979-80), lumpsum payments show a per cent increase of 1,099 per cent whereas for royalties it is 343 per cent. A remarkable increase in payments of management fees, etc, and payments for other professional service (which are also related to technology transfer) has taken place in the 80s.

The above analysis clearly shows the technology gap between India and other countries and India's continued and increasing dependence on advanced countries in general and some countries (the US) and groups of countries (Europe) in particular for technology.

Economic Situation in Developed Countries

In the earlier section, we have noted the continued domination of developed countries and the growing technology gap between developed countries and developing countries like India. Here we intend to show how the changing economic situation in the world and in the developed countries have made them to focus their attention on issues like IPRs. (Here we consider some important indicators needed for our analysis like exports, imports, trade balance, current account balance, growth rate of exports, imports, etc, for the world and some developed countries like the US, the UK, etc, and trade between DCs and trade of LDCs with DCs.)

Table 4: Dependency Ratio of Patents Sealed and Patents in Force

Year	No of Patents Sealed		No of Patents in Force		Dependency Ratios	
	Indian	Foreign	Indian	Foreign	P Sealed	P Force
1968	426	3704	3547	37816	8.7	10.7
1969	645	4308	2231	25483	6.7	11.4
1970	596	2936	2568	25753	4.9	10.0
1971	629	3294	3063	27663	5.2	9.0
1972	265	1245	3673	28650	4.7	7.8
1972-73	278	1064	3718	28718	3.8	7.7
1973-74	358	1058	3948	28270	3.0	7.2
1974-75	737	3207	3039	24758	4.4	8.1
1975-76	426	1894	2991	23453	4.4	7.8
1976-77	928	1964	2746	19780	2.1	7.2
1977-78	657	1857	3065	19795	2.8	6.5
1978-79	281	499	2469	13966	1.8	5.7
1979-80	516	1657	2786	14474	3.2	5.2
1980-81	349	670	2757	14448	1.9	5.2
1981-82	421	936	3038	14892	2.2	4.9
1982-83	405	822	3329	15291	2.0	4.6
1983-84	340	980	3523	15726	2.9	4.5
1984-85	263	1206	3008	13162	4.6	4.4
1985-86	451	1500	2549	10844	3.3	4.3
1986-87	532	1594	2004	10059	3.0	5.0
1987-88	588	1516	2150	10115	2.6	4.7
1988-89	795	2585	2584	11015	3.3	4.3

Source: GOI, Department of Science and Technology, *Research and Development Statistics* (various issues).

Table 3: Relative Dependency Ratio of Patents and Its Index Numbers

Year	Dependency Ratios of India						Index Numbers of Dependency Ratios					
	In General	With USA	With Japan	With Europe	With LDCs	With USSR	In General	With USA	With Japan	With Europe	With LDCs	With USSR
1972	3.956	1.319	0.192	2.048	0.227	0.096	100.000	100.000	100.000	100.000	100.000	100.000
1975	3.959	1.233	0.203	2.032	0.282	0.122	100.075	93.462	105.906	99.216	124.178	127.088
1976	3.030	0.944	0.126	1.598	0.196	0.091	76.595	71.570	65.550	78.020	86.206	94.772
1977	2.587	0.805	0.101	1.374	0.160	0.071	65.391	61.054	52.381	67.098	70.462	73.871
1978	2.756	0.919	0.095	1.400	0.179	0.117	69.661	69.704	49.184	68.375	78.694	121.618
1979	1.725	0.631	0.070	0.841	0.097	0.050	43.610	47.814	36.241	41.083	42.590	52.347
1980	1.740	0.566	0.067	0.917	0.083	0.072	43.979	42.895	34.883	44.769	36.600	75.347
1981	2.044	0.649	0.059	1.094	0.096	0.084	51.675	49.241	30.842	53.409	42.407	87.385
1982	2.269	0.719	0.148	1.107	0.131	0.097	57.345	54.530	76.871	54.029	57.581	100.814
1983	3.021	0.971	0.226	1.509	0.125	0.130	76.353	73.661	117.609	73.685	54.905	135.183
1984	3.598	1.185	0.214	1.861	0.141	0.107	90.951	89.837	111.148	90.868	61.952	111.148
1985	2.954	1.038	0.218	1.438	0.121	0.058	74.656	78.733	113.325	70.189	53.272	60.869
1986	2.455	0.951	0.144	1.165	0.106	0.038	62.041	72.141	74.822	56.879	46.552	39.612
1987	2.906	1.082	0.159	1.420	0.105	0.065	73.448	82.063	82.831	69.355	46.141	67.645
1988	3.504	1.318	0.208	1.568	0.118	0.156	88.559	99.942	108.109	76.562	51.810	162.642
1989	4.075	1.486	0.303	1.772	0.156	0.159	103.001	112.717	157.856	86.511	68.769	165.670

Source: Calculated from the data available at the ISID.

Table 11 shows the exports, imports, trade balance, current account balance, export and import of goods and non-factor services in GDP for the world, industrial countries in total and for some industrial countries and developing countries. The table shows an increase in trade and current account deficits for countries like the US.

In Table 12 the growth of trade in manufactures is given which shows that in the 80s there is a fall in growth rate of exports of the world in general, a relatively greater fall in exports of developed market economies to developing countries as compared to their exports to developed countries. Further while the exports from developed to developing economies has fallen to a great extent, exports from developing to developed countries shows a still greater fall. Thus the developed countries are depending less on developing countries for imports weakening the position of developing countries. Meanwhile the growing balance of payments deficits of the developed countries, especially the US has made them to search for new areas of interest to them and IPRs is one such area. Table 11 also shows that the balance of payments for Japan and West Germany are positive and they are neither the initiators, nor vociferous in demanding IPRs. While the weakness of India and LDCs have further weakened them in their bargaining power, the weakness of the economic situation of the US and other European countries have made them vociferous in the three new issues 'Services', TRIPS, and TRIMS.

Change in World Political Scenario

The change in the world political scenario has also contributed to the new emphasis on TRIPS. The fall of the Soviet Union has made this world a unipolar world with the US as the only superpower. The political and economic weaknesses in India had made it vulnerable at the very moment when the US started mounting pressure to liberalise. Many developing countries, which were hitherto opposed to the new patents regime have mellowed down and even adopted the new regime. The fall in the importance of UN agencies like UNCTAD (which also have slowly shifted to the philosophy of liberalisation) and the rise in importance of World Bank-IMF combine and the dependence of India on these organisations have enabled the US and other MDCs to pressurise India to accept the new patents regime.

To sum up, while the dependence of India on different countries for technology had prepared the ground and the economic conditions of the advanced countries have made the developed countries more vociferous, the changed political situation in the world and in India, have finally paved the way for pressurising India to change its patents regime.

III

Impact of Strengthening Patents Regime on Drugs and Pharmaceuticals

The impact of strengthening the patents regime on drugs and pharmaceuticals can be seen under the following headings: (a) Effect on prices, (b) Other effects—(i) Effects on different sections of the population; (ii) Effect on Indian industrial sector in general and by types of companies in particular; (iii) Effect on other sectors of the economy via linkages; (iv) Effect on technology transfer to India, development of indigenous technology and quality of drugs; and (v) Effect on balance of payments.

Effect on Prices

The most debated issue at present regarding the impact of strengthening the patents regime on the Indian pharmaceutical sector is one of rise in prices. However, the arguments of many supporters and opponents of India's present patents regime are not backed by data and also data given by alternative sources differ greatly. A rigorous quantification of this aspect, though not impossible, is difficult at this stage. So we have made an attempt to arrive at logical conclusions weaving together pieces of data which are readily available to us. The effect on prices can be seen by examining the following aspects: (i) Examining the changes in drug prices before the present patents regime and immediately after the introduction of the present patents regime; (ii) Examining the impact on prices in India and prices in other countries which have/have not

Table 5: Comparative Technology Indicators for Selected Countries

Country	Expenditure on R and D as Percentage of GNP		Per Capita R and D in US Dollar		Scientists, Engineers and Technicians (SET) Per Thousand Population		SET in R and D Per Thousand Population	
	R and D Per Cent of GNP	Year	R and D (US $)	Year	SET	Year	SET	Year
Brazil	0.4	1985	6.41	1985	11.23	1980	0.39	1985
Philippines	0.1	1984	0.68	1984	36.65	1980	0.12	1984
Cuba	0.9	1987	NA	NA	14.35	1981	2.01	1989
India	0.9	1990	2.76	1990	4.5	1990	0.27	1990
Pakistan	1.0	1987	2.91	1987	4.71	1990	0.15	1988
Singapore	0.9	1987	68.14	1987	26.63	1980	1.85	1987
Spain	0.6	1986	45.97	1987	36.47	1986	0.74	1987
Australia	1.3	1987	153.85	1987	53.08	1986	3.33	1988
Canada	1.4	1987	216.06	1987	184.81	1986	3.4	1988
Rep of Korea	1.9	1988	75.21	1988	53.14	1981	2.2	1988
Germany	2.8	1987	523.98	1987	77.84	1987	4.71	1987
France	2.3	1987	364.13	1987	NA	NA	5.07	1988
Hungary	2.4	1988	60.82	1988	45.76	1984	3.26	1989
Japan	2.8	1987	558.8	1987	111.14	1987	6.05	1989
Sweden	3	1987	577.57	1987	NA	NA	6.14	1987
UK	2.3	1986	226.83	1986	NA	NA	NA	NA
USA	2.6	1988	514.70	1988	21.46	1988	3.85	1988
Czechoslovakia	4.5	1988	177.43	1988	35.45	1980	6.94	1989
GDR	4.6	1988	NA	NA	103.23	1988	11.7	1989
Israel	3.7	1983	246.43	1983	82.6	1984	5.77	1984
USSR	6.2	1988	NA	NA	125.82	1987	5.97	1990

Sources: (a) GOI, Department of Science and Technology, *Research and Development Statistics*, 1990-91.
(b) GOI, DST: *Pocket Data Book*, 1989.

Table 6: Export and Import Market Shares in Per Cent of Some Selected Technology Intensive Products of Certain Countries for 1986

Country	Chemical and Allied Products		Machinery		Electrical Equipment		Primary Metals	
	Export	Import	Export	Import	Export	Import	Export	Import
USA	14.35	14.17	20.44	12.57	9.02	10.88	1.23	4.51
FRG	15.1	18.89	20.49	11.17	8.14	6.89	6.18	6.3
Japan	5.44	30.65	20.82	4.11	20.75	2.87	6.78	4.2
India	10.41	41.37	3.14	14.49	1.39	3.39	0.91	9.85
Rep of Korea	6.59	27.04	4.77	16.88	17.18	2.49	6.07	6.39

Source: GOI, Department of Science and Technology, *Pocket Data Book 1989*.

adopted the new patents regime; and (iii) Examining the value of foreign patented drugs and drug formulations in India at present and examining the possible impact on prices by strengthening the patents regime.

The present patents regime commenced with the Patents Act of 1970 which became operative from 1972. Studies by Mehrotra and others[7] have shown that the prices of drugs and drug formulations fell considerably after the introduction of the 1970 Patents Act and "both the public sector and private sector companies were involved in the technological development which helped India boost its bulk-drugs formulations". Misuse of patents by TNCs have also been highlighted in these studies. The study of Agarwal and others[8] shows that prices of many drugs outside the purview of the Drug Prices Control Order (DPCO) have also fallen. A look at Table 13 shows that the price index of pharmaceutical items is lower than the price index of all commodities for most of the years. The drug price index which shows a rise by 41.9 points by 1970-71 with 1961-62 as the base year and is lower than the index for chemicals and chemical products and for all commodities, is uniformly lower than the price increases of all commodities in the 70s and 80s. Even in the 60s the price index for other commodities was higher than the price index of drugs by the same times or higher in some years (1964-65 and 1966-67), and hence one cannot consider that the 1970 Patents Act as the main factor affecting prices of drugs. In fact the more important factor which has kept the drug prices under control directly is the DPCOs and even today 74 per cent of the drugs and formulations in India are under control. The effect of patents on prices comes indirectly through increase in input costs, necessitating price rises.

The above analysis shows that though the relatively lower rise in prices of pharmaceuticals in the 70s and 80s are due to the two important factors, namely (1) the relaxation in the patents regime helping indigenous units, and (2) the drug price control act (especially the 1970 act). The latter is not only the more important of the two, but overshadows the former in its effects. Today also the above two factors are still in effect, while the Indian drug industry has come to age and become quite competitive and capable of producing a major portion of the necessary drugs and drug formulations. As stated by Patel D S currently, this segment (Indian companies) of the (pharmaceutical) industry contributes more than 60 per cent of the country's production and demand. The national sector is involved in the manufacturing of life-saving drugs not only for the local market but also for the international market. India became self-sufficient in various raw materials by producing them indigenously ... it led to the creation of a strong R and D set-up. It also gave rise to the development of the ancillary industries and petrochemical projects. Thus a strong base was created which resulted in the growth of the industry. The post- 1980's era saw more changes in the pharmaceutical industry, as it became a global player. The industry started exporting bulk drugs which were earlier being imported. In the process the industry became a foreign exchange earner and net exporter. Today, in certain products, India is the only supplier or controls a major share of the market.[9] Further as observed by Mehrotra N N[10] the process technology involved for many of the drugs produced by the Indian sector companies "fall under the term high-technology as defined by the Ramanathan Committee of the government of India for the same while examining the technology status of foreign companies".

In Table 14 we have computed the revealed competitive advantage (RCA) and revealed comparative disadvantage (RCD) of the pharmaceutical sector of India and some developed and developing countries, following both the market share approach and Bela Balassa approach.[11] The table shows that RCA (market-share method) of India in 1988 compared to other countries is high and RCD quite low. If RCA (Bela Balassa method) is considered then India's RCA in 1988 compared to 1980 has increased and is more than all the developed and developing countries given in the table except for Indonesia and Malaysia. But RCA in 1988 compared to 1970 of India is the highest. India's RCD (Bela Balassa method) in 1988 compared to 1980 is quite low compared to the developed and some developing countries. While RCD of India in 1988 compared to 1970 is high, it is lower than many underdeveloped countries. In 1988 compared to 1980 only India, Indonesia and Malaysia have relatively higher RCAs and lower RCDs. In 1988 compared to 1970, only the US and UK have relatively higher RCAs and very low RCDs. But India has very high RCA and relatively high RCD. On the whole the above analysis shows that India's RCA has improved remarkably and RCD has become less compared to even the developed countries.

While opponents to change in the patent system emphasise that competitive position has been achieved by India due to India's patent regime, in the case of drugs and pharmaceutical we have seen that this has been possible mainly due to PCO and then due to the present patents regime. So while there is no need to fear much, any changes in the patents system, we have to be more careful of a sudden decontrolling of the prices in this sector.

TABLE 8: EXTERNAL ASSISTANCE FOR S AND T PROGRAMMES SECURED BY INDIA, 1987

	Total (Mn US$)	Percentage to Total
I Multilateral		
(Total UN system)	43.92	39.8
II Bilateral	65.36	59.2
of which		
UK	24.85	22.5
FRG	7.90	7.2
Norway	7.77	7.0
USA	6.87	6.2
Switzerland	4.54	4.1
Denmark	4.07	3.7
Italy	2.89	2.6
France	1.91	1.8
Netherlands	2.11	1.9
Australia	1.21	1.1
Canada	0.89	0.8
Sweden	0.31	0.3
New Zealand	0.04	0.0
III Non-Governmental Organisations	1.07	1.0
Ford Foundation	0.72	0.7
IDRC	0.35	0.3
Grand total	110.35	100.0

Source: GOI, Department of Sceience and Technology: *Research and Development Statistics*, 1990-91.

TABLE 7: INDIAS TRADE IN TECHNOLOGY-INTENSIVE PRODUCTS

(In Percentage)

Year	Exports (Per Cent)	Imports (Per Cent)	Value of Exports/Imports		
			Total	Technology Intensive	Others
1965-66	6.5	67.2	0.58	0.06	1.65
1970-71	17.2	62.8	0.93	0.26	2.07
1975-76	19.6	64.8	0.76	0.23	1.75
1980-81	16.9	80.1	0.53	0.11	2.22
1981-82	20.6	77.1	0.57	0.15	1.98
1982-83	28.8	78.4	0.61	0.23	2.03
1983-84	28.8	71.9	0.62	0.25	1.57
1984-85	28.7	74.3	0.69	0.26	1.9
1985-86	19.3	75.0	0.55	0.14	1.78

Source: GOI, Department of Science and Technology, *Pocket Data Book 1989*.

Comparative Prices of Pharmaceuticals

As mentioned earlier, the rise in prices of drugs and medicines in India has been lower than the rise in prices of chemicals and chemical products and all commodities. But these indices are based on a sample of 12 bulk drugs and 19 formulations only and almost all these drugs are under price control.[12] However, we should note that at present, though the number of drugs under price control has been reduced from 375 drugs (and their formulations) to 145 bulk drugs (and their formulations), actual control in terms of sales has declined only marginally from 79 per cent to 74 per cent. So, the results of the price indices (which includes the drugs under price control) broadly reflect changes in the pharmaceutical sector.

The table given by the OPPI (Table 15) shows that the prices of important drugs in India have risen in 1992 compared to 1986, though marginally in many cases. Our calculations (Table 16) of a larger sample of drugs (which are usually quoted) also show a rise in price of important drugs, also marginally in many cases. However, these drugs are not important in terms of their percentage in total consumption in India. So in Table 17 we have given the prices of some of the drugs which form a major share of India's consumption. In the case of these drugs the prices are constant or have risen very marginally. The more important aspect is that the drugs quoted by Keayla, IDMA, etc, are US patented drugs, while the drugs quoted in Table 17 are off-patent or ones whose patents have expired and are the most important items consumed by India. This further highlights the fact that in the case of a major percentage of drugs and medicines consumed in India, prices are greatly affected by patents. On the other hand, the DPCO has been a major influence on prices, while many people have been (knowingly or unknowingly) highlighting the prices of drugs patented, which form a very small percentage of the total consumption in India. In fact B K Keayla[13] has written "A committee of the US senate (Kefauver Committee) had commented in 1959 that 'Prices of certain drugs and antibiotics in India were amongst the highest in the world and that in drugs, India was one of highest priced nations'. This was before the enactment of the Patents Act 1970. It is noteworthy that prices of drugs in India are now amongst the lowest in the world... The above price comparisons are only a few examples. In most countries which followed product patents, prices of these and other pharmaceutical products are as high if not even higher!' While it is true that the US Senate had commented in 1959 that prices were very high in India and the prices after 1970 when the Patents Act 1970 was enacted were low, the low prices especially in the 70s and 80s is not a logical conclusion of changes in patents system, rather it is due to the DPCO in India which was also introduced in 1970 and the 1962 Drug (Display of Prices) Order.

Further, in the list usually taken by Keayla and others few drugs are under DPCO (while most of them are under product patents abroad), while in our list which covers a major part of India's consumption, all are under DPCO and few are under product patents abroad. Thus even by introducing product patents, a major portion of drugs (given in Table 17) will not be affected, while removal of price control (vehemently proposed by both OPPI and IDMA) will surely affect the major percentage of drugs consumed in India. Thus not only are prices for drugs low in India, a major part of them are off-patent and the DPCO has been successful in limiting the rise in prices of drugs.

If we compare the prices of some drugs in India and other countries (Table 15), we can notice that drug prices are comparatively lower in India. In fact as mentioned in the IDMA-OPPI joint report,[14] "Drug prices in India are among the lowest in the world". This is a fact confirmed by the Tariff Commission and official surveys and studies. As can be seen in Table 18, compared to advanced countries like UK and the US, drug prices in India are very much lower. But it may be argued that comparison of drug prices between India and advanced countries, by converting the prices in terms of foreign currencies to rupees may not be appropriate unless it is for purpose of trade and for imported drugs. However compared to India's immediate neighbours also (where useful comparisons can be made), prices in India are comparatively low both in 1986 and 1992 and the rise lower and fall greater from 1986 to 1992 for many drugs (Table 15). Among the Asian countries, Sri Lanka and Indonesia have joined the Paris convention in 1952 and 1950, respectively. Pakistan, like India has not joined the Paris convention. Indonesia under its liberalisation policy has extended "deregulation in investment procedures to agriculture and the pharmaceutical industry"[15] while in 1992 it accepted product patents and interestingly the prices of important drugs in Indonesia are very much higher compared to prices in India especially in 1992 and this rise cannot be due to product patents introduced in the same year. This shows that price changes in pharmaceutical sector are not mainly due to patents and as seen in the Indian

Table 9: Foreign Direct Investment-Industrywise and Countrywise

(Rs Crore)

Industry	FDI Stock End March 1987	1988	1989	Number of Foreign Collaboration Approvals Industry	1989	1990
Total	1742	2045	2302	Total	605	666
Manufacturing	1492	1768	1990	*of which*		
of which				Electrical Equipment	99	88
				Telecommunication	37	69
				Transportation	30	22
Chemicals and Allied Products	516	604	647	Industrial Machinery	59	75
Machinery and Machine Tools	210	249	294	Misc Mechancial and Engg Industry	26	88
Electrical Goods and Machinery	207	236	286	Industrial Instruments	35	38
Transport Equipment	173	199	245	Chemical (other than		
Metals and Metal Products	85	124	120	Fertilisers)	66	66

Country	FDI Stock End-March 1987	1988	1989	FDI Approvals 1990	1991	1992
Total	1742	2045	2302	128.32	534.11	3887.54
of which						
UK	901	1039	1127	9.06	32.1	117.67
USA	332	396	460	34.48	185.85	1231.50
West Germany	154	187	229	19.51	41.8	86.27
Switzerland	65	79	80	13.50	35.5	689.76
Japan	64	83	112	5.00	52.71	610.23
NRIs				5.24	19.7	439.13

Source: For FDI Stock, RBI, 'India's Foreign Liabilities and Assets as on March 31, 1989', *RBI Bulletin*, February 1993. For Countrywise FDI approvals: *Economic Survey*, 1992-93 and for Industrywise approvals: Department of Industrial Development, *Handbook of Industrial Statistics*, 1991-92.

TABLE 10: INDIA'S TECHNOLOGY BALANCE OF PAYMENTS—1972-73 TO 1988-89

(Rs in crore)

Year	Payments						Receipts						Tech-nology BoP	Tech-nology Related BoP	Total Tech-nology and Tech-nology Related BoP
	Royal-ties	Tech-nical Know-how	Techni-cians' Fees	Other Prof Fees	Mana-gement Fees, Etc	Total	Royal-ties	Tech-nical Know-how	Techni-cians' Fees	Other Prof Fees	Mana-gement Fees, Etc	Total			
1972-73	7.3	11.3	8.2	2.7	26.0	55.5	0.2	0.4	5.3	0.8	14.3	21.0	-25.8	-13.6	-34.5
1973-74	6.2	14.1	10.1	2.8	28.9	62.1	0.1	0.1	2.7	0.5	18.9	22.3	-30.1	-12.3	-39.8
1974-75	8.5	12.5	7.4	3.4	33.1	64.9	0.1	0.5	0.2	1.1	21.1	23.0	-27.3	-14.3	-41.9
1975-76	10.5	25.7	7.1	4.1	50.9	98.3	0.2	0.5	0.7	1.3	25.2	27.9	-42.1	-28.5	-70.4
1976-77	15.9	37.8	10.3	13.2	73.1	150.3	0.1	0.9	0.9	3.1	25.8	30.8	-62.1	-57.4	-119.5
1977-78	19.5	28.1	10.2	37.6	80.0	175.4	0.2	1.1	0.5	4.6	30.2	36.6	-55.4	-82.8	-138.8
1978-79	12.7	55.5	45.4	8.0	96.2	217.8	0.1	6.1	0.5	3.3	58.8	68.8	-101.3	-42.1	-149.0
1979-80	9.6	44.0	9.1	11.3	185.5	259.5	0.1	1.9	0.7	7.2	73.7	83.6	-58.8	-115.9	-175.9
1980-81	8.9	98.0	22.6	11.9	146.6	288.0	0.1	3.1	1.2	5.1	74.5	84.0	-123.2	-78.9	-204.0
1981-82	16.0	270.7	13.1	13.9	261.0	574.7	0.2	5.8	2.1	6.7	90.8	105.6	-288.0	-177.4	-469.1
1982-83	39.7	258.6	30.1	42.0	210.6	581.0	1.0	8.1	1.9	8.4	198.6	218.0	-311.2	-45.6	-363.0
1983-84	27.6	314.9	26.1	45.3	233.5	647.4	0.5	6.0	2.3	7.0	153.6	169.4	-356.1	-118.2	-478.0
1984-85	28.5	300.6	29.9	82.6	294.6	736.2	0.1	3.6	3.2	8.9	232.4	248.2	-351.7	-135.9	-488.0
1985-86	23.5	367.8	42.0	69.5	331.7	834.5	0.3	8.3	4.1	10.2	172.8	195.7	-416.4	-218.2	-638.8
1986-87	40.1	358.4	73.0	105.7	447.9	1025.1	0.6	12.8	2.7	6.6	214.3	237.0	-445.3	-332.7	-788.1
1987-88	60.4	459.3	103.0	282.0	470.2	1374.9	1.4	6.3	5.0	12.4	347.8	372.9	-608.7	-392.0	-1002.0
1988-89	180.6	316.7	160.0	230.4	714.3	1602.0	1.2	8.4	13.3	20.2	516.1	559.2	-639.3	-408.4	-1042.8

Source: *Reserve Bank of India Bulletin*, April 1992.

TABLE 11: EXPORTS, IMPORTS, TRADE BALANCE AND CURRENT ACCOUNT BALANCE OF SELECTED COUNTRIES

Item	World				Industrialised Countries				USA			
	1975	1980	1985	1988	1975	1980	1985	1988	1975	1980	1985	1988
Exports (Bn US$)	829.5	1897.6	1801.1	2694.1	568.9	1244.3	1262.2	1969.4	108.85	225.5	218.8	321.6
Imports (Bn US$)	836.6	1945.1	1878.3	2787.3	589.4	1370.1	1348.4	2041.6	105.8	256.9	346.3	459.5
Trade Balance (Mn US$)	22193	31894	12605	35946	9933	-67810	-37584	4029	8910	-25500	-122150	-126290
Current A/c (Mn US$)	2451	-31993	-70175	-66869	9657	-59392	-48888	-61593	18130	1840	-115160	-134720
Exports of Goods (Percentage)									8	9.8	6.7	8.3
Imports of Goods (Percentage)									7.6	10.8	10	11

Item	UK				Germany				Japan			
	1975	1980	1985	1988	1975	1980	1985	1988	1975	1980	1985	1988
Exports (Bn US$)	43.4	110.1	101.2	145.1	90.1	192.8	183.9	323.3	55.8	130.4	177.1	264.8
Imports (Bn US$)	53.3	115.5	108.9	189.3	74.9	187.9	158.4	250.5	57.8	141.2	130.4	187.3
Trade Balance (Mn US$)	-7272	3343	-2653	-36514	16911	8887	28507	78640	4935	2130	55990	94990
Current A/c (Mn US$)	-3417	7520	4765	-26089	4422	-13886	16977	48580	-690	-10750	49170	79630
Exports of Goods (Percentage)	25	27	29	23.6	25	26.8	33	29.7	12.9	13.9	14.7	10.3
Imports of Goods (Percentage)	26.9	24.7	28	27.4	22.1	26.9	29	24.3	12.8	14.7	11.3	8

Item	Republic of Korea				Malaysia				India			
	1975	1980	1985	1988	1975	1980	1985	1988	1975	1980	1985	1988
Exports (Bn US$)	5.08	17.5	30.2	60.69	3.8	12.9	15.4	21.1	4.3	8.5	9.2	13.3
Imports (Bn US$)	7.27	22.29	31.13	51.8	3.56	10.82	12.3	16.55	6.38	14.86	16.07	19.16
Trade Balance (Mn US$)	-1671	-4384	-19	11445	256	2406	3577	5643	-286	-5644	-5616	
Current A/c (Mn US$)	-1889	-5321	-887	14161	-496	-285	-613	1884	-148	-1785	-4178	
Exports of Goods (Percentage)	27.6	35.1	36.8		45.4	57.6	55	68	6.2	6.5	6.1	
Imports of Goods (Percentage)	35.7	41.1	35.2		47.2	55.1	50	57.4	6.8	9.8	9	

Source: IMF, *International Financial Statistics, Year Book, 1989.*

case, it is due to DPCO. India which is in a very competitive position compared to other LDCs, therefore should not fear the strengthening of the patents regime. On the other hand, regarding decontrol of drug prices, a judicious approach is needed.

Indigenous Production of Drugs Covered by Product Patents Abroad

The issue of value or percentage of indigenous production of drugs covered by product patents abroad is one where there are conflicting versions. The controversy was triggered by the statement of the United States Trade Representative (USTR) Carla Hills during her visit to India in 1992, that only 5 per cent of the products marketed in India are covered by patents. This statement was made to "persuade the Indian government that recognition of product patents as in China would not have the feared adverse effects".[16] The Indian Drug Manufacturers Association (IDMA)[17] immediately came with a study indicating that in the therapeutic groups where patented drugs are there, nearly 46.32 per cent of these groups are covered by patents in the US and patented drugs in the total pharma market is 21.47 per cent. The percentage of drugs under the different therapeutic groups are given in Table 13. The minister of state in the ministry of chemicals and fertilisers[18] stated that about 10-15 per cent of total production in the country is covered by patents abroad. The break-up of the different therapeutic groups given by the ministry are also given in Table 13. The IDMA study is based on Operational Research Group (ORG) report and the US Health Department Publications, 'Drugs under Patent' and 'Approved Drug Products' and the government statement is based on 'Available Information'. The IDMA[19] which has made a study for Ranitidine 150 mg tablets makes the following observation, "Had it not been for the Indian Patent Act 1970, it would not have been possible for anybody other than Glaxo or their licencees to manufacture and sell this product in the country. Under such monopolistic situation, Glaxo, in light of their international pricing policy would have priced the product hypothetically at least 10 times more expensive of its present sale price, i e, Rs 16.10 per tab. It would not be wrong to assume that at this exorbitant rate, offtake of this product would come down substantially. Therefore under the scenario existing after amendment of the Indian Patents Act to fall in conformity with the Dunkel's proposal, the Indian population

Table 13: Price Indices of All Commodities and Drugs and Medicines in India

Year	All Commodities	Drugs and Medicines	Percentage Increase over 61-62		Times Higher of All Compared to Drugs
			All Commodities	Drugs and Medicines	
61-62	100	100	0.0	0.0	
62-63	103.8	102.1	3.8	2.1	1.8
63-64	110.2	103.1	10.2	3.1	3.3
64-65	122.3	103.6	22.3	3.6	6.2
65-66	131.6	105.2	31.6	5.2	6.1
66-67	149.9	112.4	49.9	12.4	4.0
67-68	167.3	121.6	67.3	21.6	3.1
68-69	165.4	123.6	65.4	23.6	2.8
69-70	171.6	129.8	71.6	29.8	2.4
70-71	181.1	141.9	81.1	41.9	1.9
71-72	188.4	141.9	88.4	41.9	2.1
72-73	207.3	143.8	107.3	43.8	2.5
73-74	249.2	144.9	149.2	44.9	3.3
74-75	312.0	154.0	212.0	54.0	3.9
75-76	308.6	168.9	208.6	68.9	3.0
76-77	315.1	190.6	215.1	90.6	2.4
77-78	331.5	194.0	231.5	94.0	2.5
78-79	331.5	193.7	231.5	93.7	2.5
79-80	388.2	192.4	288.2	92.4	3.1
80-81	459.0	195.7	359.0	95.7	3.8
81-82	501.9	219.8	401.9	119.8	3.4
82-83	515.1	243.9	415.1	143.9	2.9
83-84	563.8	269.3	463.8	169.3	2.7
84-85	603.6	272.8	503.6	172.8	2.9
85-86	638.3	281.0	538.3	181.0	3.0
86-87	672.2	289.9	572.2	189.9	3.0
87-88	723.3	316.5	623.3	216.5	2.9
88-89	776.6	386.6	676.6	286.6	2.4

Source: GOI, *Indian Drug Statistics* (various issues).

Table 12: Growth of World Trade in Manufactures (Annual Average Rate of Growth)

Exports from	Years	World		DMEC		Developing Countries				Socialist Countries	
						Total		Manufactures Exporters			
		Total Trade	Trade in Manufactures	Total Trade	Trade in Manufactures	Total Trade	Trade in Manufactures	Total Trade	Trade in Manufactures	Total Trade	Trade in Manufactures
World	1965-73	15.1	16.7	15.8	17.9	13.9	13.9	20.5	22.9	13.2	15.4
	1973-80	19.5	17.9	18.7	16.6	23.7	23.0	22.9	20.6	16.7	15.5
	1980-87	3.2	7.1	3.7	8.8	1.1	2.6	4.6	8.6	4.5	5.9
Developed market-economy countries	1965-73	15.6	16.6	16.0	17.4	13.7	13.7	22.2	24.0	8.4	20.5
	1973-80	17.6	17.7	16.4	16.3	22.0	22.4	19.5	20.2	18.2	19.2
	1980-87	4.6	6.3	5.9	7.9	0.8	1.3	6.0	6.6	−0.2	2.4
Developing countries	1965-73	14.9	23.7	15.1	21.4	15.0	19.6	18.9	25.1	11.2	7.6
	1973-80	26.2	23.1	25.7	20.7	29.3	27.7	30.5	24.8	20.3	19.3
	1980-87	−1.5	14.3	−2.4	16.6	−0.6	7.8	0.5	13.9	8.1	28.6
Manufactures exporters	1965-73	19.3	27.6	21.2	34.5	17.7	20.9	21.5	33.4	10.5	10.7
	1973-80	21.5	24.2	18.0	21.3	29.1	31.4	24.9	26.9	23.4	23.3
	1980-87	9.1	12.1	11.0	14.8	5.1	6.4	8.3	13.9	5.6	11.6
Socialist countries	1965-73	12.9	14.2	16.0	18.6	13.2	10.1	13.7	12.7	12.0	14.2
	1973-80	17.3	15.3	20.6	17.7	20.1	21.6	20.8	20.2	15.0	13.0
	1980-87	5.4	5.5	1.3	5.8	8.8	6.2	11.1	17.6	6.4	5.3

Sources: UNCTAD, *Statistical Pocket Book, 1989*.

would have for its consumption a mere 1/10th of the total medicine available to them today, but at 10 times the existing prices."

The above analysis shows that the lower limits of the estimates of manufacture of products patented abroad is 5 per cent and the upper limit is 21.47 per cent. Moreover, the major player in price changes is the DPCO. As long as the composition of the list of drugs not to be patented remains unchanged, the feared danger of strengthening the patents regime in India is apparent than real. However a careful and judicious policy on price controls is needed and not simply a total decontrol of prices of pharmaceuticals as advocated by many people especially the IDMA and OPPI. In fact, it has been stated[20] that drug prices have increased as a result of India's recent liberalisation efforts, and of course this has nothing to do with patents. As expressed by Vaish (secretary, department of chemicals and petro-chemicals, ministry of chemicals and fertilisers, government of India),[21] over the seeming paradox of keeping prices under check to ensure that it reached every person, and freeing the sector from checks as demanded by the industry to ensure maximum production, "we have to see that supply line and production is maintained, yet there is need to keep control". One should also note that this is a sector involving social security and while the EEC has its own social security measures and the US is also implementing new measures on these lines, a developing country like India cannot completely underplay the importance of health care to its population under the pretext of profitability. Thus there is nothing wrong in continuing with the price control on drugs. Otherwise, firstly, the government as the largest buyer of drugs and secondly, the common con-

TABLE 15B: CHANGE IN INTERNATIONAL PRICES *VIS-A-VIS* INDIAN PRICES OF IMPORTANT DRUGS

Name of the Drug	Unit	Times Costlier in Pakistan 1986	Times Costlier in Pakistan 1992	Times Costlier in Sri Lanka 1986	Times Costlier in Sri Lanka 1992	Times Costlier in Indonesia 1986	Times Costlier in Indonesia 1992
1 Chloramphenicol	250 mg/10 caps	0.21	0.68	1.75	2.20	1.68	3.49
2 Metronidazole	200 mg/10 tabs	1.08	3.28	1.44	4.29	14.76	26.16
3 Ferrous Sulphate	150 mg/15 caps	0.10	1.41	0.55	4.21	—	4.61
4 Ibuprofen	200 mg/10 tabs	−0.23	0.82	0.68	1.39	1.08	1.56
5 Propranolol HCL	10 mg/10 tabs	1.37	1.72	1.29	0.54	—	—
6 Salbutamol	2 mg/10 tabs	2.06	—	1.67	2.53	—	—
7 Nifedipine	10 mg/10 caps	4.28	5.43	−0.08	0.84	0.70	9.60
8 Cimetidine	200 mg/10 tabs	3.57	4.25	1.20	9.80	1.57	11.19

Source: OPPI.

TABLE 14: RELATIVE COMPARATIVE ADVANTAGE OF PHARMACEUTICAL PRODUCTS OF SELECTED COUNTRIES

Country	RCA Bela Ballasa Approach: RCA 88 to 80	RCA Bela Ballasa Approach: RCA 88 to 70	RCD Bela Ballasa Approach: RCD 88 to 80	RCD Bela Ballasa Approach: RCD 88 to 70	RCA Market Share Approach: 1988	RCA Market Share Approach: 1980	RCA Market Share Approach: 1970	RCD Market Share Approach: 1988	RCD Market Share Approach: 1980	RCD Market Share Approach: 1970
USA	1.16	1.37	1.31	0.22	1.47	1.27	1.08	0.77	0.59	0.20
UK	0.99	1.19	1.18	0.43	2.18	2.21	1.83	0.75	0.63	0.40
Japan	1.02	1.01	1.13	1.18	0.32	0.32	0.32	1.22	1.08	1.10
Germany	0.86	0.94	1.04	0.65	1.42	1.65	1.51	1.01	0.97	0.60
Republic of Korea	0.98	NA	0.82	0.86	0.16	0.16	NA	0.38	0.46	0.80
Indonesia	1.99	0.42	0.81	2.04	0.14	0.07	0.32	0.85	1.04	1.90
Thailand	0.38	1.24	0.41	2.90	0.13	0.35	0.11	0.63	1.53	2.70
Malaysia	1.24	0.70	0.75	1.40	0.15	0.12	0.22	0.78	1.05	1.30
India	1.16	3.30	0.82	1.61	2.13	1.83	0.65	0.76	0.92	1.50

Note : RCA = Relative Comparative Advantage; RCD = Relative Comparative Disadvantage.

$$RCA = \frac{Xi/Xt}{Wie/Wte} \qquad \text{(Bela Ballasa)} \quad = \frac{RCA\ I}{RCA\ II}$$

(Market share Approach)

$$RCD = \frac{Mi/Mt}{Wii/Wi} \qquad \text{(Bela Ballasa)} \quad = \frac{RCD\ I}{RCD\ II}$$

Where, Xi = Exports of pharmaceuticals of the country, Xt = total exports of the country, Mi = imports of pharmaceuticals of the country, Mt = total imports of the country, Wie = Exports of pharmaceuticals of world, Wte = total exports of the world, Wii = imports of pharmaceuticals of the world, Wi = total imports of the world, I = Current year, II = Base year.

Source: Computed from United Nations, *International Trade Statistics Yearbook* (various issues).

TABLE 15A: COMPARATIVE PRICES OF IMPORTANT DRUGS IN INDIA AND OTHER ASIAN COUNTRIES

(in Rs)

Name of the Drug	Unit	India 1986	India 1992	India Percentage Change	Pakistan 1986	Pakistan 1992	Pakistan Percentage Change	Sri Lanka 1986	Sri Lanka 1992	Sri Lanka Percentage Change	Indonesia 1986	Indonesia 1992	Indonesia Percentage Change
1 Chloramphenicol	250mg/10 tabs	5.72	9.95	73.9	6.93	16.78	145.0	15.74	31.86	102.4	15.36	44.76	191.4
2 Metronidazole	200mg/10 tabs	2.76	3.65	32.2	5.74	15.64	172.4	6.74	19.30	186.3	43.52	99.15	127.8
3 Ibuprofen	200mg/10 tabs	6.13	3.71	−39.4	4.68	6.78	44.8	10.34	8.87	−14.2	12.80	9.52	−25.6
4 Ferrous Sulphate	150mg/15 caps	8.46	8.64	2.12	9.36	20.84	122.6	13.15	45.04	242.5	—	48.31	—
5 Propranolol HCL	10mg/10 tabs	1.96	3.70	88.7	4.66	10.06	115.8	4.49	5.71	27.1	—	—	—
6 Salbutamol	2mg/10 caps	1.11	1.93	73.8	3.40	—	—	2.97	6.82	129.6	10.24	—	—
7 Nifedipine	10mg/10 caps	6.00	5.78	−3.6	31.65	37.18	17.5	5.49	10.64	93.8	20.48	61.28	199.2
8 Cimetidine	200mg/10 tabs	7.96	8.75	9.9	36.41	45.92	26.1	17.54	94.52	438.8	49.92	106.72	113.7

sumer (not the common man as we will see later) will be hit by the rise in prices. So while we advocate a judicious policy in drug price controls, we see no reason to fear the strengthening of the patents regime in the case of drugs and pharmaceuticals by introducing product patents. This is not to say that the 1970 Patent Act was not useful. In fact it was useful and along with DPCO has strengthened our pharmaceutical sector. But in the present situation, when we have become competitive in pharmaceutical sector there is no need to continue with this Act in the same form. However, the pertinent question to be answered is, how exactly the patents regime can be strengthened by India in the case of pharmaceuticals? To this question, we will turn to Section IV.

Other Effects of Strengthening Patents Regime

The other possible effects of strengthening the patents regime can be explained as follows.

Effect on Different Sections of the Population: An increase in drug prices is believed to affect the common man. But as rightly pointed out by Mitra Sisir.[22] "We ought to be clear about the description of this 'common man'... But we have to make another division of the 'more common' amongst us, that is, the people who live below the poverty line". According to official estimates, this group consists of 30 per cent of our population[23] and these people hardly spend on drugs and medicines, while basic necessities like food, clothing and shelter are themselves not available to them. So the question of drug prices does not concern them. India is a drug starved country. The per capita consumption of drugs in India in 1989 was Rs 34 (Rural Rs 8). This is very low compared to other developing countries like Republic of Korea (Rs 346), Egypt (Rs 190), Turkey (Rs 159), Taiwan (Rs 159), Philippines (Rs 95), Nigeria (Rs 70), Indonesia (Rs 42) and Pakistan (Rs 43), even in 1984.[24] Further as pointed out by Mitra Sisir,[25] the expenditure on drugs in India "is generally less than 10 per cent of the total medical care cost", and medical care expenditure forms 2.6 per cent of total expenditure in India.[26] Among the other two classes, the rich and the middle class, the former can afford any rise in prices of drugs, while the latter may be subjected to hardship. However, there is the fact that even if the most liberal estimates are taken, drugs product patented abroad will not be more than 30 per cent of the drugs produced in India and again the changes in drug prices can come about mainly due to decontrol of prices, rather than patents. If the possibility of substitution of non-patented drugs for patented drugs is further explored then the effect of patents on prices can be further lessened; on the whole, strengthening the patents regime especially by accepting product patents in pharmaceuticals will not have any great adverse impact on common man in particular and the people in general.

Effect on Indian Pharmaceutical Industry: The strengthening of patents regime is considered to affect the Indian pharmaceutical industry. In the total sales of drugs and drug formulations in India the share of drug formulations is 76.5 per cent in 1989-90 (78.4 per cent in 1988-89). Therefore, it is mainly drug formulations that are important in the total sales. In fact, India is almost self-sufficient in drugs and pharmaceuticals and indigenous production to the total indigenous production plus imports is 89.4 per cent in 1989-90 (91 per cent in 1988-89). Moreover, India is a net exporter of drugs and pharmaceuticals at Rs 204.78 crore in 1989-90 (Rs 20.60 crore in 1988-89). Interestingly, the pharmaceutical sector is one in which the concentration is very less. The concentration ratio of drug formulations in 1989-90 (shown by the share of top four firms) is the lowest among all manufactures of non-primary commodities at 17.5 per cent[27] and interestingly in the primary commodities industries also only a few items are below this level.

While it is not possible to estimate the possible effect of product patents by companies (though the effect of introducing product patents would be quite less in general, as seen earlier), some indications of the process patents are available. In pharmaceuticals, we have not been able to estimate the percentage of drugs and drug formulations under process patents but total patents in drugs and pharmaceuticals[28] is 9.31 per cent of total patents sealed in 1986-87. But it has been stated that major percentage of the process patents in this sector have been granted to foreigners.[29] In fact percentage of patents to foreigners in foods, drug and medicines is 74.8 per cent in 86-87 and above 70 per cent since 74-75.[30] Of the 75 per cent market share as on year-end 1989 about 35-40 per cent is by MNCs in drug formulations (in 1989-90).[31] Since most of the important MNCs have been included in this list, the remaining 25 per cent cover mainly the Indian companies and that too small companies. Thus about 60 per cent of the market share in drug formulations is with the Indian companies and the Indian companies are a major force to reckon with. As can be seen in Table 20, in our sample of companies covering about 53 per cent of total market share, MNCs with 33 per cent market share have been granted 407 patents between the years 19/2-1989, while the Indian big companies with 16 per cent market share have only 59 patents (of which 41 patents have been granted to the two public sector companies). Though our sample is not a representative sample giving representation to different groups of companies based on the share of these groups to total market share, and though we know that it is the value of sales of patented items which is the real indicator, rather than the number of patents, the results at least indicate the following:

(1) The patents granted to big indian companies especially private companies are surprisingly low. This seems to be a reflection of their poor R and D effort.

(2) While the MNCs seem to dominate in terms of process patents, four small companies have 24 patents, which seems to be relatively higher compared to the big Indian private companies. Of course, we do not know the type of relationship of small companies given here with the big companies or MNCs. While it is known

Table 16: Prices and Price Indices of Selected Indian Drugs

(in Rs)

Drug/Dosage	Brand Name	Prices		
		1990	1991	1993
1 Cholamphemical (250 mg/10)	Paraxin	8.32 (100.0)	8.74 (105.0)	20.00 (240.3)
2 Amoxycillin (500 mg/4) caps	Moxilium	17.90 (100.0)	17.90 (100.0)	N.A. (N.A.)
3 Cefadroxil (500 mg/6) caps	Kefloxin	58.20 (100.0)	58.20 (100.0)	65.85 (113.1)
4 Cephalaxin (250 mg /4) caps	Alcephin	13.27 (100.0)	14.38 (108.4)	15.52 (117.0)
5 Doxycycline (100 mg /10) caps	Biodoxi	19.50 (100.0)	19.50 (100.0)	25.50 (130.8)
6 Norfloxacin (400 mg/4) tabs	Norilet	15.20 (100.0)	15.20 (100.0)	19.00 (125.0)
7 Ibuprofen (400 mg/10) tabs	Emflam-400 (Merck)	4.84 (100.0)	6.43 (132.9)	6.43 (132.9)
8 Flurbiprofen (50 mg/10) tabs	Arflur	12.69 (100.0)	12.69 (100.0)	15.00 (118.2)

(Contd)

that MNCs market products made by small-scale companies,[32] the benefits due to patents to these companies may also be cornered by MNCs due to such arrangements. Table 20 also shows that a substantial number of patents granted to Indians are actually in the name of the parents of the MNCs operating in India, which in effect reduces the number of patents granted to Indians. Thus in process patents, the importance of MNCs can be seen. But a note of caution is needed here. Table 21 gives the percentage of pharmaceutical sales to total sales of some MNCs and Indian companies for which data are available. The percentage in the case of MNCs is very small, while for Indian companies it is very high, at even 100 per cent in one case. In the light of this fact, we can infer that a major portion of the patents granted to the MNCs are for non-pharmaceutical items and in the case of the Indian companies, it is mainly for pharmaceuticals. So ultimately even process patents granted to MNCs in pharmaceuticals may not be really high.

In Table 22 the profitability ratios of selected MNCs and Indian companies are given. The different profitability ratios are broadly similar in the case of total MNCs and Indian companies, and in the case of most of the companies profits to net worth indicators are quite high, while profits to sale indicators are quite low. Here again, for reasons explained earlier profitability of Indian pharmaceutical companies reflect profitability in pharmaceuticals, while profitability of foreign companies reflect profitability in non-pharmaceuticals. Even imports of raw materials to total sales and dividend remittances to sales are not high and the possibility of disguising profits in these forms by MNCs seems to be less. While there is truth in the argument that profitability to sales in pharmaceutical sector is quite low, we cannot argue (as is being currently done by many) that the profitability in this sector should be allowed to be as high as in other sectors by decontrol of prices. We should note that this is a sector affecting social security and many developed countries are giving medical-care free of cost or at concessional rates and India should not allow prices to rise beyond permissible limits. Moreover, profitability to net-worth in these companies is quite high and is comparable to profitability to net worth in other sectors.[33] Earlier we had noted that there is no need to fear product patents. Since we do not have any estimate of the value of pharmaceuticals under process patents as a percentage of total value of pharmaceuticals in India, we cannot be very sure of the extent of the impact of strengthening process patents in India on the pharmaceutical sector.

TABLE 16: *(Contd)*

Drug/Dosage	Brand Name	Prices 1990	1991	1993
9 Piroxicam (10/10)	Toldin-10	5.35 (100.0)	5.35 (100.0)	8.90 (166.4)
10 Diclofenac (50/10) tabs	Diclomax	9.90 (100.0)	9.90 (100.0)	9.90 (100.0)
11 Naproxen (250/10) tabs	Naxid	16.35 (100.0)	16.35 (100.0)	N.A. (N.A.)
Anti-Ulcerants				
12 Cimetidine (400/10) tabs	Tagamed	17.34 (100.0)	17.34 (100.0)	14.14 (81.5)
13 Rantidine (300/10) tabs	Lydin	36.50 (100.0)	36.23 (99.3)	36.23 (99.3)
14 Sucralfate (1g/10) tabs	Ulcekon	13.68 (100.0)	13.68 (100.0)	13.68 (100.0)
15 Famotidine (40/10) tabs	Facid	39.80 (100.0)	34.00 (85.4)	34.00 (85.4)
Cardiovasculars:				
16 Nifedipine (10mg/10) caps	Calcigard	5.40 (100.0)	5.40 (100.0)	6.75 (125.0)
17 Atenolol (50/10) tabs	Altol	7.00 (100.0)	7.00 (100.0)	10.70 (152.9)
18 Acetmtolol (200/10) tabs	Sectral	18.10 (100.0)	18.10 (100.0)	26.49 (146.4)
19 Pentoxifylline (400/30) tabs	Flexital	138.00 (100.0)	138.00 (100.0)	173.40 (125.7)
20 Cylandelate (400/10) caps	Cyclasyn	14.40 (100.0)	14.40 (100.0)	20.00 (138.9)
21 Diltiazem (30/10) tabs	Angizem	12.00 (100.0)	12.00 (100.0)	17.68 (147.3)
22 Enalaprilmaleate (5/10) tabs	Envas	9.50 (100.0)	9.50 (100.0)	16.20 (170.25)
Antiviral/Fungal				
23 Acyclovir (5%cream) 5g	Cyclovir	39.40 (100.0)	39.40 (100.0)	49.90 (126.6)
24 Ketoconazole (200/10) tabs	Funazole	57.90 (100.0)	57.90 (100.0)	57.90 (100.0)
25 Clobetasol prop (0.05% cream)10g	Dermotyl Skin Cream	16.00 (100.0)	16.00 (100.0)	16.00 (100.0)
26 Minoxidil (60 ml)	Mintop	125.00 (100.0)	125.00 (100.0)	138.15 (110.5)
Anti-Histamine				
27 Astemizole (10/10) tabs	Alestol	9.75 (100.0)	9.75 (100.0)	10.70 (109.7)
Antdi-Auxiolytics				
28 Alprazolam (0.5mg/10) tabs	Alzolam 50	5.50 (100.0)	8.00 (145.5)	11.67 (212.2)
29 Diazepam (2mg/10) tabs	Valium	2.18 (100.0)	2.27 (104.1)	3.86 (177.1)
30 Lorazepam (1mg/10) tabs	Trapex	2.00 (100.0)	2.00 (100.0)	2.00 (100.0)
31 Trazodone Lcl (50mg/10) tabs	Trazonil	14.50 (100.0)	14.50 (100.0)	14.50 (100.0)
Anti-Cancer				
32 Vincristine (1mg/vial)	Vincristine	48.00 (100.0)	48.00 (100.0)	48.00 (100.0)
33 Vinblastine (10mg/real)	Vinblastine	92.00 (100.0)	N.A. (N.A.)	N.A. (N.A.)
Miscellaneous				
34 Allopurinol (100mg/10) tabs	Zyloric	8.60 (100.0)	8.60 (100.0)	12.04 (140.4)
35 Haloperidol (0.25mg/10) tabs	Depidol	1.90 (100.0)	2.25 (118.4)	2.90 (152.6)
36 Domperidone (10mg/10) tabs	Domstal	9.50 (100.0)	9.50 (100.0)	15.90 (167.4)
37 Gemfibrozil (300mg/10) caps	Gempar	34.50 (100.0)	38.50 (111.6)	N.A. (N.A.)
38 Nalidixic Acid (500mg/4) tabs	Gramoneg	10.61 (100.0)	11.60 (109.3)	18.00 (169.7)
39 Stanozolol (2mg/10)	Stromba	16.00 (100.0)	16.00 (100.0)	29.65 (185.3)

Note : The figures in parenthesis are index numbers.
Source: *MIMS India* (various issues).

However, strengthening process patents will mainly involve the following aspects, which are likely to affect the pharmaceutical sector. (1) Duration of the patents granted; (2) Considering imports as tantamount to working of patents in the patents granting country; and (3) Reversal of the burden of proof.

While the first issue can be allowed to be bargained upon, if needed with a quid pro quo from developed countries in the issue of Multi Fibre Agreement (MFA) (which we will discuss in Section IV), the second aspect can never be accepted as it would adversely affect the Indian drug industry, making it lose the gains already done. Even when the production is undertaken by MNCs, it should be undertaken in India. Otherwise, not only will the Indian drug industry suffer directly, but also the higher linkages of this sector will be reaped outside India as we will see in the next sub-section. In our zeal to cleanse the old system, we should not throw away the baby with the bath water. However, benefits to the Indian companies should be given in the form of tax benefits,[34] special benefits for exports which has been used well by Indian companies *vis-a-vis* foreign companies,[35] benefits for R and D investment, etc. As noted earlier, R and D investments in India in pharmaceuticals is very low by international standards. The exact break-up is not available to us. On the whole, while decontrol of prices has to be done judiciously, the Indian pharmaceutical sector including the public sector companies should be strengthened by other measures suggested above. Further the Indian pharmaceutical industry should shift more to the production of drugs which are off patent. In fact in the US the sales of generic drugs has increased from 9.2 per cent in 1980 to 19.1 in 1991[36] and definitely India should move more towards the production of generic drugs.

Effect on Other Sectors via Linkages: The drugs and pharmaceuticals sector will also affect the economy through linkages of this sector with other sectors. The study of Prasad A C P[37] shows that medical health has a high backward linkage effect. This sector falls in the IV classification of Chenery-Watanabe, i e, high backward and low forward linkages. The high backward linkages of this sector imply that other sectors supplying inputs to the medical health sector will be affected greatly when the medical health sector is affected. But we should remember that pharmaceuticals form a small percentage of total medical care and also that the effect of backward linkages hold good here as far as the growth of other sectors are concerned. However, in the case of price effects, the changes in prices of other sectors will affect the drugs and pharmaceuticals rather than vice versa. The price effect of strengthening the patent system of pharmaceuticals in India therefore does not affect much the other sectors, while the strengthening of patents or any other changes in other sectors can greatly affect this sector via the linkages (assuming however that the linkages of the medical health sector is representative of the linkages of the drugs and pharmaceutical sector, which forms a part of the medical health sector). But if growth of the pharmaceutical sector is adversely affected due to strengthening the patents regime, then it will have an adverse effect on other sectors due to the high backward linkages. This however will not happen just by accepting product patents in pharmaceuticals. However, if the clause that "importing is tantamount to working the patents in the patent granting country" is accepted while strengthening the patents regime, then the pharmaceutical sector will be affected adversely as the high backward linkages of this sector will be reaped outside the country. Devoid of this clause, strengthening the patents regime will not have much impact on pharmaceuticals via linkages.

Effect on Technology: At present, we do not intend to deal in detail with this aspect, but only state that, while strengthening of patents regime can harm the dissemination of technology, in the present situation, when all countries including communist China have strengthened their patents regime (especially they have accepted product patents) and our dependency on developed countries, especially the US for technology is increasing, refusal on the part of India to strengthen the patents regime will definitely affect the flow of latest technology and the quality of drugs. This adverse effect can be mitigated only if the Indian companies, including the government companies devote a larger amount of resources for R and D and identify good substitutes which are off patent. While as such the investment on R and D in drug industry is a poor 2 per cent of its turnover in India compared to 12 per cent in the international drug industry,[38] to further invest on R and D and mitigate the above mentioned effects the Indian companies will further emphasise their long-standing demand for decontrol of drug prices, which if done without much care will adversely affect the interests of consumers.

Effect on Balance of Payments: The balance of trade of India in drugs and pharmaceuticals is positive as can be seen in Table 23. The balance of payments of figures including non-trade items like

TABLE 17: PRICES OF IMPORTANT INDIAN BULK DRUGS OVER THE YEARS 1990-93

(in Rupees)

Name of the Drug	A/c Unit	Indigenous Production (88-89)	Imports	Total	Brand Name/ Dosage	Price 1990	Price 1991	Price 1993
Antibiotics								
1 Gentamicin (D)(NA)	Kg	883.00 (0.51)	2966.00	3849.00	Biogaracin (40mg/2ml)	7.90	7.90	8.15
2 Penicillin (D)(NP)	MMTs	330.47 (4.63)	657.42	981.89	Pentids/ (Pentids/200/6 tabs)	3.37	3.37	3.40
3 Ampicillin (D)(NP)	MT	332.56 (11.8)	16.09	348.65	Basipan (250 mg/4 tabs)	6.40	6.40	6.92
4 Streptomycin (D)(NP)	MT	243.79 (2.11)	10.04	253.83	Streptangna (10 tabs)	5.32	5.32	7.10
Sulpho Drugs								
1 Sulphamethoxazole (D)(P)	MT	1445.56 (13.56)	9.40	1454.96	Otrim (10 tabs)	7.10	7.10	7.10
2 Sulphadiuridine (D)(P)	MT	465.72 (1.37)	—	465.72	Inseptin (10 tabs)	6.79	6.79	7.62
3 Sulphagnamidine (D)(NA)	MT	219.66 (0.39)	—	219.66	—	—	—	—

(Contd)

TABLE 17: *(Contd)*

(in Rupees)

Name of the Drug	A/c Unit	Indigenous Production (88-89)	Imports	Total	Brand Name/ Dosage	Price 1990	Price 1991	Price 1993
Vitamins								
1 Vitamin C (D)(NP)	MT	868.77 (2.02)	6.90	875.74	—	—	—	—
2 Vitamin D_3 (NP)	Kg	249.00 (0.11)	—	249.00	—	—	—	—
3 Nicotinamide (NP)	MT	115.95 (0.31)	1.92	117.87	Kinetone (200 ml)	13.68	19.65 (300 ml)	19.86 (300 ml)
4 Vitamin B_{12} (D)(NP)	MT	101.63 (0.17)	216.75	318.38	—	—	—	—
Analgenics/Antipyretics, etc								
1 Analgin (NP)	MT	271.80 (0.88)	—	271.80	Novalgin (500 mg/10 tabs)	4.46	4.46	4.80
2 Aspirin (D)(P)	MT	1532.70 (0.68)	—	1532.70	Asabut (10 tabs)	2.74	2.74	5.94
3 Pethidine (NP)	Kg	515.00 (.009)	48.00	563.00	—	—	—	—
4 Ibuprofen (D)(NP)	MT	124.55 (2.40)	14.59	139.14	Affam (400 mg/10 tabs)	12.00	6.43	6.43
5 Methyl Salicylate (D)(NP)	MT	410.51 (1.02)	—	410.51	—	—	—	—
Cortico Steroids								
1 Dexamethasone (D)(NA)	Kg	343.00 (0.58)	521.20	864.20	Idizone (0.5 mg/10 tabs)	1.51	1.51	1.51
2 Betamethasone (D)(P)	Kg	932.00 (2.28)	348.00	1280.00	Betacortril (0.5 mg/10 tabs)	2.00	2.35	2.35
3 Predvisolone (D)(NP)	Kg	1923.00 (0.59)	—	1923.00	Deltacortril (5 mg/10 tabs)	3.18	3.34	—
Anti TB Drugs								
1 INH (NP)	MI	140.29 (0.39)	—	140.29	—	—	—	—
2 Ethanbutol (D)(NA)	MT	407.99 (5.42)	—	407.99	Combutol (400 mg/6 tabs)	6.76	6.76	6.76
Anti-Malarials								
1 Chloroquin (D)(NA)	MT	130.08 (1.01)	26.98	157.06	Emgmin (155 mg/10 tabs)	3.29	4.45	7.97
Anti-Dysentery Drugs								
1 Metronidazole (D)(P)	MT	436.28 (3.41)	12.61	448.89	Aristogyl (200 mg/10 tabs)	3.08	3.08	3.75
2 Iodochlorohydro-xyquinlotine (D)(NP)	MT	204.87 (0.50)	—	204.87	Stadmed Eutrozyme Plain (10 tabs)	3.78	4.11	5.50
Anti-Diabetics								
1 Tolbutamide (NP)	MT	132.88 (0.24)	3.00	135.88	Rastinon (500 mg/10 tabs)	2.50	3.00	8.77
2 Insulin (D)(P)	MU	2486.00 (0.81)	153.00	2999.00	Insulins (40-/10ml)	16.85	16.85	29.80
Anti-Asthmatics								
1 Salbutamol (D)(NP)	Kg	2736.00 (1.49)	371.06	3107.06	Salbetol (2 mg/10 tabs)	1.70	1.92	1.92
2 Terbutaline (D)(P)	Kg	335.00 (0.17)	—	335.00	Bricanyl (2.5 mg/12 tabs)	3.33	2.88	2.94
3 Theophyline (D)(P)	MT	135.91 (0.69)	132.02	267.93	Hiphylin (2 ml)	0.94	0.94	0.94
Immunological Agents								
1 Tetanus Anti Toxin (NP)	MU	7700.00 (0.09)	—	7700.00	Tetanus Anti Tonin (750 iu)	1.76	1.76	1.76
2 Diphtheria Anti-Toxin (NA)	MU	219.00 (.004)	33.00	252.00	Diphtheria Antitonin (10000 iv, 5ml amp)	34.88	34.88	34.88
Gastro Intestinals								
1 Aluminium Hydroxides (D)(NP)	MT	1378.80 (1.829)	—	1378.80	Mucaine (175 ml)	12.29	12.29	20.57 (200 ml)
Other Drugs								
1 Hydralazine (D)(NP)	Kg	224.00 (.004)	—	224.00	Corbetazine (10 tabs)	4.29	4.29	4.29
2 Heparin (NP)	MU	7439.00 (0.09)	—	7439.00	Beparine (1000 iv/5 ml)	12.27	12.27	12.77

Notes : (1)P = Patented; NP = Not Patented; NA = Not Available, and D = Drugs under Price Control.
(2) Figures in parentheses under indigenous production show percentage share in total value of indigenous production.

Source: Calculated by us by using (i) *MIMS India* (various issues), (ii) IDMA Annual Report 1992, (iii) *Drugs Under Patent* 1989 edition, Published by FOI services, USA.

payments/receipts of royalties, technical know-how fees, etc, of the pharmaceutical sector as such are not available. The companywise balance of trade and balance of payments figures are not dependable as firstly, we have data only for few pharmaceutical companies and secondly, because some pharmaceutical companies especially the MNCs are more involved in production of non-pharmaceutical items. The strengthening of the patents regime on balance of payments will depend on the type of strengthening of the regime and the way the Indian companies respond to the challenges. If it is merely accepting product patents, the effect will be less but if the clause of considering imports as tantamount to working the patents in the patent granting country is accepted, then the effect on balance of payments would be very high. While accepting product patents and furthering the flow of technology and qualitative drugs can help our exports, accepting 'imports as tantamount to working patents in India' will not have any positive effect on balance of payments.

The above discussion highlights the fact that while India has to follow a judicious, price decontrol policy, it need not fear strengthening the patents regime in pharmaceuticals by accepting product patents in pharmaceuticals. However, there are

TABLE 18A: INTERNATIONAL PRICES *VIS-A-VIS* INDIAN PRICES FOR LATEST AND IMPORTANT DRUGS

(in Rupees)

	Pack	India (Rs)	Pakistan (Rs)	Times Costlier in Pakistan	USA (Rs)	Times Costlier in USA	UK (Rs)	Times Costlier in UK
Anti-bacterials								
Co-trimaxazole tabs	10s	4.84	10.50	1.17	71.18	13.71	38.84	7.02
Amoxycillin-500 caps	6s	16.14	21.00	0.30	39.03	1.42	53.70	2.33
Cafadroxil 500 mg	6s	58.20	—	—	177.69	2.05	—	—
Cephalexin 250 mg	4s	11.98	—	—	55.63	3.64	16.50	0.38
Ciprofloxacin 250 mg	4s	40.00	—	—	105.89	1.65	81.00	1.03
Norfloxacin	4s	15.20	30.00	0.98	99.14	5.52	—	—
Amoxycillin + Cloxacillin 125 mg	6s	11.71	—	—	44.78	2.82	52.11	3.45
Doxycycline 100 mg	10s	18.70	20.25	0.08	21.01	0.12	125.82	5.73
Anti inflammatory								
Ibuprofen 400 tabs	10s	3.43	8.80	1.57	20.20	4.89	16.49	3.81
Flurbiprofen 100 tabs	10s	12.69	46.67	2.68	—	—	23.85	0.88
Diclofenac 50 tabs	10s	7.62	45.00	4.91	105.60	12.86	47.49	5.23
Piroxicam 10 tabs	10s	2.88	37.50	12.02	149.20	50.81	40.55	13.00
Naproxen 250 mg	10s	16.35	—	—	92.90	4.68	33.70	1.06
Anti-ulcerants								
Cimetidine 400 tabs	10s	17.34	65.00	2.75	153.04	7.83	79.74	3.60
Ranitidine 300 tabs	10s	26.16	210.00	7.03	348.70	12.33	234.07	7.95
Sucralfate 500 tabs	10s	7.78	22.00	1.83	—	—	32.00	3.11
Famotidine 40 tabs	10s	25.08	—	—	348.75	12.91	243.93	8.73
Mesalazine 400 mg	6s	21.00	37.99	0.81	—	—	38.58	0.84
Cardiovasculars								
Nifedipine 10 tabs	10s	3.88	38.50	8.92	60.38	14.56	31.20	7.04
Atenolol 50 tabs	10s	5.60	63.25	10.29	89.38	14.96	50.19	7.96
Acebutalol 200 tabs	10s	18.10	20.00	0.10	—	—	39.12	1.16
Pentoxyphylline 400 tabs	10s	29.57	40.00	0.35	57.50	0.94	43.00	0.45
Cyclandelate 400 mg	10s	8.22	24.35	1.96	57.22	5.96	55.84	5.79
Diltiazem 30 mg	10s	12.00	26.73	1.23	37.73	2.14	22.27	0.86
Enalapril Maleate 5 mg	10s	9.50	24.00	1.53	86.62	8.12	75.77	6.98
Anti viral/fungol, etc								
Acyclovir 3 per cent cream	5 gm	98.00 (5 per cent)	133.30	0.36	271.98	1.78	229.55	1.34
Ketaconazole 200 tabs	10s	41.28	179.00	3.34	272.94	5.61	121.69	1.95
Clobetasol 10 per cent cream	10 gm	10.16	16.00	0.57	—	—	21.85	1.15
Minoxidil 60 ml	60 ml	125.00	—	—	722.50	4.78	540.00	3.32
Anti-histamine								
Aziemizole	10s	9.50	—	—	185.64	18.54	47.25	3.97
Anti-Anxiolytics								
Alorozolam	10s	3.55	—	—	54.40	14.32	18.72	4.27
Diazepam 2 mg	10s	2.18	—	—	40.36	17.51	5.10	1.34
Loarazepam 1 mg	10s	2.00	2.19	0.09	54.64	26.32	4.54	1.27
Nitrazepam 5 mg	10s	2.74	18.37	5.70	—	—	5.83	1.13
Trazodone hcl 50 mg	10s	14.50	—	—	95.93	5.62	32.46	1.24
Anti-cancer								
Vincristine 1 mg	Vial	45.00	113.40	1.52	—	—	252.72	4.62
Vinblastine 10 mg	Vial	92.00	96.39	0.05	—	—	277.83	2.02
Miscellaneous								
Allopurinol 100 mg	10s	8.60	—	—	16.32	0.90	24.98	1.90
Haloperidol 0.5 mg	10s	1.90	—	—	21.01	10.06	2.89	0.52
Domperidone 10 mg	10s	9.50	19.57	1.06	—	—	22.05	1.32
Gemfibrozil 300 mg	100s	345.00	—	—	525.98	0.52	648.00	0.88
Nalidixic Acid 500 mg	4s	10.40	—	—	40.50	2.89	21.97	1.11
Stanozolol 2 mg	10s	14.48	—	—	52.82	2.65	42.91	1.96

Source: B M Keayla (1989).

controversial issues like "considering imports as tantamount to working the patents in the patent granting country" and "reversal of the burden of proof". One possible danger is that the drugs not to be patented in the WHO list may slowly be forced to be patented. However as of present, this danger does not exist and the already competitive Indian drug industry can cope up in the case of any eventuality. Thus the basic issue here is not whether India should strengthen its patents regime in the pharmaceutical sector, but how it should strengthen it. To this issue, we will turn our attention in the next section.

TABLE 18B: DRUG PRICES: AN INTER-COUNTRY COMPARISON, 1986
(Price to the consumer in Rs)

Name of the Drug	India	UK
Chloramphenicol (antibiotic)	6.87	21.30
Metronidazole (anti-diarrhoeal)	2.76	25.54
Ferrous Sulphate (anti-anemic)	8.46	12.03
Ibuprolen (analgesic)	6.13	7.67
Propranolol Hcl (Anti-hypertensive)	48.78	70.95
Salbutamol (anti-asthmatic)	1.11	4.57
Nifedipine (cardiac drug)	6.00	29.59
Cimetidine (anti-ulcer)	7.96	35.59

Note : Even if allowance is made for the 15-20 per cent increase in consumer prices as a result of DPCO 1987, Indian prices still compare very favourably with prices in other developing countries where also prices have gone up since 1986.

Source: OPPI - IDMA.

TABLE 19: PERCENTAGE OF INDIGENOUS PRODUCTION OF DRUGS COVERED UNDER PATENTS ABROAD BY VARIOUS THERAPEUTIC GROUPS AS PER IDMA AND GOVERNMENT OF INDIA

Drug Groups	IDMA (Percentage)	Government of India (Percentage)
1 Antibiotics	40.23	16.00
2 Antibacterials	98.80	
3 Cardiovascular Drugs	40.18	51.00
4 Non-Steriod Anti-Inflammatory Drugs (NSAIDS)	22.16	20.00
5 Tranquillisers	74.42	17.00
Anti-Asthmatics	47.53	11.00
7 Systemic Antifungals	25.66	NA
8 Anti-leprotics	69.96	NA
9 Anti-Conoulsants	65.93	NA
10 Antipeptic Ulcer Drugs	65.92	NA
11 Oral Anti-Diabetics	55.30	NA
12 Anti-Histamines	21.42	NA
13 Cyfostatics and Anti-hen Remies	32.41	NA
14 Contraceptive Hormones	88.79	NA

Sources: (1) For IDMA: IDMA, 'Intellectual Property Rights and Patent Protection's 1992.
(2) For Govt. of India: Answer to Question No 235 in the Rajya Sabha by the Minister of State in the Ministry of Chemicals and Fertilisers, Government of India, dated March 12, 1992.

IV

Modus Operandi of Strengthening India's Patent Regime

Our analysis in the previous section has shown that India need not fear strengthening its patent regime in the pharmaceutical sector by introducing product patents and in Section II we have seen that India's increased dependency on the developed world in general and on the US in particular and the fall of the Soviet Union has made it increasingly necessary for India to toe to the general line followed by the developed and other developing countries. In this situation and in the light of our study, we will see what changes India can make without foresaking its interests.

At the outset, we would like to make three things clear.

(1) We are not of the opinion that India's Patent Act 1970 was not useful. In fact, we are of the opinion, that it was useful and helped the Indian pharmaceutical sector to be competitive. But changing this Patents Act, now in a way that will strengthen the patents regime, need not necessarily be harmful for the Indian pharmaceutical sector.

(2) The fact that we advocate strengthening of the patents regime in the pharmaceutical sector, does not automatically imply that the same holds good for other sectors of the economy and for other countries at present, even in the pharmaceutical sector. This needs sector-specific and country-specific studies.

(3) The fact that we are of the opinion that the patents regime in the pharmaceutical sector of India should be strengthened, does not automatically imply that we should accept all the conditions put forth by the advanced countries or by Dunkel in his Draft Text.

The second aspect is beyond the scope of this paper and the third aspect is the subject-matter of this section.

ISSUES INVOLVED IN GATT NEGOTIATIONS ON TRIPS

There are many important issues involved in the discussion between developed and developing countries on strengthening the patents regime.[39] Here, we will consider only those issues related to pharmaceutical sector in the Indian case. They can be grouped under the following heads:

(1) Issues relating to policy matters.
(2) Issues relating to implementation and administration.

The main issues related to policy matters in the negotiations on strengthening the patents regime in the Pharmaceutical sector, especially for India are: (1) Granting product patents, (2) Duration of the patents, (3) Considering imports as tantamount to working patents and continuing non-exclusive compulsory-licensing, (4) Reversal of the burden of proof and (5) Pipeline protection.

The main opposition against granting product patents in the pharmaceutical sector by countries like India, was the fear that it would increase the prices of pharmaceuticals and that domestic production would suffer. We have seen that there is no need to fear the introduction of product-patents on these counts. What we should guard against is that under any circumstances the non-patentable drugs (especially the ones in the WHO list) are not included under the list of patented drugs. One should also be aware of the fact that developing countries including India's close and potential competitors in Asia like China have accepted product patents. While there is no need to fear granting product patents in pharmaceuticals, India need not hesitate, but take the initiative and accept granting product patents in pharmaceuticals in order to bargain against such patents in other sectors, where such a thing should not be done and/or for bargaining on other issues in the pharmaceutical sector.

The duration for which patents are granted in India's pharmaceutical sector is seven years from the date of application or five years from the date of grant, whichever is shorter while it is 14 years in most of the other sectors. The criticism against the short duration of patents in India in general and pharmaceuticals in particular is that the time is too short for the patentee to gain the fruits of his inventions, as R and D is very costly in this sector and it presently takes a minimum of five years for a patent to be granted so that the effective term gets reduced to only about two years. For introducing a new drug it takes about that long to conduct clinical trials by which time it is all over.[40] The arguments against a longer patent term in general[41] are that if a longer patent term is given the patentee may not have any incentive to start production as soon as possible... the lead time between an invention and its commercialisation is getting shorter... and due to technological or economic obsolescence most of the patents do not last their full term. The shorter duration of patents especially in the pharmaceutical sector is justified on the grounds that it affects

the common man and is a social security issue.

Let us now put the facts squarely. The duration between the date of application and grant of patent is rather high in India. Table 24 shows that for the patent applications to become fructuous in the case of all countries together and also individually, it took two-three years in the period 1970-79, with three years being the modal year while it became three-four years in 1980-88 with 4 years turning out as the mode. Though we do not have the frequency ratios particularly for pharmaceutical sector, there is no reason to believe that the patents were granted quickly in this sector. Therefore there is truth in the argument that the effective years for patents is very less (usually three years if we follow the results in our table). With only three years left, it would be difficult to popularise the product and recover the cost on R and D, leave alone gaining profits forcing the pharmaceutical companies to shift to production of cosmetics and related items. While the optimum duration for a patent is debatable and depends on the trade-off between the costs of monopoly and provision of incentives, there is definitely a need for increasing the effective term. This can of course be done by suitable administrative measures without touching policy measures. If a patent is granted within one year of application, even though one doubts whether patent office in India can be activated to such an extent, then also the effective period would only be five years, as under the Patent Act 1970, patents in pharmaceuticals can be granted seven years from application or five years from granting the patents, whichever is shorter. While we feel that there is no harm in India granting a higher duration, it can fix the exact number of years for the pharmaceutical sector (say around 8-14 effective years) for bargain, though not 20 years as given in Dunkel Draft Text (DDT).[42] In fact, it has been reported that the IDMA which has been opposing the strengthening of patents regime has been reported to have accepted that the life of a patent for a pharmaceutical product can be extended from the existing seven years to a uniform 14 years as in the case of other products and industries.[43]

In the Dunkel Draft Text nowhere has it been mentioned that imports are tantamount to working patents in the patent granting country and also people like Chidambaram[44] say that the text does not warrant such an interpretation (i e, imports are tantamount to working patents). Though the text says that imports cannot be allowed by others without the consent of the patentee, this necessarily does not mean that the patentee can himself import it. Yet the draft is slightly tricky in this issue and as stated by Chidambaram,[45] the US and less so European countries and Canada, clearly regard the text as meaning that importation is equal to local

TABLE 20: PATENTS AND MARKET SHARES OF INDIAN AND FOREIGN AFFILIATED PHARMACEUTICAL COMPANIES

Sl No	Name of the Company	PUC (Rs Crore)	FE (Per Cent)	Nature of the Company	Size of the Company	Total No of Patents (1972-89)	Parent Companies Patents under Indian Name	Market Share (As on Year Ended '89)	
								Drug Formulations	Bulk Drugs
1	Glaxo India Ltd	20.00	40	Foreign	Big	3		6.0	
2	German Remedies	6.53	36.95	Foreign	Big	Nil		2.0	
3	Bayer India	16.22	51	Foreign	Big	4	44	0.5	
4	Boots Co (India) Ltd	8.10	40	Foreign	Big	23	8	1.6	3.49
5	E Merck (India)	5.94	40	Foreign	Big	6	1	1.2	
6	Hoechst (India)	9.57	40	Foreign	Big	228	168	4.5	
7	Pfizer Ltd	11.72	40	Foreign	Big	4	103	2.5	0.67
8	Rallis India	9.50	29.25	Foreign	Big	2		1.7	
9	Sandoz Ltd	5.30	51	Foreign	Big	3		1.5	
10	Searle (India)	5.21	39.16	Foreign	Big	17		1.4	
11	Cynamid (India)	4.55	40	Foreign	Big	7	16	0.9	
12	Hindustan Ciba-Geigy	17.70	40	Foreign	Big	66	30	2.1	
13	Eskayef	5.00	40	Foreign	Big	1		1.8	
14	Burroughs Wellcome	3.00	40	Foreign	Big		3	1.9	
15	Parke Davis	12.05	40	Foreign	Big	2		2.1	
16	Reckitt & Colomn (India) Ltd	8.39	39	Foreign	Big	35	2	0.5	
17	Warner Hindustan*	2.98	40	Foreign	Big		57	0.8	
18	Hindustan Antibiotics	38.42	Nil	Public Sector	Big	27		NA	36.68
19	Indian Drugs & Pharma	110.99	Nil	Public Sector	Big	14		2.9	
20	Ranbaxy Laboratories	9.14	Nil	Indian	Big	8		2.1	
21	Unichem Laboratories	1.35	26.38	Indian	Big	10		1.2	
22	Alembic Chemicals	4.11	Nil	Indian	Big	Nil		3.0	0.99
23	Cipla	1.57	Nil	Indian	Big	Nil		2.1	
24	JB Chemicals	3.51	Nil	Indian	Big	Nil		1.4	
25	Lyka Labs	2.99	16.06	Indian	Big	Nil		1.4	
26	Ambalal Sarabhai	22.19	Nil	Indian	Big	Nil		4.0	7.1
27	Jayant Vitamins	4.37	Nil	Indian	Big	Nil		0.9	
28	East India Pharma	98.9 lakh			Medium	2		0.8	
29	Jalaram Chemicals	8.0 lakh			Medium	2		NA	
30	Ortho Pharma Pvt Ltd	7.5 lakh			Medium	1		NA	
31	Armour Pharma	3.0 lakh			Small	1		NA	
32	Kontiki Chemicals	3.0 lakh			Small	17		NA	
33	National Pharmaceuticals Pvt Ltd	1.4 lakh			Small	1		NA	
34	Rachho Pharma	1.5 lakh			Small	5		NA	
35	Ralliwolf Ltd	1.82		Subsidiary	Big	6		NA	

Note : * Merged with Nicholas Laboratories India.
Source: Calculated by us from the ISID database.

working, that it is a substitute for local manufacture. Developing countries have strongly argued against the non-working of patents stating that if a patent is only used for import purpose, non-nationals can exercise monopoly power over the protected market. Moreover there are no benefits for the importing developing country in the sense of extra production facilities.[46] Industrialised countries have argued that "it may be very uneconomical for a company to exploit its patent in all countries where the patent is recognised. Supplying foreign markets from a central production plant could be far more cost effective. Industrialised countries perceive prevention of the unauthorised copying of a protected product or process in the importing country one of the core functions of the patent. They therefore challenge the above-mentioned definition of working of a patent by stating that working also includes importing the product".[47] Our study has shown that even if product patents are granted and even if MNCs manufacture the commodity using the patented technology, the production should take place in India and not outside India. If imports are considered tantamount to working patents in the country then firstly, the very purpose of patenting for transfer of technology will be lost, secondly, the import bill will be higher leading to adverse balance of payments; and, thirdly, the high backward linkages of the pharmaceutical sector will be reaped outside the country. Thus, on no account can India accept this clause at the present stage of its development. We cannot accept the argument of Chidambaram that one way of addressing this concern is to provide for compulsory licensing for non-commercial public use without consulting the patent holder.[48] This is because "compulsory licences are not exclusive and the licensee is not put in a monopoly position and therefore lacks a reliable basis for investment and also compulsory licenses do not include know-how".[49]

One point to be noted here is that the developing countries advocate exclusive compulsory licensing, wherein the patentee loses the right to import and to market the product in the country, as he did not work the patents within a period of three years from the date of the sealing of the patent and was not able to give genuine reasons for it. Here, of course, flexibility is called for and we should not exclude the patentee from working the patent even when a compulsory licence is issued. While the patentee would not have been debarred from working the patent if he were to work it before the stipulated date, there is no need to be hard on him and prohibit him from working the patent after the date and he should be allowed to compete with others for whom compulsory licences have been issued. What however has to be guarded against is the imports by the patentee. Here the same policy of not considering imports as working of patents should hold good and thus non-exclusive compulsory licence devoid of imports can be advocated in such cases.

Another issue hotly contended between developed and developing countries is the question of 'reversal of the burden of proof. The advanced countries contend that if the competitor did really use an alternative process, he is normally the only one able to give evidence for that and therefore the burden of proof should be on the alleged infringer. This means that the latter must show that he has used an unprotected process to manufacture the challenged new product. The developing countries however contend that reversal of the burden of proof is at odds with basic legal principles in many countries where it is up to the plaintiff to provide proof and evidence; it relieves the (usually foreign) patentee from producing proof of infringement of his process patent and gives him a lot of coercive power and third parties will become less willing to invent or invest in alternate processes in developing countries because they might be sued for infringement.[50] According to Chidambaram[51] "the problem of reversal of burden of proof has been addressed in India by pointing out to Section 106 of the Indian Evidence Act, which already provides that when a fact is within the special knowledge of a person the burden is upon that person to prove that fact". In this context one has to be quite careful as the Dunkel Draft Text is a little mischievous when it says in Article 47: Right of Information that 'Parties, may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.[52] Under this clause not only the burden of proof lies on the alleged infringer, but also he has to inform the identity of other possible infringers and the burden of proof lies on these third parties as well! This can result in a lot of mud-slinging and some parties can become scapegoats sometimes at the instance of the patent holder, who may be a multinational with his own vested interests. In this context one can broadly agree with the views of Pravin Anand[53] who says that "as regards the burden of proof, it is the existing law of India that the plaintiff, in an infringement action, would discharge his preliminary burden by stating certain basic facts and the onus of establishing recipe details would be on the defendant who alone has special knowledge of them". We feel that the plaintiff should produce basic evidence for the infringement and a high penalty should be charged on him in case his allegation proves to be false. The alleged infringer should also be asked to supply details before the case is decided. However this should be applicable only for companies or producers who market the product with the intention of earning profits and not on any single individual (or research organisation) who may infringe with non-profit motives like basic research. Otherwise an extension of this principle to copyrights in software will lead to undue difficulties for individual users of software purely for research purposes. Again our view holds good only for pharmaceutical sector and need not necessarily hold good for other sectors like agriculture and software where the situation is quite different and doubts still exist as to whether the plaintiff himself is an alleged infringer of the technology which he might have modified. This is because as said by Narasimhan 'the so-called 'inventions' always ride piggy-

TABLE 21: SHARE OF PHARMACEUTICAL PRODUCTS IN TOTAL SALES OF SELECTED MNCs AND INDIAN PHARMACEUTICAL COMPANIES

Name of the Company	Nature of the Company	Gross Sales (Rs Crore)	Gross Sales of Pharmaceuticals (Rs Crore)	Share of Pharmaceuticals in Total Sales (Per Cent)
Alembic Chemical Works	Indian	123.33	106.34	86.22
Rallis India Ltd	Foreign	356.94	60.00	16.81
Cyanamid India Ltd	Foreign	66.36	31.24	47.08
Unichem Laboratories	Indian	51.21	42.91	83.79
Cipla	Indian	91.34	73.50	80.47
Ranbaxy Laboratories	Indian	90.85	75.14	82.71
Jayant Vitamins	Indian	30.64	30.64	100.00
Glaxo India Ltd	Foreign	2089.14	160.89	7.70
Pfizer Ltd	Foreign	692.80	77.21	11.14
Eskayef	Foreign	432.27	58.10	13.44

Source: For gross sales: ISID database.
For gross sales of pharmaceutical products: CMIE, Market and Market Share, 1989, 1991.

back on prior ideas and frequently not all programming techniques are published, but are transmitted by word of mouth, or presentations at conferences, making it difficult to identify the true inventor.[54]

The Dunkel Text says[55] that no party is obliged to apply the provisions of the agreement before the expiry of a general period of one year following the date of entry into force of this agreement. They are also entitled to delay for a further period of four years from the date of application. Thus all countries get a transition period of five years. Further the text also says that the developing countries extending product patent protection to areas of technology not hitherto protected can get a further five-year period transition. Thus total transition period for them extends to 10 years. Least developed countries can get a transition, period of 11 years. However, in the course of the GATT negotiations, the US is insisting on 'exclusive marketing rights' for pharmaceutical and agro-chemical products. This is called 'pipeline protection'. Thus as observed by Jeroen van Wijk and Gerd Junne.[56] "In spite of transition period, patent applications may be filed for pharmaceutical and agro-chemical products as from the date of entry into force of the agreement. These applications remain in a 'black box' until the expiry of the transitional period. In respect of the products covered by these applications, there will be a five-year period of marketing exclusivity after marketing approval, while awaiting the delayed grant of the patent. The exclusive marketing rights reduce the transition period for the protection of the pharmaceutical and agro-chemical products to zero"! Chidambaram[57] has argued for a 10-year clean transition period for countries like India without intrusion by what is called pipeline protection before they come under the new patent regime. He also quotes the example of the issue of Multi-Fibre Agreement (MFA) where "the advanced countries want a 10-year transition and during that period of 10 years the argument is back loaded, the integration percentage are inadequate and the coverage is sought to be extended to products which are not under coverage today". China which has made extensive reforms in its Patents regime, however considers that pipeline protection "does not conform with the principles of territoriality and independence in respect of the Paris convention. It will put the technically backward developing countries in disadvantageous circumstances".[58] While we have no reason to argue against

TABLE 22: PROFITABILITY RATIOS OF SELECTED INDIAN AND FOREIGN AFFILIATED COMPANIES IN PHARMACEUTICALS

S No	Year	Name of the Unit	Nature	Profits to Networth	Profits to Gross Sale	Profits to Net Sale	PbT Per Cent Networth	PbT Per Cent Gross Sale	PbT Per Cent Net Sale	Total Import (cif) Per Cent Sale	R Materials Per Cent Sale	Dividend Per Cent Sale
1	8586	Alembic Chemical Works Co	Indian	−9.54	−2.58	−2.73	−9.35	−2.53	−2.68	5.70	5.36	0.000
	8687		Big	11.67	3.27	3.46	11.67	3.27	3.46	3.00	2.72	0.000
	8788			3.32	0.81	0.85	4.09	1.00	1.05	4.12	3.98	0.000
2	8586	Rallis India Ltd	Foreign	15.71	1.78	1.82	29.88	3.38	3.45	4.86	3.19	0.076
	8687		Big	18.76	2.09	2.14	31.38	3.51	3.59	4.21	3.34	0.150
	8788			15.53	2.11	2.16	21.17	2.87	2.94	4.56	3.53	0.141
3	8586	Cyanamid India Ltd	Foreign	14.39	4.60	4.62	23.25	7.44	7.46	5.39	4.51	1.265
	8687		Big	7.69	2.37	2.38	12.41	3.83	3.84	3.37	2.83	1.169
	8788			10.06	3.55	3.58	12.03	4.24	4.28	4.12	3.65	0.428
4	8586	Unichem Laboratories Ltd	Indian	8.57	2.39	2.74	12.48	3.48	3.99	3.43	3.09	0.000
	8687		Big	6.74	1.81	2.00	9.38	2.52	2.78	3.86	2.61	0.000
	8788			5.28	1.33	1.46	7.38	1.86	2.03	3.77	3.37	0.000
5	8586	Ranbaxy Laboratories Ltd	Indian	24.78	4.89	5.12	29.22	5.77	6.03	23.65	20.31	0.000
	8687		Big	14.69	2.56	2.63	16.58	2.89	2.97	25.74	23.85	0.000
	8788			15.12	2.63	2.71	18.01	3.13	3.22	21.00	20.36	0.003
6	8586	Jayant Vitamins Ltd	Indian	64.39	14.73	14.73	64.39	14.73	14.73	0.83	0.35	0.000
	8687		Big	43.63	9.15	9.15	51.00	10.70	10.70	5.60	3.62	0.000
	8788			12.54	3.44	3.49	14.05	3.85	3.92	1.79	0.44	0.000
7	8586	Cipla	Indian	4.66	1.39	1.54	8.20	2.44	2.71	5.90	5.68	0.000
	8687		Big	11.63	3.61	3.86	16.07	4.99	5.33	6.05	5.67	0.000
	8788			8.63	2.59	2.76	10.81	3.24	3.46	6.11	5.89	0.000
8	8586	JB Chemicals	Indian	14.18	2.80	2.83	16.49	3.26	3.29	6.26	6.26	0.000
	8687		Big	14.56	3.05	3.13	16.48	3.45	3.54	5.26	5.26	0.000
	8788			18.75	3.66	3.80	22.53	4.40	4.57	5.50	5.19	0.000
9	8586	Glaxo Laboratories (I) Ltd	Foreign	14.73	4.22	4.95	26.54	7.60	8.93	2.52	1.12	0.981
	8687		Big	13.58	3.66	4.34	20.56	5.54	6.57	1.47	1.11	0.627
	8788			14.70	3.54	4.14	21.98	5.29	6.19	1.32	0.99	0.517
10	8586	Hoechst India Ltd	Foreign	18.51	4.17	4.44	20.65	4.65	4.95	6.88	6.19	0.407
	8687		Big	5.84	2.38	2.53	6.18	2.52	2.67	12.22	10.93	0.393
	8788			2.25	0.80	0.85	2.25	0.80	0.85	9.63	7.89	0.351
11	8586	Parke Davis & Co	Foreign	19.15	3.49	4.27	47.21	8.60	10.53	2.72	2.72	0.644
	8687		Big	18.27	3.41	4.26	35.42	6.61	8.27	2.31	2.23	0.656
	8788			4.89	0.95	1.19	13.43	2.60	3.28	2.58	2.16	0.653
12	8586	Pfizer Ltd	Foreign	9.63	4.42	5.04	15.99	7.35	8.36	3.22	2.96	1.717
	8687		Big	2.50	1.08	1.23	4.30	1.85	2.11	2.94	2.73	1.625
	8788			1.45	0.57	0.63	5.17	2.04	2.26	2.83	2.70	0.761
13	8586	German Remedies & Trading	Foreign	10.25	1.86	2.11	23.24	4.23	4.78	9.31	9.28	0.347
	8687		Big	−4.72	−0.90	−1.01	−4.22	−0.90	−1.01	14.03	13.91	0.360
	8788			12.47	2.62	2.96	14.76	3.10	3.50	9.49	9.40	0.000
14	8586	Burroughs Wellcome	Foreign	10.81	3.72	4.21	22.27	7.67	8.68	7.10	6.95	0.609
	8687		Big	−6.55	−2.00	−2.18	−6.55	−2.00	−2.18	10.06	9.79	0.479
	8788			6.00	1.69	1.78	6.88	1.94	2.04	9.47	9.08	0.000
15	8586	Eskayef Ltd	Foreign	23.84	7.18	11.47	68.63	20.66	33.03	2.50	2.32	0.000
	8687		Big	29.70	9.47	15.03	51.48	16.41	26.05	2.31	2.26	0.555
	8788			26.59	9.36	15.07	43.87	15.45	24.86	3.13	3.02	0.000

Source: Calculated by us from the data available at ISID.

this view and while we are aware that the question of "pipeline protection' has not even been mentioned in the original text of Dunkel, there is also the fact that we have nothing to fear in accepting pipeline protection in pharmaceuticals as we have seen that the effect of introducing product patents in the case of pharmaceuticals in India is not much and a five-year pipeline protection will not make much of a difference in this regard especially when the patents of most of the American drugs are expected to expire in 1990-95, and the Indian companies have already identified their 'target drugs' and are on the process of drawing up plans for an assault on the US market when the patent concerned expires.[59] However we need not hurry in this issue and can use it as a bait in our negotiations to get the pipeline protection granted to developed countries under MFA removed or lessened.

TABLE 23: TOTAL VALUE OF IMPORTS AND EXPORTS OF DRUGS AND PHARMACEUTICALS FROM 1973-74 TO 1988-89 AND 1989-90

(Value in Rs crore)

Year	Total Imports	Total Exports	Trade Balance
1973-74	34.16	37.33	3.17
1974-75	46.90	43.14	−3.85
1975-76	46.02	42.27	−3.75
1976-77	54.17	54.13	−0.04
1977-78	82.42	60.77	−21.65
1978-79	95.33	69.02	−26.31
1979-80	120.03	71.16	−48.87
1980-81	112.81	76.18	−36.63
1981-82	136.77	95.41	−41.36
1982-83	148.48	111.06	−37.42
1983-84	163.34	161.82	−1.52
1984-85	215.62	217.49	1.87
1985-86	267.40	194.37	−73.03
1986-87	287.59	222.95	−64.64
1987-88	349.44	289.69	−59.75
1988-89	446.91	467.60	20.69
1989-90	652.12	856.90	204.78

Source: IDMA, *Annual Report, 1992.*

There is the allegation against India that not only do its patent laws violate IPRs, but also that these laws are not properly implemented and consequently countries like the US are incurring heavy losses. Since the then USTR Carla Hills herself had said that granting product patents will affect only 5 per cent of Indian drugs, the losses to the US are presumably not due to this factor. Then the implementation of the process patents which we have granted seems to be the most important reason leading to the alleged losses. But here also there is no clear-cut picture, as people like Bhai Mohan Singh[60] have said that American companies estimate losses from the very basic stage and not the spin off stage. Further, as also pointed out by Bhai Mohan Singh[61] "when the advanced countries like the US, Japan and EC countries were in the stage of development India is in today, their laws and implementation were not any better, possibly worse". However, there are certain aspects related to implementation and administration that needs to be attended to:

(1) The time between applying for a patents and granting the patent should be reduced. This is good from India's point of view as well, as, having decided to grant patents, it is better to do it quickly, in order to get the benefit of the new technology quickly. So the administrative machinery has to be geared up to meet the needs and a complete face lift has to be given to the Patents Office and its working. In fact, the highest office sanctioning transfer of technology to India seems even to lack in giving a semblance of the latest technology and expertise which it is helping to transfer to India.

(2) In the case of wide scale infringement of the patents granted, while the government should take action and even co-operate with the patent holder in bringing the infringer to book, wherever possible, the government should also negotiate with the patent holder to charge some 'pardon-amount' and allow the infringers to use the patented process or product of popular drugs and medicines which have been copied on a wide scale.

(3) Confusing clauses in the law which make administration and implementation of patents difficult have to be removed or modified e g as mentioned by Pravin Anand,[62] "There are horrendous provisions such as Section 43, by which an opposed patent cannot be sealed in appeal even if the appellate court refuses to stay sealing. Thus in a case relating to Orissa cement, even through the Delhi High Court refused to stay sealing, the controller considered himself bound not to seal and despite a provision in the act that the appeal should be heard within one year, 12 out of the 14 years have already gone by and the appeal is still pending". Similar cases may be found even in the pharmaceutical sector. Thus a serious attempt should be made to streamline the procedure of the Patents Act and the working of the patent office to make the patent right a meaningful one.

(4) While the list giving what are not inventions can be pruned as opined by Daruwalla[63] certain conditions are not needed e g, licensing of related patents[64] which says that "at any time after the sealing of a patent any person who has the right to work any other patented invention either as a patentor or as a licensee thereof may apply to the controller for the grant of a licence of the first mentioned patent on the ground that he is prevented or hindered without such licence from working the other invention efficiently or to the best advantage possible". These issues should be settled before sealing the patent. Moreover the aggrieved parties can lodge the complaint before the patent is sealed within a given stipulated time.

Thus the Patents Act has to be carefully modified to make its implementation and administration smoother and efficient.

TABLE 24: FREQUENCY TABLE OF THE YEARS TAKEN FOR PATENT APPLICATIONS TO BECOME FRUCTUOUS

Years Taken	UK		USA		W Germany		France		Japan		India		Other DCs		Other LDCs		Russia	
	1970-79	1980-88	1970-79	1980-88	1970-79	1980-88	1970-79	1980-88	1970-79	1980-88	1970-79	1980-88	1970-79	1980-88	1970-79	1980-88	1970-79	1980-88
0	26	8	85	2	27	1	14	10	14	0	51	5	44	0	10	0	1	0
1	211	5	533	25	261	6	80	2	70	9	686	39	294	9	106	2	55	1
2	461	35	1214	233	620	104	229	24	186	59	1445	355	734	107	236	35	147	37
3	723	343	1482	1267	678	555	252	247	198	265	1979	1319	951	687	221	132	162	160
4	178	499	602	1662	283	589	124	409	86	258	466	1164	402	883	79	135	55	85
5	50	85	186	237	85	58	39	42	22	22	128	167	108	111	21	28	9	10
6	5	8	8	30	5	2	2	6	0	3	6	22	5	6	3	0	0	0
7	1	1	13	6	0	1	2	1	0	0	2	10	4	0	2	0	0	0
8	30	0	16	4	31	0	20	0	7	0	5	0	30	0	0	0	0	0
9	0	0	41	0	0	0	1	0	0	0	2	0	13	0	2	0	0	0
10	2	0	22	0	0	0	6	0	0	0	3	0	2	0	0	0	0	0
11	2	0	4	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: Calculated by us from the ISID data base.

Other Issues

Some other issues can be listed below:

(1) Whether negotiations should take place under the auspices of GATT or WIPO.

(2) Whether unilateral action can be allowed.

(3) Whether India should join the Paris convention.

WIPO vs GATT: This was an important issue when the TRIPS negotiations were beginning. But now even those people who have advocated that negotiations should take place under WIPO seem to have lost interest in pursuing their idea. While WIPO is considered to represent the interests of developing countries and GATT those of advanced countries there is no need to make much of a fuss on this issue now and the negotiations can be completed under the GATT.

Unilateral Action: The US has been resorting to unilateral action by involving the Special 301 provisions of its trade act and have targeted many countries including India for alleged shortcomings in their IPP legislations. The Special 301 provisions require the USTR to negotiate specifically on IPP with countries whose IPP standards are prejudicial to American trade interests. This unilateral action is taken side-by-side with the pressure applied in the multilateral negotiations under GATT. In fact the US is threatening to link the issue of IPRs with GSP (General Scheme of Preferences). We are of the opinion that no country should be allowed to follow such unilateral actions while negotiations under the multilateral forum of GATT are underway. The question of unilateral actions should come only if GATT talks fail. Of course the GATT negotiations should be completed speedily and successfully to avoid such embarrassments. This needs a positive outlook and sincere effort on the part of both the developed and developing countries.

Joining the Paris Convention: There are people who feel that 'it is high time that India became a member of the Paris convention of 1883 as a lot of foreign technology is accidentally lost, as owners harbouring a wrong impression do not apply in India prior to publication and by the time the fact is discovered, it is too late'.[65] But there is also great opposition by economists in India joining this convention. The disadvantages for India in joining the Paris convention and the advantage of the Indian Patents Act has been summarised by Mehrotra[66] and has been given in the Statement.

While some of the disadvantages in the list mentioned above can no longer be considered as disadvantages, in the light of our study, there are some disadvantages like the difficulty in break blocking/comprehensive repetitive patents which also hinders the development of S and T. Besides, the issue of joining the Paris convention can be decided only after making sector-specific studies of other sectors. Moreover if the reforms suggested by us are followed, then the question of joining the Paris convention will be less important from the point of the pharmaceutical sector.

Statement: Comparative Loss-Benefit Analysis for Indian Pharmaceutical Industry in Joining Paris Convention

Indian Patents Act Advantages	Paris Convention Disadvantages
To People of India	
1 No product patent on drugs, foods etc, and hence can be available at lower costs.	1 Patented products can be imported except at exorbitant monopoly prices.
2 Revocation of patents in public interest. Government can ensure indigenous production in public interest.	2 Patented products cannot be produced in the country except with the premission (licence) from the patentee (exorbitant cost).
3 Rigorous provisions of compulsory licensing.	
4 Power to government to use inventions (for people).	
5 Government can import patented drugs (public use).	
To Industrial Development	
1 Drugs not being under patent can be indigenously produced.	1 Compulsory licensing very difficult and hence monopoly market of MNCs.
2 Compulsory licensing; revocation of patent in public interest; power of government to use invention—even licence to third parties—indigenous production.	2 Effective protection against unfair(?) competition by indigenous industry (helps maintain monopoly of MNCs)
3 Can import drugs/technology for indigenous production from wherever available (cheaper).	3 Cannot obtain technology except under lincence from patentee (exorbitant cost).
4 Can also export technology/patented products to non-PC countries.	4 Can't export patented products/technology.
	5 Can't import patented bulk/technology.
	6 Difficult to break blocking/comprehensive repetitive patents.
S and T Development	
1 Scientists can patent incremental innovations/inventions.	1 Indian scientists can't patent because of (6) above.
2 Indian scientists can still continue to obtain patents anywhere in the world and get same rights available to others.	2 Restriction in industrial/technological development doesn't provide climate for further S and T development.
3 Because of bilateral agreements and membership of WIPO, etc, can still get all infomation on patents.	

Source: Mehrotra N N: 'Patents Act and Technological Self-Reliance: The Indian Pharmaceutical Industry', *Economic and Political Weekly*, Vol 24, No 19, May 13, 1989, p 1063.

V
Conclusion

In this paper we have made the followings facts clear:

(1) India's dependency for technology on the US in particular and the developed countries in general has been increasing.

(2) In the pharmaceutical sector, India is quite competitive and the prices will be affected mainly due to decontrol of prices rather than introducing product patents.

(3) While there is no need to fear granting product patents by India in the pharmaceutical sector, considering imports as tantamount to working patents cannot be accepted; duration of patents can be left for mutual bargaining and pipeline protection can be used as a bait for cancelling or reducing pipeline protection of developed countries in sectors like textiles.

(4) The administration of the patents has to be streamlined and Patents Act has to be modified.

(5) While unilateral action by the US should be discouraged when the multilateral negotiation are making headway, joining the Paris convention is not an important issue from the point of view of the pharmaceutical sector if the measures suggested by us are accepted.

(6) Greater importance to R and D and substituting non-patented drugs for patented drugs are called for in the pharmaceutical sector.

In conclusion we can say that the

patents regime has to be strengthened on the lines suggested by us to promote greater transfer of technology and join the process of international harmonisation without foresaking India's interests. Sector-specific studies for other sectors are the need of the hour.

Notes

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1 For a detailed and latest discussion on these aspects see: Jeroen Van Wijk and Gerd Junne: *Intellectual Property Protection of Advanced Technology*, October 1992 (mimeo).

2 See: Department of Science and Technology, Government of India: *R and D Statistics 1990*, p viii.

3 Griliches,' Z has argued that 'showing that patent statistics are a good indicator of inputs into inventive activity is a useful accomplishment on its own merit. It allows us an insight into what is going on in more areas and also in much more detail than is possible to glimpse from the available R and D statistics'. See: Griliches, Z, 'Patent Statistics as Economic Indicators: A Survey', *Journal of Economic Literature*, Vol 28, December 1990, pp 1661-1707.

4 This table is based on the figures given by department of science and technology, government of India.

5 See: *Financial Express*, April 23, 1993.

6 See: Government of India, department of science and technology: *Pocket Data Book 1989*, p 81.

7 See: (a) N N Mehrotra: 'Patents Act and Technological Self-Reliance: The Indian Pharmaceutical Industry', *Economic and Political Weekly*, May 13, 1989.
(b) Agarwal P S, P K Ramachandra, B V Rangarao, 'Anomalies in Drug Prices and Quality Control' *Economic and Political Weekly*, Vol 7, Nos 46 and 47, 1972.

8 Ibid.

9 See: Patel D S, 'World's Envy India's Pride' *Indian Express*, special supplement, March 30, 1993, p 4.

10 Mehrotra N N, 'Patents Act and Technological Self-Reliance: The Indian Pharmaceutical Industry' *Economic and Political Weekly*, Volume 24, No 19, May 13, 1989, p 1063.

11 Shobha Ahuja gives RCAs anti RCDs for the pharmaceutical sector using only the market share approach (see: Ahuja Shobha: 'Potential for Generating Mutually Beneficial Trade Flows between India and Pacific Rim based on Revealed Comparative Advantage', *Foreign Trade Review*, Vol XXVI, No 4, January-March 1992, pp 271-96). But the Bela Balassa approach is considered to be better than the market share approach (see: Fernando de Mateo: 'Trade in Services and the Developing Countries' in UNCTAD: *Services and Development Potential: The Indian Context*, 1989, pp 56-58.

12 See IDMA-OPPI: *Pharmaceutical Industry: Current Status and Problems*, May 1990, p 30.

13 Kanyla B K, 'Chemical-based Industries—Drugs and Pharmaceuticals and Pesticides—Foreign Pressure for Changing the Indian Patents Act, 1970' in National Working group on Patent Laws, *Proceeding of National Conference on Scientists on Science, Technology and Patents*, December 4, 1989.

14 IDMA—OPPI: op cit, p 11.

15 World Bank: *The World Bank Annual Report 1991*, p 118.

16 Staff correspondent of Business Standard: 'Drug Patents to Have Greater Impact on Prices than Feared', *Business Standard*, April 26, 1992.

17 IDMA: *Intellectual Property Rights and Patent Protection*, (mimeo) February 4, 1992.

18 Answer to Question No 235 in the Rajya Sabha by the minister of state in the ministries of chemicals and fertilisers, Government of India, dated March 3, 1992.

19 IDMA: mimeo (made available to us by IDMA, New Delhi), January 13, 1993.

20 See: Rane Wishvas: 'Rising Drug Prices', *Economic and Political Weekly*, April 17, 1993, pp 743-46.

21 See: Emerging Trends in Bulk Drug Industry, *Economic Times*, April 8, 1993.

22 Mitra Sisir: *Cheaper Drugs for the Common Man*, Booklet published by OPPI, p 9-10.

23 Planning Commission, Government of India: *Eighth Five Year Plan 1992-97*, Vol I, p 31.

24 IDMA—OPPI: op cit, p 10.

25 Mitra Sisir: op cit, p 8.

26 IDMA—OPPI: op cit, p 31(a)

27 Centre for Monitoring Indian Economy (CMIE): *Market and Market Shares for over 350 Industrial Products/Product Groups*,, February 1991, p xi.

28 Controller General of Patents, *Designs and Trade-Marks*: *Patents Eighteenth Annual Report 1989-90*, p 5.

29 See: CMIE, op cit.

30 See: Annual Reports of Controller General of Patents, Designs and Trade Marks, Government of India.

31 Annual Reports of Controller General of Patents, Designs and Trade Marks.

32 See for example: Abrol Dinesh and Amitava Guha, 'Production and Price Controls: The Achilles' Heel of National Drug Policy' in Amit Sen Gupta (ed): *Drug Industry and the Indian People*, p 161.

33 For Profitability to net worth ratios in other sectors see:
(i) Reserve Bank of India: 'Finance of large Public Limited Companies 1990-91' *RBI Bulletin*, December 1992.
(ii) RBI, 'Finances of Foreign Controlled Rupee Companies 1988-89' *RBI Bulletin*, November 1992.
(iii) —, 'Finances of Public Limited Companies 1989-90', *RBI Bulletin*, November 1992.

34 In the recent budget, the drugs and medicines sector have received both excise duty exemptions (to the tune of Rs 581 lakh) and, customs duties exemptions (the exact break up of which is not available to us at present). These changes are likely to lead to a marginal fall in drug prices as almost all companies have decided to pass on the benefits of excise reduction to consumers (see: 'Marginal Fall in All Drug Prices Likely', *Financial Express*, March 19, 1993, p 12.

35 See: 'As MNCs Pale the Locals Glow' in *Fortune India*, April 1 to 15, 1993, p 8.

36 See: *Indian Express*, April 24, 1993, p 14.

37 Prasad Ashok Chandra H: 'Services in the Development Context', *IDS Discussion Paper No 305*, IDS, University of Sussex, England.

38 See: 'Emerging Trends in Bulk Drug Industry. A Response Review', *Economic Times*, April 8, 1993.

39 For a detailed discussion on these issues see: Jeroen Vann Wijk and Gerd Junne: op cit, and C Niranjan Rao: 'Trade Related Aspect of Intellectual Property Rights Question of Patents' *Economic and Political Weekly*, Vol 24, No 19, May 13, 1989, pp 1053-57.

40 Sudvin Anand, *Protecting Your Clients Intellectual Property Rights in India*, EXPO 93 (February 6-8, 1993), New Delhi.

41 Niranjan C Rao, op cit, p 1055.

42 See: GATT: *GATT Committee on Multilateral Trade Negotiations: Uruguay Round: Documents*, MTN, TNE/W/FA, December 20, 1991. (Dunkel Committee Report), p 73.

43 See: Chandra Mohan N, 'IPR Irresistible Force, Movable Object', *Economic Times*, September 25, 1991.

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45 Ibid.

46 Jeroen Van Wijk and Gerd Junne, op cit, p 31.

47 Ibid, p 33.

48 Chidambaram, op cit.

49 Jeroen Van Wijk and Gerd Junne, op cit, p 34.

50 See: Jeroen Van Wijk and Gerd Junne, op cit, pp 38-39.

51 Chidambaram, op cit.

52 GATT: op cit, p 79.

53 Pravin Anand, op cit, p 3.

54 See: Ramachandran R: 'Scientist Cautions against Signing Dunkel Draft on TRIPS', *Economic Times*, January 6, 1993.

55 See: GATT: op cit, p 86.

56 Jeroen Van Wijk and Gerd Junne: op cit, p 52.

57 Chidambaram: op cit.

58 See: Li Yue: *Chinese Patent Law—The Patent Aspects of the Trade Related Aspects of Intellectual Property Rights Negotiations of GATT and the Revision of the Chinese Patent Law*, Extracts of the Presentation made at the 'International Convention on People's Approach to GATT Negotiations', National Workers Group on Patent Laws, February 19, 1993, New Delhi.

59 See: 'Pick Your Targets' in Murthy R C and Dasgupta Arundhuti: 'A Patent Abuse', *Business Standard*, May 26, 1991.

60 Bhai Mohan Singh: 'All Drug Patents Should Be Worked in the Country', *Sunday Observer*, November 7, 1991, p 48, Ibid.

61 Ibid.

62 Pravin Anand, op cit, p 2.

63 Daruwalla T N: 'Intellectual Property Rights in India—Protection and Enforcement' in the Bombay Incorporated Law Society: *Doing Business in India*, p 79, Bombay.

64 Government of India: *Indian Patent Act 1970*, Section 96, Chapter XVI.

65 Pravin Anand, op cit, p 2-3.

66 Mehrotra N N: 'Patents and Technological Self-Reliance: The Indian Pharmaceutical Industries', *Economic and Political Weekly*, May 13, 1989, Vol 24, No 19, p 1063.

Patent Laws: The Indian Experience
By Dr. Nitya Nand

Thus, most developed countries during their industrialisation phase had provisions in their patent laws similar to those in the Indian Patent Act, 1970, so why this pressure on us to change?

4.2.1 Inequity between developed and developing countries in regard to patent protection:

In 1988, out of about 3.5 million live patents in the world less than 1% (about 30,000) were held by citizens of developing countries. And out of these 3.5 million patents, less than 5% are likely to be commercialised in the developing countries; the restare there just to block and prevent others from using this knowledge. In India, between 1947 and 1957, 170 patents were granted for drugs and pharmaceuticals out of which almost 95% were held by foreign citizens and not even 1% of there were commercialised in India. Thus, for developing countries the patent system is a very unequal relationship and special provisions have to be made to protect national interest.

4.3 The Indian Drugs & Pharmaceuticals Industry

In view of the great social importance of the pharmaceutical industry, as it makes available essential drugs and medicines needed for health care, the Indian Patents Act, 1970 has special provisions for this industry which include:

- Product patents not patentable;
- Term of process patents limited to 7 years from the date of filing or 5 years from the date of sealing of patents;
- Licence of right and compulsory licencing.

4.3.1 Present status: These provisions have been important factors in the phenomenal growth of the industry in the post-1970 period, which is depicted in Table 1.

Table 1: Growth of Indian pharmaceutical industry

(Rs. in million)

	1970	1988
1. Investment	1500	8000
2. Productions a) Formulation	2500	26900
b) Bulk Drugs	500	5300
3. Imports	230	3490
4. Exports	97.5	4000
a) Formulations	72.2	1570
b) Bulk Drugs	25.3	2430
c) As % of production	40	150
d) Some developed countries to which exported: USSR, USA, W.Germany, UK, France, Japan. A number of Indian companies approved by F.D.A., USA for imports into USA.		
5. Research & Development: a) Expenditure	40	500
b) No. of units approved by the Dept. of Science & Technology.	--	77

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The achievements of the industry may be summed up as follows:

- Practically self-sufficient in formulation production with no import allowed or necessary except for some very recently introduced life-saving drugs;
- Around 65-70% of bulk drugs are indigenously made, exports of both of bulk drugs and formulations have increased sharply, imports have also gone up but a sizable portion of these are export related; export is to both developed and developing countries;
- Self-reliant technology base established, hence new drugs introduced abroad made available in India in 3-4 years by local production at affordable prices; in fact prices of recent drugs in India are amongst the lowest in the world (Table 2).

Table 2: Comparative Drug Prices (1988)
(Wholesale price in Ind. Rs.per pack of 10's)

		India	*U.K.*
Allopurinol	100 mg	5.84	30.3
Atenolol	100 mg	11.29	61.15
Cimetidine	200 mg	6.77	36.40
Captopril	25 mg	15.45	58.56
Diltiazem	60 mg	15.26	40.89
Haloperidol	5 mg	13.58	41.16
Mebendazole	6x100 mg	4.88	37.92
Naproxen	250 mg	12.76	31.07
Nifedipine	10 mg	3.82	29.90
Piroxicam	6x20 mg	7.20	184.75
Ranitidine	150 mg	16.15	121.67

4.3.2 Competitive character of the industry

Due to great pressure for process innovation and modification the industry has become highly competitive. A number of processes developed by it are novel, but on account of the short term of patent protection allowed in India patents have not been filed for all of them. Processes, for which patents have been filed in India, Europe and U.S.A. include: amitriptyline, catapress, ciprofloxacin, colchicine, doxycycline, indomethacin, norfloxacin, ranitidine.

The competitive character of the industry is also shown by the lower prices of most of the recently introduced drugs which are now manufactured in India as compared to international prices (Table 2) and the short time-lag of 3-4 years between introduction of a drug abroad and its indigenous manufacture.

4.3.3 Self-reliant technology base: The Indian industry has been able to establish a strong self-reliant process technology base (particularly for synthetic drugs and phyto-therapeutics) and is able to manufacture and market drugs requiring multi-step synthesis/isolation from basic stages by new innovative processes. Indian industry has introduced around 80 new bulk drugs, some of which are very recent discoveries, whose patents are still valid and hence required development of alternative more processes. Out of a total of about 500

SCIENCE AND DEVELOPMENT ISSUES

Drug Price Decontrol On Anvil

Amit Sen Gupta

THE ministry of chemicals has constituted a committee to consider changes in the Drug Price Control Order (DPCO) of 1995. It may be recalled that in 1995 the number of drugs whose prices were controlled by the government had been slashed from 166 to 74. This led to an immediate spiral in drug prices. The new move is designed to further slash price controls and thereby allow higher returns to drug companies. In fact a few months back, Vijay Kelkar, finance secretary, had commented that not more than 15 drugs should be kept under price control. These are not isolated events but constitute a chain of policy interventions that are designed to remove all controls over the pharmaceutical industry.

SPURIOUS LOGIC OF R&D INVESTMENT

When legitimate concerns were raised that an amendment of the Indian patents act would result in rise in drug prices, the ministry of chemicals and fertilisers consistently claimed that any rise in prices would be kept in check through mechanisms provided in the DPCO. It is amazing that barely three months after amendments made in the patents act, there should be talk of diluting price controls. The spurious logic that is now being offered is that drug companies have to be offered higher profit margins in order to allow them to make investments in research and development (R&D).

Price controls have already been diluted in the past decade and only 30 per cent of the turnover of the industry is under price control — down from about 60 per cent before 1995 and almost 85 per cent before 1987. Any further dilution would mean virtual abandonment of price controls. If the government is to consider this, under the garb of encouraging R&D, it will only substantiate earlier fears that a change in the patent act can only lead to a spiralling rise in drug prices.

Today investment in R&D in the drug industry amounts to even less than two per cent of sales. A dubious logic has been put forward that price controls have led to this situation. In the past decade the span of price controls has come down from over 60 per cent of the industry's turnover to around 30 per cent. If reduction in price controls is to spur R&D activity, why has there been no rise in R&D expenditure in the past decade? It may be recalled that the 1995 policy had a provision for keeping all drugs developed by indigenous R&D outside price controls for ten years. This too does not seem to have spurred any significant R&D activity in the industry. The issue of price controls have nothing to do with infrastructure development for R&D, and the two issues need to be dealt separately. It appears as though the issue of R&D is being used as a "red herring" by drug companies to lobby for price decontrol and thereby licence to profiteer.

MYTH OF MARKET COMPETITION

The government now claims that there is sufficient competition in the market in the case of most drugs, and this shall prevent drug prices from going up. To make an estimate of the effectivity or otherwise of price controls under the DPCO of 1995, an analysis of drug prices of top selling brands is presented here. A perusal of the results of this analysis would reveal the following broad trends.

There is a wide variation in prices of different brands of the same drug, i e different companies are charging different prices for the same drug. This is true for most drugs, both under price control and outside price control. Further, the top selling brand of a particular drug is not the cheapest brand. In fact, in most cases, the top selling brand is one of the most expensive of the brands available (Table 1). Top selling brands like Cifran, Norflox and R-Cin cost respectively 100.12, 128.93 and 163.52 per cent more than the cheapest brands of the same drug. If a large number of companies are able to sell the same product at varying prices in the market, the crucial factor that determines their ability to sell their product is obviously not the price of the drug. The DPCO 1995 had exempted all those drugs from price control in whose cases there was no monopoly in production. The underlying logic of this exemption was that competition in the market would not allow unrestricted rise of drug prices. However, the above analysis shows that variations in drug prices do not appear to be the determining factor in the "marketability" of a drug.

Unlike in the case of consumer goods, there is no direct relation between the drug market and consumers. Drugs are purchased by consumers on the advice of doctors or chemists. Consequently, the marketing strategies of drug companies target doctors or chemists. Doctors are not known to take decisions based on price of contending brands. Similarly, chemists have no interest in selling cheaper brands. Rather, drug sales are dependant on marketing networks of companies who are able to manipulate the prescribing habits of doctors.

An analysis of the prices of 50 top selling drugs, in the period February 1996 to October 1998, shows that the price increase for brands under price control is negligible while it is about 16 per cent for those outside price control. The period mentioned above was taken as the reference period to allow for any price escalation that may have occurred as an impact of the new DPCO since January 1995. In the one year period (January 1995 to January 1996), prices of almost all drugs went up substantially as a consequence of increased mark-up and of many drug prices being decontrolled. Thus the price increase that we see after January 1996 is the kind of continuous increase one might expect to see in the coming years. The increases are thus not one-time price escalations but indicative of the trends one might expect in drug prices.

HIGHER DRUG PRICES IN INDIA

There is a prevailing myth that drug prices in India are among the lowest in the world. This is at best a partial truth. Drugs which are still patent protected are much cheaper in India due to India's earlier patent act. It should be obvious that we have lost this advantage after amendment of the Indian patent act of 1970. But off-patent drugs (which anyway account for 80-85 per cent of current sales in the country) are not necessarily cheaper in India. In fact, generally, drug prices for these drugs are higher in India than those in Sri Lanka and Bangladesh. In fact, as Table 2 shows, prices of some top selling drugs are higher in India than those in Canada and the UK. This clearly shows that the benefits of the advantage that the Indian pharmaceutical industry enjoys over all other third world nations, in terms of the availability of indigenous technology and a large domestic market, have not been passed on to the consumers.

GLOBAL TRENDS

Controls on drug prices are exercised much more effectively in many market economy countries. In spite of strong patent protection, there are effective measures in place that allow regulation of drug prices. In Australia since 1993, new drugs with no advantage over existing products are offered at the same price. Where clinical trials show superiority, incremental cost effectiveness is assessed to determine whether a product represents value for money at the price sought. In Britain, the House of Commons health committee has recommended that the criterion of comparative cost effectiveness (as is in vogue in Australia) should be adopted by the National Health Scheme (NHS) before it agrees to pay for new drugs.

Globally, drug companies are being forced to reduce the cost of medicines. Pressure is being mounted by health insurance companies, health management organisations and governments (in countries like UK and Canada where the state provides health insurance cover) all over Europe and North America. These pressures have become stronger in recent years with the

realisation that spiralling drug costs are making health insurance cover (whether state funded or privately managed) unsustainable. While this is the direction in which price controls are moving even in developed market economy countries, our government is trying to

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TABLE 2

International Cost Comparison of Drugs

Drug	Canada	UK	India
Amoxycillin	1.75	2.59	2.89
Ampicillin	1.75	2.42	3.18
Erythromycin	1.25	2.87	3.28
Cephalexin	3.00	7.74	4.46
Propanolol	1.25	0.25	1.39
Atenolol	—	2.65	1.29
Prednisolone	1.50	1.09	1.32
Paracetamol	1.25	0.32	0.49
Haloperidol	0.13	1.60	0.55
Phenobarbitone	0.25	0.28	0.5

Source: British Columbia Children's Hospital Formulary, British National Formulary, No. 35, March 1998; MIMS India, March 1998 (prices are in Indian rupees).

TABLE 1

Relative Cost of Top Selling Brands

Brand Name	Drug	Company	Price in Nov 1997	Variation from Lowest Price (%)
SEPTRAN	Co-Trimoxazole	WELLCOME	7.72	14.88
CIFRAN	Ciprofloxacin	RANBAXY	50.43	100.12
ALTHROCIN	Erythromycin	ALEMBIC	35.69	35.04
BRUFEN	Ibuprofen	KNOLL	6.76	4.32
ZINETAC	Ranitidine	GLAXO	17.39	0.12
NORFLOX	Norfloxacin	CIPLA	47.00	128.93
R-CIN	Rifampicin	LUPIN	64.43	163.52
SPORIDEX	Cephalexin	RANBAXY	113.00	35.90

Source: MIMS, Nov.1997

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argue that market competition will keep drug prices stable.

LICENSE TO PROFITEER

At present price control is the only real regulatory mechanism in drug industry; all other regulatory mechanisms that were designed to channelise production of drugs in priority areas have been abandoned under the garb of liberalisation. But price control alone, through the medium of the DPCO, cannot meaningfully achieve the objectives laid out in the drug policy. Other regulatory mechanisms which lay emphasis on control of irrational products and availability of essential drugs are required. In their absence in India there has been a massive proliferation of dubious drugs in the market. Apart from price fixation, a large number of drugs has adverse consequences for all monitoring mechanisms related to quality control, adverse drug reaction monitoring, etc.

The present move of the ministry of chemicals and fertilisers must not go unchallenged. Those who require medicines most are least likely to be able to pay for them. We already have a situation where a major section of our population is "costed out" of the market. They cannot afford necessary medicines even if they are available. If price controls are further diluted this will only add to the monopoly loot being perpetrated by drug companies. These companies have some of the healthiest balance sheets, and their profitability has been rising. Further license to these companies to profiteer can only be provided at the expense of the health security of millions of people.

Biodiversity, Intellectual Property Rights, and GATT Agreement

How to Address the Conflicts?

Ashish Kothari
R V Anuradha

This paper examines the impact of Intellectual Property Rights (IPR) on biodiversity in general and specifically on the objectives of the Convention on Biological Diversity (CBD). It also addresses the broader issue of the relationship between the GATT/WTO Agreement and the CBD. It then reflects on the choices available to ensure that the objectives of the CBD are not undermined.

DECISION II/12 of the Second Conference of the Parties[1] to the Convention on Biological Diversity (CBD), requested the CBD Secretariat to:

– undertake a preliminary study which analyses the impact of intellectual property rights (IPR) systems on the conservation and sustainable use of biological diversity and the equitable sharing of benefits derived from its use;

– liase with the Secretariat of the World Trade Organisation (WTO) to inform it of the goals and the ongoing work of the CBD;

– invite the Secretariat of the WTO to assist in preparing a paper for the Conference of Parties (COP) that identifies the synergies and relationship between the objectives of the CBD and the TRIPS agreement.

The decisions at the Third Conference of Parties carry forward the concerns reflected at COP2 on the inter-linkages between IPR issues and trade liberalisation on the one hand, and the objectives of the CBD on the other: – Decision L 18 of the Third Conference of Parties[2] draws attention to the need for conducting case studies of the impacts of IPRs on the achievement of the CBD's objectives, including relationships between IPRs and the and the knowledge, practices and innovations of indigenous and local communities relevant to the conservation and sustainable use of biodiversity. It further recognises the need for work required to help develop a common appreciation of the relationship between IPRs and the TRIPS agreement and the CBD, in particular on technology transfer and on the three-fold objectives of the CBD, viz, conservation and sustainable use of biodiversity and the equitable sharing of benefits arising from such use.

– Decision L 12 further states that the WTO through the Committee on Trade and Environment (CTE), should consider a better appreciation of the relationship between trade and agricultural biodiversity, and collaborate with the CBD.[3]

– Decision L 8 emphasises, on the need for co-operation between the CBD process and the WTO with regard to the inter-linkages between Article 15 on access to genetic resources and the TRIPS agreement.[4]

This paper has been prepared in view of these decisions. It examines the impact of IPR on biodiversity in general and specifically on the objectives of the CBD. It also addresses the broader issue of the relationship between the GATT/WTO agreement and the CBD. It then reflects on the choices available to ensure that the objectives of the CBD are not undermined. Though the larger issue of relationship and potential conflicts between the GATT-WTO agreement as a whole and the CBD, has not been addressed in the COP3 decisions, we feel it is an equally important aspect that requires detailed analysis.

This paper is in the nature of a preliminary study. The purpose is to generate debate and discussion on the issues raised. We look forward to comments and criticism, as well as further information which elucidates the impact of IPRs and the GATT mechanism on biodiversity.

Intellectual Property Rights and CBD

IPRs, as the term suggests, are meant to be rights to thoughts, ideas, and information, especially regarding new inventions and processes. The manner in which they are sought to be realised is by enabling an inventor to exclude imitators from the market for a specified time. The effect of IPRs therefore is monopoly over commercial exploitation. The stated purpose of such rights is to stimulate industrial innovation, by offering higher returns (profits) than the market would normally offer. In its practical application therefore, the effect of IPRs is the commodification of its subject matter. Copyrights, patents, and trademarks are commonly known IPRs. While such IPRs are several centuries old, their extension to living beings and related technologies is a recent phenomenon, and one which has evoked considerable controversy.

IPRs on biological resources and related technologies/ knowledge are justified much as industrial invention IPRs are: that they stimulate innovation by giving recognition and rewards to inventors, that they encourage investments in research, and that they make possible the eventual disclosure and dissemination of related knowledge. Whether or not these goals are met is however debatable, for the evidence that the lure of private profits is the only or even the most effective motivation for innovation is by no means conclusive. For instance, the development of hundreds of thousands of varieties of rice by farmers in Asia, through selection, on-farm breeding and cross-breeding, had little to do with private monetary profit; at another level, the public sector seed breeding agencies in many countries (for example, the Indian Agricultural Research Institute) have done considerable work motivated by the spirit of public welfare. A recent study evaluating the Plant Patents Act (PPA) of the US concludes that the act has neither helped breeding as a profession nor stimulated species, genetic or even market diversification.[5] Moreover, even if it is true that in an increasingly monetised world, personal profits are a powerful incentive, IPRs on life forms have serious ethical, social, economic, and ecological implications which need to be addressed.

For the purposes of our discussion, it would be useful to keep in view the three-fold objectives of the CBD, viz, (1) conservation of biodiversity, (2) sustainable use of its components, biological diversity and the equitable sharing of the benefits derived from its use. Our contention is that IPRs would have impacts on each of these objectives. An examination of these impacts is necessary to determine whether current IPR systems run counter to the objectives of the CBD, and thereby invoke Article 16(5) of the CBD. At the outset we would like to point out that this paper does not seek to outright dismiss the notion of IPRs. The case we are trying to make, however, is that

whatever the logic behind the notion of IPRs, its extension to biological diversity would have some very serious implications. While there have been no conclusive studies in this regard, there are strong indications about the possible effects of IPR systems. Our case is that these have to be taken seriously.

(a) *Ethical Implications*

The ethic of conservation is a fundamental objective of any treaty dealing with the environment. The CBD recognises the intrinsic value of biological diversity and its importance for evolution and for maintaining life sustaining systems of the biosphere.[8] Biological diversity is defined under the CBD as the variability among living organisms from all sources.[7] Although it does not explicitly recognise the notion of the right to life for all living beings, it can be said that the overall concern of the CBD with biological diversity indicates that it accepts that notion. It is here that there arises a fundamental conflict between the concept of IPRs and the objective of the CBD to conserve biological diversity as a whole keeping in view its intrinsic worth. IPRs indicates a move towards the notion of 'might is right'. It raises the basic question: Do we as a species have the right to claim ownership over other species/ taxa; even more stark, does any one individual human being have the right to claim private monopolistic ownership over entire other species/ taxa? However inventive scientists are in engineering a new strain of bacteria or a new variety of plant or animal, the essential elements with which they are working - the building blocks of life, and life itself - are not created by them; nor, unlike industrial inventions, is the replication of the life form essentially dependent on these scientists.

For the majority of the world's civilisations, especially indigenous and traditional ones, where oneness with nature has been a part of their philosophy, and to an extent even daily practice, establishing property rights over living beings is an alien concept. What is also alien to them is to treat a part of life as a commodity to be commercially exploited. It could be argued that all notions of private property violate these sensibilities too. In the interests of a focused discussion on IPRs alone, it will not be possible for us to delve into that broader issue in this article. However, we would like to point out that the existence of the notion of private property cannot restrict the questioning of IPRs over life forms, which we feel are perhaps the ultimate violation of the sensibilities expressed above.

Serious ethical issues arise even more starkly in the case of attempts to patent human genetic material or information, which has arisen as a logical extension of the whole process of claiming ownership over life forms. The US commerce department was the pioneer in this field when it sought a patent on the human cell line of a woman from the Guyami Indian tribe of Panama which was potentially looked upon as useful in medical research. Although human genetic material falls outside the purview of the CBD, it is important to keep this in view as part the process of commodification of life. From the ethical point of view a number of uncomfortable questions arise which have not been given due consideration. As Kloppenburg asks: "Seeing our own species as a commodity, can we fail to see everything else in the same way? And if the commodity value is low, does that justify the disappearance of that bird, tribe or micro-organism?"[8]

Commodification and the accompanying assignment of monetary value over life forms, undermines the CBD's ethical approach towards conservation, which is based on the intrinsic value of all components of biological diversity.

(b) *Implications for Biological Diversity*

The emerging IPR regimes have serious implications for biodiversity, both wild and domesticated. There may be no direct impact on wild plants and animals, provided these remain outside the purview of IPRs. However, there could be severe indirect effects in the form of increased exports of natural resources for the purpose of debt repayments. Debt repayment is a major cause of environmental and social destruction in southern countries. This is exemplified by the fact of increased exports of natural resources from developing countries to meet the obligations of debt repayment. In the last few decades, attempts to repay debts by tropical countries have consisted of exporting natural resources in their raw form (timber, fish and other marine life, medicinal plants, orchids, etc), or in the form of various processed products (agro-products, bird feather goods, medicines, etc). More often than not, considerable over-exploitation of natural resources, including biodiversity, is the result. Added to the outflow of cash in the form of debt repayments would be the royalty payments arising from IPRs. It is feared that the imposition of IPR regimes over life forms and related knowledge, on third world economies, would significantly increase debt repayments.

In the case of domesticated biodiversity, the impacts are both direct and indirect. Seed companies look for the three characteristics of distinctiveness, uniformity and stability, which are essential legal requirements for asserting the claim for PBRs. An inherent outcome of this would be that repeated cycles of selection would reduce the level of variation within a plant population. As pointed out in the recent FAO Draft Report on State of the World's Plant Genetic Resources, breeders' tendency to find new genetic material within their own breeding lines leads to dependence on an even narrower elite germplasm base for crop improvement.[9] This can directly lead to widespread plant disease epidemics.[10]

Farmers may also be forced to adopt the homogeneous and genetically narrow base of modern agriculture, and be unable to innovate on even the seeds or livestock they buy. Companies will want to maximise their profits, since patenting is an expensive process, and will therefore opt for as widely adapted varieties as possible. In such situations, there would be loss of indigenous crop and livestock diversity. On the other hand, it could be argued that farmers may also be induced into reviving and innovating on traditional diversity, as a means of reducing dependence on economically-crippling patented varieties. But for a large number of farmers who are deeply enmeshed in the market economy, dependent on governments and markets for their inputs and sales, such escape routes may prove extremely difficult. It is more likely that seed companies would be able to displace a wide diversity of traditional local varieties by promoting a handful of hybrids and homogeneous modern varieties, often through governmental agricultural extension services.[11] The development of new varieties by the formal seed industry, even if spurred by IPR-generated incentives, would in no way compensate the loss of diversity of local farmers' varieties. Such a process has already characterised the introduction of new technologies such as the green revolution in the tropical countries, and would be greatly enhanced by the IPR regimes.

Of course, a complex web of practices and policies, and not IPR systems alone, are responsible for the loss of agricultural diversity. IPR systems would have the role of compounding this effect: the incentives they provide would increase the thrust towards commercialisation of agriculture, oriented more towards industries and exports rather than towards domestic and primary consumption. Such a thrust is inevitably accompanied by the homogenisation of crop varieties, since agro-industries and export markets prefer standardised products. This would have serious implications for agro-ecosystem stability and sustainability.

Promotion of monocultures has very obvious negative implications for biodiversity. In this context a question raised by India at the meeting of the Committee

on Trade and Environment (CTE) of the WTO was, whether IPRs for plant varieties militated against *in situ* conservation by promoting monocultures.[12] The clear answer seems to be: yes.

(c) *Implications for Local Communities*

The impacts of IPRs are strongest on local communities who are directly dependent on the use of components of biodiversity. This can be illustrated using the example of farmers. The form of IPRs relevant in their case is that of patents over plants and plant variety or breeders rights (PBRs or PVRs). The concept of PBRs was institutionalised by the International Convention on the Protection of New Varieties of Plants (UPOV). They provide limited monopoly to a plant breeder over the reproductive material of the variety, i e, control over multiplication and sale of the seeds. PBRs, as provided for under the 1961 and 1978 versions of UPOV, allow for exceptions in the form of farmers' privilege and breeders' exemption The breeders' exemption allows scientists and plant breeders to use protected varieties for further breeding work without asking for permission or paying royalty. This was aimed at ensuring that the socially useful activity of breeding improved varieties continued unhindered. Farmers' exemption gives farmers the right to save harvested seed for their personal reuse, and for "across-the-fence" exchange with other farmers.

However there have been increasing demands by the biotechnology industry that these exemptions be withdrawn. The amendments of UPOV in 1991 responded favourably by increasing the monopolistic nature of breeders' rights, and considerably eliminating farmers' and breeders' exemptions. Whereas previously farmers' exemption was guaranteed by the convention, now it is an optional exemption which countries may or may not grant. Unless specifically granted exemption, therefore, farmers may now have to pay royalties for saving and reusing seeds on their own farms even under PBR regimes.

This means that while the user of a patented product would have the right to use the product but not to make it; a farmer purchasing patented or PBR-protected seed would have the right to grow it, but not the right to save and replant it, unless specifically given an exemption by the country in which he resides. The farmer would have to return to the market each year to purchase seed, as has to be done for hybrids at present. It would also be illegal for farmers to pass on harvested seeds to neighbours, or to sell it on a limited scale, affecting a widespread agricultural practice followed by farmers all over the world. For instance, in India, nearly two-thirds of annual seed requirement of farmers is reportedly met through inter-farmer sales and exchange, and only the remainder through formal agencies like seed corporations.

Informal innovations by farmers are a main reason for the stability and sustainability of the agricultural system in most developing countries. And this informal innovation is not a haphazard unscientific process. It is the result of keen observation and careful experimentation In view of this it is difficult to find a rationale for a shift in the locus of innovation from the farmers' fields to the laboratories of breeders. Such a shift is definitely not necessary to promote the ethic of conservation It seems unlikely that conservation and generation of new crop varieties can be stimulated on as large a scale as is required, by a scheme that focuses only on the generation of profits and by creating monopolies over such profits. IPR systems would have the drastic impact of displacing the locus of innovation from the farmers' fields, which in turn has serious implications for the objectives of conservation and sustainable use under the CBD.

The owners of the IPR-protected plant varieties are mostly big companies. Given the power of corporate plant breeders to impose these rights and restrict farmers' and breeders' exemptions, the PBR regime becomes almost as monopolistic as industrial patents. It is of course possible to argue that farmers do not have to use the patented seed at all, and in fact that IPRs could force farmers to revive traditional seeds and farming practices. There are, however, aspects of the dominant agricultural policy in many countries which would defeat, or make very difficult, such attempts at being self-reliant. One of these is the increasing power of agro-corporations and/or governments to dictate the nature of agricultural operations on individual farms, especially in terms of pushing seeds, fertilisers, pesticides, livestock breeds, and other inputs into the rural economy. In a situation such as this, the extension of IPR regimes over crop and livestock varieties can only further trap farmers in a vice-like grip. It undermines local peoples' capacities to manage sustainable production systems.[13]

Moreover, even farmers who are able to retain a degree of self-sufficiency by relying on their own indigenous varieties, may face problems from patent holders who will increasingly claim rights not merely to varieties, but to characteristics which are common to several varieties. For example, a patent has reportedly been granted to the corporation Sungene for the characteristic "high oleic content" in sunflowers. Already, Sungene has announced that the development of any variety high in oleic acid will be considered a violation of its patent. If this stands up in the courts, it means that a patent holder could prevent others from completing research even using totally different genetic systems, and could perhaps also prevent farmers from innovating on their own high oleic acid varieties of sunflowers. The "species" patent granted in the US on genetically modified cotton and on the soyabean crop,[14] though likely to be revoked due to considerable opposition, are further indications of the ridiculous risks of the IPR system. There may, indeed, be no end to this; as Cary Fowler and others have stated: "Why not a patent for 'tasty' bread or 'high-yielding' rice or for 'good' kids?"[15]

This dramatic possibility may not be as far-fetched as one would imagine. In the case of the Harvard mouse, for instance, the patent claim in Europe is not only to the mouse, but to "a transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into the said mammal or an ancestor of said mammal, at an embryonic stage".[16] Thus it is possible

that Harvard could charge royalties on any non-human mammal, which has been developed for cancer research by injecting its embryo with an oncogene.

The other aspect of IPRs which is problematic from the perspective of local communities is when their knowledge, innovations and practices are used as the basis for research that gives rise to a patentable invention This is of significance in view of the fact that the starting point of most research related to the genetic wealth of biological resources is often the existing traditional ecological knowledge of indigenous and local communities with respect to those resources.[17] The CBD mandates that where utilisation of the knowledge, innovations and practices of local and indigenous communities leads to benefits, such benefits shall be equitably shared with the holders of such knowledge, innovations and practices.[18]

There are a number of problems and conflicts that arise from the point of view of local and indigenous communities. The IPR model which is sought to be harmonised under the TRIPS agreement, does not recognise informal community innovation Further, the notion of private, monopolistic IPRs under the TRIPS is an alien concept for many local and indigenous communities, since for them most knowledge and biological resources are communally owned and are meant to be shared.[19] The notion of collective IPRs is not recognised under current IPR models, or the TRIPS agreement. Regarding the traditional knowledge and informal innovation practices of indigenous peoples and local communities, the CTE simply states that new forms of protection adapted to the particular circumstances of local and indigenous communities do not fall within the purview of TRIPS since they were not discussed during the negotiations.[20]

The TRIPS agreement is silent on the issue of sharing of benefits with local and indigenous communities. For instance, for making sharing of benefits with local communities feasible, it would be necessary for IPR laws to have stringent norms of disclosure on the country and the community from which a patentable subject matter and information regarding its use was obtained, as well as proof of consent of the country of origin Both these requirements are mandated by the CBD. The CTE has stated that TRIPS' silence in this regard would not preclude bilateral arrangements between countries and companies to ensure such sharing, provided these are compatible with it.[21] The standard of compatibility with the TRIPS thus seems to be the material test. A question which arises is: can a country challenge another country's IPR regime on the ground that it fails to give adequate protection to informal innovations of indigenous or local communities, and is thus in violation of Article 8(j) of the CBD? The Indian delegation to the CTE posed this question at the June 1995 meeting, but there has been no response to this as yet.[22]

A point worth consideration is that the issue of extending IPRs over life forms cannot be viewed in isolation. It has to be seen as a part of a larger process of flow of resources from one country to another and the impacts this would have on the former. This becomes all the more necessary also from the point of view of assessing the whole scheme of extending IPRs in the light of its purported logic. i e, the logic behind granting of patents is that this would be a protection and incentive for the financially and infrastructurally weak inventor, and bring him just financial rewards. But modern mega-technological progress takes place almost within the framework of institutions heavily funded by rich countries or rich companies from the north. Further monopolies over these processes are sought to be established under the IPR regime, thus leading to a net siphoning out of resources from developing countries. From the point of view of the CBD, the objectives of conservation and sustainable use are clearly undermined by these processes.

Whatever be the justification for IPR systems, their application and impact raise important questions about the need for their existence. The following comment requires serious consideration: "The function of the positive historical purpose of patents is being perverted into a legitimisation of completely new structures. History is being rewritten in such a way that the protection of the weak is still being claimed, whilst protection of the strong is what is actually taking place."[23]

Exceptions Under TRIPS Agreement: Matter of Interpretation?

While TRIPS does not contain specific provisions to deal with each of the issues already raised, it does provide for certain exceptions in Articles 8(1), 27(2), and 27(3). The ability of TRIPS to answer the concerns of the CBD would partly depend on how these exceptions are interpreted.

Article 27(2) recognises that states can exclude from patentability inventions the prevention of whose commercial exploitation is necessary to avoid serious prejudice to the environment. There are therefore two preconditions to exclude inventions from patentability, viz, (i) commercial exploitation of the invention should be disallowed; (ii) such prevention of commercial exploitation is necessary for the purpose of avoiding serious prejudice to the environment. There is a further proviso to the Article according to which such exclusion should not be made merely because the exploitation is prohibited by the law of that state. This therefore implies that the WTO would have the authority to examine, interpret and decide what would constitute serious prejudice to the environment. Further it also implies that exclusion from patentability should be preceded by prevention of commercial exploitation This effectively rules out the possibility of having non-monopolistic alternatives to patenting which would require exclusion of patents, but not necessarily prevention of commercial exploitation

Article 8 of TRIPS has been cited by the CTE in its report as being a possible provision through which developing countries can take care of their interests. It reads as follows: "Member states may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote public interest in sectors of vital importance to their socio-economic and technological development." The proviso to this article states that such measures should be consistent with the provisions of TRIPS. Were it not for this proviso, Article 8 would have had much wider scope than Article 27(2). The words used, viz, "adopt measures", provides the opportunity to member states to analyse the diverse implications of IPRs as discussed above, and resort to alternatives to the current IPR model. However, the proviso to a great extent limits the ambit of those alternatives. The proviso seems to clarify that Article 8 does not provide for exceptions to the obligations under TRIPS. It suggests that any measure taken under it has to be commensurate with the other TRIPS provisions, which would include Article 27. But if this were the case, the very purpose of including Article 8(1) under the TRIPS seems a superfluous one, for states would in any case have had the freedom to take measures commensurate with the TRIPS obligations, without having been reminded by Article 8 to take care of their socio-economic and technological development. Why then has the CTE implied in its report the importance of Article 8? What is the scope and ambit of the same? Could it be used as the basis for excluding IPRs over life forms?

Another provision of interest is Article 27(3), which allows states to arrive at *sui generis* forms of protection in the case of plant varieties. This provision states: "Parties may exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, parties shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. This

provision shall be reviewed four years after the entry into force of this Agreement."

The apparent flexibility of this clause may be largely illusory. Two major points have been raised by a number of critics. First, that it forces on countries the patentability of micro-organisms and microbiological processes, leaving very little scope for a nation which may not want to patent any life forms. It is important to realise here that the terms "micro-organisms" and "microbiological processes" have been recently extended to include the genetically modified mouse patented by Harvard, as mentioned above.[24] The European Patent Office, interpreting Article 53(b) of the European Patent Convention, which is similar in structure to Article 27(3) of TRIPS, ruled that the patentability bar does not cover microbiological processes or the products thereof. To quote from the judgement: "...the general principle of patentability under Article 52(1) of the EPC is restored for inventions involving microbiological processes and the products of such processes. Consequently, patents are grantable for animals produced by a microbiological process."[25]

This case raises concerns regarding the interpretation of Article 27(3) of TRIPS: what would a patent claim over a plant or animal genetically modified through a microbiological process be treated as? One possible argument could be that unlike the EPC, TRIPS refers only to "microbiological processes", and not to "products thereof". Hence the first part of Article 27(3) could be interpreted to cover all plants and animals, whether or not they are produced through a microbiological process.

Secondly, there has been a great deal of debate to interpret the meaning of the term *sui generis*, in the case of plant varieties. Does it mean there is a possibility of actually arriving at a non-monopolistic model of protection for plant varieties, which recognises the informal innovations of farming communities and provides incentives for the same, but does not necessarily grant exclusive property rights? The fact that some form of protection is mandated under 27(3) means that the question is more of whose protection and whose monopoly. A scheme that allows for free flow may not, therefore, qualify as *sui generis* form of protection.

Further, the concept of Plant Breeders Rights under UPOV (as discussed above), is being put forward as the model for such *sui generis* protection. PBRs, it has been noted above, are also another form of IPRs which provide monopoly powers to the right holder and would have similar consequences as patents for biological diversity and for local communities dependent on biological diversity. Article 27(3) does not lay down the parameters for the *sui generis* protection, apart from qualifying it by the ambiguous term "effective". This could mean that any *sui generis* system proposed will be open to review by the WTO, to decide whether or not this is effective. The whole provision on plant varieties is to be reviewed in 1999. There is also the fear that if countries like India continue to disallow IPRs on plant varieties, the US and other industrialised nations could use their clout to push them to change. Such pressure tactics have already been used unilaterally by the US under Section 301 of its Trade and Competitiveness Act of 1988.[26]

One is tempted to argue that every state has the liberty to arrive at its own provisions for *sui generis* system to deal with plant varieties. And that this provides for the space to develop upon measures that could take the form of rewards and subsidies to farmers to follow agricultural practices that enhance agricultural diversity, but be based on a model of free exchange of seeds, with nobody having any exclusive monopoly. Such a free exchange system could also establish a rights system which is defensive, by ensuring access to anyone provided it is not used for monopolistic purposes. It is doubtful, however, whether such a system of free flow could qualify as *sui generis* for the purposes of the TRIPS agreement, as has been argued above. Another suggestion would then be to re-define the locus where the monopoly is vested, from the corporate plant breeder to the local communities. There have been suggestions for forms of protection such as Community Intellectual Rights,[27] and Traditional Resource Rights,[28] which would take into account the ecological concerns of conserving biological diversity, as well as the concerns of equity in recognising the role and contribution of local and indigenous communities.

Other Aspects of GATT-WTO Agreement *vis-a-vis* CBD

Apart from introducing a uniform intellectual property rights regime, the GATT Agreement contains several other aspects, which have a bearing on biodiversity, and would affect the objectives of the CBD.

* One thrust appears to be to free the agricultural sector from most forms of controls and interventions by governments. A direct impact of this could be the easier entry of powerful multinational agribusiness corporations into third world countries, corporations which would be able to push their crop and livestock varieties onto the farmer. The implications of this have been discussed earlier in the context of IPRs. The same would be relevant in terms of implications for the farmer due to entry of multinational seed corporations into agribusiness. Also equally troublesome are the potential impacts of industrialised agriculture for biodiversity, in the form of genetically uniform monocultures and massive doses of chemicals which would in turn have long-term impacts on soil fertility and productivity.

* Another change sought is the lowering of subsidies given to various agricultural inputs. On the one hand, this could have the impact of reducing the spread of modern agriculture (especially if fertiliser subsidies are removed), and spur a revival of organic farming methods. However, positive incentives including subsidies may need to be given to help farmers switch to organic and high-diversity agriculture; under GATT, the possibility of such incentives could be reduced. At best, the result on biodiversity of a cut in agricultural subsidies would be mixed.

* Article XI of the GATT curtails the ability of countries to restrict exports of products except through duties, taxes, or other such charges. This could have potentially negative environmental consequences, since countries would find it difficult to enforce policies restricting exports of natural resources, including perhaps even threatened species of wildlife. Regulation of access to genetic resources in fulfilment of Article 15 of the CBD, could also be undermined by the GATT-based argument that it is an unreasonable trade barrier.

* Government support for producers of agricultural products has been essential in most developing countries to off set

competition from subsidised world market prices. The Uruguay Round (UR) on Agriculture calls on GATT members to reduce their spending, direct and indirect, for domestic farm programmes. However, the US and the European Union continue to use export subsidies to maintain their position in world markets. In effect, therefore, the Uruguay Round on Agriculture enables agribusiness to continue to enjoy extensive export subsidies while farmers' supports are slashed.[29] The impact of these on local and indigenous communities is self-evident.

Theoretically it may be possible to argue that if adverse environmental impacts are felt, a country may be able to resort to the Article XX exceptions, (particularly Article XX, clauses (b),[30] (g),[31]) under GATT. However, this may be easier said than done. Firstly, Article XX does not mention "environment" as a reason for providing for substantive exceptions to an obligation under GATT. In the absence of this, it is open to interpretation. Secondly, in a situation which is increasingly biased toward the economic stakeholders, the concerns of the environment often get obscured.

Space Under CBD: Article 16(5) and Article 22

Article 16(5) of the CBD mandates the Contracting Parties to co-operate to ensure that IPRs are supportive of and do not run counter to the objectives of the CBD. The caveat to this provision is "subject to national legislation and international law". This creates some kind of ambiguity about what is to prevail over what. Are the objectives of the CBD paramount? Can non-compliance with IPR obligations be justified if they cannot be supportive of the objectives of the CBD? The weakness of the provision is enhanced in view of the fact that the Contracting Parties are only obliged to "co-operate"; there is no affirmative assertion as to the substantive obligation in this regard. It may however be argued that Article 16(5) is further strengthened by Article 22, which provides that the CBD "shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity." Both together provide a strong case for CBD to prevail over the obligations under any other agreement.

Article 22 is a highly interesting provision whose effectiveness would depend upon interpretation of the phrase "serious damage or threat to biological diversity". To justify non-compliance with a GATT obligation because of the adverse impacts on biodiversity, may be a difficult task, because more often than not, these adverse impacts are in the nature of "possible effects". There may not be hard scientific data to substantiate the same. While the environmental law regime has confronted this issue of lack of scientific certainty by means of new principles such as the "precautionary principle", the trade and economic regimes show no signs of being inclined towards the same.

A Precautionary Approach?

The essence of the precautionary approach is embodied in Principle 15 of the Rio Declaration which provides that: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environment degradation". The Preamble to the CBD also recognises this when it states that "where there is a threat of significant reduction or loss of biodiversity, lack of full scientific certainty shall not be used as a reason for postponing measures to avoid or minimise such threats." The threshold terms for application of the precautionary approach in the context of the CBD would have to be based on "threat of significant reduction or loss of biodiversity". The effectiveness of the precautionary approach would depend on how this is interpreted. What is the threshold for "serious or irreversible damage" or for "significant" reduction or loss, and who will determine this? There has been some discussion of this principle in the context of climate change,[32] but it is yet to be given serious consideration in the context of the CBD. The effect of this principle in the context of the CBD would essentially be as follows:

(a) assessment of the potential impacts of an IPR regime or a GATT obligation must be carried out before, and not after such measures are undertaken. This, in any case, is a basic principle of environment impact assessment.

(b) the burden of establishing that no real threat exists to the objectives of the CBD should lie with the Party alleging that another Party has violated GATT norms.

But again, it is difficult to say how the trade regime under GATT would react to these kind of arguments. It is always easy to insist that each issue ought to be examined in a harmonious manner in the context of all related developments, i e: trade cannot be divorced from environmental arguments; the IPR regime cannot be divorced from the issue of rights of the farmers and local communities; and so on. But these arguments based on how things "ought to be" may tend to be mere rhetoric in the absence of some kind of certainty about what is to prevail over what, and who should decide the same.

Choices to be Made

In view of the above discussion, and the mandate of the COP decisions referred to at the beginning of this paper, a number of issues arise which need to be addressed immediately:

* To begin with, case studies referred to in COP3's Decision L.18 should soon be initiated to examine the potential conflicts between IPRs and the objectives of the CBD.[33] Such studies need to specifically focus on the following propositions:
– Patents on life forms should not be made compulsory.
– Article 27 of the TRIPS should be modified, at or before the formal review in 1999, to allow for exemptions on all life forms including micro-organisms.
– The concept of *sui generis* under Article 27(3) of the TRIPS should be clarified to allow for development of alternative non-monopolistic IPRs.
* Studies also need to be initiated to understand the impact of trade liberalisation for agricultural biodiversity, keeping in view the impacts for agro-diversity, as well as for local communities.
* The general proposition that the provisions of the CBD should prevail over the GATT agreement where the principles of conservation, sustainable use and the sharing of benefits arising from the use of biodiversity are in question, needs to be examined carefully. For this purpose there has to be a clarification as to how to interpret Article 16(5) and Article 22 of the CBD. The precautionary approach should be adopted in interpreting serious damage or threat to biological diversity.
* Both national and international actions taken as a follow-up to the GATT provisions, including the TRIPS agreement, should be monitored *vis-a-vis* the impacts of such developments on the objectives of the CBD.
* To facilitate the realisation of objectives of the CBD, such as that of equitable benefit sharing, the existing IPR model under TRIPS should mandatorily specify that norms of disclosure pertaining to an IPR application should reveal the country of origin and the community which provided the knowledge about the resources pertaining to the patentable subject matter,[34] as well as proof of consent of such country and community of origin. In other words, the applicant must satisfy the requirement that the provisions of the CBD have been fulfilled.
* Article XX of the GATT agreement should be amended to specifically include concerns relating to biological diversity. The precautionary approach should again be applied here to assess threat to biological diversity. The COPs till now have avoided confronting the issue of conflicts between the CBD on the one hand, and the GATT agreement and the IPR regime on the other. The CBD Secretariat's papers on this subject have not squarely taken up the analysis, choosing instead to focus on the potential synergies between the two regimes. The potential of

case studies, if thoroughly carried out, is to provide a concrete basis for the CBD to adopt a more pro-active approach. Whether the next COP will live up to that expectation remains to be seen.

Notes

[We are grateful to David Downes from the Centre for Environmental Law, Washington and Graham Dutfield from the Working Group on Traditional Resource Rights, Oxford, for comments on an earlier draft of this paper.]

1 *Intellectual Property Rights*, Decision II/12, UNEP/CBD/COP/2, adopted at the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity, Jakarta, Indonesia, November 6-17, 1995.
2 *Intellectual Property Rights*, UNEP/CBD/COP/3/L 18 adopted at the third meeting of the Conference of Parties to the Convention on Biological Diversity, Buenos Aires, Argentina, November 4-15, 1996.
3 *Agricultural Biological Diversity*, UNEP/CBD/COP/3/L 12. An earlier alternative text on the same subject was stronger in its mandate and stated that the CBD Secretariat was to conduct a study on the impact of trade liberalisation on agricultural biodiversity.
4 *Access to Genetic Resources*, UNEP/CBD/COP/3/L 8.
5 Rural Advancement Foundation International, 'Sixty five years of the US Plant Patents Act', *RAFI Communique*, November/December 1995.
6 *Convention on Biological Diversity*, Preamble, paras 1 and 2.
7 Ibid, Article 2, para 1.
8 J R Kloppenburg, 'Changes in the Genetic Supply Industry' in Baumann et al (eds), *The Life Industry*, Intermediate Technology Publications, London, 1996, 30.
9 FAO, *The FAO Draft Report on the State of the World's Plant Genetic Resources*, Rome, 1996.
10 GRAIN, 'UPOV: Getting a Free TRIPS Ride?', *Seedling*, June 1996.
11 Ibid.
12 'Relationships between Environmental Policies and WTO Services and Intellectual Property Agreements Examined', *WTO Trade and Environment Bulletin*, August 14, 1995.
13 GRAIN, supra n 10.
14 Christine Noiville, 'Patenting Life-Trends in the US and Europe' in Baumann et al (eds), *The Life Industry*, supra n 8, p 78.
15 C Fowler, E Lachkovics, P Mooney and H Shand, 'The Laws of Life: Another Development and the New Bio-technologies', *Development Dialogue*, 1988.
16 S Dutta, 'Patent Problems', *Science Reporter*, January 1993, pp 40-44.
17 See, for example, N Taylor, *Plant Drugs that Changed the World*, George Allen and Unwin, London, 1965, where it has been explained that without the input of indigenous knowledge many of the drugs we use would not exist; N R Farnsworth, 'Screening Plants For New Medicines in E O Wilson (ed), *Biodiversity*, National Academy Press, Washington, DC, 1988, where it has been pointed out that of 111 commercially useful plant-based drugs, 74 per cent were in prior use by indigenous communities; D M Lewis, *Millennium: Tribal Wisdom and the Modern World*, Viking Publication, New York, 1992 illustrates numerous instances where the folk remedy of tribal people has lead to the pharmacopeia of modern medicine; UNDP, *Conserving Indigenous Knowledge*, an independent study by the Rural Advancement Foundation International, UNDP, Nairobi, 1994, where it is explained that indigenous knowledge has made important contributions to agriculture, pharmaceuticals, DNA research and other industrial production; Pat Mooney, 'The Law of the Seed', *Development Dialogue*, 1983, where the use of genetic resources from crop plants of indigenous farmers by seed companies is discussed.
18 *Convention on Biological Diversity*, Article 8(j), Preamble para 12.
19 D Posey and G Dutfield, *Beyond Intellectual Property Rights*, IDRC, Ottawa, 1996.
20 Committee on Trade and Environment of the World Trade Organisation, *Environment and TRIPS*, WT/CTE/W/8, June 8, 1995, 23.
21 Ibid.
22 'Relationships between Environmental Policies and WTO Services and Intellectual Property Agreements Examined', *WTO Trade and Environment Bulletin*, August 14, 1995.
23 C Weiszacker, 'Biodiversity Newspeak' in Baumann et al (eds), *The Life Industry*, supra n 5, 61.
24 S Dutta, supra n 16.
25 European Patent Office, Board of Appeal, C12N 15/00, October 3, 1990.
26 It is felt that the present GATT-WTO Agreement actually legitimises such unilateral tactics through its provisions on cross-retaliation: if a complaining party finds that retaliating in the same sector as where violation is alleged will not be practical or effective, it can retaliate in any other sector. This basically means that retaliation against non-compliance with obligations under the TRIPS could be done by withdrawing concessions in trade in another sector, say, goods, where a developing country like India is most likely to be hurt.
27 G S Nijar, *Developing a Rights Regime in Defence of Biodiversity and Indigenous Knowledge*, Third World Network, Malaysia, 1995.
28 D Posey and G Dutfield supra n 19.
29 K Dawkins and S Suppan, *Sterile Fields: The Impacts of Intellectual Property Rights and Trade on Biodiversity and Food Security*, Gaia Foundation, Minnesota, November 1996, pp 10-12.
30 Article XX (b), GATT provides for exceptions that may be resorted to when it is "Necessary to protect human, animal and plant life or health".
31 Article XX(g), GATT refers to measures that maybe resorted to when such measures are 'relating to the conservation of exhaustible natural resources, if such measures are made effective in conjunction with restrictions on domestic production or consumption'.
32 See for example, J Cameron and J Abouchar, 'The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment', *Boston College International and Comparative Law Review*, Vol 4, 1991, 1-27.
33 See, supra n 2 and accompanying text.
34 See, for example, M Gadgil and P Devasia, 'Intellectual Property Rights and Biological Resources: Specifying Geographical Origins and Prior Knowledge of Uses', *Current Science*, Vol 69, No 8, October 25, 1995.

COMMENTARY

Protecting Basmati

Suman Sahai

The Americans would not dare to call Californian wine, Champagne nor whisky produced in their country, 'Scotch'. So why have they attempted to purloin the basmati name and monopolise it by obtaining a patent?

AN American company Rice Tech has received a patent on basmati rice. This blatant infringement of India's rights and property has raised a furore in the media and justifiably so. How should India respond? In planning its counter strategy, it would not be advisable for India to merely rely on challenging the patent as is being advocated. This is the easiest and least profitable line of action, as also the most expensive. It would not be difficult to challenge the 'novelty' of the characteristics of the basmati that is patented. Any plant breeder could quite easily demonstrate that the special qualities supposed to be present in the patented basmati are found in the normal diversity of basmati populations. If one had to analyse the basmati strains of India and Pakistan, all the characteristics described for size and quality of the rice grain or for the height and behaviour of the plant, would be found. The case can be effectively made that at best the patented variety has brought a combination of favourable characters together but that is the everyday stuff of plant breeding and does not qualify for a patent.

But, just how many patents do we intend to challenge? It is clear that Indian biological resources and products are under attack from patents because these materials and products enjoy growing international markets. A special product like basmati rice not only has a huge market in the UK, Europe, the US and west Asia, it also commands premium prices there. There are other sought-after products like Darjeeling tea, Alphonso mango and Shahi litchi. Apart from these agricultural products, there are herbal drugs and nutraceuticals which are attracting increasing attention...and patents. We should be fully prepared that the number of such patents will increase in the coming years. Can we really afford to challenge every single patent?

It is a sobering thought that despite the large amount of money spent and all the public acclaim of having successfully challenged the American patent on turmeric (haldi), the patent has still not been revoked in America. The patent holders have gone into appeal and the case could drag on in appeals and counter-appeals. Can we afford the cost of prolonged litigation in American courts, and for how many challenges? Ten fifty, five hundred? Challenging the patent does not appear to be a promising strategy.

The strongest, almost inviolate defence that we have in the basmati case is that based on the geographical indication clause of Trade Related Intellectual Property Rights (TRIPs). Geographical indication is a form of intellectual property right (IPR) included along with other IPR forms like patents and copyrights, in the TRIPs chapter of GATT/WTO. This clause found in Articles 22, 23, 24 of Section 3 deals with the protection of goods that are geographically indicated. The geographical indicated protection has been specially conceived for well known speciality products which are associated with a particular region. So it is that the word 'Champagne' is claimed exclusively by the Champagne region of France which is the geographical region from which the wine derives its world famous name. No other wine, even if it is made from the same grape variety, by the same method, and is identical in taste, aroma and other qualities, can be called Champagne. The reason is that the glamour and mystique that makes Champagne an exorbitantly priced, up-market product is associated with the name and not necessarily with the quality of the wine. French Champagne producers are aggressive about protecting this name and derive every single ounce of trade advantage by claiming the Champagne market exclusively for themselves. Another well known instance of a geographically protected product is that of 'Scotch' whisky. No other whisky in the world even if it were to be indistinguishable in taste and flavour from Scotch whisky can use the name. This name belongs exclusively to the whisky producers of the Scottish highlands who derive the trade advantage of selling their whisky for five times the price of ordinary whisky. Geographically indicated rights are protected fiercely by countries like France and UK because this protection translates into monopolies in the market and high earnings.

Similar to the exclusivity of Champagne and Scotch is that of basmati rice. This very special long grain, aromatic rice is specifically associated with India and Pakistan. This is their geographically protected name which no one else can use. The focus of India's basmati challenge will have to centre around America's violation of India and Pakistans' geographically indicated rights by using the name basmati. That is the central issue of the basmati patent, not whether the patent awarded by the American Patent Office is valid or not, which of course it is not. Rice Tech's plea that basmati is a generic name, not a special name like Champagne, is a silly, contrived argument. Basmati is about as generic as Champagne and Scotch and should be as zealously protected.

The Americans would not dare to call their whisky Scotch or even American Scotch. They would as little dare to label Californian wines as American Champagne or Champagne. If they did this, they would be hauled by France and UK to the WTO Dispute Settlement Court and made to retract or pay penalties and face sanctions. Why then, it becomes necessary to ask, do the Americans dare to purloin the basmati name and even go a step further and monopolise it by a patent.

The answer lies in the sheer incompetence exhibited at the official level here. On the whole question of IPRs on biological resources, the patentability of life forms, the importance of biotechnology to the Indian economy and other crucial issues, India has still not been able to get its act together. There is no understanding of the issues among those supposed to make policy, and no policy has been formulated, much less implemented. A gaggle of assorted bureaucrats with little interest and even less knowledge, goes junketing from Geneva to Jakarta, bungling up negotiations and compromising the national interest in our most crucial sectors.

A crassly ignorant beaurocracy is also behind the defeatist viewpoint currently doing the rounds in the ministries of the government of India. The inexplicable view is being held out that we cannot do anything on geographical indication because we do not yet have a domestic law. Nothing could be further from the truth. A very strong defence is possible given the nature of current trading practices. Admittedly it would be preferable to have a law in place but its absence need not make us hesitate about asserting our claim.

In contrast to the government's diffidence in pressing its claim, India's geographically indicated rights are accepted and implemented by other nations including Saudi Arabia and the UK. The Grain and Feed Trade Association in the UK, one of the largest importers of basmati rice in the world, have stringent standards for using the term 'basmati'. Its traders can use this name only for the long grain, aromatic rice grown in India and Pakistan. Similarly, Saudi Arabia, the largest basmati importer in the world and one of the largest consumers of basmati, has labelling regulations that permits basmati from only

India and Pakistan to be labelled as such. American and Thai aromatic, long grain rices are denied the use of this name. In view of this clear recognition of our rights over the basmati name, the coyness of the Indian government to defend its case is difficult to understand.

The time has come to take some hard decisions with respect to the WTO and the defence of Indian interests in this forum which was touted as a multilateral one. This supposed multilaterism implied that member nations would abide by the same regulations. In the single most contentious issue in GATT and WTO, that of IPRs there has been an effort to harmonise an IPR regime for the world. Patent regimes for drugs and agro-chemicals, a *sui generis* system for plant varieties and geographical indication are all parts of the same TRIPs section. It is under TRIPs that the Americans have taken India to court for violating the conditions for drug patents while they think nothing of themselves violating with impunity, the conditions for geographically indicated protection.

India should take the US to the dispute settlement court of the WTO for violating its geographically indicated rights over basmati. In addition to this, India should formulate a long-term strategy to protect its bio-resources. It should mobilise the biodiversity owning countries of the world to demand that the two international treaties dealing with the use of biological resources be linked to one another. The biodiversity convention cannot have a particular framework for the use of bioresources and the WTO quite another, almost opposing one. The US has refused to ratify the biodiversity convention which acknowledges the rights of rural and tribal communities and their ownership over bioresources but it is sparing no effort to push for compliance on the biotechnology industry driven agenda in WTO. The only response to this high-handedness is to demand compliance across the board. Either all countries comply with the conditions of the two treaties or no country does. There cannot be two different standards for America and India.

Role of Local Elected Leaders in Lok Sabha Elections

Anitha K
Naveen H N
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In the rural areas newspapers and the electronic media do not, as yet play a significant role in influencing voters' choice. Documented here is how the zilla parishad leaders spend a great deal of time and effort, systematically building upon their contributions towards area development to campaign for their party candidates for the parliamentary elections and the problems they face.

A LOK SABHA election campaign provides an opportunity for local representatives to explain both macro and micro level issues to local people. Local elected representatives have a better rapport with villagers than state or national leaders and are familiar with the dynamics of rural politics, bridging the gap between national and local politics. It would be interesting to find out how these local leaders handled the campaign and issues concerning the masses at the rural areas. We decided to accompany ZP members during their election campaign. Dharwad district was selected for this purpose as the team had established rapport with ZP members and had discussed different issues related to decentralisation over the past one year.

The ZP president of Dharwad district is a scheduled caste woman. She has contested from the Janata Dal (JD) and was campaigning for the JD candidate in Dharwad. The ex-president of Dharwad district, V S Patil was elected from JD but had joined Lokshakthi headed by Ramakrishna Hegde a few weeks before the Lok Sabha election. We accompanied the ZP president, ex-president, ex-ZP members, ministers and party workers for four days during the election campaign. During this period, we travelled extensively in the rural areas of Dharwad district and covered eight to 10 villages in a day.

In rural areas, newspapers and the electronic media play a minimal role in influencing the voters. Here politicians mobilise party workers at district, taluk and village level for canvassing. This process was phased out. During the first phase, ZP members established links with different groups in the village through the existing contacts. They try to solve the internal difference in the groups and tried to explore the possibility of seeking support from other groups. In the next phase, ZP members along with local popular leaders visited villages. During this phase, they focus on meetings with party workers and village heads. The last phase of campaign was devoted to public speeches by senior leaders and door-to-door campaigns.

Local elected representatives feel that they have better interaction with villagers as compared to MLAs and MPs. The ZP president of Dharwad explained that villagers came to the office to discuss problems they face. They asked her to sanction money for the construction of roads, bridges or classrooms. She sanctioned money for the required work and in case of financial constraints, she informs them about it and promises to take up the work in the next financial year. Problems may arise during the execution of the work; people inform her about the problems, which she refers to the concerned officials. Villagers feel happy about the treatment received by them and remember this and respect her when she goes to their villages for campaigning. Villagers know that she has helped in the construction of road or a classroom – and they are willing to support the candidate she is campaigning for.

Local representatives also visit the villages often to get to know the problems faced by the villagers, ensure the progress of works or to attend social functions organised by the villagers. This helps local representatives identify themselves with local people and during the campaigning processes they believe it helps in getting votes for their candidates.

Politicians want to concentrate on their constituency in general and their native village in particular. ZP representatives visit their respective constituencies frequently to mobilise party workers to campaign. According to a ZP president, ZP members take up the responsibility of campaigning in their constituencies. If a ZP member is not efficient then the president of ZP has to campaign in that constituency. In the process of a campaign, most often public speeches are in the native place of the politicians. Politicians are familiar with the political links in their constituencies and can organise people for public speeches. Politicians feel happy that if they can convince 10 family heads then they can be sure of gaining more than a hundred votes. Hence they do not bother to meet others in the village who are usually busy working in the fields. During the speeches politicians address village leaders, family heads and party workers. They have built their vote banks over a period of time and this is essential for their career development. It is also true that people recognise local representatives as their leaders. Politicians feel that they are answerable to the problems faced by them and show interest in the infrastructure development of the village. The ZP president was listed out the activities taken up in her constituency, Morab, "I have sanctioned money for construction of bridges, now we have three to four class rooms in all the

and sale of "farm produce", and does not cover reproductive material, clause 17 could in fact allow the seed industry from preventing the farming communities from engaging in seed supply and exchange amongst farmers. The seed industry can attempt to interpret clause 17 through case law like that of Asgrov Vs Winterboer, or UK Breeders Vs Scottish potato farmers to prevent direct sales among farmers. Further, since the clause does not set limits to the kinds of contracts the seed industry could force farmers into, contracts could totally undermine the rights of farmers.

Farmers rights are also undermined by the fact that the definition of "extant variety" does not cover farmers varieties. According to Def (ix), "extant variety" means a variety notified under the Seeds Act 1966 or released by the central seed committee or its subcommittees and qualifies for protection under the provisions of this act. The farmers varieties that are a result of farmers breeding and conservation do not qualify for protection. Farmer-conservors have no rights under this legislation. But once the seed industry takes these varieties and changes some characteristics, the variety becomes protected. Even though the article 18 refers to "on-farm innovation relating to the enhancement or agrobiodiversity", there is no "protection" of this innovation. Thus while the innovation of farmers goes unrecognised, the innovation of the seed industry and researchers is recognised and protected.

The difference in treatment of farmers and industry is also evident from the treatment of essentially derived varieties which are defined in Def (viii). The fact that while varieties essentially derived from farmers varieties are treated as varieties evolved by industrial breeders, when varieties are essentially derived from the protected varieties, the "rights of the breeder of the initial variety extend to the essentially derived variety also" according to clause 7.

If a variety 's' is essentially derived from a farmers variety, on the logic of protection in clause 7, the farmer should have the first right. This is the real basis of farmers rights. The inconsistent treatment of rights related to derivation of varieties is another example of the bias against farmers and in favour of the industry in the draft legislation.

UPOV against Agricultural Biodiversity and Farmers' Rights

In India, 70 per cent of the seed supply is still from farmers, i e, it is based on farmers role in breeding and conservation. In the OECD countries, nearly all farmers are consumers of seed supplied by the seed industry. The industrial agriculture context has led to the breeders rights system of UPOV, the International Convention for the Protection of new Varieties of Plants. The UPOV convention is rigid, requiring that members adopt its standards and scope of protection as national law. The UPOV convention which has resulted in a high degree of standardisation goes against the reality of biological diversity and the socio-economic diversity of different countries. It is, therefore, inappropriate as a *sui generis* system evolved to protect plants, people and creativity in diverse realities. However, this inappropriate system is being used in the draft to produce a *sui generis* system for plant varieties. The draft uses seed industry criteria for identification and protection of varieties, rather than farmers breeding criteria.

The standardisation is built into the way plant varieties are defined in UPOV. To be eligible for protection, a variety must be:

New – the variety must not have been exploited commercially

Distinct – it must be clearly distinguishable from all other varieties known at the date of application for protection

Uniform – all plants of the variety must be sufficiently uniform to allow it to be distinguished from other varieties taking into account the method of reproduction of the species

Stable – it must be possible for the variety to be reproduced unchanged

Clause 6 of the Draft Act reproduces this criteria as the basis of protection of varieties and hence the protection of rights.

This definition by its very nature rules out farmers' varieties and destroys biodiversity, and produces uniformity as necessity. The reward under such Plant Breeders' Rights (PBR) systems does not go for breeding to maintain and enhance diversity and sustainability, but to the destruction of biodiversity and creating uniform and hence ecologically vulnerable agricultural systems. Therefore, the PBR legislation like UPOV and the present draft of the Indian legislation, is inherently incapable of protecting farmers' rights; as arising from the role of the farmers as breeders who innovate and produce diverse farmers' varieties, which form the basis for all other breeding systems.

While UPOV fails to recognise and therefore protect farmers' rights as positive rights, UPOV 1978 does have a farmers' exemption which gives the farmer the right to save seed of protected varieties. Similarly, the breeders' exemption allows researchers and breeders free access to a protected variety to use for breeding other varieties. However, UPOV 1991 has removed these exemptions. Breeders and researchers will have to pay royalty to the PBR holder to use the protected variety for breeding other varieties. The farmers' exemption has been made optional. article 15 of UPOV 1991 states:

> Each contracting party may within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder restrict the breeders right in relation to any variety in order to permit

Biodiversity Totalitarianism

IPRs as Seed Monopolies

Vandana Shiva

In India's conditions of peasant agriculture, farmers are still the major suppliers of seeds. The real basis of farmers rights is in the recognition of the collective innovation by farming communities embodied in farmers varieties, and evolving a jurisprudence that protects and rewards this collective wisdom.

THE transnational seed industry is seeking total control of seed, the first link in the food chain. And through control over seed, they control the food system. If all farmers, who are the original breeders, could be forced into the market every year, the seed industry will have a 7.5 billion dollar market.

The Life Industry: Total Control

Not only is the seed industry gaining total control over seed supply, it is also getting increasingly concentrated. As Robert Farley of Monsanto has stated: "What you're seeing is not just a consolidation of seed companies, its really a consolidation of the entire food chain". In the last year, Monsanto has taken over small start up biotech companies and large seed companies. These include: (1) Agracetus, a subsidiary of W R Grace with species patents on cotton and soybean, acquired by Monsanto for 150 million dollar; (2) Calgene, California based plant biotech firm which launched the 'Flavr-Savr' tomato. Monsanto now has a 54 per cent controlling interest in it; (3) Asgrow seed, bought by Monsanto for 240 million dollar; (4) De Kalb, bought by Monsanto for 158 million dollar; and (5) Holden, bought by Monsanto for 102 billion dollar.

Holden, is a seed company with 45 million dollar in annual sales. Monsanto has bought it at 1 billion dollars, 23 times the annual sales. Thus seed, the first link in the food chain, will fall into the hands of a handful of corporate giants who are accountable to no one, whose functioning is totally non-transparent and who control the entire food and agricultural system (*RAFI Communique*, September 1996). As Bill Frieberg, editor of *Biotech Reporter* says,

> Big agricultural company profits will need to be squeezed out of farmers, one way or the other. And there's only so much blood that can be squeezed out of the proverbial turnip (*The Biotech Reporter*, January 1997).

The stronger the rights of TNCs, the weaker are the rights of farmers since it is the erosion of farmers' rights which creates TNC monopolies.

The Trade Related Intellectual Property Rights (TRIPs) agreement of GATT/WTO is the global instrument that the biotech industry has used for gaining monopoly control over seed supply. As James Enyart, the Monsanto spokesperson has stated about shaping the TRIPs agreement: "We were the physician, the diagnostician, and patient all in one" (*RAFI Communique*, September 1996). TRIPs states that all countries must either give patents for plants or have an "effective *sui generis*" system. While it has not been explicitly stated, the seed industry would like to see the Union for the Protection of New Varieties of Plant (UPOV) implemented in every country. *Sui generis* systems could also be legal systems centred on farmers' rights and on the conservation of biodiversity, in accordance with principles of the Convention on Biological Diversity. Which *sui generis* system India adopts will depend on how democratic the processes for evolving the new legislation are.

Farmers' Rights Undermined by Seed Monopolies

Farmers have been the original breeders and seed supply has been based on farmers contribution to conservation, breeding and utilisation of diverse species and crop varieties.

In India, 70 per cent of the seed supply is still farmers' seed supply. In most industrialised countries, most farmers depend on the seed industry. However, until recently, they could save seed and exchange seed among each other, under what was called the 'farmers' priyilege'. Recent changes in plant legislation in Europe and the US have however, allowed the seed industry to take away the last remnants of farmers' freedom and enslaved them to the seed industry. Farmers have been pushed into a situation of total lack of freedom to exercise their role as breeders, or as members of a community or producers, freely saving and exchanging plant material.

On the other hand, seed legislation pushes out farmers' varieties and makes farmers' breeding an illegal activity. The case of farmer Josef Albrecht in Germany and potato seed farmers in Scotland are examples of how Seed Acts prevent farmers from engaging in their own seed production. Josef Albrecht is an organic farmer in the village of Oberding in Bavaria. Not satisfied with commercially available seed, he developed his own ecological varieties of wheat. Ten other organic farmers from neighbouring villages took his wheat seeds. Farmer Albrecht was fined by the government of Upper Bavaria because he traded in uncertified seed. He has challenged the penalty and the Seed Act because he feels restricted in freely exercising his occupation as an organic farmer by this law. During the Leipzig conference on Plant Genetic Resources, Josef Albrecht initiated a non-co-operation movement against seed legislation that denies farmers the right to freely breed and exchange their seeds in the same church from which the democracy movement against the erstwhile communist state of GDR was organised in Leipzig (Refer to *Bija*, Nos 17 and 18).

In Scotland, there are a large number of farmers who grow seed potato, and sell seed potato to farmers. They could, until the early 1990s, freely sell the reproductive material on to other seed potato growers, to merchants, or to farmers. In the 1990s holders of plant breeders' rights started to issue notices to potato growers through the British Society of Plant Breeders, and made selling of seed potato by farmers to other farmers illegal. Seed potato growers had to grow varieties under contract to the seed industry which specified the price at which the contracting company would take back the crop, and barred growers from selling the crop to anyone. The companies started to reduce the acreage and reduce the prices. In 1994, seed potato bought from Scottish farmers for 140 pounds sterling, was sold for more than double that price to English farmers, whilst the two sets of farmers were prevented from dealing directly with each other. The seed potato growers signed a petition complaining about the stranglehold of a few companies acting as a 'cartel'.

They also started to sell non-certified seed directly to English farmers. The seed industry claimed they were loosing four million pounds sterling in seed sales through the direct sale of uncertified seed potato between farmers (Tracey Clunis Ross, *Growing Problems: The Issue of Sovereignty Over Seeds*).

In February 1995, the British Society for Plant Breeders decided to proceed with a high profile court case against a farmer from Aberdeenshire. The farmer was forced to pay 30,000 pounds sterling compensation to cover royalties lost to the seed industry by direct farmer to farmer exchange.

Existing UK and European Union laws thus prevent farmers from exchanging uncertified seeds as well as protected

varieties. In the US also, farmer to farmer exchange has been made illegal, as established by the case filed by Asgrow Seed Company, now owned by Monsanto, and the Winterboers.

Dennis and Becky Winterboer are farmers owning a 500 acre farm in Lowa. Since 1987, the Winterboers have derived a sizeable portion of their income from 'brown bagging' sales of their crops to other farmers to use as seed. A 'brown bag' sale occurs when a farmer plants seeds in his own field, and then sells the harvest as seed to other farmers. Asgrow (which has plant variety protection for its soybean seeds – A1957 and A2234) started a court case against the Winterboers, on grounds that its property rights were being violated. The Winterboers argued that they had acted within the law since according to the Plant Variety Act, farmers had the right to sell seed, provided that both the farmer and seller were farmers.

The Federal Circuit Board interpreted marketing as requiring "extensive or co-ordinated selling activities, such as advertising, using an intervening sales representative, or similar merchandising or retail activities". The Supreme Court disagreed and interpreted marketing as holding forth property for sale, and hence ruled against the Winterboers (refer to US Supreme Court case no 92-2038, *Asgrow Seed Company v Winterboer*, 1995). In 1994, the Plant Variety Act was amended, and the farmers' privilege to save an exchange seed was amended through Statutes 3136 and 3142, establishing absolute monopoly of the seed industry by making farmer to farmer exchange and sales illegal.

The absolute rights of the seed industry and the absolute lack of rights for farmers has been further established in Monsanto's "Round-Up-Ready Gene Agreement" for Round-Up Ready soybeans. The agreement is meant to enforce US Patents 4,535,060, 4,040,835 and 532,505. The agreement prevents the grower from selling or supplying the seed or material derived from it to any other person or entity or saving any of the seed.

The agreement requires a payment of five dollars per pound of 'technology fee' over and above the price of seed and royalties. If any clause is violated, the grower has to pay one hundred times the damages, and this is not deemed to limit the amount of damages. Monsanto has a right to visit the fields of the farmer at any time even without the farmers' presence or permission for three years after the agreement. Thus, the right to property of the farmer is not respected. This clause has made farmers extremely outraged. As one farmer put is, "We shoot intruders".

The agreement is binding even on heirs and personal representatives of successors of growers, but growers' rights cannot be transferred without Monsanto's permission. Thus, Monsanto's rights exist over others related to the farmer, but the farmer is denied his/her rights to transfer the agreement.

In addition, the agreement has no liability clause. It has no reference on the performance of Round-Up Ready soybeans, and Monsanto has no responsibility in case they fail to perform as promised, or the ecological damage caused by Round-Up. This is especially relevant given the failure of Monsanto's genetically engineered cotton, 'Bollgard'. In the 1996 season farmers were forced to spray their fields to protect the cotton crop from Boll worm, even though the promotional material has stated that boll worms could cause no damage to Boligard cotton.

The Round-Up Ready gene agreement is thus the latest step in the seed industry claiming far-reaching monopoly rights over seeds and farmers, and bearing no ecological or social responsibility associated with the introduction of herbicide resistant or pest resistant genes into crops. This one-sided system in which seed companies have all the rights and bear no social or environmental responsibility, and farmers and citizens have no rights but bear all the risks and costs, can neither protect biodiversity nor provide food security. It is a system of biodiversity totalitarianism.

The Indian Plant Variety Legislation: Will It Protect Farmers?

In the context of the global trends of concentration of the seed industry and the undermining of all aspects of farmers freedoms through intellectual property rights (IPRs), will the Indian draft legislation on seeds and plants be able to protect the Indian farmer?

The agriculture ministry has drafted a new legislation entitled the 'Plant Variety Protection and Farmers Rights Act'. However, the draft legislation is a 'Farmers Rights Act' only in name. In substance it totally undermines the concept of farmers rights as it has evolved in the FAO Commission on Plant Genetic Resources, the International Undertaking on Plant Genetic Resources, the Leipzig Global Plan of Action, and above all, the Convention on Biological Diversity (CBD). However, the legislation has many elements which reproduce the structures of the legislation of industrialised countries, and hence can undermine farmers rights in its name. The first mechanism for undermining farmers rights is in the definition of farmers.

Farmers are defined under Def(x) as Farmer Cultivator and Farmer Conservor, but not as Farmer Breeder. Def: (x)

> Farmer, cultivator means a farmer who procures seeds of new varieties of crop plants for cultivation to whom the rights specified in Clause 17 shall apply.
>
> Farmer-conservor means tribal and rural women and men or their communities who have preserved wild species and folk varieties of economically useful plants and have added value to them through selection and identification of their useful properties.

The key role of farmers as breeders has thus been negated in the draft legislation. The legislation, therefore, reproduces the northern bias, instead of reflection the position of the south, on the issue of farmers innovation in the evolution of agricultural biodiversity.

The industrialised countries have been willing to recognise the role of farmers as conservors, but they do not want to recognise the role of farmers are innovators. The developing countries have been arguing for the farmers role in innovation, and in the FAO negotiations, they have perceived farmers rights as a means of regaining control over the resources they are losing through the internationalisation of the IPR system. The draft act has been framed from an industrialised country position, and it is failing to use the progress made in CBD and FAO on farmers rights to India's advantage.

Farmers rights reflect farmers role in breeding. Farmers varieties result from a breeding strategy different from the breeding of seed industry. This breeding strategy is different, not inferior or primitive to the industrial breeding strategy. Recent work on participatory breeding by International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) in India has shown that farmers selection criteria are more ecologically adapted than the criteria used by the seed industry or by breeders.

The most frequently identified traits for an ideal pearl variety by farmers in Rajasthan were large panicle size and high tillering. Tillering is of importance to farmers of western Rajasthan as a component of both grain and fodder yield, since tillering is associated with better adaption to low water availability and fertility conditions. Higher tillering varieties also provide better quantity and quality of fodder.

Farmers breeding criteria thus focuses on plant type or architecture for ecological adaption and fodder yields, and also on taste. Breeders neglect all these criteria that are most significant to farmers breeding and selection criteria.

Clause 17 on *Farmers Rights* states,

> Nothing shall affect the farmers' traditional rights to save, use, exchange, share and sell his farm produce of the protected variety except sale for reproductive purpose under commercial marketing arrangements. This would not apply to contractual production of different stages of seed by farmers as contract farmers.
>
> Since the right is restricted to exchange

Patents: Issues Confronting India

Biplab Dasgupta

I. INTRODUCTION.

The parliamentary debate on patents and the anti-Patents Amendment Act campaign conducted by the Left parties in recent months has brought the issue of patents to public attention. But even now the ideas about patents and about various long term consequences of the changes (some already passed and some proposed) in the patent legislation are far from clear in public mind. While issues like rising prices, unemployment, the closure of industries, or those relating to privatisation evoke immediate interest, the patent issue has so far eluded popular concern. Yet, the fact remains that these changes in patent legislation have the potential to inflict incalculable and irreversible harm to India's long term goals of self-reliant industrialisation and economic development. These would make India perpetually dependent on foreign countries and their multinational corporations (MNC) for technology, and would rule out any chance of ever catching up with the Western industrialised countries. Whatever development would take place following these legislation would be within the framework defined by the Western countries and their multinational companies, and under terms that would be primarily to the advantage of the latter.

In fact, we are dealing with not one but four types of patent issues : (a) the requirement under the TRIPs (Trade-related Intellectual Property Rights) agreement of April 1994, at Marakesh, to recast India's own patent legislation of 1970 to conform to the prescribed universalised patent format, by 2005 AD, (b) to conform to transitional rules relating to EMR (Exclusive Marketing Rights) now, as a condition for India's membership of World Trade Organisation (WTO), (c) to enact a bill on bio-diversity in order to conform to the 1993 Covention on Biodiversity (CBD); this bill is being prepared by the Ministry of Environment, and (d) to conform to TRIPs agreement provision for the protection of plant and animal varieties, by way of patents or something *sui generis* or a combination of both, to be sponsored by the Ministry of Agriculture. Of these (b) has already been passed by the Parliament and (c) and (d) are also likely to be moved during the latter part of the current budget session. (a) has become superfluous as (b) has, for all practical purposes, brought forward the agenda for the year 2005 to the year 1995.

In this paper we are dealing with some of the broader issues that have arisen in the course of this debate. In Section II we are critically examining the capitalist rationale behind patent right, in Section III the factors that led to the internationalisation of patent regime under TRIPs agreement of 1994, and in Section IV the major changes that have been forced on the national patent laws by the TRIPs agreement. Section V deals with transitional rules, effective from January 1995, and treated as preconditions for WTO membership, while Section VI focuses on 'bio-piracy' being committed by the MNCs. Sections VII and VIII examine various implications of the proposed plant varieties and bio-diversity bills. Section IX discusses why MNC participation in Indian agri-business has possible fearful consequences Section X underlines India's possible role in the coming review of the TRIPs agreement, while Section XI summarises the main findings.

II. PATENT RIGHTS: THE RATIONALE

Patent right, like copyrights and trade marks, is an 'intellectual property right'. This right relates to the mental work involved in the invention of products or of processes for making those products, such as machines or medicines, but not to products themselves. To qualify for patent right, an inventor has to prove that (a) his invention is unique, no one else has done before him what he has achieved, (b) his invention is non-obvious, that is not trivial, not something that can be easily deduced from what is already known, and (c) it is something of practical use; an idea, a theory or a mathematical formula can not be patented, but the embodiment of these ideas in the form of a product or medicine can be. If these three conditions are met to the satisfaction of the patent office after due verification, then the application for the patent right is approved.

The patent right is a time-bound monopoly. The right is an exclusive one, that is given only to him and no one else. It excludes others from the enjoyment of such right, and is valid for a specified number of years , say 10 years. Within those ten years no one else can produce this product without the permission of the patent holder. It is a property in the sense that, like any other property, land, car, house, the right can be bought and sold in the market, can be leased, gifted away, mortgaged or transferred and disposed of in other forms. The right is essentially a negative one, that is denying others the right to do anything with his patented product without his concurrence, during the period of patent.

It has been found that about two-thirds of patented products are never produced. They are patented to keep rivals away from the field, while the firms concerned continue to produce similar products catering to the same type of consumer need. In terms of traditional welfare economics, patent right has the effect of reducing consumer welfare on several counts—being a monopoly, by charging monopoly prices, by not allowing the rivals to produce the same product, and, in some cases, not producing the product at all.

Although most national patent laws provide for 'compulsory licensing', that is forcing the patent-holder to permit use of patented product by others, that is not easy to implement. At the end of the patented period any one can produce it without his permission, but, as we shall see below, by then the patented product might become so out of date that no one would be interested in it, while the patent-holder might invent, develop and patent new products catering to similar needs, thus maintaining his monopoly over the market.

The patent right is essentially a capitalist property right. In the pre-capitalist days inventions were treated as parts of an 'intellectual common' without barriers to dissemination of information about new art or technology. From the days of the invention of wheel or stone tools, or the discovery of rice or wheat crops, or of metals such as iron, brass and their uses, such technological information had been more easily accessible. In many cases, as in the case the crop varieties and handicrafts, micro communities concerned evolved those over centuries, made regular incremental changes and adapted those innovations to local environment and human needs. Acquisition and dissemination of knowledge were axiomatic and became a common heritage of mankind from which the inventor profited as much as any one else.

With capitalist development, many of those collectively owned properties, whether a village common or a particular way to design clothes, or land under communal cultivation, came to be privatised. Patenting, historically, is a part of that process. The underlying philosophy is that no one would undertake invention for its own sake, and would require to be motivated by giving him a monopoly right over his invention for a given period. Such patenting , it is argued, would allow the inventor to recoup his cost of developing this product and would compensate him for the risk he undertook, and, thus, would encourages invention and development of new things and new ways of doing old things. By rewarding the inventor in this way, it was expected, patents would encourage others to go for invention at the frontiers of scientific and technical knowledge.

On the issue, how far and to what extent patents provide incentive to invent, no clear and unambiguous answer can be given. Overall, there is no direct statistical association between the existence of patents and private R & D investment. Though stronger patent laws usually encourage more patent applications, it can not be said definitely whether those inventions would not have materialised had there been no patent protection. As we have already noted, the history of mankind is replete with inventions having deep impact on the course of development, for which the inventors were not commercially rewarded. Many would argue that the inventor, as a human being, is not solely driven by the urge to make money. The satisfaction that his psyche enjoys following an invention is a much stronger motive force than the money it brings by way of patent right.

Many of the earth-shaking discoveries have been made by men of no apparent consequence but completely preoccupied and obsessed with the quest for a particular invention, such as the flying machine of the Wright brothers, or the concept of wireless by our own Jagadish Chandra Bose. Later, many of these inventors, with little resources and marketing opportunities to make their invention a commercial success, have sold themselves and their patented products to MNCs.

In India's case, the green revolution technology in agriculture—that tripled food production in three decades—involved no patent regime. The government agents purchased a few kilograms of 'foundation seeds' from CYMIT of Mexico in cases of wheat and maize, , and from IRRI of Manila in case of rice, both research

institutions, cross-bred and adapted those to the Indian environment in the agricultural universities, notably the one located at Ludhiana, and then, after a period of 3-5 years, released those varieties to the Indian 'seed farmers' who multiplied and sold those to the Indian agriculturists. Though the technology of green revolution itself contains many of the ills of capitalist development in agriculture that we have discussed elsewhere, patent regime was not one of those. While the MNCs spend a high proportion of their gross profit on research and development, their main research direction is towards development of profitable commercial use; more of the fundamental research is undertaken by publicly owned institutions and universities.

Along with capitalist development and individualisation of other rights, rights on inventions have also been transferred from the communities to individuals and companies. Each country has passed its own patent law that is in conformity with its own requirements, given its level of development and technological advance, and human and other resource endowments. Patents laws have also been guided by the national objectives of self-reliance or industrialisation. Some have allowed unrestricted copying of foreign technologies, while some others have not. Some of the countries have applied patent laws more or less strictly than others, in line with their own development needs. But for each nation a different patent law was enacted. A patent holder in country A had to apply separately for patent rights in countries B, C,D, and so on, and subjected his application to scrutiny by the national authorities.

The fact is that, as evidenced by the global history of industrial revolution, practically all the countries of the world, some more and some less, have borrowed technologies of other countries and have adapted those to suit their own conditions. Britain being the first country to experience industrial revolution has probably borrowed less from others, while Japan, at the other end, has probably borrowed most. In 1945, at the end of the Second World War, that took a toll of 20 million lives and an equal number of handicapped youth, Japan, a country poorly endowed with natural resources, having no mines or plantations, with its towns razed to the ground and with its factories reduced to rubble, began its journey back to industrialisation in a novel way, by relying nearly exclusively on its skilled manpower. 'Reverse engineering' made it possible for them to start with the finished imported product, then to trace its elements and the relationships between those, and, thus, to find the technology and using it to replicate the imported machines by improvising with cheaper local material. In the process of 'copying' foreign technologies for 15 years, the Japanese skilled manpower acquired a vast knowledge of technologies, and then translated that knowledge into a series of inventions that in due course made it the second largest industrial power in the world. Later South Korea and Taiwan , along with Singapore and Hong Kong, replicated the Japanese technologies with their own local material and craftsmanship, while, following the 'flying geese' model, these then spread to the Southeast Asian countries beginning with Thailand.

This has always been the way technology has been disseminated in the past. In later years this practice was condemned by the MNCs of US origin as 'piracy' and as a serious infringement of their intellectual property rights. What is and what is not 'piracy' is of course a matter of national law. As long as the national laws of these countries did not describe the copying of foreign technology as illegal, they were not violating any law, and the pejorative terms such as 'piracy' could not be applied to them. To take such actions as acts of piracy would be to take a Euro-centric view of culture and values, as some have argued.

III. TRIPS : INTERNATIONALISATION OF PATENT RULES

It was in this context that the idea of an international patent regime was mooted. The MNCs argued strongly that they were losing a great deal of money because of such piracies; only an uniform, international patent system, monitored by a strong global authority, could protect them from massive losses they were incurring due to piracy. Some estimates were made in the late eighties to show that the US firms were annually losing around $61 billion from such piracy of their intellectual property; around $3-6 billion of those by the chemical and pharmaceutical industry alone. [Lesser, 1991: 1] They felt that that their position at the cutting edge of technological progress was being eroded by unauthorised copying of their intellectual property. And while 'export-back' of the 'pirated products' to USA could be restricted by US law, they felt that , such piracy restricted their markets in the other countries. A globalised patent regime was the only way to protect themselves from such 'piracy', they argued. It was also argued that, by granting and enforcing patent rights internationally, the owners of patents would no longer

require to keep details of their inventions secret, since such details would form a part of their patent application. and , thus, the knowledge itself would be disseminated more freely. On the other hand, those opposed to it claimed that patents encourage a culture of secrecy, as companies try to keep their inventions secret and safe from poaching by rival companies. Industrial espionage is a fact of life in the developed countries.

In 1990, these MNCs persuaded the government of the United States to put eight less developed countries on Super 301 'hit list', for violation of intellectual property rights, that is on the basis of section 301 of US trade legislation that prescribed economic retaliation against countries that discriminated against US companies. In 1988 IBM induced the government of USA to put Brazil on 'super 301' hit list, following allegations over a National Informatics law that was designed to protect the national computer industry; the threat was withdrawn only after Brazil agreed to amend that legislation. In 1987 and 1988, similar disputes with South Korea and Thailand on software protection were resolved after the 'offending' legislation were amended. China too came under the threat of Super 301, and was asked to introduce patent laws, and to compensate the US companies for the losses they suffered from piracy, a request that was coldly ignored.

'Super 301' is actually the section 301 of US trade legislation, under which the US Trade Representative (USTR) is authorised to initiate economic sanction against countries discriminating against the US companies. It usually starts with the publication by USTR of the list of such 'offending' countries ('hit-list'), which is usually followed by negotiations and , ultimately, capitulation by the countries concerned. [Low, 1995: 64, 87] One expert has described it as 'gunboat diplomacy' [Watkins,1992: 81], and another has found this procedure closely resembling a criminal trial.

Another section of the US trade law, section 1303, known as 'special 301', only deals with violation of intellectual property rights. It requires the trade representative of the United States to identify countries that "deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access to US persons that rely upon intellectual property protection." [Low, 1995: 64-65]

Eventually, the MNCs pursuaded their government to take up their cause during the Uruguay round of GATT negotiations (1987-

93), and to propose an international agreement on intellectual property rights. There was, however, one major snag, since one international organisation, an affiliate of the United Nations, called World Intellectual Property Organisation (WIPO) already existed in this field. Therefore, to make intellectual property negotiable by GATT, it was argued that only the 'trade-related' part of intellectual property right would be discussed in GATT. The justification given was that the protection of intellectual property rights would enhance trade. The MNCs helped the United States Trade Representative in the GATT negotiations by doing the home work for the government and by leasing out their own quality manpower. Pfizer, Monsanto and Du Pont, and Cargill Corporation were among the MNCs that played a key role in advising US government on this issue. The agreement signed at Marakesh, in April, 1994, on this subject, came to be known as TRIPs (Trade-related Intellectual Property Rights). WTO, the implementing agency for TRIPs , supplanted WIPO in due course. This was no unique experience for an established UN agency. Several other UN agencies have been similarly sidelined in the past by the World Bank associates, such as UNEP, UNCTAD and UNIDO, in their own respective fields of environment, trade and development and industries. The signing of TRIP's agreement signaled the victory of the sustained campaign by the MNCs for years against what they described as 'piracy' of their intellectual property.

Through the TRIPs agreement an international patent regime has been created. Its universal, standardised trade rules would apply to all the member countries irrespective of their levels of development, natural and human endowments and history. And, through the founding of WTO in 1995 January, an agency has been created for monitoring its implementation. Every member country has been asked by WTO to amend its national patent law to conform to that universal, globalised format. Under article 65, the developed countries have been asked to change their laws within one year, and the less developed countries within another five years, and an additional five years for legislation relating to pharmaceuticals, agrochemicals, food, alloys etc. The least developed countries have been asked to make those changes by 2005 AD.

As an international agreement, the TRIPs agreement stands in contrast with another international agreement—the Convention on Biodiversity (CBD) , signed in 1993 by 170 countries. The vast majority of the countries, including India, have signed both, oblivious of their mutual inconsistency. While CBD declared that diversity

was the essence of life. TRIPs prescribed uniformity. And while CBD assigned a key role to the collective rights of the micro communities, to TRIPs the principal concern was individualisation of rights. In its article 16.5, CBD specifically asserts that intellectual property rights must not be in conflict with conservation and sustainable use of biodiversity, a provision that has been totally ignored by TRIPs agreement.

Questions have been raised, how far this new patent regime would allow effective competition or dissemination of information. Some have taken the view that it departs from the competitive ideals and further restricts the access of the poor countries to technology. While the main thrust of GATT negotiations in the past had been against protection of domestic industries by way of tariff or quota restrictions, TRIPs is by its very nature a protective arrangement. Its article 39 provides for the protection of undisclosed information, except where necessary for public good.

Another aspect of this globalised patent regime is its differential impact on countries at different levels of development. Vaitsos estimated in 1972 that , in case of the less developed countries , 80-85% of the patents are held by foreign interests, a figure confirmed by a subsequent UNCTAD study in 1975. It is more than likely that the proportion remains the same now or has actually increased. According to a more recent document of WIPO, the citizens of developed countries hold 95% of African patents, 85% of LA and 70% of Asia. According to another source, the vast majority of biotech patents are in the name of the companies originating in the west—in 1990, 36% of those were in the name of the US companies, 32% in the name of the European Community companies, and another 23% in the name of their Japanese counterparts—an aggregate of 91%.

Given that an overwhelming proportion of patents originate in the developed world, patent protection is likely to lead to a transfer of income from the less developed to the more developed countries and , thereby, to widen income disparities between the two. The less developed a country is , at the beginning of the globalisation process initiated by WTO, the greater would be its difficulty in pushing exports and in competing with products supported by the international patent regime. Therefore, for these countries "although the export market remains an important option, it can not be the sole route." [Fishlow and Gwin, 1994: 9]. As one Fund-Bank document concluded , in 1994 : "Countries with less immediate scope for attracting high-technology investment or exporting intellectual property tend to regard TRIPS as a mechanism for transferring economic rents to technologically advanced countries." [Development Committee, 1994: 71].

Another consequence, would be a shift away from the public domain, as public funding of research and development for the overall benefit of citizens would be replaced by private companies solely concerned with their own profit.[Dommen, 1993: 10] Generally speaking, most basic scientific research are undertaken with public fund, mainly by the universities and research institutions patronised by the government. With public subsidy, "once discovered, an invention can be disseminated virtually without cost"; and it can be shown that such 'common knowledge 'products are efficient to finance publicly. On the other hand, as we have already noted, MNCs use the fruits of such basic research by making further investment on adaptive research for their commercial use. They cover only a small part of the total cost of research but then claim patent (that is monopoly) rights in order to exclude others from the fruits of such research.

Constantine Vaitsos sees in the patents a a 'defensive strategy' by foreign companies : " ... to preserve markets that were once captured through exports and are subsequently threatened by competitors and /or by the import-substituting strategies of the host countries. In this context, patents, far from providing a stimulus to foreign investment , appear to be a critical factor in blocking investments." [Vaitsos, 1972: 71] Nadal sees patents as a 'powerful instrument to achieve control over markets, even without direct investment.' [Nadal, 1977: 229; Lesser, 1991: 59] Talking about the impact of patents on agriculture, Vellve sees possibilities of higher agricultural costs and less welfare as a consequence of patenting of agricultural technologies.

TRIPs forecloses for the less developed countries of today the industrial strategy adopted by all the developed countries of today, in the course of their development in the past, Japan and East Asian countries particularly in recent years, of liberally using foreign technologies or resorting to reverse engineering, for their own technological and industrial advancement. For instance, Taiwan had loose or no international patent or copyright law, and followed the technology curve and product cycle of Japan, often purchasing second hand technology. As one leading scholar on East Asia commented:

"it is impossible to calculate how much of Taiwan's early growth was fueled by the learning that went on while trying to reproduce products protected elsewhere in the world." In the early 1980s US Trade Representative's office accused Taiwan of being responsible for 60% of counterfeit and pirated items in the world market [Brautigam, 1995: 170]

That option, good or bad, right or wrong, moral or immoral, does not exist any more. In case of Japan and other East Asian countries 'reverse engineering' was nearly always the first step towards technological self-sufficiency, a path that India can no longer take. 'Local content requirement' was another that the former used to protect their nascent indigenous industries and to keep foreign predators away; that too is banned under TRIMs (Trade Related Investment Measures). In other words, India will have to do without the two major props these East Asian countries used in their journey towards industrialisation. While the western countries and their companies are generally shy about transfering technology to the poor countries, there is a fear that IPR would further reduce such transfer and access to sophisticated western technologies.

IV. MAJOR CHANGES TO NATIONAL PATENT LAWS

As we have already noted, patent legislation has a long history in India. Beginning in 1856, the Indian patent law has been revised a number of times. The latest, the Indian Patent Act of 1970, recognises patent rights for a period of seven to fourteen years. Article 5 of the Indian Patent Act provides that in case of inventions (a) claiming substances intended for use or capable or being used as food or medicine or drug, (b) relating to substances prepared or produced by chemical processes (including alloys , optical glass, semiconductors and intermetallic compounds) no patent shall be granted in respect of claims for the substances themselves , but claims for the methods or processes of manufacture shall be patentable. Even in areas where patent is permitted, the government is empowered to reject patent applications in national interest. Further, to prevent acquiring patent rights solely with the objective of keeping the rivals out, the government retains power to reject patent and/or to make patented products compulsorily available to users.

One major change, introduced by the TRIPs agreement, has been in relation to product and process patents. In Indian patent

legislation a distinction is made between 'product' patent and 'process' patent. The Indian Patent Law of 1970 allowed process patent but not product patent, for food, medicine, agro-chemicals etc. 'Process' means, say for a medicine, the combination of various ingredients—chemicals, medicinal plants, herbs and other biological products , and so on—in specified proportions, and by using a technique or a way of combining those, that makes the production of such medicine possible. It was, therefore, possible for an Indian pharmaceutical company to buy a 'process' of making a particular medicine, in exchange of royalty paid to the patent holder in a foreign country, but then to produce the medicine by using cheap, local material. This way life-saving drugs could be sold in India at a price that is one-twentieth of their price in the developed countries.

But this can not be any more, after 2005 AD, when the Indian patent legislation would be recast according to the universal format. Under article 28 of the TRIPs agreement, this distinction between 'process; and 'product ' patent has been abolished. It is the product that is patented, while the process directly used for making that product is also implicitly patented at the same time. After 2005 AD, the 'product' can not be made locally with cheap materials, and will have to be purchased from the foreign companies at exorbitant prices. If that patented product is produced by following a different process, the onus of proving that lies with the company concerned, while the assumption would be that the existing patented product has been pirated (article 34). The hardest hit from this change would be the pharmaceutical industry and its low income consumers. As Economic Commission for Latin America and Caribbean commented: "The rules on intellectual property are a particular cause of concern, since they may raise the prices of medicines and other patented products in the short run, but may also limit access to new technologies in the longer term." [ECLAC, 1994: 44]. As another expert commented: "As for the impact of life patents on the welfare of Third world farmers, it is evident that patented agricultural technologies (seeds, biocides, etc) will increase production costs." [Vellve, 1989]

Thirdly, under the Indian patent law the maximum period for which patent right can be exercised in 14 years. Now TRIPs has made it uniform and universal at 20 years. This change has come at a time when there are weighty arguments for doing just the opposite —of revising the period of patent rights downwards. These days technologies change much faster, in a matter of three or four years.

To give an example, while radio and gramophone lasted for decades, the black and white TV, coloured TV, cable TV, VCR, multimedia, have come in quick succession, after every four or five years. In this situation, by the time the patent period of 20 years expires, there would be no takers for the obsolete technologies. Even computers do not last beyond 4-5 years, while software packages are revised every two years or so. To revise patent period upwards to 20 years now implies that the MNCs would continue to control technological advance for ever. These MNCs have sufficient money power and brain power to invest in research and development and to perpetually maintain their lead over the less developed countries, so that long before one period of patent would be over another - better and more attractively packaged - product would be launched catering to similar needs.

Fourthly, whereas life forms are not patentable under the Indian 1970 law, after it is amended in line with the TRIPs agreement, it would have to provide patent protection for the plant and animal varieties or to take recourse to a sui generis system that would serve more or less the same objective. Sui generis means something unique or distinct, but serves the same purpose. Among the rich countries nearly all, including USA and Japan opted for patent system in case of plant and animal varieties. The European Parliament was the last, as late as May 11, 1998, to adopt patents on life when a new law on patents on biotechnology was passed. The Indian government is also thinking along those lines.

V. TRANSITIONAL RULES

While, formally, under the Marakesh agreement, the amendment of patent legislation for pharmaceutical and agricultural chemical products can wait until 2005AD, the members of WTO have been asked to make certain transitional changes, as conditions for membership, that would have the effect of practically negating that concession and making the universal format instantly operative. Under Article 70.9, countries are required to grant exclusive marketing rights (EMR), for five years. Under EMR, it would no longer be necessary for a patent holder to apply separately to each country for patent rights. Once a product is patented in any one country, it becomes automatically and universally applicable to all the member countries of WTO, even without any examination of the validity of their claims - in terms of their novelty, non-obviousness and having

practical use — by the country/government concerned. Nor would the country/government be permitted to impose conditions that safeguard the interests of the domestic industry, e.g., by way of compulsory licensing rights. Every country is bound to give exclusive marketing rights to that patent holder, who has obtained patent anywhere in the world, as long as that country is a member of WTO. Given that the overwhelming majority of patents are owned by the rich country companies, the benefit of this provision would accrue overwhelmingly to the multinational companies of rich country origin.

The second condition for WTO membership is popularly known as 'mailbox'. Under transition rules the members are asked to set out application procedures as if such protection are already available. After the transition period had expired, those countries are expected, under article 70.8 of the TRIPs agreement, to grant applications that were filed during the transition period patent protection for the remainder of the patent term, counted from the filing date. This mailbox provision—meaning an arrangement for receiving patent applications, mainly from the multinational countries— assumes that our patent law would be amended by the year 2005 AD, and until then this the government will receive patent applications in order to determine the position of a company in the queue. This is an extra-ordinary piece of legislation that is based on the probability of the passing of another legislation in some future date.

VI. THE ISSUE OF BIO-PIRACY.

A major issue concerns patent rights on seed varieties. Under the TRIPs agreement, plant varieties are expected to be protected in one of the following three ways—by patents, by a sui generis system, or by a combination of the two.

Ever since the conclusion of the Marakesh agreement, prompted by this provision, there has been a mad rush from the large multinational firms to collect germplasms of wild plant varieties located in the less developed countries. Hordes of such multinational agri-business and pharmaceutical firms are descending on India and other countries that are economically poor but rich in biological wealth, and are scouring the countryside, forests and bushes for plant varieties. These MNCs are taking selected specimens out of the country, by means legal or illegal, and then, after some tinkering and cross-breeding with other varieties, producing new varieties that they are claiming to be unique and distinct, and

then patenting those in their own countries. Once patented such varieties become the private property of the patent holder until the time when the patent right expires. Under EMR, if the amendment discussed above is passed, the patent holders of a product patented anywhere in the world would drive out indigenous competitors from the Indian market.

This process of stealing and plundering the biological wealth of the third world countries , which accounts for nearly two-thirds of the total, by the multinational firms originating in the West, has come to be known as 'bio-piracy'. The countries rich in biological wealth and poor in economic terms account for top ranks in terms of mammal, bird and plant varieties. India figures eighth in rank in terms of both mammal and bird species, but no developed country figures among the first eight. Countries topping these lists, such as Indonesia, Brazil, Peru, Mexico, or Columbia, are also ahead of the developed world in terms of diversity of plant variety. Since 1971, a network of gene banks and international centres for the assembly of germplasm collection are operating, and by mid-nineties the number of such centres became 227, spreading over 99 countries that account for 90% of landraces of such crops as wheat, cron, oat and potatoes. But this does not take away the need for the conservation of plant varieties in situ. Ex-situ preservation is possible only for a fraction of the species, and preserve selected species not the ecosystem, and thus risks the loss of speices that are reliant on the symbiotic relationship within an eco-system.

The most talked about case of bio-piracy has been the patenting of neem tree, which is a part of the Indian folk culture and whose medicinal and other properties had been known to the Indian people from time immemorial.. Nor is such patenting confined to Indian medicinal plants : e.g., the male sterile variety of Quinon, a high protein cereal of Andean countries was patented in the United States in 1994, though it was only a discovery. The irony of such patenting is that patented products, processed by the foreign companies, would now have to be purchased by Indians who are used to getting those free in nature. Similar patent rights have been claimed on other medicinal plants—e.g., haldi, salal, dudhi, gulmendhi, bagbherenda, karela, amla, jar amla, anar (pomegranate), rangoon ki bel, castor, vilayeti sisham, chamkura—whose properties had been known to Indians, as in the case of neem, from time immemorial. However, in case of haldi, another highly important plant with medicinal properties, the US medical school was forced

to revoke patent on its use for healing wounds, in 1987, after Indian protest.

Recently Ricetec, a Texan seed breeding company collected some specimens of the basmati rice plants from India and Pakistan, then cross-bred those with some high yielding varieties, and claimed that it had produced a new rice variety. Earlier they were selling their products as 'texmati' (that is basmati of Texas) or 'kasmati' (basmati of Kashmir), playing on the word 'mati' to attract consumers. Now they have dropped those pretensions and are selling their rice as 'basmati' and have patented their product in the United States.

The developed world's double-speak is also revealed in the way they refer to the 'common heritage of mankind'. The developed countries demand that all germplasms be recognised as a public resource and a part of the heritage of the mankind. That would give them the right to collect germplasm in the wild or as landrace varieties without compensation on the ground that these belong to the 'common heritage of mankind'. But, after improving the variety through research and experimentation, they do not hesitate to sell these against payment, to poor countries including those from which such germplasm had been originally collected. This developed country attitude has led the less developed ones to make two specific demands: first, that the companies collecting those germplasms should pay for those to the local communities to which they belong, and, second, in line with the 1993 Convention on bio-diversity, that these should be treated as coming under the sovereign right of a nation and not as something 'international' and belonging to nobody in particular.

One way of countering this type of bio-piracy is to take recourse to the concept of 'prior art', that is some evidence that what is being claimed as 'novel' in the patent application had been known already. The major difficulty here is that the US courts insist on documentary evidence of such 'prior art' that is difficult to find in a society where 'oral tradition' dominates. Another solution to the problem of bio-piracy that suggests itself is to patent the Indian plant varieties in India itself, before it is done by any one else, to save those from poaching. That is to play the game by the rules of these predator firms, but quickly and more efficiently before further damage was done. The snag in following such a step is that patenting involves individualisation of rights, whereas plant varieties like those relating to neem, haldi or basamati were evolved by a large

number of small communities of farmers, spread over a large area, working collectively and sharing their discoveries with others, and over a period of several centuries. How would one find the 'owners' of those plant varieties in terms of intellectual property rights, when all those who played some role in their development—through selection and adaptation of plant varieties, but without erecting any barrier to the flow of information within or between these communities—constituted what could be described as, following Vandana Shiva, 'Intellectual common' ?

Many argue that life can not be patented, or otherwise subjected to individual ownership; companies like Ricetec are not 'inventing' anything, but are merely 'discovering' what had been known in India or Pakistan from time immemorial. These are not like machines to be invented, but life forms that can not be created. Rights on those varieties belong to these communities. Obviously communities, working separately and independently, can not exercise their rights on their own and protect those against agencies such as MNCs which are out to encroach on those. In a sense the government of a country holds that sovereignty as the custodian of the interests of those communities and individuals living in those. Several UN resolutions, such as the 1975 UN resolution on Towards a New International Economic Order, and the 1993 Convention on Bio-diversity had recognised those rights of the governments over natural, mineral and biological resources.

One opinion is to work out a balance between the right of access by foreign firms for the purpose of what they describe as 'bioprospecting' and the recognition of the right of the commnity to this biological resource. About a quarter of the pharmaceutical products marketed by the US firms are plant-derived, but the communities remain unpaid despite such massive use of their resource. Some would prefer some compensation, or benefit-sharing or royalty to be paid for this use to the community. [Swanson, 1997: 103] Some others are skeptical that adequate compensation can be estimated or paid given the gross disparity between the two sides—the community and the company in terms of resources, knowledge and influence.

On the other hand, there are those who feel that, without some form of recognition of individual rights—in the form of patent or some *sui generis* system—given the international climate, India would lose out. The international climate was not that unfavourable

until recently as, unlike United States and Japan, Europe did not recognise patent on life form. The European patent law, under article 12(1a) excluded for ten years from joining convention, food and pharmaceutical products as such and horticultural and agricultural processes in general. India and other third world countries could seek and possibly obtain the powerful support of the European countries during TRIPs review in 2000 AD. Patent laws in every European country, based on European Patent Convention (EPC), excluded in absolute terms patents on plant and animal varieties in order to preserve free access to research and develop a diverse range of options. But, since 11 May 1998, Europe has accepted patenting of life form.

VII. SUI GENERIS, PLANT VARIETY LEGISLATION AND UPOV

As things stand now, following the TRIPs agreement, India will have to provide patent protection to plant varieties by 2000 AD, or choose a sui generis system, or a combination of both. Sui generis system is something that is unique, that a country has adopted on its own, but which provides protection to plant varieties. This provision sounds quite generous, but when it comes to brass tacks, it does not make much difference from the patent system. As in the patent system, the understanding in Fund-Bank-WTO circle is that sui generis too would allow for individualisation of rights on plant varieties. Establishment of private property in village common, water, plant and other major inputs of agriculture, and even on national parks and highways, in place of communal ownership, is considered by this trinity to be essential for safeguarding environment. A combination of privatisation of rights, appropriate pricing that reflects the scarcity value of a product, and an efficiently functioning market, they claim, can solve all the environmental ills. Since we have elaborately discussed this issue elsewhere, here we are desisting from engaging ourselves in an analysis that would show why this view is wrong, and is indeed dangerous to our biological wealth.

One alternative usually suggested in India, as a kind of sui generis, is to adopt UPOV (International Plant Breeders' Rights Convention), a soft patent regime that arose from an international convention in 1961, supported by 37 countries. UPOV was twice amended, in 1978 and again in 1991, and the option to join the

1978 option closes in April, 1999. The official arguments given in support of UPOV are as follows : (a) that it would give the country two alternatives—UPOV and WTO-led TRIPs—to choose from , (b)that this would encourage investment in plant breeding from domestic and international sources, as breeders would get protection with minimum formalities and costs, and (c) that it would help to avoid numerous bilateral agreements, while the need for a sui generis in place of patents would be satisfied.

A major criticism of UPOV is that it protects the interests of the plant breeders, by giving it monoply rights that are analogous to patents, while ignoring those of the farmers and making those secondary to the former. Under its 1991 version, if the farmer fails to pay royalty his harvest can be seized by the breeder. The right of the breeder over the plant variety is an individualised one, while the community rights have been ignored and the right to reuse and exchange seed by the farmers has been severely restricted. UPOV too is in conflict with CBD, as uniformity of seeds is a criterion for the recognition of the rights of the breeders. A major reason for concern is that already 40% of the seed market is in the hands of ten companies, and UPOV might reinforce this tendency towards concentration. This would give MNCs legal ownership of plant varieties that contain genetic information obtained from farmers' own fields, obtained in many cases without paying any fee.

There are complains that plant breeders are charging high prices under UPOV. This international agreement has allowed plant breeders to claim exclusive marketing rights in varieties developed them by crossing the previously existing ones. This has revealed a serious dichotomy - whereas access to raw germsplasm, gathered from the poor countries and stored in gene banks is virtually free, the improved germplasms patented in the rich countries by rich country companies are being sold to the less development countries at high prices. This controversy led, in 1986, to the less developed countries' seeking recognition of 'farmers' rights', and for an international mechanism to give effect to it, though so far nothing concrete has been done to achieve this.

VIII. BIO-DIVERSITY LEGISLATION

A bio-diversity legislation is expected to fulfil two requirements : (a) conforming to Convention on Bio-diversity (CBD) of 1993, and (b) safeguarding Indian biological wealth against bio-piracy.

The first draft prepared by the Ministry of Environment, after wide consultations, was brushed aside and a new draft was prepared on the basis of the report of an expert committee, headed by Dr. M S Swaminathan, the famous agricultural scientist. The draft gives easy access to foreign firms , including those to 7500 highly valued indigenous medicinal plants, in exchange of a fee to be paid to the community in the name of 'benefit-sharing'. Though it is projected as an attempt to balance the rights of the foreign firms to have access with those of the communities where such plant varieties are located, as in most other cases , there can be no level playing field between the two sides. The idea of benefit-sharing would allow the all-knowing and powerful multinationals to pay a small amount to the innocent and unknowing communities having no idea of the economic price of their resources, in order to gain the right of 'bio-prospecting' and thus to arrogate to themselves the rights of these communities. In the long run, this benefit-sharing might force India to pay out a great deal more in the form of royalties for buying those plant varieties, now patented elsewhere, than what the country would obtain from such paltry 'compensations'. One suggestion is to force the companies concerned to compensate the farmers from a fund created from royalties earned from such patents by the companies.

Further, this draft does not explicitly recognise communities, but talks about 'persons' with whom benefits would have to be shared by the companies. The amount of compensation for access, to be paid by the foreign companies, would be decided by a national bio-diversity authority to be set up under the bill. It also stands in contrast with an article in Panchayat (extension to the scheduled areas) Act of 1996 that provides that state legislation should be in tune with traditional management practices relating to community resources. Worse still, it does not explicitly take into account national sovereignty and indigenous knowledge, and, in the name of conservation, might even be used (as in the case of forest legislation) to deny access to the local communities.

IX. ROLE OF MULTINATIONAL AGRI-BUSINESS FIRMS

In India, there is still little awareness of how powerful, and how potentially harmful, these multinationals are. These are very large entities, the largest among them having annual turnover fig-

ures that are close to the national income of a country as big as India with 96 crore people. They offer the highest salaries and, therefore, attract the best of brain-power in the world: engineers, mathematicians, chartered accountants, managers. Because their tentacles are spread to practically all the countries of the world, through affiliates and subsidiaries, they aim at profit maximisation at the global level, often at the cost of the interests of the host nations, and can effectively hide their illegal transactions in terms of 'book-keeping' transfers between affiliates.

They also operate vertically—in case of an oil company, from searching for oil to its marketing through development, production, refining and transporting—and also horizontally, in collusion with other oligopolistic corporate giants operating in their fields. Empirical evidence amply confirms their refusal to transfer technology or in bearing risk in entirely new areas. The Indian enterprises would be no match for them in competition, and there could be no level playing field between these giants and the Indian dwarfs, as observed by Mahatma Gandhi in another context.

The new patent regime would provide them with monopoly to sell their commodities in Indian market, and no Indian or competing foreign enterprise would be able to market those in India. Product patent rights together with the monopoly marketing rights in the hands of the multinational companies would become a lethal combination that would destroy Indian industries and eliminate any hope of achieving self-sufficiency or development The period of patent, at 20 years, would be too long, and, by the time it ended, the multinational companies would be ready with some new, more fashionable, more attractive and more user-friendly to reduce the release of patent right to a matter of no consequence. In East Asia the governments carefully kept these predators out of the way of the nascent indigenous enterprises in the same field, by invoking 'local content requirements' that made heavy demand on the foreign enterprises in terms of deployment of local manpower, material and so on, or by high tariff, prohibition or quota restrictions. Such local content measures can not be implemented now by India, as TRIM (Trade related Investment Measures) under Marakesh agreement rules out those and demands that the foreign companies be accorded 'national treatment' and no discrimination be practiced against them.

Even during the British colonial rule the British economic

interests seldom directly participated in agricultural production, except in plantations located in sparsely populated areas. Now they are planning to enter India's countryside in a big way, by taking part in waste land development and also by linking their processing activities (e.g., with respect to tomato) with direct agricultural production. As they have done in other countries, they will follow two parallel systems - plantation and contract production. In plantations they will work with their own hired labour, while under the contract system they would give inputs and technology to the contract farmers, would expect them to operate under their specification and norms, and to deliver their products to the company. The prices of both inputs and outputs would be determined by them and imposed on the farmers, who would lose their independence.

Apart from production directly linked to processing, for the rest of the agricultural economy the multinational agribusiness firms wish to become the main supplier of seed and other inputs. Here too they would try to make the farmer completely dependent on their supply. Recently, these agree-business companies have developed what is significantly known as the 'terminator technology'. This technology makes the seeds sterile , that is incapable of being used for the second time for germination. The objective behind developing this technology is not to allow the peasants to use the same seed again and again and to force them to go back to the multinational companies for new seeds every year. While agricultural is synonymous with regeneration, renewal and reproduction, this technology strikes at the base of such predominant features of agricultural life making seeds infertile and unsuitable for multiple use. More dangerous is the fear that, even in cases of those who do not use this 'terminator' seed, pollens from the latter would spread over a very large area and would make even other seeds infertile.

Apart from the terminator technology, those relating to fertiliser and chemicals are also making the peasants further dependent on MNCs for supply in place of self reliance practised in the past. They are developing weedicides that are specific to a particular seed variety that it would not harm. Such weedicides would make it possible for the farmers to spray chemicals even when the crop is standing. Similarly, fertiliser and pesticides specific to a particular seed variety is being produced. In other words, the farmer would be forced to depend exclusively on a package of seeds, chemicals and fertilisers supplied by a particular MNC.

Over time, the concerned MNC, by investing an enormous amount on R & D, will do everything to make the peasants perpetually dependent on it, by producing new packages every few years. As we have noted, in the background of the spate of suicides in Punjab and Andhra, many of the chemicals are spurious and adulterated, while often these MNCs push the farmers to use chemicals more than is good for the plant itself. In the mid-1980s, 30 farmers of two of the most prosperous cotton growing districts of Andhra committed suicide because the pesticides killed off the main target pest, which allowed other pests suppressed by the main paste grow at an alarming speed and destroy the crop.

X. TRIPS REVIEW IN 1999

What should India's position be on this issue? It is possible to take a mini-max approach, striving to undo as much of the damage done to us as possible, while keeping an eye on the minimum that can be achieved even within the WTO framework should a drastic revision of the Marakesh agreement becomes politically infeasible. Much depends on the political will of the government. While conforming to the 1994 Marakesh agreement and recasting the domestic patent law in line with the international patent regime, there is some room for maneuver by making skillful use of some of the articles of the agreement. Virtually all patent laws exclude mere ideas or theories; patents are intended to apply to the embodiment of those ideas. The national laws can be so drafted that the flow of ideas is not obstructed.

Further, under articles 27.2 and 27.3 of the Marakesh agreement, the countries may deny patent protection., for reasons of public order, morality or for protecting human, animal or plant life or for protecting environment. Protection can be denied for certain inventions such as those which involve "diagnostic, therapeutic and surgical methods for the treatment of humans and animals, and plants and animals (other than microorganisms) and biological processes (other than microbiological processes) for their production". [UNCTAD, 1994: 189; Schott, 1994: 118] Reference to public order and morality virtually permits the member countries to do what they had been doing already , as being acceptable to public morality. 'Immorality' can means things like obscenity, blasphemy, breach of peace and immoral activities, while the French counterpart of 'public order', 'ordre public' is closer to 'public policy' than to 'public order'. The United Kingdom used this provision to refuse a patent on contraceptive device twice. Until now there has been a tendency on the part of the Indian government to go overboard in their enthusiasm in implementing the Marakesh agreement, e.g., on subsidy withdrawal. This tendency has to be reversed.

Under the Marakesh agreement, article 27(3)(b) of the TRIPs agreement was to come for review in 1999. Now that review has been postponed till April, 2000. Still it is only about a year away. This review will give the less developed countries the opportunity to rectify at least a part of the injustice done to them during Dunkel negotiations of 1991-93, and the Marakesh agreement of April, 1994, and to create a momentum for further and more drastic changes in their favour in the future years. The bargaining power of the poor countries was at its lowest, following the disintegration of the Soviet Union, when the Dunkel negotiations were going on, and the third world countries including India played virtually no role in pushing their own interests. Whatever negotiation was conducted was between Europe and the United States, with Japan also playing a vital role. Among the third world countries only the East Asian ones—South Korea, Taiwan, Hong Kong and Singapore—were consulted some times, but not India or other countries. The Marakesh agreement was imposed on them as a fait accompli. By now, in 1999, the world environment has changed , and the Southeast Asian crisis has exposed the hollowness of the theology of the unholy trinity of World Bank, IMF and WTO. There is now a greater understanding of the harmful implications of Marakesh and WTO among the third world countries.

What India can do to rectify the injustice of 1994-95? The answer is : India alone can do little. In world trade negotiations, more than the number of countries on either side of the argument, what counts is the share of a country in world trade. India's share is a dismal half of one percent, between 0.5% and 0.6%. At the time of independence it was 2.7%, that is five times more. The long reign of the Congress party governments over the last half century has successfully brought down India's share to this shamefully low figure. But while India alone can do very little, it can combine with others to do a lot. Rather than being brow-beaten by the United States and WTO and bending our knees, the time available now should be used to mobilise opinion among the third world countries so that the TRIPs review of 2000 AD becomes favourable to the poor countries. India has to play a leadership role, a role that India played in

the Fifties, and one that small countries like Sri Lanka or Bangladesh can not play. And pending that review India should not give in on a crucial matter like these two WTO preconditions on EMR and Mailbox, that will weaken our resolve and bargaining power.

The very first step should be to form a South Asian Common Market or Free Trade Association (SAFTA). During the United Front regime these countries agreed to make SAFTA operational by the year 2000 AD, and a great deal of progress was achieved in terms of identifying complimentary trade possibilities. A major fall out of the mushrooming nuclear cloud of Pokhran has been to undermine the efforts of the United Front government, to build bridges with India's neighbours, leading to the establishment of a South Asian Common Market by 2000 AD. The trust needed for such economic cooperation has virtually disappeared since. Still, there can be no retreat from such a goal. Such customs unions or trade blocks allow, even within the framework of WTO, trade concessions to block members that are not otherwise available. Such advantages are taken by the developed countries who have formed their own trade blocks - such as European Union or North Atlantic Free Trade Association (NAFTA).

There are also similar trade blocks among third world countries, e.g., ASEAN of South-East Asian countries, Andean Pact of some Latin American countries, CACM (Central American Common Market), Caricom(Caribbean Community), Mercosur (Mercado Caomu del Sur), and, in Africa, PTA (Preferential Trade Area for Eastern and Southern Africa), UDEAC (Union Douaniere et Economique de l'Afrique Centrale) and West African states. There is no reason why we should not do what others are doing already, by taking the leadership in forming a trade block of South Asian countries. Once such a block is formed it will be easier to negotiate with ASEAN, Andean Pact or OAU (the Organisation of African Unity) for forming a bigger trade alliance. Negotiations can also be initiated within fora like G15, G77, and with countries like China, Brazil and Russia, as well as the European ones such as Italy, Belgium, Denmark and Holland, to create a new international climate to amend, if not to eliminate entirely, injustice done to the poor countries by way of 1994 Marakesh agreement.

XI. CONCLUSIONS

This paper, dealing with various implications of the proposed changes in patent legislation under the TRIPs regime, underlines the serious risk of total technological dependence on foreign MNCs that India and other poor countries carry. It also proposes what India can do, by mobilising third world opinion during the coming review of the TRIPs agreement , to rectify, at least in part, the injustices that have been done to them by the Marakesh agreement of 1994. A major implication of this paper is to reject the two major, and mutually contradictory, rationale behind India's meek compliance with TRIPs—that (a) India has nothing to fear from internationalisation; it is so full of intellectual power that, by taking advantage of the new patent regime, India can flood the world market with its own patents, and (b) India is weak, can not take on the economic might of the West, and has to take the transitional rules and other aspects of the TRIPs as a fait accompli. The government has carefully avoided a national debate on this issue, despite pleading by the Law Commission and various research bodies for an in-depth clause by clause examination of the proposed changes, scared as it is of informed public opinion on such a sensitive issue that has irreversible, harmful bearings on the future course of India's development. Nor has it incorporated in the recently passed patent amendment bill the safeguards that even TRIPs agreement embodies, or followed the US policy of disregarding international legislation that is inconsistent with national law or self-interest.

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Indian Pharmaceutical Industry: Effect of Proposed Product Patent Regime

Amit Sen Gupta

US statesman Thomas Jefferson remarked, "Ingenuity should receive a liberal encouragement". Jefferson introduced the first patent bill to the US Congress in 1790. It became the Patent Act, upon which US patent and trademark law is built. His comment sums up a popular notion of intellectual property rights, one that is promulgated to a large extent by industries. Discoverers and inventors are thought to deserve special reward or privilege because of the benefit of their discoveries or inventions to society. Benefiting society is not considered a reward in itself, and, true to classical economic theory, certain incentives are needed to encourage invention or innovation.

The strongest proponent of strengthened intellectual property provisions as part of the World Trade Organisation (WTO) is the United States. Not coincidentally, the companies most concerned about intellectual property are U.S.- based. Individual companies, as well as industry groups like the Pharmaceutical Manufacturers Association (PMA) and the Intellectual Property Committee (IPC), a coalition of 13 major U.S. companies, including IBM, DuPont, General Motors, Merck and Co. and Pfizer, had strongly lobbied with the U.S. Govt. on intellectual property issues.

The industrialized and developing countries' conflict over intellectual property protection of pharmaceuticals mirrors the broader conflict over protection for high technology. High technology multinationals claim "imitation goods", many emanating from the Third World, cause them to suffer large losses. The industrial countries do not say, however, that in order for the multinationals' to recover those 'losses' a massive transfer of income from the poor countries to the rich would be required. Third World countries dispute these claims. They point to the historical record of the industrialized countries, most of which did not have strong intellectual property laws when they were developing. For

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example, the United States in the nineteenth century and Japan through most of the twentieth engaged in exactly the sort of activities the United States now labels piracy. More recently, the "four tigers" of East Asia -- Taiwan, South Korea, Hong Kong and Singapore -- industrialized with the help of weak intellectual property protections.

The WTO agreement includes provisions which require changes to be made in the Indian Patents Act of 1970. Such changes would have a direct bearing on the Drug Industry in the country. In fact the Indian Drug Industry has especially been targeted by the Pharmaceutical MNCs for alleged violation of the principles of "free trade", which supposedly provides the philosophical underpinning of the WTO agreement. It is another matter that the principles of free trade in an unequal world are designed almost entirely to benefit those who are more equal than others, namely countries in N.America, Europe and Japan. Moreover a strong Patent regime, as outlined in the WTO agreement is harmful to the interests of not only the Third World but also a large number of people in the developed world.

Intellectual property rights (IPRs) come in five varieties: patents, plant breeders' rights, copyrights, trademarks and trade secrets. This paper seeks to focus on the area of patents, and more specifically on the possible impact of a change in the 1970 Indian Patent Act, in line with the WTO agreement, on the Pharmaceutical Sector in India. The major substantive change being sought by the U.S., European Union and Japan in the Pharmaceutical Sector is a switch to a Product Patent Regime from the present Process Patent Regime. The shift from a process patent regime to the recognition of an exclusive right on production and commercialization, is likely to lead to changes in the market structure and in the conditions for access by consumers to pharmaceutical products. The implications may be examined with regard to drug prices, impact on health care and self reliance in the Indian industry:

Impact on Self Reliance

The Indian Drug Industry has built up a base for production of almost all bulk drugs from basic stage using innovative process technologies. A major role has been played by various CSIR laboratories. This has been possible because of Indian Patent Act of 1970 which allows Process Patents and not Product Patents in the area of vital areas including drug production. One of the proposals in the WTO agreement

requires India to change its Patent Act to include Product Patenting for a period of 20 years. If the Indian Patent Act is changed in line with the WTO agreement, in one sweep this base will become meaningless. Today the Industry is not, by and large in a position to invest in development of new product technologies. Investment required to develop a new product with definite therapeutic advantage is far in excess of the total turnover of most Indian companies. Compare the present R&D expenditure of about 100 crores annually to the estimated cost of development of a new drug, which is about $ 300 million or roughly Rs. 950 crores. In fact, anticipating change in the Patent Act many MNCs have closed down their R&D facilities in India. These include the facilities run by Ciba Geigy, Boots, Hoechst and Rhone Poulenc. Many have also started the process of winding up their bulk drug manufacturing facilities in the country, anticipating change in the Patents Act. For such a change, where importation would be seen as working of a "patent", would mean that the interests of MNCs are better served if they directly import drugs and earn "super" profits through the time tested method of "transfer pricing". A change in the Patents Act will greatly help MNCs, who control new product technologies, to take over the Indian market and "rig" drug prices and drug availability at will.

There is a danger of regressing to the pre 1970 situation when the Indian drug market was controlled by MNCs and drug prices in the country were one of the highest (in real terms) in the world. The American Senate Committee (Kefauver Committee) had in fact cause to comment on this situation in the 1950s[3]. The situation then was to an extent saved by the development of a strong Public Sector (HAL & IDPL) especially in antibiotic production. With progressive emasculation of the Public Sector even that "safety net" does not exist. Today the Global Drug Industry is poised for a new "revolution", using biotechnologically engineered drugs. At this stage if we change to a product patent regime, we shall eventually hand over the Indian Drug market to MNCs who control this new emerging technology. A major section of Indian Industry in the pharmaceuticals sector had opposed a change in the Indian Patents Act of 1970. But today some have changed track and many seem ready to follow suit. They see an opportunity in tying up with MNCs as junior partners to target the huge generics market in the United States. While this may provide some immediate benefits to a few Indian companies, in the long run their very survival is at stake as

the "uncaged" MNCs prepare to take over the Indian Market once again.

Implications of a product patent regime are not limited only to the area of technological self reliance. Technological dependence on MNCs is the proverbial "thin edge" which will be used by MNCs to establish their suzerainty over the Indian Drug market (a position they had lost after the mid seventies). They will then again start charging exorbitant prices for drugs in the Indian market. If we refer to Table I, we can see that between 1985 and 1996 the categories of drugs which show the maximum rise in sales are categories which include overwhelming majority of drugs still under Product Patent or whose Product patents have expired recently. In other words if we had a product patent regime today, the drugs showing fastest growth would have been priced way beyond the capacity of the average consumer.

It has been argued in certain circles that by agreeing to change the Indian Patent Act, essential drugs will not be affected. This again is not borne out by facts. It needs to be remembered that there is no absolute entity called essential drugs. New drugs are constantly being introduced and old drugs become obsolete. It is totally unacceptable to argue that the poor people of India shall have to remain satisfied with old near obsolete drugs even when better alternatives are available in the World Market.

Impact on Health Care

Let us examine here three real scenarios which affect the poorest in this country - all possible fallouts of changes in the Indian patents Act.

1) There is today a resurgence of Tuberculosis in the world related to AIDS. These new cases are almost always resistant to conventional ant-T.B. drugs and require treatment with new generations of ant-T.B. drugs - all of which are under patent protection. India accounts for the largest number of T.B. cases and even today half a million die of T.B. in the country. Can we safely ignore the disaster if this virulent form of T.B. sweeps across the country and our patients are deprived of these life saving anti-T.B. Drugs because we have sold our souls - and much more - to the WTO?

2) Falciparum Malaria, the most virulent form of the disease, is already rampant in the country. Many strains are already resistant to

Table 1 : CHANGING PATTERN OF RETAIL DRUG SALES -- 1985 TO 1996 (Figures in '000)

	1996		1992		1989		1985		
Therapeutic Group	Value	percent	Value	percent	Value	percent	Value	percent	% change (1985 to 1996
QUINOLINES	3187521	4.72	1744458	4.53	-	-	-		
CEPHALOSPORINS	2576634	3.81	1254401	3.26	477457	2.27	83463	0.71	2987.16
ANTI DIABETIC	1160849	1.72	493109	1.28	213649	1.02	99045	0.84	1072.04
CARDIAC THERAPY	2395296	3.40	1147929	2.98	470153	2.24	212344	1.80	980.93
ANTI EPILEPTICS	706373	1.05	340099	0.88	186716	0.89	65655	0.56	975.89
ANTIEMETIC	922188	1.36	369529	1.01	201848	0.96	91296	0.78	910.11
HYPOTENSIVES	991801	1.47	433982	1.13	175848	0.84	104781	0.89	846.55
ANTACID etc.	3030905	4.48	1790065	4.65	898627	4.27	375779	3.19	706.57
MACROLIDES	1301584	1.93	652952	1.70	384703	1.83	161929	1.38	703.80
SYSTEMIC ANTIHISTAMINE	1163986	1.72	684380	1.78	293214	1.39	149402	1.27	679.10
AMPI/AMOXY/CLOX	4247658	6.28	2515369	6.54	1263622	6.01	551748	4.69	669.85
COUGH & COLD PREP.	3855555	5.70	1857988	4.83	1086320	5.17	525252	4.46	634.04
PSYCHOLEPTICS	1151355	1.70	638270	1.66	278028	1.32	161563	1.37	612.64
ANTI ASTHMATIC	1442635	2.13	775677	2.02	424128	2.02	210292	1.79	586.02
ANTI INFLAM/RHEUM	3748957	5.55	2217417	5.76	1176726	5.60	570355	4.84	557.30
TOP. CORTICOSTEROID	1457866	2.16	794162	2.06	445001	2.12	255329	2.17	470.98
SEX HORMONES	1278522	1.89	766729	1.99	370927	1.76	236159	2.01	441.38
HEPATIC etc.	682436	1.01	365949	0.95	225622	1.07	132601	1.13	414.65
MINERAL SUPPLEMENTS	682512	1.01	392072	1.02	211761	1.01	139393	1.18	389.63
GENERAL NUTRIENTS	1305410	1.93	758531	1.97	519279	2.47	268550	2.28	386.10
VITAMINS	4160010	6.15	2353495	6.12	1486687	7.07	945837	8.03	339.82
ANTI T.B.	2221193	3.29	1493832	3.88	757107	3.60	507538	4.31	337.64
SYS. CORTICOSTEROID	1079769	1.60	554532	1.44	332000	1.58	255455	2.17	322.68
ANTIANAEMIC	1830572	2.71	1038274	2.70	699183	3.32	436898	3.71	318.99
ANTI PARASITIC	1959325	2.90	1166858	3.03	749532	3.56	467818	3.97	318.82
ELECTROLYTES (ORAL & IV)	637097	0.94	449930	1.17	278316	1.32	158792	1.35	301.21
ANALGESICS	1798505	2.66	1144683	2.98	676147	3.22	448946	3.81	300.61
ANTI SPASMOD/CHOLINERGIC	798395	1.18	426096	1.11	306164	1.46	203501	1.73	292.33
ANTI DIARR/ DISINFECT	942429	1.39	551739	1.43	313923	1.49	248497	2.11	279.25
DIGESTIVES INC. ENZYMES	858835	1.27	545152	1.42	357894	1.70	246946	2.10	247.78
TETRACYCLINES	1083589	1.60	737617	1.92	508635	2.42	398557	3.38	171.88
TRIMETHOPRIM COM.	964931	1.43	961144	2.50	751962	3.58	508440	4.32	89.78
TONICS	569014	0.84	460426	1.20	412360	1.96	359902	3.06	58.10
TOTAL	67592595	100	38471053	100	21030743	100	11775823	100	473.99

Source: ORG Retail Audit for relevant periods

conventional drugs like chloroquine (including a large number of cases detected in the capital city of Delhi every year). New drugs are being developed, *but again they will be under patent protection.*

3) Enteric Fever (Typhoid) resistant to the conventional drug - Chloramphenicol - is widespread in the country today. Some studies indicate that in some regions 40-50% cases are resistant. In such cases the drug of choice is Ciprofloxacin - a new drug which is still under patent production but is being manufactured in India using new process technology. The price of the drug, which started at Rs.24 per tablet has already come down to Rs.8. This could not have happened under a Product Patent regime.

These examples are indicative and not exhaustive. But they illustrate that a strict Product Patent regime is not designed to serve the interests of a vast majority of the people. This is true even for a bulk of people living in the developed North. In the U.S. a major concern today is the spiralling rise in drug costs that has pushed health care beyond the means of a large number of poor people. In Canada state run hospitals are facing closure due to the huge rise in drug prices as a result of changes made in Canada's Patent Act. Before any changes are made in the Patents Act of 1970 we would do well to ponder on such, and other, global experiences that are unfolding today.

Impact on Drug Prices

A major element of the campaign against changing India's Patent Laws, in order to comply with requirements of the WTO agreement, has focused on the alleged fact that Drug Prices are lower in India than other countries. Hence, it has been argued that a change in India's Patent system would lead to massive increase in the prices of Drugs.

While a lot of rhetoric has been used by both sides in this debate, the claims and counter-claims have not always been based on hard facts. In order to put this debate in its proper perspective, an analysis of comparative prices of Drugs in different countries is presented here. The countries chosen include four developing countries from South Asia - India, Bangladesh, Pakistan and Sri Lanka, and two countries from the developed World - Canada and U.K. The countries of South Asia were chosen as they, broadly, are at similar stages of development and their

economies function under familiar constraints. The two countries with developed market economies are similar to the extent that both retain strong state support to health care and have mechanisms to regulate cost of health care including those of drugs. India with its liberal Process Patenting system as regards to pharmaceuticals (now under suspended animation) is the only country in this study not to have a Product Patent regime as yet (if one discounts the 1995 amendment which could not by passed by Parliament).

Drugs chosen for the analysis fall under two groups. The first group comprises of six drugs - Amoxycillin, Co-Trimoxazole, Diazepam, Erythromycin, Frusemide and Propanolol - which have been in the market for a long time and are not under patent protection (process or product) in the countries analysed. While an analysis based on these six drugs cannot be termed as exhaustive, they are fairly representative of the drugs in the Indian market. Of the 5 top selling products in the Indian market, formulations made of these drugs account for 3, and of the top 20 these account for 7 viz. Althrocin, Septran, Roscillin, Novamox, Mox, Ampoxin and Voveran. Althrocin - a formulation of Erythromycin - is the top selling brand with an annual turnover of Rs.4.24 crores. The second group is comprised of three newer drugs - Ranitidine, Diclofenac and Nifedipin - which are still under Product patent outside India or have come off Patents only recently. These drugs too are fairly representative with formulations based on two of them - Zinetac containing Ranitidine and Voveran containing Diclofenac - being listed at the 6th and 20th places respectively among top selling products in the ORG Retail Survey.

The retail prices of these drugs have been compared in the six countries. Where different brands have varying prices, the lowest price has been taken for purposes of comparison. In order to show the relative position in different countries, average cost of each basket of drugs (comprising of 6 drugs in the basket of older drugs and 3 drugs in the case of newer drugs) has been computed. This computation was done by taking the price of each drug as 1 unit in the case of India. Based on this the relative cost of each of the drugs in the countries studied have then been calculated, and a mean value for each basket calculated from this. To show the real impact of drug prices the relative cost and mean cost, adjusted against the GDP per capita has also been shown.

The analysis is shown in Tables II and III. We see from Table II that the average cost of older drugs is the highest in India. The cost is 3 times that in Sri Lanka and even higher than in U.K. and Canada. Adjusted against GDP per capita, cost of these drugs works out to be 5 times that in Sri Lanka and 12 to 16 times that in U.K. and Canada. The position is the complete reverse in the case of newer (Patent Protected) drugs. Table III shows that in the case of these drugs, prices are lowest in India. These drugs are 3 to 13 times more expensive in the other countries studied. Even when adjusted against GDP per capita the cost of these drugs work out to be the cheapest in India.

This interesting outcome exposes chinks in the arguments put forward by the two contending Industry Associations in the pharmaceutical sector in India - the Indian Drug Manufacturers Association (representing Indian Companies) and the OPPI (representing Multinational Companies). IDMA has consistently argued that drug prices are the lowest in India and a change in Patent Laws would reverse this position. The above analysis clearly shows that drug prices are lower in India only in the case of Patent protected drugs. We find from our study that in the case of other drugs, prices are higher in India than even developed industrialised countries. Given the fact that drugs in the Indian market, which are under Product Patents globally, account for only 10-12% of total pharmaceutical sales, this means that by and large Indian drugs are costlier.

This is indeed a strange situation as logically India should have an edge over almost any country in the world in this respect. Unlike Pakistan, Bangladesh and Sri Lanka India has the indigenous capability to manufacture most drugs. Further economies of scale should favour Indian manufacturers in comparison to these South Asian countries, given the much larger size of the Indian market. Compared to U.K. and Canada, Indian manufacturers enjoy the advantage of much lower infrastructural and labour costs. A conclusion one can draw is that the Industry in India is either unwilling or incapable of passing on the results of these gratuitous circumstances to the consumer. In fact, to the contrary, companies in India (both Indian and MNC) have receive a further bonus in 1995 in the form of the new Drug Price Control Order, where price control mechanisms have been further relaxed by drastically reducing the span of control and by increasing the profitability allowed

Table 2: Comparative Costs of Older Drugs
(Not Patent Protected)

	COST IN $ OF 100 UNITS (Tablets /Capsules)						Av. Cost for basket of 6 Drugs where cost in India=1*	Real GDP Per Capita in Dollars (1991)	Adjusted Cost of basket of 6 Drugs (according to GDP/capita)**
	Amoxy-cillin	Cotrim-oxazole	Diazepam	Erythro-mycin	Fruse-mide	Propal-olol			
INDIA	9.00	3.00	3.00	12.00	1.00	3.00	1.00	1510.00	1.00
BANGLADESH	6.00	3.00	—	10.00	1.00	1.00	0.77	1160.00	1.00
PAKISTAN	5.00	3.00	3.00	5.00	0.60	1.00	0.65	1970.00	0.50
SRI LANKA	4.00	1.00	0.14	5.00	0.60	0.60	0.34	2650.00	0.19
CANADA	8.00	6.00	0.50	6.00	0.50	—	0.81	19320.00	0.06
UK	7.00	5.00	1.00	6.00	—	—	0.82	16340.00	0.08

Source: Retail Drug Prices in the Asia-Pacific region, K.Balasubramaniam, HAI News, December 1995 and MIMS, India for relevant period.

* Calculated by taking cost of each drug in India as 1 unit and computing the relative cost in other countries. Then the average of the basket of drugs has been taken. Where data for all drugs not available, average computed on the basis of no. of drugs on which data is available

** Calculated by multiplying average cost with the ratio of GDP per capita in India, with the corresponding figure for each country. This gives a rough measure of the financial impact of buying drugs in each country.

Scheme. The scheme's objectives are to secure the provision of safe and effective medicines to the NHS at reasonable prices. The scheme was renewed in 1993 for five years and is currently under review. The House of Commons Health Committee has now recommended that the criterion of comparative cost effectiveness (as is in vogue in Australia) should be adopted by the NHS before it agrees to pay for new drugs.[3]

Present Trends in Pharmaceutical Industry

In the last two decades, while the Indian Drug Industry has grown considerably, a several disturbing trends are discernible. As these trends would have a bearing on changes within the Industry in case the Indian Patent Law of 1970 is changed to allow Product Patents in Pharmaceutical, a discussion on some of these trends would serve to highlight some relevant concerns.

Emphasis on Expensive Drugs

Most manufacturers are vying for the up-market section of the Indian consumer who can pay heavily to 'buy' health care. Production of expensive drugs outstrip demand while less expensive drugs are in short supply (see Table 4) Thus the indifference shown by companies towards production of low-cost essential drugs. In doing so the Industry is also in danger of falling into a self-destructive loop where 1000 manufacturers fight for the market for drugs among 5% of the population who can pay. This acts as a major constraint to further development of the Industry. With a Product Patent regime, such a trend can only be accentuated, leading to larger sections of the people being "costed out" of the market for drugs.

"Free" Market Ethos of the Reform Process

A study of the production pattern of monitored bulk drugs shows that larger companies are not interested in producing bulk drugs, but rather prefer to act as mere traders and middlemen by concentrating on the formulations market. In such a situation there can be no justification in liberalising production controls, and in fact more stringent production controls are called for.

The logic of the market forces is even less applicable to the Pharmaceutical Industry than other sectors. Unlike consumer goods, drugs are not purchased by the consumer on the basis of his choice or preference. They are purchased/ consumed on the advise of the medical pro-

Table 4 : DIFFERENCES IN PRODUCTION BETWEEN EXPENSIVE AND INEXPENSIVE DRUGS[40]

INEXPENSIVE DRUGS				EXPENSIVE DRUGS			
DRUG	UNIT	DEMAND	PRODN.	DRUG	UNIT	DEMAND	PRODN.
Antibiotics							
Penicillin	MMU	330.00	304.40	Cephalexin	T	121.00	158.66
Chloramphenicol	T	200.00	80.84	Cloxacillin	T	64.00	127.47
Doxycycline	T	13.00	1.89	Amoxycillin	T	201.00	375.04
Pain Killers							
Aspirin	T	2042.00	1624.37	Ibuprofen	T	241.00	736.64
Anti-Leprosy							
Dapsone	T	64.00	12.00	Clofazimine	T	3.20	6.11

fession. The Drug companies have built a market for their drugs through their extensive marketing network. The consumers have little or no choice in such a 'rigged' market and are forced to buy anything and everything that Doctors are 'induced' to prescribe by the 'friendly neighbourhood' medical representative. This is surely not the best climate for market forces to stabilise prices. In a regime where product patents are allowed, market forces will be even more ineffective in containing prices of drugs.

With rapid developments in Science and Technology there has been an explosion in the number of drugs which are available in the market. Unfortunately only a small minority of drugs entering the market offer therapeutic advantage over existing drugs. For example of the 348 new drugs from the 25 largest US drug companies between 1981 and 1988, the US FDA said that at the time of introduction : 3% (12 drugs) made an "important potential contribution to existing therapies"; 13% made a "modest potential contribution; and 84% made "little or no potential contribution". A French study of 508 new chemical entities marketed in the world between 1975 and 1984 found 70% offered no therapeutic improvement over existing products. (5) This, in effect, contradicts conventional claims that better Patent protection leads to introduction of superior therapeutic regimes, and as a consequence, better health care.

Increase in Imports

After having built a self reliant Industry much of the gains are today sought to be frittered away. In recent years import dependence in the Industry has grown (see Table 5).

Table 5 : PRODUCTION, IMPORTS & EXPORTS OF PHARMACEUTICALS (1997-98 - est.)

(FIGURES IN RS. CRORES)

Production of Bulk Drugs	2,623
Production of Formulations	12,068
Exports	3,080
Annual Rate of Growth of Exports (since 1990-91)	18%
Imports	2,711
Annual Rate of Growth of Imports (since 1990-91)	29.3%

Source : Centre for Monitoring of Indian Economy (CMIE)

The excess of exports over imports is an illusion and likely to disappear soon given the much higher rate of growth of Imports in the 1990s. If the above trend continues India may soon become like any 'Banana' Republic, depending largely on imported bulk drugs. The trend of increasing imports can only worsen when Product patents are allowed, especially as the IPR agreement under WTO contains a clause that equates importation as with working of a Patent. That is, the patent holder has no obligation to actually manufacture locally, and has the full freedom to import from his country of origin. The present Indian laws prohibits such activity, and can offer other manufacturers the option to produce locally if the original patent holder refuses to do so.

MNCs Concentrate in Irrational and Inessential Areas

The Govt. would do well to go back to the Hathi Committee report of 1975 detailing the sins of omission and commission of the Foreign Sector in the Drug Industry, when it is set to roll out the red carpet for MNCs. Nothing has changed since then, in fact the situation has worsened. The Foreign Sector are the worst offenders when in comes to production of irrational and hazardous drugs and non production of essential drugs. In fact the Small Scale Sector produces more Bulk Drugs than the Foreign Sector. The measures in the 1978 Drug Policy restricting this Sector, is the single most important factor responsible for the growth of the Indian Drug Industry in general and the Indian Sector in particular. The foreign sector has never in the past brought in new technology and will not do so in the future. Easy access to MNCs through a Product patent regime will only result in emasculation of the Indian Drug Industry. Table 6 shows the comparative contribution of different sectors in different therapeutic groups. It clearly shows the reluctance of MNCs to produce drugs in areas of importance for the health needs of the country.

TABLE 6 : SHARE OF MNCs IN DIFFERENT THERAPEUTIC GROUPS

(figures in Rs.crores)

THERAPEUTIC GROUP	TOTAL MKT. OF TOP 200 BRANDS	SHARE OF TOP 200 BRANDS	SHARE OF MNCs TO SHARE OF TOP 200 BRANDS	% SHARE of MNCs
VITAMINS	345.8	191.0	184.5	96.60
STEROIDs	212.3	102.1	94.6	92.66

NUTRIENTS & MINERALS	163.6	59.5	52.4	88.06
COUGH & COLD & ANTI ALLERGIC	377.3	160.7	129.2	80.40
ANTI-INFLAM./ANALG., & ANTI SPASMODIC	413.4	226.6	150.0	66.18
RUBS & BALMS	48.0	41.1	26.6	64.96
ANTACID etc.	259.9	143.1	84.5	59.04
ANTI ANAEMIC	145.4	61.6	29.0	47.03
DIABETES, CVS., EPILEPSY, etc	422.6	134.9	56.3	41.77
ANTI ASTHMATIC	123.5	27.6	11.1	40.22
ANTIBACTERIALS	1254.2	761.8	224.9	29.53
ANTI PARASITIC/ ANTI DIARRHOEAL	236.9	67.6	17.4	25.71
ANTI T.B.	177.7	104.5	18.6	17.84

Source : ORG Retail Survey of top 200 Brands, December 1994.

MNCs Reduce Productive Activities

A recent trend in the Industry would need mention here. Since 1990-91 there has been a discernible trend of a dwindling market share in the case of Multinational companies (see Table 7). Along side this trend there have been a spate of mergers and tie-ups in the Industry in the last few years. Many of these mergers have been a consequence of mergers that have been taking place globally among giant Transnational Pharmaceutical Companies. Bristol-Myers, Sqibb, Hoechst Marion Roussel, Novartis (merger of Ciba and Sandoz) and Pharmacia and Upjohn are all recent products of the trend in mergers. While the above has had its repercussions in the Industry, Indian companies like Piramal (which acquired Nicholas and some other Cos.) have also got into the act in the domestic Industry. Prominent tie ups between Indian firms and foreign Cos. include those between Ranbaxy and Eli Lilly, Cadila and American Herbal Products, Nicholas Piramal and Reckitt & Colman, Cheminor Drugs and Schien, Sarabhai and Magainin Pharma, etc.

Global Trends Towards Increased Monopolies

This global trend towards merger of Drug TNCs has been sparked off due to two kinds of compulsions. Globally, Drug Companies are being forced to reduce the cost of medicines. Pressure is being mounted by Health Insurance Cos., Health Management Organisations (HMOs) and Governments (in countries like U.K. and Canada where the State provides Health Insurance cover) all over Europe and North America.

Table 7 : SALES TURNOVER AND MARKET SHARE OF TOP 20 COS.

	SALES 1990-91	SHARE 1994-95	MARKET SHARE % 1990-91	1994-95
Ranbaxy	285.14	765.85	4.8	7.0
Glaxo	288.93	482.77	4.8	4.4
Lupin	126.52	334.49	2.1	3.0
Cipla	98.05	295.83	1.6	2.7
Hoechst	196.74	281.74	3.3	2.6
Dabur	45.33	260.36	0.8	2.4
Pfizer	111.64	211.99	1.9	1.9
SOL Pharma.	20.65	210.23	0.5	1.9
Sarabhai	118.50	209.92	2.0	1.9
Torrent	--	199.63	N.A	1.8
Dr.Reddy's Lab.	52.96	194.76	0.9	1.8
Alembic	123.25	192.72	2.1	1.8
Knoll	77.80	189.02	1.3	1.7
HAL	103.03	198.00 (est)	1.7	1.7 (est)
Kopran	--	180.01	N.A	1.6
IPCA	60.11	178.49	1.0	1.6
Smithkline Beecham	97.02	178.32	1.6	1.6
Burroughs Wellcome	93.10	175.18	1.6	1.6
Cadila	74.67	175.00 (est)	1.2	1.6
Parke Davis	94.36	148.39	1.6	1.3

Source : Centre for Monitoring of Indian Economy (CMIE)

These pressures have become stronger in recent years with the realisation that spiralling Drug costs are making Health insurance cover (whether state funded or privately managed) unsustainable. In all these countries there is a major move to insist on generic prescription in most cases, thus opening up a huge generics market. The ability of leading Drug TNCs to operate in this market is obviously compromised, as they do not have the advantage of using their Brand Images to corner large chunks of this emerging market. They are thus forced to compete on more or less equal terms which a large number of lesser known Cos, and also sell drugs at relatively cheaper rates. In the U.S., for example, from 1995 through 1997, generic drug prices showed a double-digit rate of decrease. Large Drug TNCs are thus in the process of working out new strategies -- which include greater cartelisation in the form of mergers and tie-ups -- to maintain their suzerainty over the global Pharmaceuticals market. Companies like Rhone-Poulenc and Bayer are already getting into the generics market.

A second compulsion which is changing the face of the Industry relates to a factor which has been both a major strength and a major source of weakness for Drug TNCs. Large Cos. have generated huge profits through the Patenting of top selling Brands. A classic example of this is Glaxo, the global leader in the consequence, Glaxo is desperate to place a new patented product that can match the kind of profits Zantac was able to generate. In other words R&D and Patenting efforts are to be driven, not so much by actual therapeutic needs, but by the need of Drug Cos. to maintain their super profits at present levels. Simultaneously, new Drug development has become more expensive because of more stringent regulatory laws. It is now estimated that the cost of putting a new molecule on the market is approximately $820 million (approx. Rs.3000 crores). This is a major reason for the trend towards global mergers, as individual Cos. wishing to retain the huge growth rates of the 1970s and 80s, are trying to pool resources for R&D. It must be remembered that such mergers do not necessarily mean greater emphasis on Scientific research in the Industry. Burroughs Wellcome's merger with Glaxo, about three years back, is a case in point. After Glaxo's takeover of Wellcome in 1995, some 12% of Glaxo's 62,000 workers lost their jobs (including a significant no. engaged in their R&D wing), and Beckenham, Wellcome's giant research complex near London, was closed.

As a consequence of the above shifts in the industry we are possibly looking to a new situation, where 10-12 large Transnational conglomerates will survive as "research based" Cos. that is Cos. that will be in the business of drug development and patenting. This will leave the much larger non-patented or generics market to a large number of Cos. The decline of market share for TNCs in the Indian market has been commented upon earlier. It is possibly a reflection of the reluctance of large TNCs to be satisfied with the moderate returns that the Indian market provides, in the absence of a strong Patent Regime. In fact many TNCs have been engaged in the divesting of their productive assets in the country -- for example the sale of Hoechst's Research unit in Mulund to Nicholas Piramal and Pfizer's proposal to sell its huge Ankleshwar plant. TNCs in India appear to have placed their bets on a twin-strategy. Wait for the Indian Govt. to capitulate to pressures and bring in a strong Product Patent regime, at which stage they would enter the Indian market with renewed vigour to reap super profits from their

patented products. In the mean time they wish to limit their stakes in terms of maintaining productive assets, and are preferring to maintain a toe-hold in the market through tie-ups with Indian Cos. The apparent decline in market share may just be a temporary aberration that would be wiped away if India brings in a strong Product Patent regime. It may be mentioned here that it is being anticipated that Biotechnologically engineered drugs are poised to bring in a new revolution in medicine. Upward of 300 such drugs are in various stages of development and the patents for most of these would be held by large TNCs. The response to this new situation by Indian Cos. have again been twofold. Some have used the opportunity to increase their Market share (Ranbaxy, Dr.Reddy's Labs, Cipla, Cadila, Sol, Dabur, etc.). Others have increased their clout manifold (like Nicholas Piramal) by multiple acquisitions. The most point however is, whether the present boom for large Indian Cos. can be sustained in the face of proposed changes in Indian Patent laws.

Product Patent Regime in Promoting Innovation and Disclosure of Information

The standard argument in favour of strong patent protection in pharmaceuticals has held that such protection ensures early disclosure of innovations and thus promotes faster dissemination of knowledge, and that it is just compensation for investments made by Drug Cos. on new product development. Patents permit their holders to forbid the use, sale or manufacture of a product or process for a limited time (generally seventeen to twenty years) in the countries in which the patents are granted. In theory, patents are more advantageous for both the patent holder (presumably an inventor) and society, since intellectual property protection is considered society's payment for the full disclosure of information about the patented object . "Full disclosure" usually means providing enough detail for a "person skilled in the same or the most clearly related area of technology to construct and operate" the patented object. We shall, in this section, examine the validity of both these claims.

Just how far Intellectual Property Rights should extend, has become a matter of professional and public discussion. Can information provided by patients acting in the public interest legitimately be considered the intellectual property of a pharmaceutical company? Should licensing authorities and pharmaceutical companies be permitted to li-

cense and market a drug, respectively, without making available all the evidence about the beneficial and adverse effects of the drug. Pharmaceutical companies claim that clinical-trial reports are commercially valuable intellectual property. In practice, to support the marketing of their new products, most manufacturers make some of their intellectual property generally available by publishing some of the reports upon which their successful licence applications were based. Unfortunately, these reports are not generally representative of all the evidence. A report in 1980 showed that studies submitted in support of applications for new licences for drugs in which side-effects had been shown were less likely than others to be published[6]. There have been innumerable recent instances of suppression of vital information by Drug Companies about their products, even in an environment of strong patent protection. A few of these would merit mention here.

The Journal of the American Medical Association reports that a drug company suppressed research which showed that generic thyroid drugs were as effective as its own branded product for almost seven years. A randomised trial had concluded that two brand name and two generic forms of thyroxine sodium (levothyroxine) were bioequivalent and interchangeable without loss of therapeutic efficacy in most patients for the treatment of hypothyroidism. The two brand name products were Synthroid -- the most commonly used brand in the United States, and Levoxine (now renamed Levoxyl) -- a newer, cheaper product similar in price to generic forms. The authors of the study estimate that using generic or less expensive brand name products in the United States could save $356m a year.

These findings were published in 1997, despite being ready for publication in 1990. In 1987 Betty Dong and colleagues from the department of clinical pharmacy at the University of California Medical Center in San Francisco were asked by Flint Laboratories, the manufacturer of Synthroid, to carry out research comparing their drug with three others. Both sides apparently expected the study to show that Synthroid was superior. By the end of 1990, when the study was complete and it became clear that all four preparations were bioequivalent, the results were sent off to Boots Pharmaceuticals, which had taken over Flint Laboratories.

Dr. Rennie says that over the next four years Boots "waged an energetic campaign to discredit the study and prevent its publication. The study was eventually submitted to JAMA in April 1994, and a publication date was set for 25 January 1995. On 13 January 1995 Dr. Dong suddenly withdrew her manuscript from publication, citing impending legal action by Boots. Apparently, Dr. Dong had signed a restrictive covenant at the beginning of the study stating that all information gathered in the study was confidential and could not be published or released without written consent from Flint Laboratories.

In March 1995 the pharmaceutical branch of Boots was taken over by Knoll Pharmaceuticals. The FDA wrote to the company saying that its assertion that Synthroid was pharmokinetically superior to other preparations was misleading and that the information should not be disseminated. Under pressure from the FDA Knoll agreed on 25 November 1996 to allow the research to be published, but it still insisted that the conclusions were not supported by the data[7].

Drug companies submitting licensing applications to the Food and Drug Administration (FDA) in the United States will now have to reveal whether researchers involved in a drug trial have any financial interest in the company. The new regulations aim to eliminate possible data bias arising from financial considerations. Effective from February 1999, the new rules will require companies to disclose whether clinical investigators have received stock and patent options, payments in the form of research grants, gifts of equipment, consultant fees, and honorariums from lectures.

Drug companies routinely recruit doctors and scientists to study their products and to conduct clinical trials. Clinical investigators may receive substantial compensation for participating in these studies, and these may then be used to support an application to the FDA. A recent article [8] found that doctors who had a financial relationship with manufacturers of calcium channel blockers were more likely to consider them safe and promote them over competing antihypertensive treatments than those who lacked such relationships[9].

The problems that can result from inappropriate concern about intellectual property are illustrated in the case of human albumin solution, a blood product that has been used in the treatment of hypovolaemia and burns since 1941. The licensed indications for albumin are the

emergency treatment of shock, the acute management of burns, and clinical situations associated with hypoproteinaemia. In the UK alone an estimated 1,00,000 patients are treated with human albumin solution each year, at a cost to the UK National Health Service of close to 12 million pounds.

To investigate whether treatment with human albumin is beneficial, a systematic review of randomised controlled trials comparing albumin with crystalloid (an alternative to albumin) was undertaken by members of the Cochrane Injuries Group. The results gave considerable cause for concern, and were therefore communicated to UK Department of Health on April 6, 1998. In each of the categories corresponding to the licensed indications, the risk of death among patients treated with albumin was higher than that among patients in the comparison groups. Overall, the risk of death in patients receiving albumin was 14% and the risk of death in patients not receiving albumin was 8%.

On April 29, 1998, the researchers received the published papers that had been used by one of the three manufacturers, CENTEON, in support of its application to renew its licence for albumin in 1992. The application included only ten of the 18 trials that were available in 1992. The application contained no description of the search strategy used to identify trials for the renewal application, no critical appraisal of the quality of the included trials, and no quantitative synthesis of the results. In other words, information available which raised doubts on the efficacy of human albumin, had been deliberately suppressed for six years.[10]

A dispute between a medical researcher and her drug company sponsor has led Toronto's Hospital for Sick Children to commission an external review of how it monitors clinical trials sponsored by drug companies. Scores of the hospital's scientists and researchers signed a petition calling for an independent inquiry into the dispute between Dr. Nancy Olivieri and the Toronto based pharmaceutical company Apotex. In 1995 Dr. Olivieri agreed with Apotex to test the drug deferiprone in clinical trials on young patients with thalassaemia - a potentially fatal disorder affecting the clotting of blood.. When Dr. Olivieri's research led her to believe that the drug could lead to liver fibrosis, she decided to inform the patients and their families, other researchers, and regulatory agencies. Her findings were published in the New England Journal of

Medicine. She reported that five of 14 deferiprone treated patients had progression of hepatic fibrosis. She suggested that deferiprone may be toxic to the liver, may accelerate the progression of hepatic fibrosis in patients with thalassaemia, and hence should be used with caution. When Dr. Olivieri decided to go public Apotex reminded her of a confidentiality agreement she had signed with the Company, and have threatened legal action.[11]

Closer examination, thus, reveals that intellectual property rights have no necessary relation to invention, innovation or ingenuity. IPRs exist to gain advantage over economic competitors, create monopolies and recoup the costs of R&D. Monopolistic control has propelled western economic development and the progression of industrial society has evolved with the evolution of the patent system. Patents, hence, are linked less with invention, innovation and ingenuity per se, than with industrial applications and regulation of the market. The theory that incentive is responsible for innovation is typically found in economic systems based on competition, where people are thought to gain and lose at each other's expense, and reward is associated with advantage. It is a moot question whether this sort of prompted "ingenuity" should be rewarded too often and too liberally, especially with the growing concern with the possibility that too much protection may create overinvestment in the production of knowledge.

Further, it needs to be understood that even in the U.S. and Japan, an enormous part of research is State funded. The lines, therefore, between what constitutes "basic research" by a company and what it draws from public funded research, are blurred. Let us look at one key sector, where Patenting activity is at its peak - Biotechnology. In 1990 alone, the US government spent more than $3.4 billion to support the R&D of biotechnological applications. Japan's Ministry of International Trade and Industry (MITI) announced in 1981 that biotechnology, as well as microelectronics and new industrial materials, were a key technologies. The MITI laid out $58 million for biotechnology in 1990, including several public-private research projects.

When the US introduced IPRs in the Uruguay Round as a new issue, it accused the Third World of 'piracy'. The estimates provided for royalties lost in agricultural chemicals are US$202 million and US$2,545 million for pharmaceuticals. However, as the Rural Advance-

ment Foundation International (RAFI), in Canada has shown, if the contribution of Third World peasants and tribals is taken into account, the roles are dramatically reversed: the US owes US$302 million in royalties for agriculture and $5,097 million for pharmaceuticals to Third World countries, according to these latter estimates. In other words, in these two biological industry sectors alone, the US owes $2.7 billion to the Third World.[12]

Conclusion

Finally, an over-arching tendency in the Industry - applicable to both large Indian Cos. and TNCs - needs to be taken note of. Over the years many large Cos. have cut down Bulk Drug production, and are increasingly acting as mere traders. In many therapeutic groups, major production is accounted for by the Small Scale sector. In many cases the latter is depending heavily on imported bulk drugs, i.e. they function as suppliers of imported bulk drugs to large Cos. The trend is discernible, as commented upon earlier, in the sharp rise in the rate of growth of imports. This tendency has been fuelled by liberalisation in the Industry -- making imports easier and also the scrapping of ratio parameters which earlier made it mandatory that a certain percent of a Co's turnover should be made up of by bulk drug production. The Indian industry is thus faced with the twin danger of a resurgent Foreign Sector poised to strike, armed with a strong Patent regime, and an Indian Sector that is increasingly dependant on imported Bulk Drugs. A possible safeguard against such threats -- the Public Sector -- has all but been wound up. The implications for self reliance and Health Security are obvious.

Contrary to the reforms ideology the market does not regulate prices of drugs, as demand primarily depends on prescription habits of doctos, disease profiles, drug resistance etc. Hence the market cannot ever be a proper mediator of prices of drugs. The oligopolistic nature of the Industry, where few companies have monopoly within various therapeutic groups, makes the operation of the market even more infructuous. The present policy of abandoning price and production controls has already led to unjustified rise in prices. The concessions to the Foreign Sector mark a dangerous shift in our policy framework. These concessions and a possible change in the Indian Patents Act will return the Drug Industry to the situation prevailing in the fifties - a situation where TNCs can earn super profits due to their control over technology and brand

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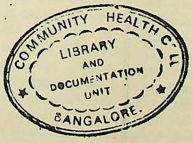
Dunkel Proposals

A Death Knell for the Indian Drugs And Pharmaceutical Industry

P.K. Ganguly



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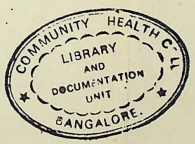

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A Death Knell for the Indian Drugs and Pharmaceutical Industry

USA, the gendarme of world reaction, in its drive for a new world order, has been utilising the international financial and trading organisations to transnationalise the world economy under its hegemony. With this objective it utilised the IMF/World Bank, the financial organisations of the international monopolists, to compel India to frame its economic and industrial policies as per their dictates. With the same objective it is utilising the multi-lateral forum, the GATT, in which it is the most dominant partner, trying to blackmail India to surrender to the proposals made by Arthur Dunkel, its Director General. Simultaneously, at bi-lateral level, it has kept its own Trade Laws—the Super and Special 301 hanging like Damocle's Sword over India. All are with the objective of dominance to the extent of changing the domestic laws of the country and tilt its policies to give absolute power and positions for the multinationals to conduct the economic governance of the country in their favour.

Three Pronged Attack

The Dunkel proposals are a combination of three pronged attack through the so-called Trade Related Investment

Measures (TRIMS), Trade Related Intellectual Property Rights (TRIPS) and General Agreement on Trade in Services (GATS). The proposals postulate most dangerous provisions to undermine the economic sovereignty of the country, like no restrictions on foreign equity participation; no restrictions on areas of investment; no licensing; no export obligation to fund imports; free import of raw materials, components and intermediates; no obligation to use locally available products and raw materials; foreign investors to be treated at par with domestic companies in all respects; and above all, repeal of all laws and policies by India which put restrictions on above.

Although the three strategies, TRIMS, TRIPS and GATS are interlinked and orchestrated to enable the multinationals to have control over the Indian economy, the TRIPS singularly constitute one of the worst forms of neo-colonial exploitation of the country by the multinationals. They demand that India has to amend its Intellectual Property Laws like the Indian Patents Act, Trade and Merchandise Mark Act, Foreign Exchange Regulation Act, Atomic Energy Act, etc and join the Paris Convention on Patents. India's Agriculture and Pharmaceutical industry will be directly hit, if the TRIPS proposals are accepted by the Government. The purpose of this article is to focus on the Drugs and Pharmaceutical industry of the country, which is related to the life and health of the people.

Pharmaceutical Industry in India

It is to be noted at the outset that the drugs and pharmaceutical industry in India is already under the strangle hold of the multinationals. India was one of the pioneers in the quest for scientific knowledge and developed various indigenous medicines. Dr. P. C. Ray, T. K. Gajjar and S. S. Sokhey, etc were among the leading luminaries in this process of indigenisation. They made efforts to develop Serums, Vaccines, Penicillin, Streptomycin, Anti-Malaria, Anti-Leprotic drugs, etc. Above all, they made efforts to develop the public sector to achieve self-reliance in the production, and research and development of life saving and essential drugs according to the disease pattern of the country.

With this objective, at a later stage the Hindustan Antibiotics Ltd (HAL) was established in 1954 with technological

assistance from WHO and UNICEF. Later in 1961 the Indian Drugs and Pharmaceuticals Ltd (IDPL) was established with Soviet assistance. With its vast infrastructure and main plants at Rishikesh and Hyderabad, the IDPL was equipped to produce life saving and essential bulk drugs from the basic stage. A surgical instruments plant of IDPL was also established at Madras later. Later on three units, viz Bengal Immunity, Bengal Chemicals and Pharmaceuticals Ltd and Smith Stanistrent & Co. Ltd, which became sick in the private sector, were taken over and nationalised by the Government. Efforts to make the country self-reliant in production of drugs through the public sector triggered off a new situation.

Multinationals' Hold in Drug Industry

However, the policy of wooing the multinationals by the Government of India gradually nipped the developing indigenous medicines and the process of indigenisation in the bud and exposed the people to the international capitalist racketeering in drugs and pharmaceuticals. The motive of production by the multinationals being only profit, the needs of the people, the pattern of diseases in India, research and development and the problem of banned and irrational drugs were all thrown into oblivion. Today the multinationals control about 78 percent of the drug production in India, 16 percent of the production are in the hands of the Indian private sector and only 6 percent are produced in the Public Sector. It is to be noted that most of the life saving and essential bulk drugs were produced in the public sector and small scale units. The multinationals refused to produce essential and life saving bulk drugs because of low profit return. Instead they sell over 60,000 formulations in the country. According to World Health Organisation (WHO), 80 percent of these drugs are non essential and irrational. Besides, a number of drugs available in India are banned in the parent countries of the multinationals, as they have been found to produce dangerous toxic side effects. But under pressure from the multinational drug cartels' organisation, the Organisation of Pharmaceutical Producers of India (OPPI), the Government has not been able to stop the entry of such drugs in the country.

Pointing to these realities, the Hathi Committee in 1975

recorded that the activities of the multinational drug firms in India were anti-national and recommended for their nationalisation. But the Hathi Committee recommendations have been thrown into the waste paper basket by Government. Along with this the government also threw into oblivion the Alma Ata Declaration for Health for All by 2000 AD, to which it is a party.

Major and Dangerous Shift in Government's Policy

On the contrary, the Rajiv Government made a major and dangerous shift in the economic policy in 1985. The policy called for virtual disbandment of the public sector and self-reliance and made the entry of the multinationals easier by initiating the process of delicensing, decontrol and deregulation. The drug policy formulated in 1987 in tune with the economic policy was a bonanza for the multinational drug cartels. The policy brazenly announced that there will be no more public sector units in the drugs and pharmaceutical units, as India had already acquired self-reliance. IDPL and other public sector units were thrown into competition with the giant multinational drug firms. With import liberalisation even intermediaries were allowed to be imported making different units of IDPL idle and forcing under-utilication of the plant capicities at different levels. The conditions of the smaller units like Bengal Immunity and Bengal Chemicals became worse. Growing sickness became the feature of the public sector units. And now the Narasimha Rao Government has given further bonus to these multinationals by further resorting to delicensing, decontrol and deregulation and initiating the process of dismantling the public sector. But still these international vultures are not satisfied. And hence the Dunkel proposals on the issue of Intellectual Property Rights, pressurising India to be a member of tha Paris Convention on Patents.

Paris Convention

As has been noted earlier, the demands under TRIPS constitute one of the worst froms of the neo-colonial exploitation. The imperialists headed by the USA want to take back India and and other third world countries to the colonial period and 'rule'

over them by pressurising them to become members of the Paris Convention. The Paris Convention on Patents was held during the colonial period in 1883. The convention was attended by 15 countries. A draft prepared by the USA for the protection of industrial property was adopted which turned the Intellectual Property Right to Industrial Property Right. The draft stated that the countries to which the convention applies constitute a a union for the protection of Industrial Property. Nullifying the very definition of Patent right for Intellectual Property, the draft stated that it did not concern the interest of the investors, not even that of the producers, but was aimed to protect the Industrial Rights of the member countries. The first Article of the Convention stated that Industrial Property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agriculture and attractive industries and to all manufactured or natural products. It means that if some one invents a herb, which gives materials for production of life saving drugs, and if it is patented, none will be allowed to cultivate that herb. The objective behind protecting the Industrial Property Right was to establish Product Patent Right out of Process Patent Right and not to allow any other country to produce the same product even through a different process.

One of the malpractices indulged in by the drug multinationals to exploit the third world countries was only to patent a particular product in a third world country without producing it there and go on importing the product from the parent country and sell it in the third world country at exhorbitant prices—5 to 6 times more than that in the parent country. In this way while garnering huge profits, they kept the country away from acquiring self-reliance and at the same time caused huge drainage of foreign exchange licensing system in medicines after the enactment of the Indian Patents Act, 1970 to safeguard public interest. The Paris Convention forbids compulsory licensing by any country and stated that compulsory license would not be applied on the ground of failure of work or insufficient work on patents in that country.

The other provisions of the Paris Convention include decontrol observance of the principle of equal national treatment to foreign investors. It means that no special treatment can be

given to any domestic sector for their growth. That is, the proces of self-reliance and indigenisation and even the development of the small scale sector have to be grounded. And finally to fortify the provisions, the convention stated that for successful application of the Paris Convention domestic laws of the countries have to be amended if needed. To further fortify the provisions the convention stated that no Article of the convention can be amended unless agreed to by 80 percent of the member countries.

Thus it can be seen that the Dunkel proposals, particularly on the Intellectual Property Rights were drafted from the pages of the Paris Convention formulated during the colonial rule more than one hundred years ago, when imperialism was on the ascend. Taking advantage of the present tilt of the correlation of class forces in favour of imperialism, the USA is coming fast on the third world countries to create its new world order, i.e. back to the old imperialist order with the neo-colonial drive. India is its special target as it is its largest trade partner in the third world with a surplus of exports of drugs aad pharmaceuticals to USA.

In the light of above it is necessary to examine the development of the drugs and pharmaceutical industry, especially after the enactment of the Indian Patents Act in 1970, which has come into sharp contradiction with the Dunkel Proposals on Intellectual Property Rights.

Patent Laws in India

The first Patent Act was enacted in India during the British regime in 1856, which was taken from the English Patent Act of 1852. In 1911 the Indian Patents and Designs Act was enacted, establishing a system of Patents in the country. The British regime amended this act several times according to their needs.

After independence the Government appointed the Teckchand Committee (1948) and then the Ayyangar Committee (1957) to look into the question of Patents. Both Committees made identical recommendations that patents should not be granted to enable patentees to enjoy monopoly to import the patented product to exploit the poor nation, instead Patents should protect development of Indian industries from aggression of foreign capital. They also recommended that Patents should

be granted to encourage inventions and that they should be worked in India on a Commercial Scale. They further recommended that for the survival of its own industries, India should not be a member of the Paris Convention. It is also pertinent to note here that during this period a debate was also going on to formulate an industrial policy of the country as well. Although the Industrial Policy Resolution was finally adopted in 1956 pronouncing a leading role for the public sector to develop a self-reliant economy, the debate on Patents went on much longer due to a strong lobby in favour of the multinationals, who tried to subvert any law projecting self-reliance. The Pharmaceutical and Allied Manufacturers and Distributors Associations Ltd (PAMDAL), the main spokesman for the drug multinationals in India and later the MNC's own organisation, vizo the organisation of Pharmaceutical Producers of India (OPPI) were at the forefront of such nefarious designs. However, their efforts could be overcome and the Indian Patents Act was passed in 1970.

Indian Patents Act, 1970

The Indian Patents Act which was ultimately formulated on the basis of the above recommendation, although not a panacea in itself, did have the following features, which helped the growth of the drugs and pharmaceutical industry in the country.

a) National interest was given priority over the interest of the Patentee.

b) Product patenting was not allowed in chemicals and drugs & pharmaceutical products, alongwith several other matters. Drugs or medicines included all medicines for internal or external use of human beings or animals; all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals; all substances intended to be used for or in the maintenance of public health, or prevention or control of any epedemic disease among human beings or animals; insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants; all chemical substances which are ordinarily used as intermedinates in the

preparation of or manufacture of any medicine or substances above referred to.

c) Only Process patenting was allowed permitting manufacture of the products through any different process. The term of such process patent was also kept lower in pharmaceuticals as compared to other invention. It was five years from the date of grant or 7 years from the date of application, whichever was shorter. This gave a good scope of research and development in drugs and pharmaceuticals and develop alternate technologies to suit Indian conditions.

d) Compulsory License: For Process Patenting in medicines also the Act provided for "Compulsory License" after the expiry of three years from the date of granting the Patent. This means that the Government empowered itself to revoke the Patent if it was found that the Patented substance has not met the requirement of the public or was not available at reasonable prices. With such licensing the Government forced the Patentee to work the Patent in the country.

e) Patentee was not allowed to import at his own price.

f) Burden of proof of violation of Patents is on the Patentee. This means if a Patent holder brings a complaint of violation of his Patent Right, then he has to prove it, and not the accused. It is in tune with the general law that the prosecution has to prove the guilt, and not the defendant.

Demands of the Dunkel Draft

The Dunkel proposals demand reversal of all the salient features of the Indian Patents Act. They demand equal treatment to foreign companies. That means India must forsake its national interests and help growth of the mulinationals in the country subverting its own industries, the public sector and self-reliance. It is a demand to abolish FERA, IDR Act etc. They demand product patenting and process patenting both, and for a period of 20 years, instead of the present maximum of 7 years for process patenting only. This virtually means permanent dependence on imports of all medicines as stated above

at exhorbitant prices. They demand that the Government must shed its authority to revoke a Patent on the ground of its non-working or high price. Further, working of a Patent should be deemed to have been made on import of the product. This means complete de-licensing and decontrol and the national Government should function only in name under the command of the giant multinationals without any power or authority of itself. And finally the most audaciously ridiculous—the burden of proof of violation of Patents must lie on the accused. So there cannot be any rule of law, but only rule of jungles—the survival of the fittest—the multinationals. This virtually means that cases of violations will be a regular feature and the accused —an Indian industry will be put on the dock in a foreign country and pay the penalty.

Development of the Pharmaceutical Industry after the Indian Patents Act

Despite the giant multinationals operating in the pharmaceutical industry, the national sector did record a diversified growth and development after the enactment of the Indian Patents Act in 1970. This growth can be seen in in-house Research and Development (R&D) and creation of a self-reliant technological base; in indigenous production of life saving and essential bulk drugs and formulations at much cheaper prices; in achieving near self-sufficiency in the production of bulk drugs and almost total self-sufficiency in production of formulations; and above all, growth in exports.

As product patenting is not allowed, Indian scientists and national laboratories and enterpreneurs could develop process technologies to produce a number of life saving and essential drugs through indigenous technologies within 4-6 years of their introduction in international market by the multinationals. These include anti-bacterials, anti-TB, anti-hypertensive, anti-asthamic, anti-rheumatic, anti-ulcer, anti-thelmentic drugs, etc. Apart from this, the national sector including the small and medium sectors and the public sector have started producing about 100 bulk drugs through indigenous technologies. The national sector has also started manufacturing many new drugs through indigenous technology, whose patents are yet to

expire in the world. According to UNIDO, "India is technologically developed enough to be totally self-reliant with rich capability for the discovery of new chemical entities." The acceleration in production of essential and life saving bulk drugs by the Indian Sector can be seen from the fact that in 1975 the Indian sector produced 62 per cent bulk drugs, while the foreign sector produced 38 per cent. In 1987 bulk drugs production by the Indian sector was 82 percent, while that by the foreign sector came down to 18 percent only. Similarly in the production of formulations, the Indian sector produced 50 percent in 1975 with the same contribution by the foreign sector. In 1987 the Indian sector produced 60 percent of formulations, while the foreign sector produced 40 percent.

Similary in exports the performance of the Indian Pharmaceutical Industry has been phenomenal. It has risen from Rs. 165 crores in 1983-84 to Rs. 640 crores in 1989-90. Because of quality and competitive prices the export performance is on the rise. India is a gainer by about 700 million dollars with USA by way of more exports than imports of drugs.

Prices of Drugs in India

There has been a hue and cry by OPPI and even some Indian sector, supported by the bourgeois press that the prices of drugs in India are the lowest in the world. They propagate that prices of drugs in India have not been raised for years although prices of all commodities are increasing. The OPPI even called for a strike in the industry in last August to pressurise the Government to increase the prices of drugs. They even tried to force to workers and employees to go on strike, which of course they refused. But the realities must be known by the people. It is only after the enactment of the Indian Patents Act and the price control on some life saving and essential drugs imposed by the 1978 drug policy formulated by the then Janata Government in pursuance of the recommendations of the Hathi Committee, that prices of these drugs could be brought down to some extent. It is because of development of indigenous technologies that the Indian drug prices could be made competitive in the world market.

But before the Indian Patents Act, the drug prices in India were among the highest in the world. The multinationals imported the life saving and essential drugs and sold them in India at 5 to 6 times more than that in their parent countries. And a large number of these drugs were banned in their parent countries. The US Government in 1978 had even amended its Foods & Drugs Act to allow export of even such banned and hazardous drugs to the third world countries at high prices. Even the Kefauver Committee of the US Senate had stated in 1959 that, "The prices of certain drugs and broad-spectrum antibiotics in India like Areomycin and Achromycin (by Cyanamid-USA) are among the highest in the world. As a matter of fact, in drugs India generally ranks among the highest priced nations in the world—a case of an inverse relationship between percapita income and the level of drug prices."

It is to be noted that notwithstanding the mischievous propaganda launched by the OPPI, over 70 percent of the Indian population does not have the access to the modern medicines despite their "lowest" prices.

Consequences of Accepting the Dunkel Draft

It is now easy to visualise the consequences if the Dunkel proposals are accepted by the Government. India will come under the neo-colonial net of the monopolistic intellectual property regime of the USA and other imperialist countries as visualised by the Paris Convention of the colonial period. India will have to change all its Patent and other Intellectual Property Laws. If Process Patent is changed to Product Patent, no new products can be introduced by the Indian sector as at present. The country's research activities in process research for new drugs, chemicals, pesticides, etc will have to be stopped as all these will become patentables for 20 years. Self-reliance and the process of indigensation will have to be buried, as the country will become entirely dependent on imports, not only for patented raw materials, but also for patented finished formulations of drugs and medicines for human beings and animals as defined in the Indian Patents Act. The inevitable result will be closure of our national laboratories and research institutions. And

prices of all such drugs and medicines will be unimaginably exhorbitant, as there can be no price control. Thus India will be back to the pre-patent Act days when the prices of drugs were among the highest in the world. Already as stated before, over 70 per cent of the population do not have the purchasing power to buy the medicines. Moreover, as there can be no control by the Government whatsoever, instead of life saving drugs, banned, spurious, irrational, and hazardous formulations will flood the Indian market. Coupled with this, as these medicines will have no relation with the disease pattern in the country, health care programme of the country will be a mockery. This will get a further set back, as the budgets of the various Governmental institutions responsible for implementation of health care programmes will have severe pressure due to the high prices of the medicines. The socalled programme of of Health for All by 2000 AD will have to be buried. Above all, export activities would receive a serious jolt, and with the inevitable rise in imports, India's balance of payment position will be further worsened. Prescriptions of Dunkel and prescriptions of IMF will together push India yet closer to the debt trap. Finally, the question of "brain", to which the Government has remaind so callous. With little opportunities that will remain for the highly qualified scientific and technical manpower of the country for indigenous technological research, India's loss to the developed country through brain drain will be colossal. This will be the net result of the neo-colonial technological exploitation through TRIPS.

The Forthcoming Drug Policy

The policy of liberalisation obviously had have its impact on the drug policy. Although the 1978 drug policy did some justice to the Hathi Committee, the multinational drug cartels started sabotaging it by increasing prices, under producing life saving bulk drugs and over producing irrational formulations with impunity. The 1987 drug policy by the Rajiv Government in tune with the then new economic policy not only unceremoniously buried the Hathi Committee, but started grating denigrating the public sector as well. IDPL and

other public sector drug units were thrown into competition with the giant multinationals and started getting sick. Now the Narasimha Rao Government under IMF conditionalities have brazenly started dismantling the public sector and inviting the multinationals. With the economic sovereignty itself being at stake, the self-reliant moorings of the Intellectual Property Rights of the country have become weak. The Government is dangerously vacillating at the GATT level. It remained supine before USA's Special 301. The strong lobby of OPPI and the Indian monopoly sectors under ASSOCHAM and FICCI are pressurising the Government to go the Dunkel way and join the Paris Convention. Only the sole voice of objection has come from Indian Drug Manufacturers' Association (IDMA), the Organisation of the medium national sector. But the Government has already started tilting under pressure of the OPPI. Prices of almost all the life saving and essential drugs have recorded steep hike during the last one year of the IMF dictated new economic policy.

Diabolical Offensive

In the above background the Government is exercising on a new drug policy. A Committee of Secretaries under the Ministry of Chemicals has been entrusted a draft to policy. As reported in the press, this draft policy has been turned with the new economic policy. It has recommended sweeping delicensing, decontrol and deregulation and suggested increase of prices of drugs much beyond the "compensation" already allowed against devaluation, grounding all control on prices of life saving and essential drugs. The Dunkel proposals on TRIPS have successfully intervened on several issues. Reservation of certain drugs for production in public sector units are being removed. Four public sector units including the biggest, IDPL have been put in the hit list. "Discriminations" between the Indian Sector and foreign sector is going to be removed to satisfy the demand for equal treatment. FERA and MRTP have already been virtually dismantled. Compulsory quota of basic bulk drug production is being removed. Now the last straw remains about the change of the Patent Laws. The danger signals are there. It is to be noted that if the new

economic and industrial policy is a surrender of India's economic sovereignty, surrender to the Dunkel proposals and TRIPS will sound the death knell for the Indian Drugs and Pharmaceutical Industry.

What is required at this juncture is a broad front for struggles. Not only those of the drugs and pharmaceutical industry, but all sections of the workers and the democratic and patriotic forces must unite to effectively resist this most diabolical offensive on the country.

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IMPACT OF DUNKEL-GATT PROPOSAL ON DRUGS, CHEMICALS AND PHAMACEUTICAL INDUSTRY IN INDIA

Naresh Banerjee

The GATT (General Agreement on Trade and Tariff) proposal was originally conceptualized and formulated as a multilateral trade policy to encourage and ensure freedom of international trade. With a view to arive at a consensus, the member states including India met several times through the first round (Geneva 1947) to the seventh round (Tokyo 1973-79) and the proposals were examined and discussed thread-bare. Finally in the eight round (Uruguay 1986) the then Director General Arthur Dunkel formulated and finalised the proposals by laying down a 32-page document in which all the suggestions and amendments put forward by the developing and under developed member states were rejected. This document is now referred to as Dunkel Draft. Subsequently after several meetings of the governing body at Montreal (1988), Geneva (1989), Brussels (1990) and after meetings held in 1991, it came out with a 436 page final document highlighting (a) Trade related investment measures (TRIMS), (b) Trade related intellectual property rights (TRIPS) and (c) General agreement on trade in services (GATS).

In summary, the measures proposed in the Dunkel Draft are:

(i) No restriction of foreign equity participation,
(ii) No restriction on areas of investment,
(iii) No licensing,
(iv) No export obligation to fund import,
(v) Free import of raw materials, components and intermediates,
(vi) Foreign investors to be treated at per with domestic companies in all respects.

All these types of measures and agreements appear to be intended for global domination by the multinationals in almost every spheres of socio-economic life including the area of drugs and pharmeuticals.

Before adoption of the Indian patent act (1970), the drug price in India were amongst the highest in the world. This was reported by the American Senate Committee headed by the Senator Kefauver in 1963. Since the introduction of Indian patent act (1970), the growth of domestic section has been significant in respect of price, availability, early introduction, self-reliance in manufacture, and also in export potential of drugs. This is evident in the dat a as presented in Tables I, II, III, IV and V.

The Indian patent act 1970 clearly provides the patent rights of a drug to remain in force from 5 years to 7 years. There is scope for manufacturing the patented product through alternate process. The Dunkel-GATT proposal advocates both product and process patent to be incorporated so that no one can manufacture the patented product through alternate process. It also recommends that the patent period should continue for 20 years with scope to extend it for a period of about 20 years more by the end of which the product would become obsolete. Because of the Indian patent act 1970, the problem of drug lag has been almost nonexistent in India (Table IV).

India is now capable of manufacturing most of the bulk drugs (over 80%) required for producing most of the essential drugs and the significant share of Indian patents in therapeutic groups, as on 31st March, 1993, are depicted in Table V.

The open door policy for unrestricted FERA equity, unchecked foreign imports with investments by the giant multinationals of the developed industrial countries will undoubtedly cripple our indigenous industry, self-sufficiency technological progress and research in the field of drugs and pharmaceuticals. The Dunkel-GATT proposal, it is rightly apprehended, shall adversely affect the economic and political sovereignity of India, shall compel us to do away with the Indian patent act 1970, shall retard the growth and development and achievement in the field of drugs and formulations. The rise in the price of drugs will be inevitable. With the high rate of morbidity and with the huge population still lying below the poverty line, very few would be able to have access to modern health care. Drug needs to meet the goal of 'Health for All by 2000 AD' will go by default.

Table I : Drug production growth in India.

Year	Worth of drugs produced.
1973-74	Rs. 500 Crores.
1992-93	Rs. 5,400 Crores.

Table II : Drug exports from India.

Year	Worth of drugs.
1985-86	Rs. 140 Crores
1992-93	Rs. 1281 Crores.

Table III. Drug Prices in UK, USA, Pakistan and India. In Indian Rupees (1992-93).

Drugs	UK	USA	Pakistan	India
Ranitidine (300mg) x 10.	481.31	744.65	260.40	29.03
Diclofence (50mg) x 10.	95.84	239.47	55.80	5.67
Norfloxacin (400mg) x 10.	252.77	626.15	125.50	39.36
Ciprofloxacin (500mg) x 4	315.96	305.21	234.63	51.00
Atenolol (50mg) x 10	103.21	228.36	86.63	7.50
Astemizole (10mg) x 10	100.50	436.36	120.90	6.00
Vincristine 1mg vial	542.92	1068.37	323.16	28.90

Table IV : Relative delay in introduction of new drugs in India.

Drugs	Introduced in world market	Introduced by national section	Time Gap
Salbutamol	1973	1977	4 years
Mebendazole	1974	1978	4 years
Rifampicin	1974	1980	6 years
Naproxen	1978	1982	4 years
Brombexine	1976	1982	6 years
Ranitidine	1981	1985	4 years
Captropril	1981	1986	4 years
Norfloxacin	1984	1988	4 years

Table V : Share(%) different therapeutic groups of Indian patents as on 31st March 1993.

1. Antibiotics	40.23	9. Anti-peptics ulcer drugs	65.92
2. Antibacterials	98.80	10. Oral-anti diabetics	55.30
3. Systemic antifungals	25.66	11. Anti-asthmatics	47.53
4. Anti -leprotic	69.96	12. Anti-histamines	21.34
5. Cardio-vasculars	40.18	13. Cytostatics & anti leukemics	32.41
6. NSAIDs	22.16	14. Contraceptive hormones	88.79
7. Tranquilizers	74.42	15. Anti-diarrhoeals	90.00
8. Anticonvulsants	65.93		

The call given by the Government of India to introduce free market economy to compete with the giant multinationals who are armed with the global economy, production base and market their command, is like calling upon goats to compete with tigers. Everyone knows what would be the fate. The people are being pushed under an indirect colonical rule.

All section of the people of India, committed to the welfare of people, should join hands to launch mass movement to forestal this suicidal anti-people move by the Government of India.

DRUG ACTION FORUM – KARNATAKA

C/O Community Health Cell, No.367, Jakkasandra I Main, I Block, Koramangala, Bangalore – 560 034.

An appeal to the Honourable President of India

INDIAN PATENT ACT, 1970

We, the signatories to this appeal,

- having reflected seriously on the impact of the amendments to the Patent Act, 1970,
- concerned about the impact of the changes on the availability and affordability of drugs, especially on the socio-economically poor citizens of our country,

Appeal to The **President of India**, as the Head of the Republic, as follows:

The Indian Patent Act, 1970 had been drafted carefully, keeping in view our Values and Ethos and following National and International standards. Repeal or amendment of the provisions of the Act, along the lines now proposed, will adversely affect our people.

This is particularly so with regard to production and use of sorely needed medicinal drugs. The cost of drugs will escalate (it has already increased) and will become non-available people, particularly the poor, if the patent laws are altered.

We, therefore, request you, The **Honourable President of India,** to ensure that profit motives of a few affluent countries or large multinational corporations do not pressurise us to change the law, which was passed after widespread consultation and much thought, and which has been functioning well in the interests of our people.

The Indian Patent Act, 1970, may be retained undisturbed.

We remain.

Name	Designation	Signature

Name	Designation	Signature

Refuse Approval to Patents Ordinance

The following memorandum was presented to the President of India by the National Working Group on Patent Laws on January 6, 1999.

There is *no* immediate urgency in regard to the Ordinance on the Patent Laws at this juncture since, even as per WTO rulings, we need to amend our law before April 19, 1999, and there is ample time for this to be made part of the agenda for Parliament during the Budget session for which a Bill is pending.

We would draw your kind attention to the report of the People's Commission on WTO (consisting of eminent personalities, Justice V.K. Krishna Iyer, Professor Yash Pal, Professor Prabhat Patnaik and Professor S.K. Sinha) in which they have discussed this issue at length. The present discussion appears to be to scuttle all discussion and steamroller the EMR route, which is only *one* of the two alternatives available even under Sections 70.8 and 70.9 of the TRIPs Treaty.

As the issue is under discussion between the NWGPL and different political parties, the Ordinance would unwarrantedly jump the gun. We would like to add that under the extant provisions of Articles 70.8 and 70.9 of the TRIPs Agreement, under the Bill before Parliament Exclusive Marketing Rights (EMRs) for a minimum period of five years must be granted—once applications are made for the same—for all products for which a party may hold a patent in a member country, and for which an application may be in the 'mail box' opened after January 1, 1995 in India. Incidentally, *no* qualifications or safeguards would be consistent with the WTO, as the government appears to suggest. It is understood that some 3000 such applications are pending in the mail box, and even if these applications are *totally rejectable*, we would—under the present Bill (which would become the Ordinance)—be forced to grant EMRs for five years, for the 'mail box' is not even supposed to be opened until December 31, 2004.

Thus, the Patents Bill—and the Ordinance proposed—is wholly against India's interests, and there must be other alternatives available which need to be examined thoroughly, perhaps through a Select Committee of Parliament. While that is a matter for Parliament to decide, we urge you, Mr President, to refuse to accord approval to any Ordinance on the subject, since the next Parliament session is due in February, well before we are required to meet the deadline for amending our Patent Laws to conform to the WTO ruling.

We urge, Mr President, that for reasons advanced above, you may kindly refuse to approve any Ordinance that the government may submit to you, and advise the government to process the Bill through Parliament.

For and on behalf of the
National Working Group on Patent Laws

Arun Ghosh
Co-Chairman

B.K. Keayla
Convenor

Patent capitulation

Eager to meet a WTO deadline, the BJP-led Government opts for a legislative course that will be deeply divisive, without taking into account the larger implications of the step or the context of domestic opinion.

SUKUMAR MURALIDHARAN

MONTHS of rancorous internal debate and an adverse ruling by the Dispute Settlement Body (DSB) – the watchdog of global trade – preceded the Union Cabinet's recent decision to amend the Indian Patents Act, to bring it in line with the norms mandated by the World Trade Organisation (WTO). Considering the deep schisms within the Bharatiya Janata Party over the issue, the Cabinet decision must undoubtedly count as a brave one.

Yet, it is easily lacking in conviction, when viewed against the tenuous parliamentary arithmetic of the BJP-led coalition and the fate of an earlier effort at amending the Patents Act – still fresh in political memory.

In effect, the BJP-led Government has promised to resurrect the Patents Act (Amendment) Bill that was passed by the Lok Sabha in March 1995 and then allowed to lapse (*Frontline*, May 19, 1995). The P.V. Narasimha Rao Government considered withdrawal the prudent course rather than have the bill run the gauntlet of hostile forces in the Rajya Sabha. With few exceptions, all the parties of the Opposition had made it clear that they would vote against the amendment. Among the most vociferous in its opposition was the BJP.

Since then, India was taken before the DSB by the WTO for its failure to conform to the statutory norms of patent protection. At issue were two clauses of the WTO agreement – 70.8 and 70.9 – which were quite transparently the industrialised countries' efforts to dilute the gains won by developing nations over the length of time that would precede transition to the new regime of patent protection.

In their formulation, these two clauses are an object lesson in how concessions granted in seeming good faith in one part of a treaty can be completely neutralised in another. Developing countries were, as a rule, afforded a transition period of five years for full compliance with the WTO agreement on intellectual property protection.

In addition, countries that followed a system of process patents rather than product patents in certain areas of technology – as India did in drugs and pharmaceuticals for instance – were given another five years to extend the new regime to these specific areas. India, which as a developing country was entitled to the exemption of five years, is hence obliged to adopt the WTO rules on patents by the year 2000 and to introduce product patents for drugs and pharmaceuticals by the year 2005.

Yet, the possible benefits of this transition period were diluted by the compulsions of article 70.8, which insisted that all member states should, from the date of entry into force of the WTO agreement, institute "a means by which applications for such patents could be filed. This clause, popularly known as the "mailbox" stipulation, required the Indian patent authorities to begin receiving applications for product patents in drugs and pharmaceuticals from January 1, 1995.

Although the patent would be granted only after 2005, the applicants would enjoy the special privilege of "exclusive marketing rights" (EMRs) in the intervening period subject only to the condition that their application for a patent must have been granted in one other member country of the WTO. Known as the "pipeline protection" in legal jargon, EMRs serve as a precursor to formal patent protection, and are different only in degree and not in kind.

In a milieu of disparate legal systems – where turmeric and basmati rice for instance have been granted patents in certain countries – the havoc that could be caused by such a provision is readily apparent. The Patents (Amendment) Bill of 1995 sought to establish the mailbox system and institute EMRs, but failed at the stage of parliamentary scrutiny precisely because it failed to assuage these concerns.

Rather than tackle these apprehensions frontally, India chose a rather disingenuous tack in hearings before the DSB. It was argued on behalf of the country that the system of receiving mailbox applications was in place, though without formal legal backing. Between January 1, 1995, and January 31, 1998, no fewer than 2,212 mailbox patent applications had been received, none of which had been rejected or invalidated, India's representative argued. The failure to get the Patents (Amendment) Bill passed in Parliament was, by this criterion, immaterial. The system of receiving applications for product patents still remained in place.

The plea gained little credence. The DSB observed in agreement with the European Union and the United States that there was a degree of "legal insecurity" surrounding these applications. Although not invalidated or rejected at the time of the hearing, their tenuous legal basis could conceivably lead to such an outcome in future. And as for clause 70.9 of the WTO agreement, India was, by its own admission, in default on the requirement that EMRs be accorded to applicants who had filed product patent claims in the mailbox.

In combination, these two findings implied that India earned no reprieve. The DSB ruling, later upheld by the Appellate Board, obliged India to put in place the necessary legal framework for ensuring conformity with WTO norms on patents by April 1999.

The confidence of international investors being a precious commodity in days of global uncertainty, the Government set about the task of ensuring conformity with a degree of earnestness. A signal was sent out, though it was perhaps of symbolic rather than substantive importance, when the BJP-led Government quietly signed on to the Paris Convention early in August this year.

Sentiments obviously had been subdued since the peak of agitational fervour against the Paris Convention was hit just over a decade ago. Before the agenda of intellectual property protection was integrated into trade policy and brought under the jurisdiction of the WTO, the Paris Convention had been the chosen vehicle for intrusion into sovereign spaces by commercial interests from the advanced nations. But the Government's decision on accession drew few adverse comments in August.

Today, there is a distinct attitudinal change among sections involved with the patents issue. There is a strong line of advocacy which believes that EMRs engender a monopoly and are antithetical to the public interest. B.K. Keayla, convener of the National Working Group on Patent Laws, is a fervent advocate of the view that the balance of advantage for India lies in dispensing with the transition period and moving directly to a regime of product patents.

In support of this argument, Keayla

Principles at a low premium

SUKUMAR MURALIDHARAN

THE insurance sector provides the backdrop for another spectacular change of heart by the Bharatiya Janata Party. Nine months into its tenure, the coalition Government led by it has shed all residual anxieties about national sovereignty and the security of public funds, and announced a sweeping set of liberalisation measures for the insurance sector. The more than probable legislative mishaps aside, the public sector monopoly in insurance will soon be a thing of the past. Foreign entities will be entitled to participate in insurance to the extent of 26 per cent equity holding in an Indian venture. With participation by non-resident Indians and foreign institutional investors, the overseas equity stake in Indian insurance companies could go up to 40 per cent.

Curiously, these decisions have been taken in conjunction with a legislative measure which is fairly limited and modest in its purpose – to provide statutory backing to the Insurance Regulatory Authority (IRA), which now functions on the strength of a presidential ordinance.

In mid-1997, the United Front Government had sought in vain to introduce a legislation with precisely the same purpose, though without undertaking any firm commitments about eligibility to participate in the liberalised ambience of insurance. Finance Minister P. Chidambaram managed to recruit the support of the Congress(I) to this cause though the Left constituents of the U.F. remained opposed to the move. He then approached the BJP in a bold bid to recruit trans-partisan support. The BJP, while giving him a number of positive signals, made its support contingent on one condition – that the IRA Bill would specifically rule out the entry of overseas investors into the insurance sector.

Chidambaram had then argued that this was beyond the province of the IRA Bill. The question of eligibility to participate or otherwise would be taken up in amendments to the Insurance Act, 1938, which would follow the formal constitution of a regulatory body, he said. Following the BJP's refusal to entertain this plea, the U.F.'s version of the IRA Bill was hastily withdrawn from Parliament.

In just over a year, the BJP has evidently gone from strident advocacy of a swadeshi perspective in insurance to an attitude bordering on the permissive. In fact, the package of measures its Government proposes seems to adhere closely to the recommendations of the R.N. Malhotra Committee on Reforms in the Insurance Sector, which submitted its report in early 1994. The thinking today is reportedly to insist on a minimum share capital of Rs. 100 crores for new insurance companies. A promoter could have a share no higher than 40 per cent and no lower than 26 per cent. And while the Malhotra Committee did not differentiate between overseas and domestic enterprises, the Union Cabinet today has chosen to define the threshold of participation by foreign entities.

Several vital aspects of the new insurance industry norms remain to be worked out. Particularly crucial would be the investment guidelines that are enforced to regulate the deployment of funds by the insurance companies. Security being of the utmost priority in the insurance sector, the public sector enterprises are today obliged to put most of their funds into gilt-edged government securities which offer relatively modest returns. The Malhotra Committee had been rather critical of this rule and proposed that insurance companies and pension funds look with greater favour on maximising returns through judiciously placed investments in the stock market.

An examination of the deployment of household savings shows that the importance of life insurance policies and pension funds has remained relatively unchanged over the years. Since the early 1980s, when the share markets went through successive cycles of boom and bust, the proportion of household savings invested in insurance and pension funds remained inflexible. In contrast, the proportion that goes into the share market has fluctuated very widely over the years. Between security of investments and returns, the household sector in India seems already to be exercising a judicious measure of choice. It is not quite clear that they need a new set of insurance norms that will alter this pattern of disposition of their savings.

The privatisation of insurance raises exactly this possibility. Even if the threshold of share capital for entry into the sector is retained at the relatively high level of Rs. 100 crores (as against the Rs. 50,000 in the case of public sector companies), it is not clear that all potential liabilities and assets will be perfectly matched. If, on top of this, companies are enabled to plough insurance funds into a volatile stock market which is yet to rid itself of the latent possibilities of abuse, there would seem to be a rather high – and perhaps unacceptable – element of attendant risk. The mitigating circumstance perhaps is that there is little sign that the BJP-led Government will be able to overcome survival anxieties in the near future and depart from its hitherto undistinguished legislative record. ■

points to the large number of applications that have been received for the grant of product patents – an annual average of over 700 since the mailbox was opened on January 1, 1995.

In authentic terms, no more than 50 inventions are made in a year which could qualify for patent protection, claims Keayla. "Pipeline protection", in other words, could be a permit for a rampage of monopoly interests. India would be obliged to grant an applicant an EMR subject only to the condition that the applicant held a patent in another member-country of the WTO.

With patent systems in many countries becoming increasingly permissive – as exemplified in the grant of patents on turmeric and basmati rice – "pipeline protection" would be little other than a route to endless litigation, governmental fatigue and a triumph by default of global monopolies which have no dearth of legal resources.

For a while, it was reported that the Group of Ministers constituted to examine this question was divided over the best option available to India. Two of the four Ministers seemed to believe that there was some merit in going directly to a system of product patents which would be symmetric in its application for domestic and overseas entities. The other two were unconvinced that the residual benefits offered by the WTO in the form of the transition period could be so easily dispensed with.

In finally deciding this question, the Government went by the calculation that the bulk of the mailbox applications received will not be granted patents in another WTO member country and would not be eligible for EMRs. Failing an examination of the content of the applications received, there would seem little to choose between this and the alternative viewpoint.

Evidently, the point at issue is simply that the Indian Government entered into international obligations without considering the context of domestic opinion. On finding that it could not sustain the attendant commitments, it made an elaborate pretence that domestic concerns were immaterial, since the formal requirements of the WTO treaty would be met by default. Under the pressure of a WTO deadline, it has opted now for a legislative course that will be deeply divisive. ■

Forum of Parliamentarians on Intellectual Property

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Special meeting of the Forum of Parliamentarians on Intellectual Property held on July 24, 1996 in Conference Room 'B', Parliament House Annexe, New Delhi.

STATEMENT

A special meeting of the Forum of Parliamentarians on Intellectual Property was held on 24th July, 1996. The meeting was convened in the background of the press report about the American demarche to the Government of India on the so called failure of the Government of India to amend the patent laws and strong reaction in Parliament of the senior Members of Parliament belonging to different parties on July 19, 1996 to the issues arising out of the reported demarche. Several parliamentarians and a number of eminent experts participated in the Forum meeting.

The following participants spoke at the meeting:

Members of Parliament

Dr. Murli Manohar Joshi, Shri Chandra Shekhar, Shri Jaipal Reddy, Shri George Fernandes, Dr. Ashok Mitra, Shri Prithviraj Chavan, Shri M.A. Baby, Shri Rup Chand Pal, Shri Dipankar Mukherjee and Shri Nilotpal Basu.

Eminent Experts

Dr. Nitya Nand, Shri S.P. Shukla, Dr. Arun Ghosh, Shri J.C. Jetli, Shri B.K. Keayla, Dr. Vandana Shiva, Dr. Rajeev Dhavan and Shri Dinesh Abrol.

The meeting recalled the Declaration on TRIPs Patents Regime issued at the Conference of Parliamentarians on Intellectual Property held on 24th January, 1996 and an appeal by the National Working Group on Patent Laws titled "Priority Agenda for the Parliamentarians" on 21st May, 1996.

The meeting noted with satisfaction that the composition of the 11th Lok Sabha has undergone a transformation resulting in an overwhelming majority for MPs belonging to the political parties who have been strongly opposing the unequal treaty of New GATT/WTO, particularly the Agreement on TRIPs. It was felt that this development would impart new strength to the struggle against the unequal Agreement on TRIPs.

The meeting re-affirmed the country's sovereign and inalienable right to have an intellectual property regime which would promote public interest and ensure self-reliant development in social, economic and technological spheres. The meeting reiterated its strong opposition to the unequal and unacceptable Agreement on TRIPs incorporated in the New GATT/WTO and its resolve not to allow amendments to the Indian Patents Act, 1970 so as to make it conform to the regime visualised in the TRIPs Agreement.

In this context, the meeting noted that according to U.S. Administration itself as many as 48 countries have yet to amend their patent laws and most of the developed and developing countries have not complied with their so called obligations under the TRIPs Agreement. In addition, there are 45 other least developed countries who have clear 10 years to apply the provisions of the TRIPs Agreement. Thus there are 93 countries who have yet to amend their patent laws. In the circumstances, there was no justification whatsoever for any industrialised country to mount pressure on India in this regard.

Patents - The International Farce

[Translated from the Editorial published in the Kannada magazine, Taranga]

The British, and, before them the Mughals, apart from snatching away India's freedom, seemed to have snatched away the patriotism and pride of the countrymen. Even now, our country is being looted in umpteen ways. Are we not resilient enough to resist such assaults?

Today, America, Japan, Europe and other countries are looting the natural resources of the country. They are hindering/restricting our growth, research and scientific development. Though fully aware that all this unfair, we have allowed it to get out of hand. Why this cowardice?

Basmati rice, neem, gooseberry, bitter gourd, turmeric, grapes, mustard, ginger, black cummin, brahmi, sitaphal, jackfruit, pomegranate, black pepper, isabgol .... the list goes on and on. Nearly 30 items have been patented. We have lost our rights over these things. In other words, these cannot be used by Indians anymore. If we need to use them, we have to write to America or japan for permission.

This is international piracy. Can there be a bigger insult than going with a begging bowl to other countries for the ingredients/items we use in our culinary/Ayurvedic preparations?

There have been many protests by farmers, scientists and lay persons regarding this issue. Objections have been raised.

Now and then, we hear news about the Government of India intending to lodge a protest and initiate a movement against this unfair practice. Pharmaceutical companies have also made the requisite noises. Inspite of all this, the daylight robbery has not stopped. In the guise of civilization, trade and economic betterment, should this go on?

India is a unique, vast land. The weather of the land is diverse. We have regions of extreme cold, rain and deserts. No other country in the world has such a diverse wealth of natural resources. But, are we not capable enough to preserve and use our natural resources in a proper manner? Probably, we may even destroy and sell the birth place of one of the great souls of this land, if there are monetary gains!

Having recognized the potential of Ayurvedic medicines for profit-making., the greedy pharmaceutical companies of America are poised to make billions of dollars from every grain, grass, leaf and fruit possible. According to estimates, 25% of prescriptions in America have drugs with herbs as one of the ingredients. This trade amounts to 20-30 billion dollars per annum. In Canada, England, Australia and other countries, it touches more than 70 million dollars.

These medicines need nearly 2,50,000 varieties of herbs. Half of them are available in India. Some are available only in India. And, the global looters have been quick to realise that India is a soft target.

There have been instances of multiple patenting of the same herb by pharmaceutical companies in America, where the trade war between companies is intense. Neem has 65 patents, turmeric has 15, mustard 10, gooseberry 20 .... The list is endless. Where is the end to this international sacrilege of looting the natural resources of another country and claiming it as their own?

Patents are framed by multinationals. Is our Government unaware of this fact? Can't we do anything to stop this unfair trend? Has the Government ever thought seriously about initiating action in this regard? Why this unholy silence?

India also has a patent law. It dates back to as early as 1970 - an outdated law. Is it not possible to modify this law to face today's challenges? Are the people's representatives - the MPs aware of this problem? Are they really eager/interested to know more?

The multinational pharmaceutical companies of America and Europe are scheming to distort this outdated patent law of ours. India has already lost a few times in this patent imbroglio. One by one, all our natural resources are being patented outside our country. Such resources then become the sole property of that country. Later, India stands to lose all the rights over the patented resources.

The pharmaceutical companies manufacturing Ayurvedic medicines in India are in real, deep trouble. Slowly, the multinationals are establishing their stranglehold over this area. And, our companies are helpless against this assault. In reality, these patents are a violation of our farmers' rights. They strike at the core of our natural resources. In essence, native wisdom culled over centuries of civilization will be rendered useless.

Patents have been brought out in the name of NRI scientists also. This is just for their convenience - akin to hanging us by our own rope.

When we say that we are hospitable nation, it doesn't mean that we can be cheated out of what is rightfully ours. It is wickedness unlimited. How many Indians have faith in our political system, where the politicians are forever involved in internal squabbles, that they have the capability to rescue us from this whirlpool?

- Santosh Kumar Gulwadi

What is Patenting ?

G. Utkarsh

Neem, Turmeric, Basmati.....! Screened, manipulated and patented! These famous Indian plants are amongst many that may trigger biotechnological innovations, only to be eventually patented, often abroad. Having over-exploited India's bulk resources like timber, spices, silk, cotton etc. as raw materials for few centuries, the developed countries now set to capitalise on our genetic resources and wisdom. No doubt, future wars would be fought more with intellectual ammunition than physical or nuclear.

Intellectual Property Rights

Intellectual Property Rights (IPRS) refer to exclusive authority provided by the government to the first innovator for manufacturing and marketing the innovation, prohibiting other parties unless licensed by the IPR holder, on payment of fees or royalty.

Patents, the most relevant form of IPRS for pharmaceuticals, are primarily used to protect industrial innovations. Depending upon the country, the patent lapse after 7 to 20 years and thereafter anyone can commercialise the innovation. Copyrights are used to protect artistic expressions for about 50 years. Trade secrets, renewable after every 7 years, protect the undisclosed information like recipes. Plant breeders' rights, trademarks, geographical indications, designs, databases, are some other forms of IPRS.

Patenting Innovations

Patents are granted on novel, non-obvious and useful innovations. Knowledge already in the public domain (e.g. Ayurvedic formulations) is not considered novel and hence, not patentable. If the innovation is a mere discovery (e.g. new species) and does not involve an inventive step, it is not patentable. Further, just the knowledge of using a plant or a mixture of herbal extracts to cure a disease is not patentable in India. Screening, isolation of active ingredients and demonstrable market potential may however render the invention patentable. A patent application must specify sufficient details of the method of invention so that anyone skilled in that art must be able to repeat the same without the help of the inventor. The disclosure statement must also include adequate reference to existing public knowledge. Based on such specifications, the patent authorities and experts scrutinise the application by referring to existing literature and patent documents. The patent claims and summary are also publicised for a few months (e.g. through gazette notification) to invite oppositions, if any, generally prior to the approval.

Patenting Life

Scope, application procedure and period of IPR protection varies across countries. Further, protection needs to be separately obtained in each country. The Trade Related Intellectual Property Rights (TRIPS) section in the General Agreement on Trade and Tariff (GATT), is an effort by the developed world's industrial lobby to homogenise and strengthen the IPR regimes world over. The 130 member countries of the GATT are obliged to provide strong IPR protection to domestic as well as foreign innovations in all the fields of technology. Only natural plants and animals other than microorganisms and essentially natural methods for their reproduction are not patentable. Patents must now be granted 20 years and on products as well, not just process.

Till recently, many countries provided partial or no IPR protection in health and food sectors. In India, only 7 years duration process patents were granted in the pharmaceutical sector. Thus, Indian drug companies vigorously manufactured many imported drugs by slightly modifying the patented process and sold it at much lower prices. This benefited the public and the Indian industry much to the dismay of the foreign manufacturers. However, after 2005 AD India and other developing countries are obliged to provide product patents in all sectors, posing threats to these reverse engineering technologies, and the domestic industry, also making new drugs very costly.

Biopiracy

Industries in the developed countries argue that developing a new drug takes 10 to 12 years and nearly US $400 million. They advocate strong and longer IPR protection to this investment as the drug manufacturing is easy to copy and manipulate. However, this argument overlooks the valuable diversity of crop plants, medicinal plants and the people's knowledge that the developing coun-

tries have been freely providing to the developed world. The developed world industries have made huge profits from the resultant new drugs, crops and cosmetics. However, these products are patented and sold at exorbitantly high prices even to those countries that contribute the biodiversity and knowledge as raw material. Since IPRS protect only commercial inventions, day to day domestic use of bioresources are not prevented. Grandmothers can freely use Tulsi or Turmeric for domestic health care. Ayurvedic vaidyas or pharmacies can continue to sell their powders and syrups unabated, but they cannot today claim a share in the profits generated from a derived drug, which will most likely be patented. Such inequitable sharing of benefits lead to a growing discontent and eventually gave birth to the International Convention on Biological Diversity (CBD) 1992, the political weapon of the developing countries.

CBD and Genetic Resources

CBD, signed by 170 countries, reaffirms the sovereign rights of the nations. Article 15 requires member countries to transfer genetic resources on the basis of prior consent and mutually agreed terms. These conditions, however, do not apply to genetic resources obtained prior to the convention i.e., 1992. For instance, Kew gardens and herbaria in UK house the most exhaustive collection of Indian plants. These specimens can be easily used to extract genetic material without India's consent just as the US developed its controversial variety from Basmati rice strains procured in the last decade. Thus, biodiversity rich southern countries can set terms of benefit sharing only in future transactions, if any. Further, a biodiversity rich country can dictate terms only if the genetic resource is endemic i.e. exclusive to it. Otherwise, a neighbouring country can offer the shared resource on more competitive terms.

CBD and Traditional Knowledge

Article 8 j of the CBD requires member nations to respect and preserve the knowledge of local people and apply it only with their approval, involvement and equitable sharing of benefits. Article 10c requires member nations to protect customary usage of biological resources. Article 16(5) mandates nations to ensure that IPRS are supportive of and do not run counter to the CBD objectives. However, most of these provisions cannot be operationalised without enacting corresponding national legislation. Unfortunately, the approvals relate only to undisclosed information. Much of the traditional knowledge is already in the public domain - in the form of computerised database with quick search facilities, often housed in developed countries (like NAPRALERT in Chicago, US). Industries access this information without any consultation or benefit sharing with the original contributors. MNCS are also actively engaged in tapping the folk knowledge through local agents. CBD provides the spirit though not the weapons to fight the misappropriation of such public domain knowledge.

Say no to Patents?

Taking a clue from the CBD, IPR regimes are being widely opposed through various seemingly conflicting strategies. Environmental and social activists altogether reject patenting of life citing three reasons - monopolies are socially unjust as they lead to exorbitant prices; monopolies often lead to monocultures, which are unsustainable in the long run; and monopolies over life are unethical, as humans have not created life. However, most governments including developing countries in the world do not seem to buy this view today and have signed GATT. Costa Rican Biodiversity Act does not disqualify all IPRS on life, but prevents IPRS on all innovations similar to traditional knowledge. Costa Rica being a small market, invited little reaction. Even if India decides against patenting of lifeforms, innovations based on genetic resources and knowledge originating in India will continue to get patented abroad, without any consent or benefit sharing.

The monopolies are socially unjust as they lead to exorbitant prices and monocultures, which are unsustainable in the long run; and also lead to monopolies over life, which is unethical, as humans have not created life.

The Indian government seems inclined to allow product patents very soon. The patent bill to meet

our obligations under the World Trade Organisation (WTO) could not be passed in December 1998 parliament session due to the resistance from the activists. However, the government keen to avoid any penalties and multilateral sanctions from the WTO, immediately issued an ordinance to provide for exclusive marketing rights (EMRs), if not product patents. Even the budget session of the parliament may be advanced to get the bill approved before the WTO deadline. Internationally, most of our neighbours have already enacted strong IPR regimes, including China, which is not a WTO member yet.

Patent Wars?

Government institutions such as the Council for Scientific and Industrial Research (CSIR) joined the patent war by filing many patents in India and the US e.g. relating to the use of Neem. However, CSIR's success in commercialising its invention is limited. Cost of filing and maintaining patents abroad are also prohibitively high and the CSIR lacks money to commercialise the technology. Private sector is in no better shape, barely few Indian companies like Ranbaxy or Dr. Reddy's Lab have some capability for R & D to generate patentable innovation. No wonder, of the 500 and odd patent claims filed in India last year more than two third were by the foreign agencies, especially MNCs ! It seems unlikely that Indian scientific community can protect much of the innovations based on the enormous diversity of traditional formulations, estimated at about 10,000 in Ayurveda alone.

Further, the rationale driving the patenting spurt by the public sector institutions seems to be that of providing Indian public with less costly products before the foreigners can monopolise those. However, if CSIR can successfully commercialise its inventions abroad, it can even make profits. Unfortunately, CSIR has given no thought to sharing such benefits, if any, with Ayurvedic or folk medical practitioners. In fact, most of the CSIR missions do not fully involve Ayurvedic experts. CSIR patent relating to use of 'Piperine' in treating tuberculosis, based on Ayurvedic formulation Trikatu, is a case in point. Such non-participatory approach is against the spirit of the CBD. No doubt Indian R & D should gear up for patenting, but it must also encourage complimentary strategies.

Sui Genris IPRs for undisclosed information

One of the alternative strategies advocates modifying the existing IPR regimes so as to make them less costly, simpler and sensitive to the requirements of the folk scientists. For instance, Kenya has begun to grant petty patents (also termed as utility or soft patents) to folk medicinal formulations. These require less precise specification, need not prove market potential, are cheaper and easy to apply. Similarly, special forms of copyrights, geographical indications, trademarks can be evolved to protect cultural expressions, denominations and symbols. Trade secrets are being used in Ecuador to protect undisclosed community knowledge being computerised by the local University.

Indian R&D should gear up for patenting, but it must also encourage complementary strategies

The most efficient way to protect the undisclosed information is to empower people to negotiate information transfer agreements i.e. contracts with the entrepreneurs and/or the government. The rewards could be in the form of spot payments, milestone payments and direct share in the royalty once the product gets commercialised. Such contracts are not uncommon in Peru, Philippines or Africa. To provide teeth to such contracts, it is necessary to modify the IPR legislations to enforce submission of relevant contract/ transfer agreements as a proof of the prior informed consent.

However, granting such IPRS to an individual may cause injustice due to the presumption that other persons are ignorant in that art. In reality, only a person in proximity to media, legal advice and other resources may be able to register an IPR claim. To minimise this, it is necessary to publicise the claims for petty patents contracts etc. and invite the public oppositions. Nevertheless, utility of *sui generis* i.e. independent IPRS could still be limited, as the industries would claim IPRS over so called distinct innovations.

Acknowledging the public origin of IPRs

The patent spree or the *sui generis* IPR protection may after all benefit only a few innovators, primarily individuals. To protect people's rights in relation to vast store of public

knowledge requires broader solution. These rights could be in the form of entitlement to information regarding application of their knowledge, to share benefits of such knowledge, to demand favourable terms for transfer of technology including those protected by IPRS, to nurture local R & D and protect customary usage of biological resources. Towards this end, the IPR laws must be amended to require mandatory disclosure of all the available public knowledge regarding an innovation. Further, the IPR authorities must conduct exhaustive search prior to grant of an IPR to examine the claims of novelty and inventiveness. Such disclosures will also allow the public to challenge incomplete or misleading claims.

This is illustrated by the patent granted by the US patent office to use turmeric in powder form for wound healing. The US laws do not mandate scrutiny of public domain knowledge abroad while granting a patent. Further, no public hearing is invited prior to the approval. Nevertheless, when CSIR took proper steps to prove that such a usage was traditionally known and under current research, the US court revoked the patent.

Promoting the public knowledge

Operationalising people's rights would require documentary evidence about the existing knowledge and practices, besides modified IPR regimes. The documentation must begin at the level of villages, recording knowledge, practices and perceptions of individuals. Local schools and colleges can prepare such registers with the help of the local knowledgeable individuals. These registers could be maintained at the local panchayat offices. Urban R & D institutions can integrate this information with the public domain resources through databases.

Such databases must be linked to commercial benefits through a public biodiversity fund. The fund must promote public knowledge and conservation, by rewarding people and providing them social incentives. This fund could support meetings of folk practitioners and farming practices for promoting exchange of knowledge. Venture capital fund may be provided to grassroot innovators to experiment putting their ideas into practice.

The public fund can be generated by sharing the royalty derived from innovations based on public domain knowledge and a modest tax on sales of biodiversity based products, such as medicines. It can also be raised by diverting perverse incentives such as wasteful expenditure on the modern primary health care system that eventually erode sustainable traditional practices. Such public fund must be created using the provisions of CBD. GATT and TRIPS do not prevent such recognition to traditional knowledge, taxation measures and environment friendly incentives.

Indian response

Many Indian NGOs such as FRLHT, MSSRF, KSSP, SRISTI, Navadhanya are actively encouraging documentation of public knowledge. IISc has already prepared 50 village level biodiversity registers in several states. Even grassroot NGOs and people's science movements from Karnataka and Andhra Pradesh have voluntarily launched such documentation in many villages.

Acknowledging the public mood, the Indian government's November 1998 draft of the proposed Indian Biological Diversity Act makes significant promises. It envisages documentation of bioresources and knowledge, commitment to protection of public knowledge through *sui generis* system, scrutiny of IPR applications, obligation to oppose unjust IPRS, equitable benefit sharing provisions etc. The Act provides a broad framework and spirit though leaves much to the rules to be framed. Most unfortunately, the Act neither enforces disclosure of traditional knowledge in the IPR applications nor links the benefit sharing to documentation, perhaps leaving it for the ongoing Patent Act amendments.

The proposed Patent Act amendments seem to exclude innovations based on Indian medicine system from patentability. This would help keeping prices of new Ayurveda based drugs low. However, India must then also prepare for probable retaliatory measures by the developed countries and also forgo share of benefits if such products are manufactured, patented and sold in say in Norway or US.

Recently the World Intellectual Property Organisation, a UN body marginalised by the WTO, has initiated discussions to safeguard the traditional knowledge. India must support such political developments and lobby with other developing countries to work within the constraints to modify national IPR regimes and eventually the TRIPS when it is reviewed this year.

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could participate effectively in their development.

(10) In decentralised planning top priority should be given to education, health, water and sanitation facilities as these directly effect society's welfare and the women of the community.

(11) Keeping in view the importance of the panchayats, particularly zilla panchayats, the central government instructed the state governments in 1995 to put DRDA under the control of zilla panchayats. But so far these instructions have not been acted upon by the state government. Hence it is recommended that they are operationalised without any further delay.

(12) Women's share in government service is low in comparison to that of the males. The women representatives said that they could not easily interact with male employees at the block as well as elsewhere. Hence as in panchayats at least one-third of the posts in government services should be reserved for women.

(13) The panchayats' self-mobilised resources will enable them to assert as institution of self-governance. Hence, they should make efforts to raise their own resources through tax and non-tax measures. In this context imposing of all taxes listed in the panchayat act is a worthwhile preposition to be acted upon.

The recommendations which have emerged from the organisation of these camps may also be equally applicable to those other areas which are having the same social, economic, educational, and cultural background as the Gangoh KP.

The reservation of one-third seats both of members and chairpersons of the PRIs for women under the 73rd constitutional amendment was a right step towards their participation in decision-making in the decentralised governance. But in most cases their roles have been actually performed either by their husbands or any male member of the family as has been revealed through these camps organised in Gangoh KP. The women are not aware about their powers and authority. The traditional mindset of the males towards the females, which one poet described as "Man for the war and women for the hearth", is responsible for this injustice to women. The only remedy for this malady is to make the women aware by imparting to them training about local governance and the environment in which they are living. Hence, training-cum-awareness building programmes followed by workshops should be organised in a sustained manner for women's empowerment. The experience in these four camps indicates that training-cum-awareness building programme initiated in the Gangoh KP was appreciated by the women as well as men. Although the programme schedule was not adhered to in its entirety, the course contents were found quite relevant as they touched upon all the vital issues of decentralised governance and development. Older people of the area also said that for the first time they had seen such a programme in their life. In brief, the organising of the programme created an awareness that would have its spread effect in coming days to foster better working of panchayats. That was the general consensus.

Patents on Life, India and the TRIPs Mandate

V Manoj

Developments in law have kept pace with those in the field of biotechnology. However, the various judicial bodies which have been called upon to address the issue have not ventured to look at the issue objectively and examine the moral, ethical and environmental dimensions. As a result, judicial process has often recognised undesirable standards incompatible with the larger social needs.

LAW in the area of life patenting has been developing in the west for the last two decades, keeping pace with the developments in biotechnology. Biotechnology either directly or indirectly deals with living subject matters.[1] The advancements in this area proved that genetic constitutions of living beings can be altered.[2] This resulted in the emergence of genetic engineering as a scientific revolution which promises even the creation of new forms of life. The subject matters of biotechnological inventions are micro-organisms, hybrid plants, genetically engineered animals, human genes and cell lines. The high commercial potential of genetic researches made this branch of science a focal point of trade and investment. Consequently, claims for patents on these living inventions have started coming up along with a demand for better patent protection for biotechnological inventions. This led to a situation where law and legal systems were compelled to address the issue of granting patents on living beings, particularly in the context of globalisation of trade and investment.

The various judicial bodies which were called upon to address the issue, did not venture to look at it objectively in the light of the moral, ethical and environmental dimensions involved in it. The resultant judicial process therefore failed to reflect upon the competing rationale involved in it. This gave rise to the legal recognition of undesirable standards incompatible with the larger social needs thereby lacking universal acceptability.

Patents on Life

The US supreme court in Chakraborty case[3] liberally interpreted the patentability norms contained in 35 USC Section 101, and held that a man-made micro-organism is patentable. This was the first patent on a life form. The court, in the case, considered whether a micro-organism constitutes a manufacture of composition of matter within the meaning of the statute. The court in a 5:4 majority judgment interpreted the above expression as including living subject matters also. The reasons behind the judgment are not very clear. The court went against the legislative intent behind the provision dealing with patentable subject matter. As Brennen J, said in his dissenting judgment,[4] the court has misread the applicable legislation. The minority view reflects the concern of the judges in going against the legislative direction because the legislative language has chosen carefully to limit patent protection to inanimate objects. On the other hand, it is evident from the majority view that the decision is throughly influenced by a number of socio-economic factors. But, the court observed that the grant or denial of patents on micro-organisms do not affect in any way the pace of the genetic researches. The court did not venture to make a value judgment on the relative merits and demerits of genetic engineering.[5] But the decision created a tempest in the intellectual circles resulting in heated debates about the various ramifications of providing patents on life forms. The debate still goes on.

Subsequent to Chakraborty case[6] the court in Ex Parte Allen[7] extended patent protection to multicellular organisms. A few days after the decision in this case the PTO commissioner in the US issued a statement which reads as follows:

> The patent and trademark office now considers non-naturally occurring non-human multicellular organisms, including animals to be patentable subject matter within the scope of 35 USC.[8]

This statement is now reflected as the policy in the manual of patent examining procedure.[9] Based on this policy the US

Patent Office granted the first patent on an animal the Harvard Oncomouse.[10] The patent was for a transgenic non-human mammal. The mouse disclosed in this patent was bearing activated oncogenes in its genome and as a result had an increased susceptibility to cancer.[11]

Even though this patent is generally referred to as the Harvard Oncomouse patent, the claims allowed under the patent were of considerable breadth not limited to the mice.[12]

After the Harvard Oncomouse patent, no patents were issued till 1992 and in December 1992 further patents were granted on transgenic mice. Patenting of living beings in US is no more confined to micro-organisms. In 1995 the scientists at the University of Utah succeeded in finding BRCA, the breast cancer gene. They got it patented in US and the small biotech company which they started to commercially exploit the invention turned to be a market giant.[13] Subsequently, W French Anderson of the National Institute of Health (NIH) of US obtained a broad patent on human gene therapy in 1995. Mammals, human genes and cell lines, nothing is left out now from the purview of patents in US.

Developments in Europe

The European Patent Office (EPO), following closely the US patent office practices, has granted numerous patents on all sorts of biological materials.[14] Though not explicitly mentioned, it is generally accepted that EPC allows patent protection for micro-organisms.[15] The Technical Board of Appeal of the European Patent Office in a number of cases upheld EPO's decisions in granting patents on plants and seeds.[16]

The question of patenting an animal came up for consideration before the EPO examination division and the EPO Technical Board of Appeal in the Harvard Oncomouse, patents claims.[17] The decision of the examination division not to accept the claims on animals as such was set aside by the Board of Appeal. The Board held that "the exception to patentability under Article 53(b) of the European Patent Convention applies to certain categories of animals but not to animals as such".[18] The decision of the board really reflects the political considerations involved in this issue. The Board finds the probable enviromental risks and the sufferings of the animals on one side and the usefulness of the invention on the other side as the two competing rationale. But the Board did not venture to make a value judgment on the issue. Instead it left the matter for the examination division to act upon.

In the Green Peace Case[19] the Board of Appeal took an altogether different stand. In this case the Board held that claims on genetically engineered plants are not acceptable. Following this decision, now it will not be possible to obtain a European patent on genetically engineered plants or seeds because these will include plant varieties which come under the purview of the exclusion provision under Article 53(b) of the European Patent Convention. The Board was called upon in this case to explain the expressions *ordre public* and 'morality' occurring in article 53(a) of the European Patent Convention. The Board held:

> It is generally accepted that the concept of *ordre public* covers the protection of public security and the physical integrity of individuals as part of the society. This concept encompasses also the protection of the environment. Accordingly under article 53(a) of EPC, inventions, the exploitation of which is likely to breach public peace or social order or to seriously prejudice the environment are to be excluded from patentability as being contrary to *ordre public*.[20]

Explaining the concept of morality the Board held that it is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture.[21] Therefore the Board opined that an invention which does not conform to the conventionally accepted standards of conduct is to be excluded from patentability as being contrary to morality.

This seems to be a proper exposition of the balancing of interests envisaged under article 53 of the European Patent Convention. But the new biotech directive cuts at the root of this and brings a new set of patentability norms.

The European Parliament passed the directive on biotechnological inventions on July 16, 1997. The proposal of a council directive on the legal protection of biotechnological inventions was first put forward in 1988. After six years of negotiations between the EU institutions the directive was introduced before the European parliament in 1993. On March 1, 1995 the European parliament rejected the directive. Recently the proposal was reintroduced before the European parliament and of all the 510 parliamentarians, 378 voted for the directive, with 113 voting against and 19 abstentions. Even though the European parliament has passed the directive, to have the force of law, it has to be ratified by the European council of ministers.

The EC biotech directive broadens the European patent regime and brings within its scope a wide range of biological materials. Article 2 of the directive defines the expression biological material in the following lines:

> biological material means any material containing genetic information and capable of self-producing or capable of being reproduced in a biological system.

According to article 4(2) of the directive, plants and animals as well as elements of plants and animals are patentable subject matters. The new patentability norms provided in the directive exclude human beings as a whole and human embryos from patentability. The decisions of the European parliament to give the green signal to the directive attracted criticisms from various corners. Environmentalists and NGOs call it a clear demonstration of democratic unaccountability.[22]

India and TRIPs Mandate

The above-mentioned march of law has deeply influenced the patentability norms set under the TRIPs Agreement. The TRIPs, under article 27, mandates for patenting of micro-organisms.[23] India being a member of the World Trade Organisation is required to provide product patents on micro-organisms before January 1, 2004.[24] The Indian Patent Act, in its true spirit seems to have excluded all living beings from patentability. Section 3 of the act categorically states that an invention which is contrary to well established principles of natural laws or the intended use of which would be contrary to law or morality or injurious to public health are not inventions for the purpose of granting patents. The question here is: do these provisions exempt from patentability inventions relating to living beings? If they do, the mandate of the Patents Act goes against the TRIPs requirement and there arises a conflict between the two.

In the TRIPs Agreement also an attempt is made to strike a balance between the conflicting values on patenting of living beings. This is evident from the incorporation of the morality, *ordre public* provisions in article 27(2) of the Agreement. TRIPs in article 27(2) provides that the member countries can exclude from patentability such inventions, the prevention of the commercial exploitation of which is contrary to protect, *ordre public*, morality, human life, animal life, plant life, health and environment. The operation of this clause is limited by a proviso which says that an exclusion cannot be made merely because the exploitation is prohibited by law. But article 27(3), though allows the exclusion of plants and animals from patentability, brings micro-organisms within its purview. This in fact goes against the jurisprudential basis of article 27(2) resulting in an erosion of the balance aimed to strike by incorporating certain basic norms for excluding even living beings from patentability based on morality principles of sovereign states. But from the review provision in article 27(3) it appears that the framers of the TRIPs were aware of these conflicts. Article 27(3) provides for a review

of the patentability criteria, to be made, four years after the date of entry into the WTO Agreement, i e, January 1, 1999. As far as India is concerned the attempt should be to bring specifically inventions on life within the coverage of the general exclusion under article 27(2).

As regards plant varieties are concerned the TRIPs mandate is to provide protection by patents or by *sui generis system* or by a combination of the both. Since patents on plants attract scathing criticism in the above lines, the alternative is the *sui generis system*. An effective *sui generis system* also demands for the private property rights over plants through a statutory mechanism. Therefore all the arguments based on the above-mentioned provisions equally apply to such a legal mechanism.

The provisions in section 3 of the Patents Act are to be analysed in the light of article 27(2) of TRIPs. Since these provisions encompass the notion of morality in the Indian territorial context, the TRIPs objection for making certain inventions illegal by statutory measures does not have any bearing upon it. In fact article 27(2) of TRIPs justifies the mandate in section 3 of the Patents Act. Any attempt to interpret the above-mentioned provisions is to be made in the light of a jurisprudential enquiry as to the notion of morality in the Indian context.

TRIPs in article 27(2) expressly recognises the need to protect human, animal and plant lives, as well as health and environment. This reflects the concern regarding the long-term social risks associated with the commercial exploitation of biotechnological inventions. Since trade motives foster the commercialisation of biotechnology, the environment risk arguments have a larger economic dimension. But granting private property rights stands central to all these different arguments. Therefore the morality issue has a direct bearing on the environment-based arguments against the deployment of biotechnological inventions.

This again prompts a joint reading of article 27(2) of TRIPs and section 3 of the Indian Patents Act. The reasoning here is identical to the one which we have raised in the morality context. Section 3 of Patents Act has to be read in consonance with article 27(2) of TRIPs thereby reasserting the strength of 'the morality, public order, environmental protection' arguments against life patenting. Any attempt to override or nullify these provisions violate the basic norms, which they stem from. Therefore article 27(3) is to be restructured so as to receive universal acceptability. This becomes easy because article 27(3) gives room for renegotiating the patentability norms in TRIPs. Attempts are to be made persistently to renegotiate the TRIPs patentability norms by highlighting its fallacies instead of framing proposals on micro-organism patenting and to bring amendments to the Patents Act.

Notes

1 The expression biotechnology despite its long standing tradition is not properly defined. But several attempts have been made to comprehensively define the term biotechnology. An OECD study defines biotechnology as the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services. See Bull, Holt and Lilly, *Biotechnology, International Trends and Prospectives* (OECD, Paris, 1982), p 21.

2 See Micheline L Gravelle, 'Biotechnology – An Overview', *10 Canadian Intellectual Property Review I*, p 1.

3 Diamond vs Chakraborty (1980) SC, 447, US 303.

4 With whom White, Marshall and Powell, JJ, joined in the dissenting judgment

5 The Court observed: "What is more important is that we all without competence do entertain these arguments, either to brush them aside as fantasies generated by fear of the unknown or to act on them". *Supra*, n 3, para 8.

NEW DELHI

Falling in Line, Smartly

BM

The government has been very vocal about its supposed achievement in recording a build-up of exchange reserves. The WTO has taken this seriously and has now suggested that the quantitative restrictions on imports be lifted. And the government has promptly accepted the directive.

THE World Trade Organisation (WTO) has proposed that India should shorten the five-year transition period for the removal of quantitative restrictions on its imports. The government has treated this proposal as a directive and has fallen in line promptly. In addition to the transitional facility under what is called an international treaty for promoting a multilateral trading system under the aegis of WTO and also because of its weak balance of payments position, India has been exempt so far from the obligation to lift quantitative restrictions on imports. It was agreed in the WTO consultative mechanism in the last three years that "it would be neither prudent nor feasible to consider general lifting of quantitative restrictions". In January this year, however, the WTO reviewed India's BOP and ruled that it had improved and warranted the lifting of quantitative restriction.

The Indian delegation to WTO consultations in Geneva was placed in an awkward position. The government in India has been advertising the build-up of exchange reserves as a signal achievement of its economic liberalisation and globalisation policy. This was meant essentially for home consumption to garner political gains for the performance of the economic reform policies in the last five years. But this advertising gimmick has been taken advantage of by the developed countries to activate the WTO to press home their demand for the removal of all restrictions on their exports to India. India's ardent economic reformers, on their part, have found in the latest move for removing quantitative restrictions on imports a favourable opportunity to assert and push forward their liberalisation-globalisation objectives. It is not fortuitous either that their demand for scrapping FERA and for the full convertibility of the rupee has lately become strident.

The union commerce ministry, when it announced the import-export policy for five years, beginning 1997-98, had gone slow on the removal of quantitative restrictions on imports. Conditions were said to be yet inappropriate for an unrestricted import spree. The exchange value of the rupee had, after all, eroded sharply in the previous two years which made imports very costly in rupee terms; the volume of exports had to go up substantially to earn dollars and export promotion measures had really not clicked. The trade and current account deficits too have been widening. The commerce ministry is now being forced to go back on its cautious stance on the liberalisation of imports. But the union finance ministry even before WTO demanded removal of quantitative restrictions on import to bring down tariff barriers to levels below what was required under the WTO timetable. The push for import liberalisation, with all its implications, is thus gaining momentum. Its impact is bound to be severe for the Indian capital goods manufacturers who are facing demand recession. But its impact will be even more visible and sharp in respect of the goods of current consumption – to subserve not only the elitist demand in the upmarket. Agricultural commodities, processed and non-processed, among them foodgrains, too will have free access to the Indian market and compete against the domestic products. The government is already inclined to rely on imports to overcome temporary shortages and stabilise prices of essential wage goods. But the removal of quantitative restrictions and lowering of tariff barriers on their import, including of foodgrains, are bound to have adverse implications for the domestic producers, the farmers and craftsmen.

Significantly, even as imports are proposed to be further liberalised, disinvestment of government equity in large public sector industrial undertakings (PSUs) too is being rapidly streamlined. The earlier lethargy and confusion in this regard is being removed. The disinvestment programme cannot, after all, be limited merely to the shedding of government equity in driblets for raising revenue to narrow its budgetary deficit. It has to be part of the wider structural adjustment process for the privatisation and gloablisation of the Indian economy. The Disinvestment Commission has come forth with the recommendation for 'strategic sale' of PSUs and has identified, in its second report, five major PSUs – Bharat Aluminium, Bongaigaon Refinery and Petrochemicals, Hindustan Teleprinters, Indian Telephone Industries and Madras Refineries to start with for their 'strategic' sale. It has recommended that the sale of PSUs should be thrown open to private business interests not only Indian but foreign as well. It has simply ignored and overturned the proposition that the government should retain its management control over PSUs in the core sector and disinvestment by the government in their case should not exceed 49 per cent of their equity. As matters stand, it is not on the cards that Indian business interests will have either financial resources or technological and management capability to take them over and run large PSUs efficiently. Public investment for industrial development, after the initial spurt between mid-1950s and mid-1960s started decelerating afterwards and by the 1970s this had led to the obsolescence of many of the established PSUs. Renovation and technological upgrading has to be a continuing process for maintaining and improving their efficiency. But their original rated capacity actually tended to suffer considerable erosion. Much before the sale of the government equity in PSUs was started under the spell of the privatisation – globalisation philosophy, many of these undertakings were also attempted to be linked to foreign TNCs in the name of introducting new technologies. This encouraged import of equipment associated with the introduction of their technologies and management practices in PSUs even though they were out of step with the economic and social environment in India. These developments have now paved the way for the 'strategic sale' of PSUs to TNCs.

The western developed countries and their international financial institution had tried to discourage public investments for building modern industries when India embarked on planned development after gaining political independence. When, however, they failed to block these investments, they tried to regulate and distort the technological and engineering parameters of PSUs and subvert their management principles. It has been hard going for public sector undertakings to grow but they made laudable progress in many directions. Under the pressure of vested interests, domestic and foreign, and sabotage by their agents in influential positions, administrative and political, the ground had been prepared steadily and over time, to strangulate commercial and industrial enterprise in the public sector. Combined with withdrawal of budgetary support, government equity in PSUs has been diluted in the so-called economic reform era to raise revenue for current consumption of the government. The so-called 'joint sector' concept too has been sought to be promoted in such strategic areas as oil, steel and power. This has not yielded the spectacular results for the simple reasons that foreign interests have demanded control in these areas on exorbitant terms. The economic reformers now seem to have decided that 'strategic sale' of PSUs to multinational corporations is the best option for them.

The change in the political line-up behind the UF government headed by Inder Kumar

Gujral, has evidently become still more favourable for the economic reformers lobby. The reformers seem now determined not to brook any dithering or hesitation on the honouring of the international obligations of the government or the logic of the privatisation-globalisation process. Finance minister P Chidambaram sees the inflow of foreign funds by way of direct and portfolio investments, deposits and credits as the only panacea for the ailing and stunted Indian economy. The adverse implications for the balance of payments position do not bother him. This is the same mindset that has driven him to cut domestic taxes for the rich without making in his budget 'conventional' estimates of the revenue losses for the government on this account. But the balance of payments problem is not something which can be cavalierly wished away. India's exchange reserves are only seemingly large. They are not composed of dollars earned. They are almost entirely based on the accumulation of borrowed funds which have been frozen by the Reserve Bank of India and have not been used as in the past for investment or social welfare, albeit inefficiently. The major portion of reserves is composed of the volatile portfolio investment and unreliable NRI deposits. The reckless commercial borrowing to push up the economic growth rate in the second half of the 1980s resulted in the external payments problem in 1991. The imprudent reduction of tariff barriers and lifting of quantitative restrictions on imports in the second half of the 1990s may in the prevailing conditions when reserves can easily melt and exports are not picking up, push India into a far more grave balance of payments position into a couple of years. Combined with the planned decline and, eventually total stoppage of public investment in industry as well as agriculture, prospects for economic growth, let alone social justice, will be blighted.

The economic reformers have indeed persuaded themselves, frankly and without any reservation, that only the rich and the upper segment of the middle class can be depended upon to be their articulate political and social support base. According to their highly exaggerated estimates, this support base can grow in due course to be more than 30 per cent of the Indian population. They are, therefore, devoting themselves to satisfy their requirements and demands and give precedence to their claims in economic policy-making. They also believe that foreign capital inflows combined with political support of foreign powers and the network of international institutions set up by them will help to achieve their economic, social and political objectives in India. Their anxiety is to ensure that the so-called 'international obligations' should be promptly and enthusiastically honoured by India. This is becoming more and more manifest. It is forthright in renouncing unilaterally the right to take advantage of the transitional facilities embodied in the WTO system for the enforcement of the multilateral treaty obligations. The bargaining position of India in the WTO and all international institutions is, therefore, weakening to a dangerous extent.

Cogentrix Power: Uneconomical

V Ranganathan

The power generated by the Mangalore Thermal Project is about twice as costly as competitive power available in global markets. Moreover, a proper analysis of alternatives, including that of hydro power and pit-head thermal power from other locations has not been done.

THE growth rate of demand for electricity for the developing countries is much higher than that of developed countries. According to the World Bank 'to meet the current demand for electricity, and to provide service to the two billion people currently doing without, developing countries will have to invest an estimated 100 billion dollars per year over the next decade. In fact, it is estimated that by 2010 the developing countries will have surpassed the OECD countries in total installed generating capacity, if they can raise the needed capital' [World Bank/IFC 1994].

Nearly two-thirds of the incremental demand for electricity for the whole world will be coming from developing countries – of which China and India will account for the major share – while the developed countries will be facing a tapering off of demand. The international power equipment industry is facing a glut and they have only the developing countries as their potential customers. But then the power sector in the developing countries is neither having the finances to buy the equipment now, nor are their utilities financially sound to qualify for loans. Hence the structural reform, mainly to facilitate equipment sales of developed countries to developing countries through promotion of IPPs and tariff reform (price increase) to make the buying utilities able to pay for the equipment purchase.

To be sure, power sector reforms are sweeping throughout the world, not only in funds starved developing countries, but also in developed countries including the UK, the US, Australia and Japan. But then there is a big difference. The reforms in the developed countries are aimed at making the electricity sector more efficient by bringing down the prices to the consumer by replacing monopoly with competition wherever possible. But in India and most other developing countries, the reforms are driven by resource mobilisation objective and the need to reduce fiscal deficit. Electricity supply expansion is sought to be achieved from private sector financing instead of government financing. This, in turn, has made the reform process externally driven, principally by the World Bank, which has put 'reforms' as a conditionality for its loans. However, while insisting on the reforms, the World Bank's prescription has been ad hoc and piecemeal with a blurring of the distinction between the ends and the means. The end objective of reform is introduction of competition to bring down the prices and improve quality. Privatisation is a means, wherever it will lead to competition. Achieving private ownership without achieving competition, will only displace public sector inefficiency with private sector monopoly profits and there is no guarantee for improvement. The World Bank has been chanting the mantra of privatisation whereas it should be chanting the mantra of competition. This is also illustrated in Mexican energy sector reforms. There with the advent of Mexican crisis, the World Bank and IMF imposed conditionalities to 'open up', viz, allow the Mexican public sector oil companies – which were a 'pride' of the nation – to be bought by the US multinationals [Rodriguez-Padilla 1996].

By now it is established that competition is possible in the electricity generation industry. This should result in a price convergence, except for some minor differences due to location. The glut in the electricity equipment market, which can open up possibilities of sales below full cost of equipment, is also to be borne in mind. In the US, coal based electricity prices are in the range of 4 to 4.5 US cents (about Rs 1.57 per kwh @ Rs 35 = 1 dollar exchange rate) and are falling. In UK the average pool output price in 1988-89 was 2.08 pence per kwh (Rs 1.20 per kwh @ Rs 58 per 1 GBP) [Green and Newbery 1992].

A one paise increase in tariff, for a 1,000 MW plant at 80 per cent plant load factor means an increased payment of Rs 7 crore per year, which for 30 years at 12 per cent interest rate, works out to a present value of Rs 56 crore.

Comparison of Alternatives

in 1993, Janson and Lako conducted a study of analysis of alternatives for the thermal power plant at Mangalore [Janson and Lako 1995]. They considered four alternatives, viz, power plant at Mangalore with imported coal from South Africa, power plant at Mangalore with domestic coal from Talcher, pit-head plant at Talcher with HVDC line from Talcher to Cuddapah, and finally LNG based combined cycle power plant. Both financial and economic analysis were done, the latter taking the border prices sans

World Trade Organisation and National Sovereignty

The Final Act embodying the results of the Uruguay Round of negotiations has foisted an unequal treaty on the developing countries in all its economic and social aspects. The treaty is virtually a charter of obligations for the developing countries. It is a global conspiracy of the developed nations, not only to blunt the economic growth in the developing countries but also to set in motion an era of "degrowth", both in the industrial and in the agricultural sectors. Developing countries are likely to face serious obstacles, in the form of technical barriers, in their pursuit of the achievement of all round economic growth. The claim, that all countries are supposed to benefit from the new framework, sounds hollow.

Paradoxically, in the area of transfer and dissemination of technologies, the Uruguay Round does not bring in freedom from monopolies. In the area of market access, the commitment to reduction of tariff barriers and abolition of non-tariff barriers would make the markets of the developing countries more vulnerable to unequal competition. Similarly, binding commitments for imports, particularly in the area of agricultural products would create imbalance in the future production and growth in the agricultural sector. The new global patent system, as proposed by the TRIPs Agreement, would strengthen monopolies. Particularly in the area of health care, it will increase the sufferings of the poor and aged, manifold. The Service sector would also be exposed to the shifting of control over resources, in the financial sector, in to the hands of powerful foreign institutions. Thus the Final Act will transform the whole business environment, by strengthening the control of global monopolies — the implications of which for the developing countries, in particular, would be far reaching.

Without going into minute details, we will attempt to identify major obligations and their implications for the developing countries in all the three sectors of the economy — industry, agriculture and the service sector.

Obligations in the Industrial Sector

Tariff Reduction

The GATT 1947 rules allowed a lot of flexibilities to the developing countries, for regulating their imports, because of the balance of payment problems. The developing countries had flexible options in determining the operation of tariff barriers in the shape of customs duties, and could also employ restrictive import measures. Thus the industrial sector enjoyed a sort of protection in the domestic markets. The Final Act incorporates Uruguay Round Protocol to the GATT, 1994. Under this protocol, the member countries were required to submit various schedules for most favoured nation tariffs, tariff quotas, preferential tariffs, non-tariff concessions, commitments limiting subsidisation in agriculture products, etc. The tariff reductions agreed upon by each member are supposed to be implemented in five equal rate reductions, except as may be otherwise specified in a member's schedule. The first stage reduction was made effective on the date of entry into force of the agreement establishing the WTO, i.e. 1.1.95. Each successive reduction was to be effective on January 1 of each of the following years. The final rates were to become effective no later than four years from 1.1.95. Complying with the requirement of protocol, India submitted their schedules in February 1994. The exact analysis of the proposed reductions in the tariffs are not available. However, broadly speaking, the government agreed to reduce the base rate of duty from 105% to 40%. The government has been more than enthusiastic — it brought down the peak rate of duty to 40% in the short span of 1996-97. It has proposed a further reduction of the peak rate to 30% in the budget for 1997-98. This steep reduction in tariff rates has already had a grave impact on the small scale and medium scale sector companies. In fact it has resulted in dumping of chemicals and many other products from China into our country.

Removal of Non-Tariff Barriers

The Final Act also incorporates "understanding on the balance of payments provisions of the GATT 1994". It provides that the member countries would confirm their commitment and publicly announce, as soon as possible, time schedules for the removal of restrictive measures taken for balance of payment purposes — i.e. those allowed under article XVIII : B of the GATT. It is understood that out of the 4,798 HS-Lines notified by the Government of India, 4,433 HS-Lines were under Quantitative Restrictions (QRs). Consultations between India and the Committee on Balance of Payments Restrictions were held in 1994 &1995. During the 1995 consultations, the committee noted that "in the context of deteriorating balance of payments situation, it would be neither prudent nor feasible to consider the general lifting of quantitative restrictions on imports at this stage".

A meeting of the committee was again held on January, 20-21, 1997 in Geneva. In this meeting, India's BOP cover came up for review by the WTO committee. The International Monetary Fund is reported to have stated to the committee that in view of an improvement in India's BOP position and foreign exchange reserves, use of Article XVIII : B and imposition of import restrictions were no longer justified. On the basis of the brief cleared by the Union Cabinet for the Indian delegation to Geneva talks, only the programme of import liberalisation with regard to manufactured goods were covered for phasing out quantitative restrictions over a period of five years. Import restrictions maintained by India at present cover 34% of manufactured products — mostly consumer durables and non-durables — but as much as 70% of all farm products. The WTO committee has given time for submission of a programme for phased removal of QRs on imports till the beginning of June 1997. If QRs are removed, Indian industry — particularly in the medium and small scale sector — would face unequal competition from imports in the case of manufactured goods, thereby threatening its very survival. Moreover, the unrestrained flow of imports would result in a steep increase in the import bill. The Indian government should, even at this stage, seek postponement on the decision on removal of restrictions, because of the balance of payments problem, based on the following considerations.

- A significant portion of the foreign exchange reserves is highly volatile.
- The size of the reserves is hardly sufficient to sustain 3-4 months of imports.
- The craze for imported consumer goods among a section of the elite, with adequate purchasing power, could result in a surge of imports.
- Export earnings are not growing at a satisfactory rate.
- Protectionist policies adopted by the developed countries, particularly in the areas of textiles and agriculture, are standing in the way of significant growth in exports.

Obligations in the TRIPs Agreement

The TRIPs Agreement for global patent system imposes a range of obligations. The developing countries have been in the process of evolving their national patent systems, which are in tune with their stage of development. Such systems are designed to balance the rights and obligations of patent-holders. Contrary to this, the TRIPs patent system seeks to impose a global patent model which is virtually a charter of rights for the patent-holder. Member countries are supposed to change their patent laws in accordance with the provisions of the TRIPs Agreement.

The changes are supposed to be made in two phases. In the first phase, developing countries like India, who have no product patent system for pharmaceuticals and agro-chemicals, are supposed to amend their laws to accept product patent applications for pharmaceuticals and agro-chemicals from 1.1.95. Although the patent rights on these applications can be granted only after 2005 — i.e. at the end of the 10 year transition period that the agreement on TRIPs allows to developing countries like India — product patent applicants are required to be given exclusive marketing rights (EMR) after marketing approval has been obtained, for a period of five years This implies that even before a patent is granted, a patent-like monopoly over the market of the product can be enjoyed by the patentee.

These two obligations virtually negate the 10-year transitional period in the said two fields of

technology. These obligations will have a serious impact, not only on the pharmaceutical industry but also for the general public. The industry will not be able to introduce new products. Moreover, new products — which would be monopolised through the medium of exclusive marketing rights — would be available at prices beyond the reach of an overwhelming majority of people.

In addition to the obligations during the transitional period, the obligations to change the patent system would result in extending patent rights to all industrial and agricultural products. The patent rights would also extend to imports; i.e. importation of the patented product by the patentee would be treated at par with domestic production. Moreover, the patent holder would have exclusive rights to import.

In addition, provisions relating to safeguarding of public interest, as provided in the Patents Act, 1970, would have to be radically amended. The proposed new laws, in line with the TRIPs Agreement, would have no provisions for Licensing of Right or Compulsory Licensing for commercial purposes. Both these provisions are part of the existing Indian Patents Act, 1970, and they allow the government the option of curbing or withholding the monopoly rights of a patent holder in national interest and in order to safeguard the health needs of the people. Deletion of these provisions in any new Act would lead to significant rise in prices of protected products, and would also prevent the entry of the domestic industry into new products.

There is another significant obligation, which is at variance with existing laws. In cases of alleged infringement of patent rights, if a case is filed in court, the defendant will have to prove that he has not infringed the process patent of the patent holder (reversal of burden of proof). This provision puts Indian companies at an obvious disadvantage, given the high legal costs and the ability of foreign patent holders (MNCs) to pledge funds for frequent litigations.

In a report prepared by UNCTAD in July 1996, on the implications of TRIPs on developing countries, it is stated that the implementation and enforcement of rules, disciplines and procedures called for in TRIPs would require large investments for setting up or improvement of administrative mechanisms. This has special relevance for India. The scope of the Patents Act, 1970 is limited in nature. There are no legislations for plant varieties, geographical indicators, integrated circuits, etc. The staff of the offices administering the industrial properties are small and inadequately equipped. Provisions in the TRIPs Agreement, such as "reversal of burden of proof" will require large modifications of the existing legal framework. In India today, patent examiners still perform manual searchers of prior applications, because of limited access to computers and international data bases. There is already a growing backlog of unprocessed applications. A steep rise in applications is likely in the near future. In order to cope with this pressure, the Patents and Trade Marks Office will have to be substantially strengthened and modernised.

Obligation In the Agriculture Sector

As in the industrial sector, GATT 1947 rules permitted flexibility for the developing countries for regulating their imports, because of BOP problems. Agriculture was mostly kept out of the purview of the GATT because of the exceptions sought by the developed countries (primarily the U.S.) in the 1950s. This allowed these countries to strengthen their agriculture production by numerous non-tariff measures and liberal grants of subsidies. By the end of the 1980s, when their agriculture had made substantial progress, developed countries like the U.S. and countries of the European Union felt the need to find markets for the export of their surplus in the agriculture sector. Even the Uruguay Round of GATT negotiations, which was officially proposed to be concluded by December 1990, were delayed for three years due to conflicts between the U.S. and the European Union regarding national policies relating to agriculture. U.S. producers and exporters faced competition in the world markets due to high subsidies granted to producers in the European Union.

The midterm review of the Uruguay Round of GATT negotiations agreed upon a long term objective for reforms of trade in agriculture so as to "establish a fair market oriented agricultural trading system and that a reform process should be initiated through the negotiations of commitments on support and protection and through the establishment of strengthened and more operationally effective GATT rules and disciplines". It was further agreed that "long term

objective is to provide for substantial progressive reduction in agricultural support and protection sustained over an agreed period of time". Thus specific binding commitments have been provided in the Agreement on Agriculture in each of the following areas:

- Market Access
- Domestic Support
- Export Competition
- To reach an agreement on sanitary and phyto-stationery issues.
- To secure at least a *sui generis* system or a patent system for protection of new plant varieties.

Market Access

Agriculture market access concessions — relating to bindings, reduction of tariffs, and to other market access commitments — were submitted to the GATT secretariat by all member countries by the middle of February 1994.
Member countries are not allowed to maintain quantitative import restrictions, variable import levies, minimum import prices, discretionary import licensing, non-tariff measures maintained through state trading enterprises, voluntary export restraints and similar border measures other than customs duties. These restrictions are supposed to be converted into tariffs, excepting as otherwise provided in Article 5 and Annexure 5 of the Agreement on Agriculture. The implementation period for the Agreement on Agriculture is 6 years, commencing in the year 1995 (except for the purposes of Article 13 of the Agreement relating to new constraints, the implementation period is 9 years commencing in 1995).

Hitherto, under Article XVIII : B, India has been able to continue with measures to restrict imports, for balance of payment purposes. But in the committee of BOP restrictions meeting held on January 20-21 1997 India has agreed to the removal of its legal right on these restrictive import measures. Given this record, it is not clear how long we would be able to delay the phasing out of restrictions on imports in agriculture. The implementation of the Agreement on Agriculture would make us extremely vulnerable. The only safeguards that would be available (once right to restrictive import measures are foregone) will be in the form of tariff restrictions. Such a situation can wreck the balance of growth of agricultural products in India, which is just on the threshold of self reliance in the area. The extent to which such disruption does take place would only be known during the implementation period, as we start exposing the agricultural sector to the vagaries of globalisation.

Domestic Support

The term "Aggregate Measurements of Support" (AMS) in the Agreement on Agriculture denotes the annual level of support, expressed in monetary terms, provided for an agricultural product in favour of the producers of the basic agricultural product; or non-product-specific support provided in favour of agriculture producers in general (other than the support provided under programmes that qualify exemption from reduction under Annexure 2 of the Agreement on Agriculture). The Agreement on Agriculture provides two separate levels of ceilings on AMS — 5% in the case of developed countries on product-specific and non product-specific domestic support. For developing countries *de minimis* percentage of ceiling has been prescribed at 10 percent. There are no reduction commitments needed in the case of those countries which are below these ceilings. All those countries whose agricultural support is above these ceilings had to indicate their reduction commitments in the appropriate schedule by mid-February 1994. Members have flexibility to bring down domestic support by 20% in a period of 6 years. Further, these levels of support can also be brought down on the basis of budgetary support for the relevant products. This kind of flexibility will thus be available to adjust the subsidy within the products which fall in the category of support above the ceilings.

Certain programmes, like measures to encourage agricultural and rural development, investment subsidies generally available to agriculture in developing countries, and agriculture input subsidies to low income or poor resources producers are exempt from domestic support reduction commitments. Similarly, there are a number of other Government Service Programmes listed in Annexure 2 of the Agreement on Agriculture which are also exempt from inclusion in the Aggregate Measures of Support. However, for programmes under which

stocks of foodstuffs for food security purposes are retained by the Government and released at administered prices, the difference between the acquisition price and the external reference price (if the former is higher) has also to be included in the AMS.

Export Competition

Members are required to reduce the value of direct export subsidies to a level that is 36% below the 1986-90 base period level, over the 6-year implementation period. The quantity of subsidised export is to be reduced by 21% over the same period. In the case of developing countries, the reductions required are two-thirds of those required from developed countries over a 10-year period. No reductions apply to the least developed countries. Products that are not subject to reduction commitments is prescribed under the Agreement. However, during the implementation period developing countries may take recourse to subsidies to reduce the cost of marketing exports of agricultural products, or of internal transport and freight charges on export shipments. The Agreement on Agriculture also calls for further negotiations to be initiated before the end of the fifth year of implementation.

Agreement on Sanitary and Phyto-Sanitary Issues

The Agreement on application of sanitary and phyto-sanitary measures concerns the application of food safety and animal and plant health regulations. It recognises Government's right to take sanitary and phyto-sanitary measures but stipulates that they must be based on scientific basis and be applied only to the extent necessary to protect human, animal or plant life or health and should not arbitrarily or unjustifiably discriminate between members where identical and similar conditions prevail. The members are supposed to be encouraged to base their measures on international standards, guidelines and recommendations wherever they exist. However, members may maintain or introduce measures which result in higher standards if there is scientific justification. It is feared that in the guise of sanitary and phyto-sanitary measures, various arbitrary standards would be stipulated to block imports by the developed countries (from developing countries) even when there are binding commitments to open up their markets to the extent stipulated in the Agreement.

Sui generis System for Protection of Plant Varieties

Member countries are supposed to evolve an effective *sui generis* or patent system for protection of plant varieties. At present India does not have a system for protection of plant varieties. The key issue in this respect is, how the rights of Indian farmers can protected vis-a-vis the rights which might be given to the plant-breeders. The time frame for legislating this measure is 5 years. The extending of intellectual property protection to agriculture would seriously impede research programmes undertaken by public or private institutions, as well as agricultural universities. Dominant TNCs would be allowed to seek exclusive rights over the planting material. The obligation to legislate does not lay down the scope and extent to which the protection may be provided.

It would be in India's interest if exempt categories are clearly laid down. From the point of view of food security and health needs, at least plant varieties relating to foodgrains, vegetables and fruits (and even medicinal plants) should be excluded from the domain of plant-breeder rights. It is also necessary for India to examine and analyse systems (for protection of plant varieties) which might be adopted by other developing countries, who are similarly placed. It must be remembered that the obligation to legislate does not extend specifically to all plant varieties. Further, the WTO is also scheduled to review various national systems for plant-breeder rights during 1999. It might be prudent to wait till then, instead of arriving at a hasty decision to extend intellectual property rights to plant varieties immediately.

In conclusion it might be stated that the commitments and obligations undertaken by the then government in the WTO are clearly inimical for all-round growth of various sectors of the economy. Moreover, when these obligations are assessed against Constitutional guarantees pledged to our people, most of them would be seen to be *ultra-vires* our Constitution.

Contributed by *B.K.Keayla*

"World Class" Patents : An Invitation to Disaster?

(IDMA Study)

"World Class" or "Modern" patents are new terminologies recently adopted by U.S. MNCs and U.S. Trade Representatives to designate a patent system, which provides much more stronger patent protection to rightholders, than even TRIPS Agreement.

People often use these terms under the belief that these refer to a modern and progressive patent system, which will promote research and technological development. It would be instructive to know the implications of the expression "World Class" patents.

Till 1992, the developed countries were happy with the protection available under Paris Convention, and during GATT negotiations, had been insisting on all countries joining Paris Convention.

Having achieved a higher level of protection under TRIPS, they are now aiming to make further inroads by making the system fool-proof in favour of MNC patent holders, by inducing or forcing the developing countries to accept the "World Class" patent system under threat of Special 301.

The term "World Class" is used apparently to create a false impression that it is a more progressive patent system designed to promote research, and industrial and technological development.

There is no single document specifying the requirements of World Class patents. But from the complaints made by U.S. MNCs and U.S.T.R. against different countries during last three years, their expectations of "World Class" patents can be spelt out as set out below:

1. SCOPE AND COVERAGE OF PATENTABLE SUBJECTS:

(a) All fields of technology with no limitations.

(b) Both product and process patents to be covered.

(c) Even discoveries (as distinguished from inventions) are also patentable.

(d) "Discoveries" being patentable, field will be extended to all natural products and living beings, including microorganisms occurring in nature.

Plants and agricultural products will also be covered.

Animals, and part of human beings will also be patentable.

(e) The following will also be patentable:

- New use of known-substances;
- new use of known-processes;
- Combination products by mixing two or three known-substances;
- methods of testing an analysis;
- methods of surgical, curative, prophylactic or other treatment of human beings and animals;

(f) Inventions of Bio-technology, genetic engineering etc. – clones -

Note: - None of these (except micro-organism and plant varieties) are required to be covered even by TRIPS agreement. Indian Patents Act, 1970 does not cover any of these. Except product patents for all other products except drugs and medicines, pesticides, insecticides, foods etc., for which only process patents are allowed.

2. THE CRITERIA OF PATENTABILITY ARE LAX

The standards of each of the criteria of patentability, prescribed by TRIPS, namely, (i) new, (ii) involving an inventive step; and (iii) capable of industrial application, are considerably relaxed in the World Class patents, to allow even common place items like turmeric powder, new products, combination drugs, new uses of known-drugs etc. to be treated as satisfying the patentability requirement and patents are granted, almost for the asking. Even methods of treatment and diagnosis are accepted as satisfying the industrial application test.

For considering - "new" novelty and "inventive step" - i.e. non-obviousness, only the printed and published matter is to be taken into account. This means traditional knowledge passed on from generation to generation by actual use or orally, is to be ignored and can be patented. The turmeric powder patent is a case in point.

Under the TRIPS Agreement and the Indian Patents Act, 1970, it is possible and permissible to prescribe and maintain higher standards of patentability criteria.

3. THE PROCEDURES ARE DESIGNED TO AVOID DETAILED SCRUTINY AND PUBLIC OPPOSITION UNDER THE PRETEXT OF AVOIDING DELAY IN GRANT OF PATENTS

The pre-grant departmental scrutiny of the patent specifications and applications is required to be brief and expeditious. Departmental scrutiny is confined to available records in the patent office. Definite time frame is to be provided for disposal of the application. Publication of the application before grant is also avoided. In the process, even common place subjects, like use of turmeric powder gets patented.

Procedure and opportunity of Opposition by members of public should also be avoided.

Provision could be made for publication and "re-examination of the patent", post-grant.

This has the effect of shifting the burden of proof from the claimant to the objector, as grant of the patent is normally treated as prima facie proof of its validity. The objector has to prove the invalidity.

Both as per TRIPS and the Indian Patents Act 1970, departmental scrutiny, prior publication, and opposition by other interested parties are permissible before grant.

4. BROAD CLAIMS

In case of chemical patents, broad claims covering millions of compounds on basis of research and disclosure of only a few compounds, is to be allowed on hypothetical consideration, and application of doctrine of equivalents.

In case of microorganisms, claiming of entire species may have to be permitted.

Such claims are hypothetical and presumptuous. They are not supported by actual research or experimental work. There are no disclosures to support such claims. As such there is no contribution to scientific knowledge or technological advancement. The community does not get any benefit in consideration of such claims.

On the contrary, such claims block and deny to other research workers a large field for further research and development.

TRIPS and the Indian Patents Act 1970 do not require patent protection to be extended to such hypothetical claims.

5. IMPORTATION AS WORKING OF PATENTS

Importation has to be accepted as working of the patent. Under U.S. Law, the patentee need not

produce, import or actually use the patent in the country. Yet he gets a right to prevent others from using, producing or researching.

TRIPS Agreement (through Paris Convention) accepts importation as working for the purposes of resisting revocation of patent on ground of non-working, but compulsory licences can be issued if working is only by importation.

The Indian Patents Act 1970 insists on working of the patent in the country.

6. THE TERM OF PATENT

The term of patent should be 20 years. In case of commodities, like drugs and medicines, where approval of regulatory authority is required for marketing, the 20 year period will be counted from the day, market approval is given for the commodity or drug by the F.D.A. Thus the period can be extended upto a further five years.

TRIPS and the Indian Patents Act 1970 do not require any such extention to be granted.

7. USE OF INVENTED PRODUCT FOR TRIALS FOR REGULATORY APPROVAL OR RESEARCH WORK PROHIBITED

While the patent is in force, whether during the original term or extended period, use of the invention for experiments, research, or even clinical trials for generating data for market approval and introduction of the drug after expiry of the patent is prohibited. The result is that after expiry of the patent, other manufacturers cannot introduce the drug, and the consumer will be denied alternate source for a further period of about 2 years. Thus, in effect the 20 year term gets extended to about 24 to 27 years.

Neither TRIPS nor the Indian Patents Act, 1970 prescribe any such requirement.

8. LICENSING PROVISIONS

The Licensing provisions are either totally excluded (as in U.S.A.) or rendered almost illusory by rigid procedures or conditionalities.

Thus alternate source of supply is denied during the entire term of patent.

Neither TRIPS nor the Indian Patents Act, 1970 prescribes any such requirement. TRIPS through Article 5 of Paris Convention, read with Article 8, allows licensing.

9. ENFORCEMENT OF PATENT RIGHTS AND REMEDIES BY JUDICIAL AND ADMINISTRATIVE AUTHORITIES TO BE EXPEDITIOUS AND STRONGER

Enforcement of the patent rights should be expeditiously allowed by administrative and judicial authorities. The customs authorities can be asked to stop imports. The police authorities can be asked to conduct raids and file criminal actions. The Courts are required to dispose off the cases expeditiously, i.e. within months and not years, and remedy should normally be preventive injunctions plus damages.

No such compulsions under TRIPS or the Indian Patents Act 1970.

10. DAMAGES

Damages should include actual loss of profits and compensation for price reductions resulting from competition.

Requirements under TRIPS and the Indian Patents Act 1970 not so strict.

11. STATE USE OF PATENTS

States use of patents is not to be permitted, except in case of emergencies and that to limiting in

point of time and scope. For state use also, economic value of usage of patents is to be allowed as compensation.

Though under U.S. Law – 28 U.S.C. 1498, the Federal Government has reserved all the powers, they insist on other countries not reserving any such powers. TRIPS Agreement, properly applied, permits such sovereign power reservation.The Indian Patents Act, 1970 makes specific provisions.

These are the stringent conditions and requirements of the "World Class" patents, which the U.S. MNCs the U.S. Trade Representatives expect.

The provisions of TRIPS Agreement are by themselves detrimental to national interests. Yet it contains some provisions, which soften, to some extent, the severity of its adverse impact. **The "World Class" Patents would be simply disastrous. It would be an uncontrolled monopoly of the worst type, with the State being reduced, not only to a helpless and mute spectator, but also an unwilling accomplice, abettor and supporter, of exploitation, lending its judicially and administrative machinery to enforce such patents against the poor, unsuspecting millions of its countrymen.** It would arm the MNC right holder with weapons, against which there can be no protection. In fact, the State itself would be a helpless victim.

Whether such patent protection promotes original research and industrial development in an advanced country, like U.S.A. is debatable, but for a developing country, like India, it would be disastrous and totally prevent any research and would actually result in closure of many industrial units.

"World Class" Patents in the Indian context is an invitation to disaster.

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'Patent laws to be in tune with WTO, but will Safeguard National Interests' : Dr Murli Manohar Joshi

The government will amend the patent law to honour commitments to the World Trade Organisation, but will take steps to safeguard national interests, officials have said.

"We have to adopt a new patent law and it should be and it would be to honour our international commitments and also to safeguard our national interests," Science and Technology Minister Murali Manohar Joshi told a news conference.

"The Industry Ministry is already on the job," he said.

Asked if the government was ready to adopt product patents, Joshi said: "We can do it provided we design and chart out certain methods". India has until April 1999 under the World Trade Organisation's schedule to bring in a new law to replace the existing one.

Joshi said he would brainstorm for two days next week with experts from the Council for Scientific and Industrial Research in Bangalore to decide on a strategy to help Indian industry become competitive with the help of technological innovations.

The meeting on May 11 and 12 will also discuss emerging opportunities in biotechnology, efforts to preserve traditional knowledge and scientific innovations to help common people, he said.

He promised that the new government would contest the WTO's conditions at the agreement's review in 1999. Conditions such as phasing out of quantitative restrictions in textiles, and other issues, would be opposed, he assured. India would also try to present its case at the WTO meet next month, he said.

Union Human Resource Minister Murli Manohar Joshi, intervened to clarify that the WTO agreement was renegotiable and India would do everything to bargain the treaty in its favour.

Source: Sudesh Verma, Business Standard, 4 May 1998.

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TRIPS

India on Special 301 Priority Watch List

The United States has named India in the Special 301 priority watch list for what it termed as non-compliance with its obligations under the Trade Related Intellectual Property (TRIPS) agreement.

The Clinton administration has placed 13 other countries and the European Union on the list, US Trade Representative Charlene Barshefsky on 2 May 1998 said.

"India's patent and trademark laws continue to fall well short of providing adequate and effective protection," the release said.

"India has enacted modern copyright legislation, but improvements continue to be necessary in the enforcement area," it noted.

Of the nations named in the list, the US Trade Representative is required to decide which should be designated "priority foreign countries", the release said.

The term means countries that "have the most onerous and egregious acts, policies and practices which have the greatest adverse impact (actual or potential) on the relevant US products, and are not engaged in good faith negotiations or making significant progress in negotiations to address these problems".

UNCLE SAM WIELDS HIS STICK

- The Clinton administration has accused India of non-compliance with its obligations under the trade related intellectual property agreement
- 13 other countries and the European Union have been placed under Special 301
- Pakistan has been included in a separate watch list as Washington looks forward to Islamabad moving "quickly to improve protection for intellectual property"
- "Earlier, India had been named as a "Priority foreign country" under the Special 301 section of US trade law in 1991-93.

Noting that Pakistan in 1997 took necessary steps to implement its obligations under the TRIPS agreement, Ms Barshefsky said it has been included in a separate watch list as Washington looks forward to Islamabad moving "quickly to improve protection for intellectual property".

An action stronger than putting a country on a priority watch list is when the USTR heads for the "priority foreign countries" list. The USTR defines them as follows: "Those countries that have the most

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SPECIAL ARTICLES

Indian Patents as Competitive Instruments

Dream and Reality

Amiya Kumar Bagchi
Uttam Kumar Bhattacharya

This paper attempts an evaluation of certain aspects of the working of the Indian patent system as embodied in the Act of 1970. It places the Indian patent system in the context of the global patent scenario; it also discusses the relative strengths and weaknesses of the system in respect of its encouragement of innovation and competitive process. The cases of biotechnology and pharmaceuticals have been taken up to highlight the position. The necessity of a rationally constructed innovation system for overcoming the lacklustre performance of the Indian patent system emerges out of the study.

I
Patents as Competitive Instruments

DESPITE the possible existence of stray instances of rewarding inventions under pre-capitalist systems, it may be claimed that granting patents for new products and processes is an innovation made by capitalism. Patents were used as devices to advance knowledge and bring the new knowledge eventually (that is, after the expiry of the patent life or through licensing) into the public domain. But they were also used as instruments of competitiveness – by the individual firm against all potential or actual competitors, and by governments in their bid to strengthen their own countries against foreigners.

In England, for example, patents were used by Lord Burghley, a principal minister of Queen Elizabeth I as means of establishing industries which were already operating abroad but for which technologies and entrepreneurs were not available in England of the time [MacLeod 1988: 11-14]. Letters patent were, of course, used by the Crowns of England to confer monopolies on court favourites or their friends and relations in the production or vending of particular products [MacLeod 1988: chapters 3-5]. But they were also used by many entrepreneurs to try and break into the monopolistic privileges enjoyed by guilds of clothiers, drapers, brewers and so on. Finally, when innovation became a regular activity associated with the industrial revolution, inventors in many areas tried to protect their profits by taking out patents. The owners of the Watt-Boulton steam engine patents defended their monopoly privileges, and in general quite successfully, for more than a quarter of a century. Some economic historians such as T S Ashton and students of technology such as F M Scherer have held the long patent life of Watt's engine to be at least partly responsible for the relatively slow diffusion of steam power in 18th century Britain [Scherer 1965/1984; von Tunzelmann 1978: 292-94].

Patents acted both as instruments of aggression to break open monopolies and as instruments of aggressive defence of monopoly privileges. Recent work has further underlined the importance of competition in technology and patent wars both as influence on the degree and nature of competitiveness of industry and as an outcome of existing structures of concentration of economic power in an industry. Under wide sets of assumptions, firms which can move first and can devote larger funds to R and D competition are found to have a significant advantage over their laggard or weaker rivals in obtaining patents and building up new positions of vantage [see, for earlier work on this, Scherer 1967/1984; for a survey of more recent work, see Reinganum 1989; see also Leininger 1991]. The R and D intensity of firms, of course, varies according to industry, and according to firm size, and can change over time. So does the propensity of firms engaging in R and D to take out patents [for a survey of the empirical work relating to the US, see Bound *et al* 1984]. Moreover, in many countries, trade secrets are protected even when patents are not involved. For example, in the highly publicised case of the IBM which accused Hitachi and Mitsubishi of violating intellectual property rights and won a settlement estimated at US $ 300 million, no patent claims were involved [Kinmouth 1987:179]. To take another example, devices other than patents had been used for a long time for defending proprietary rights in improved breeds in the US chicken-breeding industry [Burgos 1992].

Thus the statistics of patents as such are only an imperfect indicator of the inventiveness of an industry or a country or its potential as an aggressive competitor [Schmookler 1966; Scherer 1980]. There are further problems in using the numbers of patents as indicators of inventiveness or competitiveness at the international level. This applies in particular to comparisons between patent applications or even patent grants in Japan and the US or UK. Unlike in the UK or the US, where applications for patents are based on claims for first invention, and are rigorously examined in regular order by the concerned patent offices, applications for patents in Japan need not be examined at all for seven years [Jacobs 1994: 3-8].[1] In the event 40 per cent of all applications for patents in Japan were withdrawn before examination could come up. According to the study by Okimoto and Saxonhouse (1987) nearly half of the applications made by Japanese to their own patent office were rejected, and in the US the ratios of approvals to the Japanese patent applications were also low in comparison to that of the US and European countries [Okimoto and Saxonhouse 1987:391]. However, the sharp rise in applications for patents since the system was introduced reflected the Japanese determination to use patents as tools of competitiveness. The strategies of taking out patents even for small and mundane innovations and the growing enthusiasm for applications of patents in the home country and abroad even when those were often turned down in course of patent examination also reflect the competitive zeal of the Japanese entrepreneurs; they would not generally leave unturned any possibilities of patent protection in order to improve their relative positions.

In Japan, patent applications often give insufficient detail about the invention claimed, but priority in application can make the ground for an exclusive licence [Kinmouth 1987; Wineberg 1988]. Fees charged for patent application and examination in Japan have also been low compared with those obtaining in the US (details are in the note 3). It has been hence alleged that the numbers of patent grants and *a fortiori* of patent applications tend to exaggerate the inventiveness of the Japanese. However, if we also consider those characteristics of the Japanese patent system along with the basic intention behind them – namely, that new processes or products must be quickly diffused – and the procedures

that make it more difficult for foreigners to obtain patents in Japan than in ways available in western countries [Wineberg 1988; Kotabe 1992], patent statistics can be regarded as index of the aggressiveness with which the Japanese defended their domestic economic space and used that strong home ground as a base for international aggressiveness in the relevant fields.

Students of R and D and inventiveness have, therefore, continued to use time series of numbers of patent applications and grants as important indicators of changes in a country's inventiveness or its structure of industry and associated changes in allocation of resources for innovation. They have also continued to use international comparisons of patent statistics for assessing the international competitiveness of countries and changes in their competitive strength over time [Watanabe 1982; Evenson 1984]. We will also follow these examples in the sequel, but the caveats mentioned above must be born in mind when judging the significance of the relevant data.

In India, a patent system was introduced by the British government in 1856, primarily in order to defend the proprietary rights of British patent-holders. The 1856 Act was replaced by the Industrial Patent and Design Act of 1911, again primarily on the model of British legislation. The numbers of patent applications and grants remained low and the vast majority of the patents granted were acquired by foreigners [Kuruvilla 1956].

The contrast between India and Japan, which started on its path of development of modern manufacturing industry much later than India, is as marked in this area as in most other sectors of industrial management and development. Japan passed her first patent law in 1885 and soon the numbers of patent applications and granted far exceeded those of India's. Moreover, Japan introduced utility models the protection of which did not embody original inventions but would be very useful commercially. If we include the numbers of utility models as further indicators of competitive energy in the field of commercial rivalry then India's position would pale further into insignificance. What is more striking still is that in Japan foreigners owned only a minority of patents granted - the proportion never exceeded a third of the total number of registration in any decade before the 1960s [Watanabe 1982: Table 3].

In India, the 1911 Act was thoroughly overhauled and a new Patent Act was passed in 1970, and came into operation in 1972. As we shall see, one of the effects of the new act was to allow Indians to make headway in patent registrations in India, especially in the field of drugs and pharmaceuticals. A death sentence was pronounced on that Act when India signed the new GATT treaty and the government of India passed an ordinance on January 3, 1995 (*Gazette of India, Extraordinary*, January 3, 1995) allowing all signatories to the World Trade Organisation agreement to avail of the Indian Patents Act, 1970, whether or not they had entered into any separate bilateral or multilateral agreement with India in respect of patent systems. The government has also declared its intention eventually to align the Indian patent system to suit the TRIPs provisions of the new GATT treaty. In effect, the Indian patent system (under the Patent Act, 1970) lasted only for a period of about 21 years and the current paper is to be seen as essentially a post-mortem investigation of the patient's health when it was alive – unless India and other afflicted countries can successfully demand a new round of multilateral trade negotiations leading to a thorough revision of the GATT treaty so as to make more room for autonomous, nationally regulated innovation systems.

II
Indian Patents in an International Perspective

In an earlier paper [Bagchi, Banerjee and Bhattacharya 1984] we had studied the working of the Indian Patents Act, 1970 from 1972 to 1980. In this paper we shall scrutinise the data on patents from 1970 to 1993-94 and provide an interpretative framework. In the present study, we shall confine our attention to the data on patents, the R and D environment of Indian industry and its international setting, and put forth a few hypotheses regarding the comparative performance of the Indian innovation system within that restricted domain of study. An enquiry into the link of the social environment with the generation and diffusion of innovations will be left out of the purview of our enquiry.

Before we proceed, let us point out again that not all innovations lead to patents, not all patents embody major innovations and not all patents sealed or even licensed actually lead to changes in processes or products on the factory or office floor. Some kinds of innovations are more amenable to patenting than others (for example patenting in chemical field), and some environments are conducive to the protection of intellectual property rights through patents and some may be protected by other devices (for illustrations of the way proprietary rights in chicken-breeding were protected in the US for a long time through devices other than patents [Burgos 1992]. Not all countries which have become affluent capitalist societies provided a patent system to protect intellectual property even at the beginning of the 20th century. Moreover, as has already been noted, the laws relating to patent protection differed greatly from country to country in terms of their demands for originality, priority, public disclosure, and so on. So the number of patents applied for

TABLE 1: NUMBER OF PATENT APPLICATIONS IN INDIA BY INDIANS AND FOREIGNERS, 1970 - 1994

Years	Indians	Foreigners Resident In India	Foreigners	Total
1970	1116 (21.7)	162	3864	5142
1971	1231 (28.3)	185	2929	4345
1972	1180 (31.9)	142	2373	3695
1972-73	1143 (31.4)	136	2360	3639
1973-74	976 (28.0)	174	2341	3491
1974-75	1148 (33.7)	66	2192	3406
1975-76	1129 (37.7)	34	1833	2996
1976-77	1342 (93.2)	23	1739	3104
1977-78	1097 (38.7)	37	1736	2870
1978-79	1124 (38.3)	13	1795	2932
1979-80	1055 (35.4)	37	1888	2980
1980-81	1159 (39.2)	19	1776	2954
1981-82	1093 (36.6)	19	1877	2989
1982-83	1135 (36.8)	–	1950	3085
1983-84	1055 (33.5)	25	2065	3145
1984-85	1001 (30.2)	2	2316	3319
1985-86	999 (28.3)	–	2527	3526
1986-87	983 (28.2)	–	2506	3489
1987-88	930 (26.9)	–	2527	3457
1988-89	1077 (29.9)	5	2516	3598
1989-90	1039 (28.4)	1	2621	3661
1990-91	1180 (31.4)	1	2583	3764
1991-92	1293 (36.4)	–	2259	3552
1992-93	1228 (35.4)	–	2239	3467
1993-94	1266 (32.7)	–	2603	3869

Notes: 1 Patents Act 1970 was made effective from April 20, 1972.
2 Figures in brackets are percentages of the total.

Source: Patent Office : Patents : *Annual Report* of the Controller General of Patents, Designs and Trademarks under Section 155 of the Patents Act 1970, (henceforth Patents : *Annual Report* in short) (different issues).

or sealed is only a very incomplete and imperfect index of innovative activity in any country, and this applies to the Indian case.

In Tables 1, 2 and 3 we have reproduced the figures for patent applications, patents sealed and patents in force in India between 1970 and 1993-94. The figures for 1970, 1971, and 1972 are also given because they provide some idea of how the relevant numbers were behaving just before the Indian Patents Act, 1970 came into force (formally, it came into operation from April 20, 1972). The numbers of patent applications, etc, have been divided as between those originating from or held by Indians and foreigners (including Indian and foreign firms and research laboratories).

The following observations can be made on the basis of the figures in these tables. First, the numbers of patent applications by Indians have fluctuated erratically and show no time trend over the 25-year period. The numbers of total applications dipped sharply between 1972-73 and 1980-81 but then rose smartly in the 1980s and declined again in the early 1990s. There was virtually no time trend overall either in the totals of patent applications by foreigners or in total numbers of patent applications. Secondly, the patents sealed in India showed erratic fluctuations (probably more erratic than in the case of patent applications) in the cases of those granted to foreigners as well as Indians. Up to 1982-83 there is some sign of a decline in the total numbers of patents sealed, especially in the numbers granted to foreigners. The numbers of patents sealed in favour of foreigners sharply rose up to 1974-75 and then dipped to a low figure of 670 in 1980-81 (compared with 3,207 in 1974-75 and 3,294 in 1971, Table 2) but rose again in the 1980s reaching a peak of 2,585 in 1988-89. This peak was, however, lower than the figures reached in the early 1970s, and the numbers of patents sealed in favour of foreigners had come down again except in the last year, viz, 1993-94. Since the numbers of patents sealed in favour of foreigners always exceeded those in favour of Indians, the overall numbers of patents sealed also display a sagging profile over time.

The clearest trend, however, is visible in the stock of patents in force. Patents in force are those for which renewal fees have been paid in addition to those which have been freshly granted (within the last two years). The patents need not actually be worked even though renewal fees are paid. The total number of patents in force declined steeply from 1972-73 to 1980-81. Most of this decline was contributed by the decline in patents in force taken out by foreigners. The latter number was virtually halved between 1972-73 and 1980-81. Patents in force continued to decline in the 1980s, though at a smaller rate. By 1992-93, patents in force held by Indians had come down to a mere 1,034. From our analysis it comes out that Indians held about the same proportion of total number of patents in force in 1991-92 as they did in 1972-73; but the total number of patents in force in 1993-94 was only a half of the corresponding number in 1972-73. In any case, patents granted to Indians never rose above a third of the total number.

What may be the proximate reason for the decline in the numbers of patents in force?

TABLE 2: NUMBER OF PATENTS SEALED OR GRANTED IN INDIA TO INDIANS AND FOREIGNERS, 1970 - 1994

Years	Indians	Foreigners	Total
1970	596 (16.9)	2936	3532
1971	629 (16.0)	3294	3923
1972	265 (17.5)	1245	1510
1972-73	278 (20.7)	1064	1342
1973-74	358 (25.3)	1058	1416
1974-75	737 (18.7)	3207	3944
1975-76	426 (18.4)	1894	2320
1976-77	928 (32.1)	1964	2392
1977-78	657 (26.1)	1857	2514
1978-79	281 (21.9)	1000(a)	1281
1979-80	516 (23.7)	1657	2173
1980-81	349 (34.2)	670	1019
1981-82	421 (30.3)	936	1357
1982-83	405 (33.0)	822	1227
1983-84	340 (25.7)	980	1320
1984-85	263 (17.9)	1206	1469
1985-86	451 (23.7)	1500	1951
1986-87	532 (25.0)	1594	2126
1987-88	588 (27.9)	1516	2104
1988-89	795 (23.5)	2585	3380
1989-90	519 (27.5)	1371	1890
1990-91	379 (25.4)	1112	1491
1991-92	551 (32.9)	1125	1676
1992-93	251 (19.7)	1021	1272
1993-94	442 (25.3)	1304	1746

Notes: 1 Percentages in brackets indicate percentages to the total number
2 (a) This information is based on the *Annual Report* 1978-79. However, according to the 1979-80 *Annual Report* the figure was 999.
Source: Same as Table 1.

TABLE 3: NUMBER OF PATENTS IN FORCE IN INDIA: INDIANS AND FOREIGNERS, 1970 - 1994

Years	Held by		Total Stock of Patents
	Indians	Foreigners	
1970	2568 (9.1)	25753	28321
1971	3063 (10.0)	27663	30726
1972	3673 (11.4)	28650	32323
1972-73	3718 (11.5)	28718	32436
1973-74	3948 (12.2)	28270	32218
1974-75	3039 (10.9)	24758	27797
1975-76	2991 (11.3)	23453	26444
1976-77	2746 (12.2)	19780	22526
1977-78	3065 (13.4)	19795	22860
1978-79	2469 (15.0)	13966	16435
1979-80	2786 (16.1)	14474	17260
1980-81	2757 (16.0)	14448	17205
1981-82	3038 (16.9)	14892	17930
1982-83	3329 (17.9)	15291	18620
1983-84	3523 (18.3)	15726	19249
1984-85	3008 (18.6)	13162	16170
1985-86	2549 (19.0)	10844	13393
1986-87	2004 (16.6)	10059	12063
1987-88	2150 (17.5)	10115	12265
1988-89	2584 (19.0)	11015	13599
1989-90	2468 (18.4)	10941	13409
1990-91	2238 (21.4)	8210	10448
1991-92	1206 (11.7)	9093	10299
1992-93	1034 (10.3)	8997	10031
1993-94	1995 (21.5)	7281	9276

Note: Figures in brackets indicate percentages to the total number
Source: Same as Table 1.

One reason may be the paring of the period of the general validity of patents from the earlier 16 years to 14 years under the 1970 Act, and more importantly the slashing down of the period of validity of patents in the field of food, drugs and medicines to seven years under the new Act. Table 4 indicates that a decline in the number of renewals under the old Act was a major contributory factor to the decline in the stock of patents. Another factor was the working out of the bulge in numbers sealed in 1974-75.

However, the major reason for the decline in the stock of patents in force was a decline in the numbers of patents applied for and eventually sealed. Four principal factors seem to underlie this decline. First, the patents that the foreigners filed for were for technologies that were relatively old and hence becoming rapidly obsolete in the advanced capitalist countries. With competing processes and products being imported into India as finished products, intermediates or production technologies, the patentees found it less and less useful to renew their proprietary rights in the form of patents, especially since the procedures for application and sealing were dilatory and effort-consuming. Secondly, the rate of obsolescence of products and processes patented accelerated world-wide, and this higher rate of attrition of patents in force reflected this global phenomenon. Thirdly, Indians may have learned better to invent around the patents taken out by foreigners and hence the latter found it less and less attractive to take out patents. (Of course, it might be objected that if Indians became better at circumventing the foreigners' patents, the latter could have done so on the basis of patents taken out by foreigners in their home countries and in third countries as well. But as against that, it is almost certain that few Indian firms or organisations carried their search process beyond India's borders. Even the patent information system provided by the government of India for use by firms doing business in India – badly organised though it was – was hardly utilised by Indian firms.) Fourthly, the regime of foreign collaboration agreements and their legal interpretation in Indian courts had acted as a disincentive against local R and D [Bagchi and Dasgupta 1981] and the government had encouraged foreign collaboration agreements on a more and more lavish scale, especially in the 1980s [Goyal *et al* 1994]. This may have acted as a further deterrent to both Indians and foreigners paying fees to take out patents – the former because they could get more secure proprietary rights through collaboration agreements and the latter because they found that their presumed proprietary rights could be effectively nullified by processes imported through foreign collaboration agreements.

The continued dominance of foreigners in the total number of patent applications filed or patents sealed is in conformity with the situation in many developed countries where also foreigners account for a larger share than local firms, organisations and individuals [Evenson 1984]. However, there are wide variations among these countries in respect of the relative salience of patents granted to foreigners. In Japan, for example, the numbers of patents granted to foreigners were generally less than half of those granted to nationals. Moreover, between 1967 and 1980, the relative importance of foreigners in the numbers of patents granted came down further; while the numbers of patents granted to Japanese nationals virtually trebled over this period, those granted to foreigners actually declined. In the US, by contrast, the numbers of patents granted to US nationals came down between 1967 and 1980 but those granted to foreigners went up. Thus foreigners, who had accounted for less than a quarter of all US patents in 1967 came to own about a third of US patents in 1980. As Table 5A reveals, these trends continued unabated for the US and Japan up to 1992, so that nationals accounted for only a little more than 50 per cent of total numbers of patents granted by the US in 1992, whereas in Japan nationals accounted for about three-quarters of the patents granted in that year. In the UK, the world leader in technology in the 19th century, foreigners already accounted for three-quarters of 40,995 patents granted in 1970; by 1992, the number of patents granted had come down to 37,827 and foreigners accounted for about 87 per cent of that

TABLE 4: NUMBER OF PATENTS RENEWED IN INDIA, 1980 - 1993

Years	3rd	4th	5th	6th	7th	8th	9th	10th	11th	12th	13th	14th	15th	16th	Total
1980-81	1188	1301	1519	1210	1379	988	923	982	559	46	12	11	–	–	10118
							(1)	(6)	(255)	(735)	(846)	(679)	(708)	(600)	(3830)
1981-82	1179	1179	1297	1269	975	1005	800	740	816	499	23	8	-	-	9790
								(3)	(12)	(165)	(565)	(696)	(515)	(476)	(2432)
1982-83	1828	1880	1936	1989	1581	1041	1017	937	756	706	398	35	-	-	14104
									(1)	(1)	(187)	(522)	(555)	(466)	(1732)
1983-84	1495	1371	1370	1432	1345	905	734	688	662	630	603	374	–	–	11609
									–	(2)	(5)	(122)	–	(420)	(549)
1984-85	1197	1194	1220	1139	1243	1027	820	581	583	590	560	467	–	–	10621
													(399)	(100)	(499)
1985-86	1560	1563	1565	1485	1265	952	860	704	523	550	556	454	–	–	12037
													(324)	(85)	(409)
1986-87	1890	1893	1828	1651	1480	1187	979	834	686	485	471	455	–	–	13839
														(100)	(100)
1987-88	1765	1760	1729	1732	1329	1134	987	794	687	573	421	417	–	–	13328
														(85)	(85)
1988-89	3064	3074	2008	2087	1655	1165	1029	876	737	607	524	363	–	–	17189
1989-90	2062	1983	1897	1940	1512	1261	955	895	744	663	595	455	–	–	14962
1990-91	1408	1425	1471	1609	1546	1195	1105	855	791	675	589	472	–	–	13141
1991-92	1452	1448	1456	1593	1702	1277	1099	1004	804	723	612	507	–	–	13677
1992-93	1326	1327	1331	1371	1505	1342	1103	887	830	651	599	476	–	–	12748

Notes: 1 No renewal is required for the first two years.
2 According to the Patents Act 1970, patents are valid generally for 14 years. Patents on drugs, medicines and food articles are valid for 7 years from the date of Patent applications (Section 53 of Patents Act 1970).
3 As per the old Patents and Design Act 1911, patents were valid for 16 years.
4 Figures in the brackets indicate patents renewed under the old Act, 1911.
5 Generally patents should be renewed within six months of the period prescribed for the payment of the renewal fees. However, Controller of Patents can allow lapsed patents to be restored.

Source: As in Table 1.

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reduced total. We have presented figures of patent applications and grants for three other advanced capitalist countries, viz, Germany, France and Denmark, and also for the Republic of Korea. We see in the case of France and Germany that the numbers of patents taken out by residents exceed those taken out by non-residents. But in the case of the two smaller countries, viz, Denmark and South Korea, the numbers granted to non-residents exceed those to residents. However, we notice that the rates of growth of patents granted to residents and non-residents alike in South Korea are far higher than in the case of all other countries (including of course, India) (table 5B).

The data compiled by Evenson (1984) reveal another curious characteristic of patent registrations. The US, West Germany (that is, the former Federal Republic of Germany), France, UK, and even smaller developed countries such as Denmark, Belgium and Netherlands all had a considerably larger number of patents registered in the name of their nationals in foreign countries than in their home countries. In the case of such countries as Denmark, Belgium, Netherlands and Italy the numbers of patents held by nationals abroad was of the order of five to 10 times the numbers held by them in their homeland. Our analysis of data for the subsequent periods (viz, 1982, 1984 and 1986) indicated similar trends particularly in the cases of the US, Germany, UK and France (Tables 6A and 6B). Part of the reason for this could be multiple registrations including registrations in countries which were signatories to the Paris Convention. But part could also be attributed to the greater stringency of proof of inventiveness required by domestic laws, part could be due to the patenting of even minor innovations (which are actually utility models) in countries (mostly, poor market economies) with very inadequate means for verification of claims of originality, and part could be due to the patenting of products and processes by branches or subsidiaries of multinationals which did not find it worthwhile or feasible to defend patent rights in their home countries. These data suggest that to portray patent holders in developed countries as passive victims of piracy by developing countries was far from the truth. To take one example to illustrate this point, we can cite Mashelkar, Director, National Chemical Laboratory (NCL) NCL made certain innovations in metallocenes, a catalyst which could be used for making polyolefin polymers. However, Exxon, the US-based MNC, a major patent holder on metallocenes sued any new company entering this field in order to pre-empt any threat of future competition. NCL found it difficult to break this barrier of highly-founded litigiousness [Mashelkar 1995: 17-18 and see also Vaitsos 1972].

TABLE 5A: NUMBER OF PATENT APPLICATIONS AND GRANTS IN SELECTED COUNTRIES, 1970 - 1992

	Patent Applications			Patents Granted		
	(R)	(NR)	Total	(R)	(NR)	Total
			USA			
1970	72343	30832	103175	47073	17354	64427
1971	71089	33640	104729	55988	22328	78316
1972	65943	33355	99298	51515	23293	74808
1973	66935	37144	104079	51501	22638	74139
1974	64093	38445	102538	50643	25632	76275
1975	64445	36569	101014	44603	25391	71994
1976	65050	37294	102344	44162	26074	70236
1977	62863	38088	100931	41383	23886	65269
1978	61441	39475	100916	40979	25123	66102
1979	60536	39959	100494	30605	18248	48853
1980	62098	42231	104329	37152	24675	61827
1981	62404	44009	106413	39225	26545	65770
1982	63316	46309	109625	33896	23993	57889
1983	59391	44312	103703	32872	23990	56862
1984	61841	49443	111284	38364	28837	67201
1985	63874	53132	117006	39554	32107	71661
1986	65487	56946	122433	38124	32736	70860
1987	68671	65136	133807	43518	39437	82952
1988	75632	71712	147344	40497	37427	77924
1989	82956	78704	161660	50185	45354	95539
1990	91410	84690	176100	47393	42973	90366
1991	89024	88364	177388	51184	45330	96514
1992	94017	93274	187291	52254	45189	97443
			UK			
1970	25227	36874	62101	10343	30652	40995
1971	24771	36307	61078	10376	31178	41554
1972	24337	35944	60281	10116	32678	42794
1973	22472	37840	60312	9357	30487	39844
1974	20545	35705	56250	8971	28837	37808
1975	20842	32558	53400	9120	31569	40689
1976	21797	32764	54561	8855	30942	39797
1977	21114	33309	54423	7722	28827	36549
1978	19384	30940	50324	8464	32359	40823
1979	19468	25198	44666	4182	16618	20800
1980	19612	22000	41612	5158	18646	23804
1981	20808	18406	39214	6076	16848	22924
1982	20530	16563	37093	4686	24904	29590
1983	19893	14798	34691	5655	22599	28254
1984	19093	13735	32828	4442	14425	18867
1985	22044	48138	70182	6087	28393	34480
1986	22892	50529	73421	5403	27526	32929
1987	23253	53256	76509	4609	24050	28659
1988	24098	60077	84175	4447	25117	29564
1989	24031	66203	90234	4234	26663	30897
1990	24398	73493	97891	4361	27818	32179
1991	24253	71280	95533	4492	29582	34074
1992	24092	75149	99241	4642	33185	3782
			Japan			
1970	100513	30318	103831	21404	9475	30879
1971	78425	27360	105785	24795	11652	36447
1972	101328	29072	130400	29101	12353	41454
1973	115221	29593	144814	30937	11391	42328
1974	121509	27810	149319	30873	8753	39626
1975	135118	24703	159821	36992	9736	46728
1976	135762	25254	161016	32465	7852	40317
1977	137991	25015	161006	43047	9561	52608
1978	141517	24575	166092	37648	7856	45504
1979	150623	23946	174569	34863	9241	44104
1980	165730	25290	191020	38032	8074	46106
1981	191621	24686	216307	42080	8824	50904
1982	210897	24427	235324	4223	8378	50601
1983	227708	24977	252685	45578	9123	54701
1984	256195	26119	282314	51690	10110	61800
1985	274398	30997	305395	42323	7777	50100
1986	290238	32323	322561	51276	8624	59900
1987	311062	33076	344138	54087	8313	62400
1988	308954	36464	345418	47912	7388	55300
1989	317609	39855	357464	54743	8558	63301
1990	333373	43419	376792	50370	9031	59401
1991	336096	44357	380453	30453	5647	36100
1992	338107	46349	384456	78994	13106	92100

III

Effectiveness of Indian Patents as Competitive Tools: Cases of Biotechnology and Pharmaceuticals

The effectiveness of the patent system can be partly measured by the number of patents taken out within the country and abroad and by the use of patents within the country. In our earlier paper we indicated some of the factors which affected adversely the utilisation of patents in India [Bagchi, Banerjee and Bhattacharya 1984: 300-02]. The situation has not improved since then. The data on applications by Indian nationals for patents abroad (Table 7A) and patents granted to them by foreign countries (Table 7B) reveal that India has a poor record in this field in comparison with most developed countries. The patents applied for by Indian nationals abroad are only a fraction of patents applied for by them at home, and the patents granted are even smaller fraction: the proportion of patents granted to those applied for abroad seems to have declined rather than risen over time. There are several reasons for this. One of them is certainly the costliness of procedure for taking out patents abroad: it generally costs US $ 1,000 or far more for completing all the formalities in the US[1] and few cash-strapped government laboratories (which are major holders of Indian patents among nationals) are prepared to engage in such a venture. Secondly, of course, the statistics also reveal the poor competitive spirit (and strength) of even the few Indian firms or organisations which consider it worthwhile to take out patents in foreign countries.

For a slightly closer look at the worth of Indian patents, we have used the work of a number of investigators attached to the CSIR and NISTADS in the field of biotechnology [Gupta and Subbaram 1992; Karki and Garg 1993]. Biotechnology in the sense of purposive use of biological organisms by human beings is, of course, as old as the domestication of animals and the practice of agriculture. However, biotechnology in the modern sense of deliberate interference in the basic structures of biological organisms including their constituent cells and genes dates from the period after the second world war and the vistas of genetic engineering opened up by the successful modelling of the genetic structure of the DNA molecule by Francis Crick and James Watson in 1953. The intensive commercial exploitation of genetic engineering started in US in the 1970s. The beginnings of the university-industrial complex [a phrase due to Kenney 1986] in biotechnology can be dated to the foundation of Genentech in the US in 1976. [Fransman 1991:5]. Soon, scores of firms had been set up with the help of risk embracing venture capital and the US government and courts

TABLE 5B: NUMBER OF APPLICATIONS AND GRANTS OF PATENTS IN SELECTED COUNTRIES, 1976 - 1992

	Patent Applications			Patents Granted		
	(R)	(NR)	Total	(R)	(NR)	Total
			Germany			
1976	31065	30640	61705	10395	10570	20965
1977	30247	30154	60401	10815	10934	21749
1978	30308	28184	58492	11581	11933	23514
1979	30879	24305	55184	10895	11639	22534
1980	28683	19900	48583	9826	10362	20188
1981	29841	16738	46579	6537	6892	13429
1982	30668	17158	47826	8279	8027	16306
1983	31658	15445	47103	10709	10204	20913
1984	31984	13225	45209	11402	10356	21758
1985	39625	43478	83103	13215	20162	33377
1986	40875	45233	86108	15347	23648	38995
1987	40980	47501	88481	16194	23703	39897
1988	42872	53126	95998	15704	23186	38890
1989	43265	59162	102427	16904	25329	42233
1990	43890	66459	110349	16569	26291	42860
1991	43404	65783	109187	16756	26434	43190
1992	45911	69298	115209	17833	28687	46520
			France			
1976	11471	28419	39890	8420	21334	29754
1977	11811	28167	39978	8361	22684	31045
1978	11445	25692	37137	8083	22447	30530
1979	11303	20871	32174	6846	17772	24618
1980	11000	16989	27989	8438	19622	28060
1981	10945	13723	24668	6855	14622	21477
1982	10681	11561	22242	7764	16180	23944
1983	11147	10029	21176	7323	17720	25043
1984	11333	8864	20200	7651	16015	23666
1985	13512	42602	56114	9835	27695	37530
1986	13919	44929	58848	9362	26187	35549
1987	14656	47951	62577	8523	21890	30413
1988	14921	53463	68384	8822	23134	31956
1989	15468	59474	74942	8301	24578	32879
1990	15707	66177	81884	8923	26226	35149
1991	15819	63256	79075	9221	26360	35581
1992	15978	66060	82038	8462	29753	38215
			Denmark			
1976	821	5080	5901	208	2068	2276
1977	832	5055	5887	200	1837	2037
1978	938	4946	5884	243	1867	2110
1979	895	4645	5540	250	1891	2141
1980	964	4605	5569	192	1453	1645
1981	1085	4745	5830	163	1276	1439
1982	1095	4706	5801	224	1306	1530
1983	1167	4920	6087	180	976	1155
1984	966	5312	6278	212	877	1089
1985	917	7376	8293	200	854	1054
1986	1036	7871	8907	186	772	958
1987	1090	7670	8760	212	917	1129
1988	1331	9883	11214	344	2471	2815
1989	1339	9561	10900	339	2277	2616
1990	1788	37659	39447	364	2012	2376
1991	1729	38035	39764	301	2308	2609
1992	1854	42507	44351	363	3410	3773
			Republic of Korea (South Korea)			
1976	1436	1825	3261	191	288	479
1977	1177	1962	3139	104	170	274
1978	989	3026	4015	133	294	427
1979	1034	3688	4722	258	1161	1419
1980	1241	3829	5070	186	1446	1632
1981	1319	3984	5303	232	1576	1808
1982	1556	4368	5924	274	2335	2609
1983	1599	4795	6394	245	2188	2433
1984	1997	6636	8633	297	2068	2365
1985	2702	9092	11794	349	1919	2268
1986	3642	10479	14121	458	1436	1894
1987	4872	13964	18836	596	1734	2330
1988	5699	17091	22790	575	1599	2174
1989	7021	19635	26656	1181	2791	3972
1990	9083	22304	31387	2554	5208	7762
1991	13255	22899	36154	2553	6138	8691
1992	15957	24200	40157	3570	6932	10502

Notes: 1 (R) = Residents and (NR) = Non Residents. 2 Until 1989, 'Germany' means only the Federal Republic of Germany (FRG). However, since October 3, 1990 Germany was unified. But only after May 1, 1992 was the law of Germany extended to the erstwhile GDR area.

Sources: 1 World Intellectual Property Organisation (WIPO), *Industrial Property Statistics* (IPS), various issues.

2 WIPO, 1983: *100 Years Protection of Industrial Property Statistics*. Geneva, WIPO.

rewarded all that effort by recognising the patentability of life forms and thus creating new barriers against the diffusion of the patented inventions [Kenney 1986; Feller 1990].

In India, despite the creation of a much acclaimed centre for biotechnology during the last phase of the prime ministership of Indira Gandhi, research in or commercial exploitation of biotechnology has had a rather poor record and India has fallen behind most advanced market economies or the burgeoning economies of East Asia in this field also. Patent citation statistics used by Gupta and Subbaram (1992) and Karki and Gargi (1993) do nothing to dispel this impression.

Karki and Garg (1993) based their evaluation of the worth of Indian patents in the field of biotechnology filed in the US on citations given in the *Science Citation Index*. This is again a selection and imperfect method of evaluation but it gives some indication of the degree of potential international competitiveness of Indian patents in this particular field.

The field of biotechnology in the study by Karki and Garg was broadly defined to include inventions broadly related to "processes for the production of drugs, medicines, biocides and food, including the processes employing the use of micro-organisms" [Karki and Garg 1993:167].

We have to remember in this context that the Patents Act of 1970 does not permit the patenting of products or of living organisms, invented or otherwise.[4] In the field of biotechnology thus defined, there was a total number of 1,049 patents filed in India over the period 1972-1990. Of these 750 were filed by foreigners (413 patentees) and only 299 (about 28 per cent) by Indians (113 patentees). Eighteen multinational companies held about 40 per cent of the foreign patents, whereas in the case of Indian patents public research organisations held about 45 per cent of the patents [Gupta and Subbaram 1992]. A scrutiny of the time pattern of Indian-filed patents reveals no upward trend. However, there was a spurt over the period 1987-90; in four years 94 Indian patents in biotechnology were filed; and in the three years of 1975-77, 62 patents had been taken out. Otherwise on an average 10 to 15 patents were filed by Indians in the field of biotechnology during the period 1972 to 1986.

Among foreign countries the US and Japan together accounted for 325 patents filed,[5] but in their case and in the case of all foreign countries there is a distinct downward trend in the number of patents filed [Table 1 in Karki and Garg 1993:167]. Within the field of biotechnology, out of the total of 1,049 patents the largest number of patents (378 or 36 per cent) occurred in the pharmaceuticals subsector, followed by the number belonging to unclassified 'others' (359 or 34 per cent) and then at some distance by the number of patents (139 or 13 per cent) belonging to food industry [Karki and Garg: 168, Table 3]. These figures give some indication of why the foreign drugs and pharmaceuticals lobby was so active in trying to overturn the Act of 1970

TABLE 6A: NUMBER OF PATENTS APPLIED FOR BY NATIONALS IN HOME AND FOREIGN COUNTRIES, 1982 - 1986

	Patents Applications by Nationals in					
	Home Country			Foreign Countries		
Countries	1982	1984	1986	1982	1984	1986
USA	63316	61841	65487	67197	69687	140142
UK	20530	19093	22892	16712	15865	36284
Japan	210897	256195	290238	36505	27201	71726
FRG	30668	31984	40875	39799	36841	93523
France	10681	11333	13419	15502	14725	37167

TABLE 6B: NUMBER OF PATENTS GRANTED TO NATIONALS IN HOME AND FOREIGN COUNTRIES, 1982-1986

	Patents Granted to the Nationals in					
	Home Country			Foreign Countries		
Countries	1982	1984	1986	1982	1984	1986
USA	33896	38364	38124	56510	56179	69266
UK	4686	4442	5403	10496	11859	20436
Japan	42223	51690	51276	24328	19329	36536
FRG	8279	11402	15347	35141	35050	50356
France	7764	7651	9362	12920	15133	22306

Note: FRG = Federal Republic of Germany (at present Germany).
Source: WIPO : *IPS*, various issues.

TABLE 7A: NUMBER OF APPLICATIONS FOR PATENTS FROM INDIAN RESIDENTS TO FOREIGN COUNTRIES, 1976 -1989

Years	UK	USA	FRG	France	Japan	Canada	Australia	Total*
1976	9	39	4	2	5	6	1	81
1977	25	27	5	2	4	5	2	93
1978	14	24	4	2	6	7	2	106
1979	14	25	6	1	–	4	2	64
1980	9	23	1	1	4	6	3	69
1981	14	22	–	2	6	5	3	90
1982	5	20	3	–	1	12	1	61
1983	5	15	1	–	5	2	1	58
1984	17	30	7	5	12	18	4	152
1985	25	25	17	9	11	10	1	150
1986	15	36	11	8	5	10	4	135
1987	11	26	6	5	3	14	2	101
1988	13	41	5	6	3	10	2	123
1989	24	50	12	14	4	25	8	284

TABLE 7B: NUMBER OF PATENTS GRANTED TO INDIAN RESIDENTS IN FOREIGN COUNTRIES, 1976-1989

Years	UK	USA	FRG	France	Japan	Canada	Australia	Total*
1976	17	18	–	4	1	14	2	76
1977	12	17	1	8	1	8	6	63
1978	10	17	2	5	–	3	1	55
1979	5	15	3	1	–	6	1	40
1980	3	10	1	–	3	5	2	50
1981	5	6	–	1	3	5	2	53
1982	5	4	–	1	2	4	2	40
1983	10	14	1	2	–	5	1	50
1984	6	12	1	–	–	6	–	38
1985	9	10	5	4	1	5	–	58
1986	7	18	4	1	1	4	1	62
1987	5	12	2	3	–	2	2	48
1988	6	14	6	5	2	4	5	64
1989	2	14	2	2	1	1	1	41

Note: * Total includes other countries also.
Source: WIPO : *IPS*, various issues.

and bring in the TRIPs provision of the new GATT treaty signed on December 15, 1993.

To judge the relative importance of Indian patents in the international context, Karki and Garg analysed the patent citations for five successive years from the date of first publication. They found only six citations of Indian patents, of which three were filed by the CSIR, two by the Central Council of Research in Ayurveda and Siddha and a sixth by an individual (P Khanna). However poor the record might be as judged by this measure, it still underlines the importance of utilising the resources of the CSIR and of paying more attention to the inheritance from the traditional medical sciences of India and to the enormous stock of biological resources occurring in nature in India.

The Indian drugs and pharmaceutical industry is not alone in using patents as competitive instruments. For example, in the UK, the pharmaceutical industry intensively exploited the patent system. Barring the case of penicillin, most antibiotics and other new drugs were patented by such firms as Pfizer, Parke Davis and Burroughs Wellcome and the patents were used to increase their competitive power or defend entrenched positions. These firms have large R and D outlits of their own and the US and British firms captured a large size of overseas markets by using patents and marketing strategies [Taylor and Silberston 1973: chapter 10; Mamdani 1992:3-4]. Pursuing a different strategy in the early 20th century such as confiscation of many German patents and blockading the markets of the western companies, Japanese firms were able to capture large markets for drugs and pharmaceuticals [Bartholomew, 1989:231].

In British India, in the absence of patents for indigenous medicines (particularly ayurvedic), foreign pharmaceutical firms seized most of the modern pharmaceutical markets and thus they destroyed many of the effective domestic pharmaceutical businesses [Bala 1991]. In the post-independence period the inconsistencies of government policy (particularly with regard to R and D) often proved damaging to the competitive strength of the local business units [Chaudhuri 1984].

However, the Patent Act 1970, through its provision of process patenting for a short span of time (five years from the date of sealing) rather than the right for product patenting for a full length of time (i e, 14 years), gave the Indian pharmaceutical Industry a competitive edge over the rival foreign companies. High tariff rates on bulk drugs and basic chemicals and the compulsion to develop alternative process engineering skills helped the domestic firms to develop manufacturing capabilities and help them produce the relevant products at a cheaper cost from the basic stages. The drug price control policy for major life-saving bulk drugs, along with a five-year exemption from price control for the newest drugs, strengthened the position of Indian companies. Quality control, professionalised management and R and D gave the domestic firms a competitive environment; they began to perform well even in the export markets. According to one recent study, the domestic companies could control 70 per cent of the domestic formulations market and 85 per cent of the bulk drugs market and accounted for 85 per cent of the exports of drugs (*Business India*, December 5-8, 1994, p 55). In another study, covering the period from 1989-90 to 1992-93 it has been found that in India the leading pharmaceutical companies (42 companies) did well both in terms of sales and profits [Bandopadhyay and Das 1995]. It was also observed that the domestic firms did better than MNCs both in terms of rate of growth of sales and profit margins (*Capital Market*, December 5, 1993, pp 12-13 and Nachane 1995:263).

On the basis of the GATT agreements, product patents with a life-span of 20 years would come into effect in India within the year 2005, if not earlier. Several authors have discussed the possibly adverse impact of the new regime on the price and levels of production of drugs [Dhar and Rao 1993, Thomas 1993; Prasad and Bhat 1993; Kenyla 1994; Sahai 1994]. With the imposition of new intellectual property laws along with the progressive delicensing of drug production and decontrol of drug prices carried by the central government, there is every possibility that Indian companies would face a situation close to the pre-1970 period. How far the domestic firms will be able to swing the pendulum in their own direction would most likely depend on the capabilities of the local firms on several fronts. They might, for example, explore markets for generic products whose patents have expired, try and improve the levels of R and D particularly in treatment of diseases typical to tropical countries (where Indian companies enjoyed traditional superiority) and expand the production of the drugs in which India enjoys comparative cost advantages. The domestic firms might also collaborate with medium- and small-sized foreign companies in order to get access to markets in other countries.

Upril now, around 7 per cent of the total patents granted in India have been related to drug or medicines (Table 8). If we examine the numbers of patents for processes of manufacture of food, drugs or medicines (which are valid for seven years from the date of application) we observe (from Table 9) that every year roughly 30 to 50 patents (in numbers) were granted to Indians in these fields. If the domestic companies cannot develop proper infrastructure and marketing powers to utilise those patents which they consider to be commercially viable, then it would be very difficult for them to gain competitive strength. The problems have become further complicated with the broadening of the definition of 'utilisation of patents' after the GATT agreement; no penalties can generally be imposed on the patentees just for non-use of patent in a particular country, if it is being used at least in any one country which is a member of the World Trade Organisation (WTO).

IV
Lacklustre Performance of India's Innovation System

The Indian patent system is only a part of the innovation system of the country. The latter would include all those processes and institutions which would aid or hinder learning by doing, learning by using,

TABLE 8: NUMBER OF PATENTS RELATED TO DRUGS OR MEDICINES, INDIA, 1986-1994

Years	Patent Applications	Patent Granted
1986-87	214 (6.13)	185 (8.76)
1987-88	198 (5.73)	124 (5.89)
1988-89	221 (6.14)	300 (8.86)
1989-90	216 (5.90)	146 (7.72)
1990-91	258 (6.86)	87 (5.84)
1991-92	323 (9.09)	118 (7.04)
1992-93	234 (6.75)	94 (7.31)
1993-94	273 (7.06)	145 (8.30)

Notes: 1 Figures in brackets are in percentage of total patents applications and granted respectively.
2 Separate lists for Indian and foreign patents are not presented by the patent office.

Source: *Patent Office: Annual Report*, 1990-91 onwards.

TABLE 9: NUMBER OF PATENTS GRANTED TO THE METHODS OR PROCESSES OF MANUFACTURE OF FOOD, DRUGS OR MEDICINES IN INDIA, 1980-1994

Years	Indian	Total
1980-81	26	111
1981-82	31	121
1982-83	38	148
1983-84	29	141
1984-85	29	95
1985-86	17	155
1986-87	50	198
1987-88	40	139
1988-89	58	344
1989-90	46	166
1990-91	34	97
1991-92	45	128
1992-93	21	106
1993-94	58	175

Note: These patents are valid for 7 years from the date of application or 5 years from the date of sealing of the patent whichever period is shorter (see section 53(1)(a) of the Patent Act, 1970).

Source: *Patent Office : Annual Report*, various issues.

incremental innovations on the shop floor, the flow of adaptive innovations, locally innovated technologies and their use, and the diffusion of productivity raising changes in general. There is plenty of evidence of the malfunctioning of the Indian innovation system in this larger sense, especially in the non-agricultural sectors of the economy.

The contrast between the malfunctioning of the innovation system in the Indian economy and its potential for synergistic contribution to the growth in productivity and in income can be easily illustrated by taking the case of the South Korean economy. As in most other areas of modern manufacturing and associated activities, South Korea was a late starter compared with India in setting up any kind of innovation system. For example, while the roots of the Indian CSIR go back to the second world war period, the South Korean equivalent of the Korea Institute of Science and Technology (KIST) was not established until 1967 [Bagchi 1987:53]. Once it was set up, however, the South Korean government took decisive steps to link up the KIST and its successor, Korea Advanced Institute Science and Technology (KAIST), with manufacturing units. These institutes were from the beginning mission-oriented, and were expected to earn most of their income from research contracted for with producing units. But the latter were reciprocally obliged to produce clear programmes for absorption and adaptation of technology imported from abroad and were therefore obliged to set up their own R and D units or to go to a publicly sponsored R and D set-up for chalking out a technology absorption path. By contrast, while recommendations were made by a number of review committees set up to examine the working of CSIR laboratories effectively linking those laboratories up with the activities of manufacturing units, the latter were not obliged to chalk out a programme for absorbing or adapting imported technology. (This remains the fly in the ointment spoiling the effectiveness of the Abid Hussain Committee recommendations obliging CSIR laboratories to earn 40 per cent of their incomes from contract research.) In fact, firms regularly opted for a foreign collaboration route, bypassing various requirements regarding ceilings on payment of royalties for licences of patents or manufacturing blueprints obtained from foreign firms [Bagchi and Dasgupta 1981]. Moreover, South Korea did not permit the growth of a Trojan horse in the form of a large number of foreign-controlled firms with only a marginal interest in the indigenisation and adaptation of imported technology."

One of the key aspects of a national system of innovation is the amount and quality of expenditure on R and D. Here again, India was in advance of South Korea down to the 1970s. In 1970-71, Indian expenditure on R and D as a percentage of GNP was 0.35 per cent, way below the 1 per cent of GNP Mahalanobis had pleaded for in the late 1950s [GOI 1994:50]. But at that time, R and D expenditure as a proportion of GNP at 0.34 per cent was marginally below that of India [Bagchi 1987: 55]. By 1982, however, the percentage of R and D expenditure to GNP was already 0.95 in the case of South Korea, whereas that percentage was not reached in the case of India until 1986-87. In the Indian case, the corresponding proportion marginally increased to 0.96 per cent in 1988-89 and then slipped to 0.89 per cent in 1990-91 [GOI 1992:50]. In the case of South Korea, the percentage of R and D expenditure to GNP had gone up to 1.9 per cent by 1988 [GOI 1994:380].

The contrast between India and South Korea in respect of the private sector contribution to R and D expenditure is equally stark, and it could be argued that the failure of the Indian private sector to engage in R and D activities is a major factor behind the poor performance of India's innovation system, including the patent system component of that larger system. In 1970-71, private funding of R and D accounted for less than 10 per cent of total national R and D expenditure in India. By 1980-81 it amounted to about 14 per cent of the national R and D expenditure, and in 1990-91 it fell short of that 14-per cent figure [GOI 1992:49]. In contrast, in South Korea in 1970-71, private funds already accounted for 33 per cent of total R and D expenditure, by 1982 private sources contributed 60 per cent of the national R and D expenditure and by 1987 private funds accounted for 80 per cent of the national expenditure on R and D [Kim 1993:370].

The argument that excessive government regulation or the excessive weight of the public sector in the economy are responsible for the poor performance of the Indian innovation system or the private sector component of that system is not persuasive because in respect of the degree of government regulation or the prominence of the public sector, South Korea compared well with India for most of the period covered [Bagchi 1987; Amsden 1989; Haggard 1990; Wade 1990; Singh 1994; Lee 1995; Bessant and Kaplinsky 1995]. There is also little evidence that the economic liberalisation process which received a strong impulse from 1985[5] did anything to improve the innovational or technology absorption record of Indian industry. The increase in firm size, increased foreign competition or increase in the foreign equity component of capital invested in India were expected to stimulate R and D activities and their quality. On a study of the record during the years 1985-1991 it was found, however, that "foreign equity [was] negatively associated with R and D intensity" [Alam 1993:52] and firm size and increase in degree of competition through a greater degree of opening up of the foreign trade sector had no discernible impact on R and D activities. On the contrary, a larger import of raw materials and components through the easing of the foreign trade regime, was also "negatively related with R and D activities" [Alam 1993].

There is a provision in the Indian Patent Act 1970 that every patentee and licensee should regularly (after six months) keep the Controller of Patents informed about the actual utilisation or working of patents (section 146(2) of Patent Act 1970). But in reality, no compulsion was ever used to get such information from the patent holders even at the time of renewal of patents. Each year only about one-fourth of the patents in force, contained information about the status of the patents (whether they are being utilised or not). So exhaustive data on patents worked were never available. On the basis of the data available, it has been found that only around 3 to 5 per cent of total patents in force were actually worked in India (Table 10).

Again, in India a large number of patent

TABLE 10: NUMBER OF PATENTS WORKED IN INDIA UNDER DIFFERENT FIELDS, 1985-1992

Years	Chemical	Mechanical and General	Electrical	Total
1985	86	169	70	325
1986	107	395	102	604
1987	151	318	89	558
1988	155	301	118	574
1989	64	172	53	289
1990	80	134	38	252
1991	93	210	40	343
1992	63	156	52	271

Notes: 1 Annual Reports of the Patent Office did not present separate lists for Indian and foreign patents worked.

2 Patents holders often did not disclose information regarding the working of patents though there is a provision in the Patent Act to do so (see Section 146(2) of the Patent Act 1970), so the list might not be exhaustive.

Source: Same as Table 8.

applications are kept waiting, pending the submission of the final examination report. According to the Annual Report of the Patent office only around 25 to 30 per cent of the total patents to be examined in a year are actually being examined; (one reason for this is the insufficiency of qualified staff in the Patent Examiner section). Every year around six to seven thousand patent applications are being carried forward to the next year for a future examination. Thus in the process, the innovations often lose their competitive edge and the patent applicants often lose interest in obtaining their patents. In India normally it takes 2 to 4 years to get a patent finally sealed, even when applicants are persistent. These data underscore the lack-lastre performance of the Indian patent system as an instrument of innovation and competitiveness.

The success or failure of the innovation system has ultimately to be judged by the extent to which it promotes growth of productivity and national income per capita in an economy. But within a capitalist system, the use of R and D and patents for protecting national markets and penetrating foreign markets are important criteria which can be used for judging the effectiveness of the innovation system of a country. By these criteria the Indian patent system introduced in 1972 can claim only a limited success at best. This is not to deny the significant advances made especially in the area of drugs and pharmaceuticals obtained with the help of the Patents Act of 1970 [see, for example, Kealya 1994]. This is also not a suggestion that the scuttling of the 1970 patent system on the dictates of the new World Trade Organisation or a further crippling of the national innovation system, through the sacrifice of national autonomy in policy-making according to the IMF-World Bank gospel, is a way forward. The enquiry should be directed towards designing a national innovation system of which a rationally constructed patent system will be a major component.

Certain simple measures can be suggested to improve the working of patents as competitive weapons. They would include wide and intensive use of the patent information network and efficient dissemination of such knowledge both among large and small firms, extension of service of the patent office for giving opinion and suggestions to the domestic researchers (or research units) about the scope for patented inventions in specific fields; employment of more professionals who are able to read and write patents properly and obey official formalities; and creation of funds for development of patents and for management and marketing of domestic patents. Active and well-maintained linkages among research institutions, industrial organisations and patent office are also necessary for achieving the implicit or explicit objectives underlying the creation of a patent system. In-house patent search service, effective screening of unworked patents and lapsed patents to retrieve the usable technologies, and imparting of training to utilise international patent information, could be considered further as some of the vital steps to strengthen both the institutional support and innovative environment of the firms.

Notes

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1 In Japan, unless the applicant or a third party makes a written request within a period of seven years from the date of filing of patent applications, the patents will not be examined, then the patent applications will be treated as withdrawn. However the applications could be converted into applications for utility models (minor invention). Similar types of rules are followed in Germany also. In South Korea the applications could be left unexamined for five years [Jacobs 1994: J-8, G-9, K-21]. In addition, in Japan, through a provisional publication of patents (*Kokai*) each patent application is laid open to the public inspection after 18 months from the date of application. Then the applicant enjoys the implicit right to get compensation from any third party who is commercially working the invention sought to be patented. However, the right can be exercised only after the post-examination publication of patents (*Kokoku*). But even then the law is strong enough to protect the applicant against infringement by others.

2 Utility models are minor innovations. They also indicate any novel device relating to shape, construction or assemblage of articles. The registration laws are less strict here. The rights conferred by utility models are similar to those conferred by a patent, however utility models are protected for a shorter duration. Several nations such as Germany, Japan, Spain and South Korea give additional protection to these utility models.

3 Patenting as such is an expensive business in the US. It often requires professionals who can successfully draft the patent right which should be protected. However, in the US there is a two-tier system regarding the payment of fees for patents. The small entities, i.e., independent investors, small firms with less than 500 employees and non-profit organisations generally enjoy a concession of 50 per cent regarding payment of such fees. However, the status must be established in respect of each patent applications. Still the total fees for patent registrations and maintenance are very high. In April 1994 the filing fees was US $ 355 for small entities and US $ 710 for others; patent issue fees were US $ 585 for small entities and US $ 1170 for others. These exclude the renewal or maintenance fees which are payable after three years and attorney fees which are again exorbitant. If we include all such fees the total cost might cross even US $ 10,000. (See the *Manual for the Handling of Applications for Patents, Designs and Trade Marks throughout the World*, (in short, *Manual*), Amsterdam, Octrooibureau Los en Stigter, Supplement No 70, April 1994, Section US, pp 29-35 and also Jacobs 1994, pp US4-US9.)

The application fee for patents in Japan (since January 1988) is 14,000 Japanese yen (or about US $ 110 at the 1988 conversion rate) and the patent examination fee is 58,000 Japanese Yen (or about US $ 455). However, in Japan patent renewal fees are quite high. The fee is about US $ 500 after nine years and then it is doubled after every two years, thus the fee becomes about US$ 4,000 (or 512,000 Japanese Yen), if anyone wants to keep the patent valid up to 19 or 20 years. Moreover, the charge will be 10 per cent more (in yen) for each additional claim for invention. (See the *Manual* Supplement No 58, September 1988, Section on Japan, pp 1-18 and the IMF, *International Financial Statistics* for the conversion rates.)

However, in India the fee for patent registration is negligible. Until 1992 it was within US $ 20. In 1995 the fees were revised, still one can take out patents in India at a cost within US $ 30. However, these exclude the attorney fees which vary generally from US $ 100 to US $ 300 depending on the nature of complications of the patents (the information is based on interviews with the Patent Agents and the Patent Office : Annual Report).

4 However, under the Budapest Treaty 1977 which is followed by several countries, viz, the US, UK, Germany, France, Japan and South Korea deposits of micro-organisms are protectable. The US Patent and Trade Mark Office (PTO) determined that non-human multi-cellular living organisms including animals are patentable (US Supreme Court Judgment 1980, Ananda Chakrabarty case). However, in India there is still no national facility for depositing micro-organisms.

5 See Fransman and Tanaka (1995) for evidence of the Japanese advances in biotechnology and Office of Technology Assessment (1984) for the US data.

6 We have used the case of South Korea for illustrative purposes only. With only slight changes, the proposition about the catching-up in national systems of innovation would go through in the cases of the People's Republic of China and Taiwan as well [Hagchi 1987: chapters 3 and 4; Haggard 1990: chapters 4 and 8; Wade 1990: chapters 5-9, Hong 1992, Kim 1993; and Hou and Gee 1993].

7 For the details regarding such liberalisation policies see the Government of India, *Economic Survey*, various issues since 1985.

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TRIPS NEGOTIATIONS IN GATT - MAIN ISSUES

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PRESENTATION AT THIRD- WORLD PATENT CONVENTION
HELD ON 15TH-16TH MARCH, 1990

Distinguished participants and friends, I will hold this Session. It is very important Session. The issue of Intellectual Property has been discussed for quite a long time. For the developing countries, we all recognise the Intellectual Property Right, but for some items which are very important to the people's life, such as pharmaceutical brand and animal varieties, agriculture and so on and so forth and non-patentable.

As we have listened in the morning session that there are so many aggressive moves launched by the developed countries to press us to amend our Patent Law for their interest.

One of the important moves is to bring the Intellectual Property issue into the GATT Negotiation in the topic of TRIP, Trade Related International Property Negotiations. Therefore, in this session we are very pleased to have Dr. Abdulqawi Yusuf from the Technology Programme, UNCTAD to tell us about what is going on in the Trade Negotiations in GATT. Let me invite Mr.Yusuf,please.

Dr. Abdulqawi Yusuf, Technology Programme, UNCTAD, Geneva - Thank you very much, Madam Chairperson and Mr. Co-Chairperson, it is a very daunting task for me to speak to you about the TRIPS Negotiations in the presence of some of the major actors in those negotiations, who have been involved in the Uruguay Round since its very beginning like Ambassador Jamal and Ambassador Zutshi. But I will try to give you an overview and a summary of the main issues that are at stake in those negotiations, especially, as seen by an observer.

I will, first of all, briefly address the genesis of these negotiations and then move on to the proposals that have been presented by the developed countries in order to realise the goals that they have fixed for themselves during these negotiations. I will then set out the implications of these proposals for the developing countries and the reactions or the responses provided by them. The Punta dei Este Declaration on the Uruguay Round defined two objectives, as far as the TRIPS negotiations were concerned. The first objective was to clarify GATT provisions

and elaborate as appropriate new rules and disciplines in order to reduce the distortions and impediments to international trade and taking into account the need to promote effective and adequate protection of Intellectual Property Rights and to ensure that measures and procedures to enforce Intellectual Rights do not themselves become barriers to legitimate trade.

This objective was interpretted in different ways by the participants to the GATT negotiations. For the developing countries, the main issue was the clarification of existing GATT principles and GATT provisions on Intellectual Property in order to ensure that measures and procedures to enforce Intellectual Property would not constitute a barrier to legitimate trade; whereas the developed countries put the main emphasis on the account to be taken of the need to promote effective and adequate protection of Intellectual Property. Thus, the latter group, argued that the national laws and regulations which existed in most countries were inadequate, as far as the protection of Intellectual Property is concerned and that their enforcement was weak. This applied also in their views, in the existing international conventions like the Paris Convention and the Berne Convention, which they had characterised as toothless Conventions.

The second objective was to develop a multi-lateral framework of principles and rules concerning the international trade in counterfeit goods. This was an objective that was shared by all the participants in the negotiations. The developing countries felt that they could join an International Code on Counterfeit Goods and that this objective should receive maximum attention as far as the TRIPS negotiations were concerned. However, the developed countries, who first floated this idea in the late 70's and early 80's felt that it was already outdated and that what was needed now was strong and more effective norms and standards on Intellectual Property coupled with enforcement measures. So, they maintained that a Code on Counterfeit goods was not really the major objective and should not be the main focus of the negotiations, but that the elaboration of standards and norms, which would go beyond the existing Conventions should be the objective of the Negotiations. This gave rise , of course, to an animated debate on what would be the main focus of the negotiations and which objectives should be pursued by the participants to the negotiations.

The turning point of this debate came in April, 1989 with the adoption of the TNC, April next, i.e. the Ministerial text of the mid-term review of the MTN Negotiations. This turning point vindicated their position held on the developed

countries as far as the interpretation of the mandate of the Punta del Este Declaration was concerned. It vindicated their position on several points. First of all, the TNC text of April 1989 listed the TRIPS issues which should be debated and discussed at the Uruguay Round of Negotiations. And it listed these issues as the following :

1. The applicability of the basic principles of the GATT and of relevant International Intellectual Property Agreements or Conventions ;

2. The provision of adequate standards and principles concerning the availability, scope and use of Trade related Intellectual Property Rights ;

3. The provisions of effective and appropriate measures for the enforcement of Trade Related Intellectual Property Rights ;

4. The provisions of effective and expeditious procedures for the multi-lateral prevention and settlement of disputes between Governemnts including the Applicability of GATT Procedures ; and

5. Transnational arrangements aiming at the fullest participation and the results of the Negotiations.

So, as you can see, the position advocated by the developed countries, which was to elaborate norms and standards of Intellectual Property ; to establish effective enforcement measures at the national level for these norms and standards and to link these two to the Dispute Settlement Provisions of GATT and to examine the applicability GATT's dispute settlement procedures were actually confirmed and affirmed in the TNC Declaration or Text of April, 1988.

Two other paragraphs, one on transitional arrangements in order to ensure the fullest participation to the negotiations or through the results of the negotiations and the other one on the concerns of the developing countries were added to this list of issues that should be examined by the negotiators in the TRIPS Negotiations.

The paragraph addressing the development needs of the developing countries is couched in a very cautious language and reads as follows :

> " That the participants agree that consideration will be given to concerns raised by participants related to the underlying policy objectives of their national systems for the protection of Intellectual Property including developmental and technological objectives."

Before turning to the proposals presented so far by delegations, it would be useful to examine very briefly what exists today at the international level and what is being sought by the proponents of the new system of Intellectual Property Rights, which should be negotiated in the Uruguay Round of Negotiations. What do we have today at the international level ?

As part of an overall system of norms and principles governing Intellectual Property Rights, we have two sets of instruments i.e the national laws and regulations of the countries of the world and the international conventions on Intellectual Property Rights. These two sets of instruments form together the Intellectual Property System at the international level. The existing conventions make provision for the existence of national legislation, which are different from each other, to enable individual States to design their legal systems in a way which corresponds to their national interests and to their technological and economic development objectives.

The International Conventions, to which I am referring here are the two most important ones, i.e. the Paris Convention on Industrial Property/ protection and the Berne Convention on Copyright. There are a number of other conventions which deal with more specific objects of intellectual property rights. These International Conventions have certain common features. One basic feature which is shared by all these Conventions is the principle of national treatment. This principle has been included in the Conventions in order to facilitate the application of national laws to the nationals of all the members of the Union in an equal manner in the sense that foreigners are entitled to the same treatmentas nationals. Of course, the Conventions themselves establish certain minimum standards which should be taken into account in the formulation of national laws and regulations, but they leave much discretion and leeway to the governments to regulate the acquisition and enjoyment of Intellectual Property Right in a way which is in consonance with the public interests and public policy objectives of the State granting such rights to foreigners and to its own nationals. Thus, the international conventions allow the member States the freedom to determine the rights and obligations of the property-holder and the level and scope of protection to be granted. It is, therefore, up to the member States to lay down the requirements for granting such rights in their national laws and regulations.

The other international instrument which contains some provisions relevant to Intellectual Property Protection is GATT. GATT contains certain provisions which are of relevance to Intellectual Property, but which were primarily aimed at ensuring that the adoption by governments of measures to enforce laws and regulations on intellectual property rights would not result in arbitrary and unjustifiable obstacles to international trade. Thus, the GATT provisions on Intellectual property Rights are of a permissive nature, in the sense that they allow governments to adopt whatever laws and regulations they deem necessary on Intellectual Property Rights so long as those laws and regulations do not constitute an arbitrary and unjustifiable obstacle to international trade. This has been the situation up to recently when the TRIPS Negotiations were launched in 1986.

Now, what are the objectives underlying the TRIPS Negotiations ? What is the substance of the proposals that have been tabled by the developed countries who are the proponents of this new approach to the regulation of intellectual property rights at the international level. These proposals would first of all, imply the adoption of a set of minimum standards and norms of world wide application on IPRS. These minimum standards and norms would be based on the laws and regulations which are at present in force in the technologically most advanced countries of the world. However, it should be recalled that to-day's industrialised countries made full use in the past of the freedom to determine the scope and level of intellectual industries or to develop local competitive capacity.

According to these proposals, enforcement measures at the national level would also be based, as far as possible, on those already existing in the laws and regulations of the most technologically advanced countries. Of course, when you talk about enforcement measures, you talk about administrative and judicial procedures and what is being sought here is the worldwide uniformisation and harmonisation of the administrative and judicial procedures necessary for the enforcement of Intellectual Property Rights.

The standards norms and enforcement measures established at an eventual TRIPS agreement would be linked to the dispute settlement procedures of the GATT and to the framework of rights and obligations on trade in goods. Thus, party, which would not apply the obligations undertaken in an IPR Agreement would be sanctioned for a non-compliance with this

obligation and would see its advantages and rights under the GATT framework withdrawn by other contracting Party, which might feel that there has been an impairment and nullification of their advantages from an IPR Agreement. Now, let us look for a moment at the precise nature of the standards and norms which would form part of an eventual IPR Agreement, as envisaged by the proposals of the developed countries in the area of patents since the subject-matter of our discussions here is mainly on Patents.

These proposals would imply the extension of Patent Protection to plants, plant varieties and animals. They would imply the extension of Patent Protection to chemical and pharmaceutical products, to food products ; thus restricting or abolishing totally the freedom that Governments have enjoyed up to now to exclude certain products from patentability in conformity with their developmental and technological needs. With respect to duration, they would fix a minimum of 20 years duration for patent protection in all countries. As regards local working, there would be no obligation on the foreign patentee to work his invention in the country granting him the patent. With respect to compulsory licensing, no compulsory licenses would be granted except on judicial review and according to some proposals, no compulsory licenses should be granted at all.

These are just some of the examples of the provisions that would in substance be included in a future agreement on TRIPS in the area of patents. Similarly, high standards of protection are proposed for trade marks, copy-right and integrated circuits. What are the implications of these proposals for the developing countries ? As you know, the granting of Patent protection and of Intellectual Property Rights in general, is based on a tension between two public policy objectives. On the one hand, the need to provide incentives to private individuals or enterprises in order to promote creativity and innovativeness ; and on the other hand, the need to ensure that the fruits of that creativity are disseminated to those who could benefit from it in a way that is conducive to the economic welfare and well-being of the society granting this monopolistic and exclusive right.

The challenge of the law, therefore, is to strike a balance between these two public policy objectives and to find the degree of protection most compatible with the desired social goal. It would then be wrong to surmise that the objective of providing incentives should take precedence over the social needs for diffusion of knowledge. However, it seems that the proposals now being considered in the TRIPS Negotiations are based on this assumption suggest that priority be given to the provision of incentives rather than to the dissemination of technological knowledge. Nevertheless, the protection of technology is not an isolated issue in itself, but must be seen along side the access to an promotion of technology and the promotion of technological innovation. So, as Surendra Patel said earlier, the rights of IPR owner must be balanced by the obligations of these IPR owners. Developing Countries have always placed a major emphasis in their national legislation on IPR and on Patents, in particular, on adequate disclosure of the patented product or process, on the local working of such an invention, on compulsory licensing and on the possibility of parallel imports.

The other major emphasis of legislation in developing countries and up to a very recent period, in the legislation also of most developed countries, was the control of the abusive use of IPRs. Governments had the discretion to lay down the terms of IPRs they grant and the conditions under which these rights should be exercised. But this power would be lost, if the present proposals were to be adopted in an IPR Agreement. There would be no countervailing limitation on the IPR owners as to how they may use or abuse their rights. Restrictive practices are wide-spread in licensing agreements, especially, between enterprises of industrialised countries and enterprises of developing countries. An attempt was made in the negotiations on an international Code of Conduct on the Transfer of Technology to deal internationall with this type of abusive practices so as to eliminate them. These efforts have not yet succeded because of the deadlock in the code negotiations.

Since these proposals do not take into account the concerns of the developing countries, how should they respond to them? I can only give you my own personal view on this matter. Upto now we have had two phases of the TRIPS Negotiations and the developing countries have adopted certain strategies at each one of these two phases. The first phase of the negotiation started with the Punta del Este Declaration and ended with the adoption of the April TNC Text of 1989 while the second phase was introduced with the adoption of that text is still under way. During the first phase of the

negotiations, the developing countries tried to avoid any substantive negotiations on the elaboration of norms and standards on IPR within the GATT framework. They tried to put the main emphasis on the elaboration of a counterfeit code and on the clarification of GATT provisions on IPRs. They did not make any detailed proposals on the issues that were under negotiations. This strategy came to an end with the adoption of the April TNC text which spelled out the specific issues to be negotiated from that moment onwards, the developing countries have been trying to underline the basic principles which should inspire and inform an International Agreement on IPRs in the Uruguay Round of Negotiations. However, they have not yet addressed the bolts and nuts of such an Agreement in the sense that they have not yet tabled detailed provisions which could be considered as a counter-proposal to the proposals presented by the developed countries.

In my view, it is high time that the developing countries presented their own detailed proposals on the issues under discussion. You may recall that in the 1970's, the developing countries set out to revise the Paris Convention because they were not satisfied with the provisions of the Paris Convention. They are not up to now satisfied with certain aspects of the Paris Convention. Justice Iyer underlined that this morning. Now they are being asked to adopt norms and standards above and in addition to the Paris Convention with which they were not satisfied. Therefore, they should come forward with a response based on their national legislation and on the public policy objectives underlying that national legislation. Even the April, 1989 TNC Text on TRIPS recognizes the need to take into account such public policy objectives. I believe that concrete proposals by the developing countries which clearly articulate their specific concerns in the area of TRIPS are called for at this juncture. The developing countries should see to it that any text which emerges if a text ever emerges from these negotiations, fully reflects their concerns in a most detailed fashion. They should strive to have their concerns and aspirations fully taken into consideration and placed on an equal footing with the proposals of their partners from the developed world.

Thank you, Mr. Chairman.

GATTastrophe : A close Look

By Dinesh Abrol

Joint- convenor, National Working Group on Patent Laws.

URUGUAY ROUND NEGOTIATIONS

The following report is prepared by Dinesh Abrol, Joint Convenor, National Working Group on Patent Laws, and is based on participation in the NGO GATT Steering Committee Meeting in Brussels from November 28 to December 1, 1990 and the lobby work during the GATT conference from December 3-8 1990. The report is presented in two parts. In part I, the comments deal with the progress in the Uruguay Round of GATT Negotiations and the implications for developing countries. In part II, the proposals of NGO meeting are reported and discussed from the point of view of the tasks ahead for the National Working Group on Patent Laws in India.

Part I

The message from Brussels is loud and clear. The threat of recolonization for the developing world is not over and has only been postponed by a few months. Perhaps, this may also not hold true for long. The arm twisting by industrialised world will start soon to force the developing countries to come to terms with the Geneva Process which is to start again from January 15, 1991.

Non-governmental organisations are very concerned about the current directions in the Uruguay Round Negotiations. These negotiations will deeply affect people's capacity, in the world as a whole, to decide about their own development in a democratic and sovereign manner. The NGOs are concerned about the impression being created that the governments of some countries including India are bent on destroying multilateralism in trade. They are being warned of the choice between a collapse of the system and triggering of a depression. There are predictions of gloom and doom being made. Developing countries are being threatened of dire consequences of the bilateral arm twisting which will follow the failure of the round. The European community and the U.S. tried their best to involve the developing countries in sharing blame for the failure of the round. Germany held a press conference and accused India of blocking progress in the negotiations because of its stand on TRIPS. Carla Hills of U.S. met the Indian Commerce Minister, Prof. Swamy and spoke of lack of co-operation from India on the negotiations on TRIPS and Financial Services. It is another matter that thanks to the failure of the U.S. and the European Community (EC) to reach an agreement on Agriculture, progress in the other fourteen topics had to be stopped on the last but one day of the GATT conference.

Developing countries marginalised

Right through developing countries were marginalized as participants in the negotiations. In many green room (1) discussions, they were prevented from even being associated with the drafting of agreements. In the greenroom on TRIPS, only after protest, Egypt was allowed to join the negotiations on behalf of the African world. The practice of permitting ten

parties each from the developing and industrialized world meant that less than 10 percent of the contracting parties among developing countries were able to participate in the final drafting of agreements in the various specific green rooms.

Developing countries are partly to be blamed for this marginalisation. They did not make any concerted effort to have their voice heard. There was only one press conference by the informal grouping of developing countries. In contrast, the European Community and the U.S. held an average of two press conferences per day. In addition, several individual European countries were separately holding press conferences. The informal grouping of developing countries met only once to discuss their marginalisation.

Developing countries stand leaderless

The lack of leadership within developing world has been the main reason for marginalisation at the Uruguay Round Negotiations. It would not be wrong to say that the shadow of April 1989 compromise by India on the subject of TRIPS was still very much evident on the face of developing world. It appears that all the bilateral efforts made by the subsequent government had not erased the scars left by the decision to agree to discuss the topic of substantive norms and standards of intellectual property in the forum of GATT.

In the only press conference held by the informal group of developing countries, the stand put forward was quite weak. Although the statement made by Brazil on behalf of the informal group of developing countries expressed clearly the anguish and resentment of developing countries, it lacked teeth. While the neglect of the concerns of developing countries in the areas of agriculture, textiles and market access was pointed out, the field was left wide open to compromises in the new subjects such as TRIPS, TRIMS and Services. The ambassador from Brazil had no option but to state that "the developing world was disunited on the new areas. He had to admit that there were tradeoffs involved and each area would be examined on its merit by the concerned developing country.

The lack of leadership was reflected in the absence of a role played by G15 and G77. G15 met to only discuss the setting up of its secretariat. The Uruguay Round Negotiations was not even an agenda item in their meeting.

Firm leadership needed

Formally speaking, the African world had reiterated firmly its to opposition to the proposals of the industrialised world on the new areas. India is publicly standing as a wall on the issue of TRIPS. Peru, Egypt and many other developing countries are quite agitated with the way the negotiations have been handled by the fellow countries. They are willing to make a common cause. But there is no one to lead developing world. The developing world

failed in its duty towards its people. If it does not get united to deal with the threats to its sovereignty and well being. India should take a firm stand on the interests of developing countries.

Currently, developing countries including India are prepared to tradeoff the new areas for concessions in the traditional topics such as agriculture, textiles, tropical products and market access This misfortune was not only discernible in the conference but this view was also privately discussed everywhere in the corridors. It is public knowledge that concessions will be okayed in the area of TRIPS, TRIMS and Services if some crumbs are thrown in the area of agriculture and textiles to the developing world. The people of developing world should thank the European farmers who have saved them for the time being from the GATTastrophe

GATT Balance Sheet

To formulate our future strategy, it is necessary to prepare at this juncture a technical cum political balance sheet on the important topics. I deal The topics relating to such as textiles, tropical products, agriculture, TRIMS, Services and TRIPS are reviewed here below with the interests of developing countries in view.

The key issues in the chairman's text are "integration process", "product coverage", "growth rates", "transitional safeguards" and "strengthened GATT rules". The objective of integration is to dismantle Multi-Fibre Arrangements (MFA) and other GATT inconsistent restrictions in a progressive manner. The modality selected for the removal of the MFA restriction in the chairman's text provides only for a step by step integration. Immediately, only 10% of the textile products would be gattified. The next 15% of the proposed liberalization of textile products would occur only at the end of ten years. The proposed next installment of further 20% liberalization would materialize only at the end of 15 years. This implies that the chairman's number provide for 45 percent of the total imports volume to be integrated into GATT by the last stage. That leaves 55 percent to be integrated overnight when the transition period expires. These figures speak infact for themselves. During the whole of the transition period, if only 45 percent can be agreed upon for integration, it is inconceivable that 55 percent can be integrated at the end particularly when it is likely to contain the core of protection. It seems to be totally incredible because the importing industrialized countries are insisting on including the entire "section XI of the HS code" as the product coverage of the transitional arrangement. This will bring under its purview textile raw materials like raw natural fibres, both processed and unprocessed, which have been outside the scope of the MFA. This means that rather than gattifying textiles industrialised countries are expandng the basket of products under MFA.

Further, the attempt of EC to classify the products for restrictions into three categories- most sensitive (43.3%), sensitive (26.1%) and non-sensitive (30.7%) clarifies also loudly that the restrictions in the most sensitive group would not be touched at all during the transitional period. It is told that the same situation is likely to prevail in other importing countries, particularly in Canada and the Nordic countries where restrictions are concentrated in the clothing segment. This expansion of MFA to include pure silk and natural fibres, to classify products into three categories and to provide for sub-product wise quotas rather than global quotas should make the intentions of industrialized countries quite clear. Those who have still some illusion regarding the nature of concessions being accorded in textiles to the developing world including India should revise their opinion.

The terms to be provided for growth and flexibility (switching between subproduct categories and time spans in using quotas) is also an important issue for the developing world. There are also issues relating to the base levels and whether these should be first increased, the growth rates on the base levels during the integration process and the question of minimum growth rates. There are further questions whether during the transition period, the present MFA sanctioned selective safeguards, namely restrictions based on the source of import should continue or whether there is need for a non-discriminatory, approach in its application.

Tropical Products

Although India does not have much direct interest in tropical products (addition of new products and tariff cuts), it should be made here clear that the offers have been thrown to divide the developing world. A recent study completed by UNCTAD indicates that industrialized countries gain much more by their "revised offers" for liberalised trade through tariff concessions in Tropical Products than the Third World Countries. Of the $ 746 million of additional products under the revised offers, only about $ 245 million would come from the Third World Countries or a 1.7% increase in their exports. In terms of benefits to the Third World countries, the effect of revised offers in absolute terms range from $ 140,000 for Norway to $ 140 million for EEC, and 0,2% increase in the case of the US to 13.6% for New Zealand. The imports from the African region would decline by $ 118 million, due mainly to erosion or loss of preferential margins currently enjoyed by these countries, principally on the EEC markets. The Latin American gain, 95%, is mainly on the EC markets, while Australia (42.1%), EEC (21%) and Japan 20%) account for the 83% increase from Asia. The industrialised countries as a group are the largest gainers from the "revised offers". Several factors are responsible for these results. Firstly, in a product like coffee which alone accounts for 75% of the trade covered by the "revised offers", the offers of tariff reduction on an MFN (most-favoured-nation) basis will not create growth because third world countries already enjoy preferential

rates that in many cases are zero. Although the tariff elimination would result in dramatic increase in imports of processed coffee, but at least in the short to medium term stimulation of processing i the Third World is unlikely. Also, for products also produced in the North, such as cut flowers and processed products, liberalization offers on the MFN basis bring benefits not only to the Third World Countries but other too gain in a big way.

Agriculture

The conflict over what would be substantial and progressive reduction of support and protection to agriculture in the EC so as to minimise trade distortion has overshadowed the concerns of developing countries. The concerns such as food security\sovereignty, export\ ecological dumping of farm products from the North in the South and the right of nations to protect consumers and to ameliorate unemployment, malnutrition and rural underdevelopment, were completely neglected in the negotiations.

The issues requiring special attention from the point of view of developing countries on the topic of agriculture are "special and differential treatment", "anti-dumping disciplines", "special safeguards" "speed and rate of cuts", "scope and specificity of product coverage", "criteria to be used for exemption of certain products", "modalities for tariffication and reduction", "reduction of border protection and export support merely on the basis of percentage figures or also on strengthened GATT disciplines and rules and sanitary and phyto-sanitary provisions.

From the standpoint of developing countries, the major issue is special and differential treatment to Third World countries. While there is general agreement that this has to be permitted, but the treatment in what form is yet unresolved. The chairman's text and some of the proposals and offers would provide derogations only so long as domestic price in Third world countries is not higher than world prices at border - a price which infact is politically determined by the subsidised exports

Industrialized countries must reduce their subsidies first to zero and ask then a reduction in subsidies from developing world (under whatever name) of the EC, US and other exporters.

The next demanding same treatment on the reduction of subsidies to the developing countries as to the industrialized world is totally unacceptable.

There is now overwhelming evidence that the agricultural policies of industrialized countries, in particular the subsidized dumping of surplus output, have contributed to a deterioration in export earning and terms of trade for the south. In addition, by diminishing the capacity of the producers to feed their countries and systematically undermining efforts to encourage self-reliance, industrialized countries have-and-are contributing to world hunger.

A high share of agriculture in our GDP, the high percentage of the population deriving their livelihood from agriculture, predominance of small and uneconomic holdings, imperfeetions in the input and product markets in the agricultural sector and the high proportion of food stuffs in the allocation of household budget in these countries, has necessitated government intervention for development and maintenance of public sector infrastructural facilities and supply of credit and other inputs at subsidized prices in many developing countries including India.

None of these subsidies is aimed at generating structural surpluses which are then disposed of in the world market, thereby distorting trade. For these reasons, linking the flexibility and commitment by developing countries to free at frontier price (politically determined by the industrialized world) is not acceptable to developing countries. This may be also kept in mind that for a long time to come many major trading partners would have their domestic prices higher than free at frontier prices. The proposed provision of special and differential treatment is therefore completely unbalanced and unacceptable.

Developing countries must be exempted from commitments for tariffication. The indent of the chairman's text relating to developing countries on the issue of border controls is neither sufficient nor adequate. For a developing country like India, with large segments of population at subsistence level, price fluctuations of agricultural commodities can have serious social and political implications. In such a situation, border protection by means of Quantitative Restrictions (QRs) for stability for developing countries like India is fully justified. On the lack of possibilities to resort to measures which are consistent with the present provisions of Article XVIII for balance of payments reasons or commensurate with their trade, development and financial needs, any concession by developing countries to the industrialized world can play havoc with the population of their countries.

TRIMS

In TRIMS, the key issue is whether there should be a prohibition of some trade related investment measures (TRIMS). Developing countries on the other hand, have argued that they cannot accept any blanket prohibition of any TRIM. Developing countries have pointed out that they need TRIMS in order to ensure that the foreign investment is utilized in consonance with the overall development strategy of their economies. For development purposes, the developing countries impose on foreign investors requirements related to local content, export performance and transfer of technology. TRIMS are required to control the Restrictive Business Practices (RBPs) of transnationals. These measures can be used to neutralize the effects of anti-competitive behaviour and practices such as restrictions of purchases, sale and distribution channels; price manipulation; market allocation; etc. Developing countries are still

struggling to get the major trading partners to agree that what is required is a case-by-case examination of the investment measures, a determination of adverse trade effects, if any, and a formulation of measures to eliminate them.

SERVICES

In services, significant issues remaining unresolved are:"application of MFN principle", "definition of services","definition of commercial presence", "transparency", etc. There is as yet no definition of "service provider" and hence it is not clear whether it would cover enterprises or individuals. The new definition about establishment of commercial presence could result in foreign service enterprises getting a right of establishment. This implies that while it is uncertain whether the labour related services would be included in the agreement, but the agreement creates definitely space for foreign service providers to obtain backdoor entry into related services and goods.

The US is unwilling to grant MFN principle without derogations. There are derogations included in respect of benefits it accords to countries under its bilateral commerce and navigation treaties. These derogations would enable where it is multilaterally agreed, non-application of this principle to activities in specific sectors covered by other international and bilateral agreements of the U.S. and other industrialized countries. On the question of provisions for increasing participation of Third World Countries in world trade and expansion of their service exports, the instrumentality is subjected to application of the provisions of agreements relating to progressive liberalization, market access and commercial establishment/presence.

The discussions have covered the content of the proposed annexes for telecommunications,construction, professional services, financial services and labour mobility. The U.S. and other industrialized countries oppose any provisions or annexes for labour services enabling mobility (as different from individual immigration) and for visa and work permits for labour and professional services involving labour mobility. In the telecommunications sector, the U.S. and other industrialized countries want to prevent the cross subsidisation of services. In India, the practice of cross-subsidisation of rural services by charging higher fees for some of the services used by business or well-off customers will become unjustified if the agreement is allowed to go through as such. Once this principle gets accepted in the telecommunications sector, it is certain that similar demands will be made in other sectors too.

TRIPS

The negotiations on Trips stand now at a critical juncture. It is believed that the green room on Trips was busy drafting closing paras of the final agreement when the secretary, commerce decided to pull out the delegation from the exercise because of the failure of the round on the subject of agriculture. It is certain

that had there occurred a break through on the night of 6th December in the agriculture green room, the Indian delegation would gave landed in the country with a text which could only have meant a funeral for the Indian Patent Act, 1970 and technological self reliance.

Firstly, the imposition of this text would have implied the inclusion of *sui generis* plant protection and micro organisms as a patentable subject matter. The sui generis protection which we would have been required to grant has to be compatible with the draft new act appearing in the diplomatic conference for the revision of the International convention for the protection of new varieties of plants (UPOV 1990). Under the proposed amended legislation, the new provision regarding the exemption to breeders restricts severely the traditional freedom available to the plant breeders to use plant material of any kind.

Further, the amended Upov convention provides now also for a cross linkage between the plant breeders rights and the rights of gene patenting. In the conclusion of foreign collaborations, we would have opened ourselves to a blackmail on the restrictions in respect of the rights related to gene patenting.

These provisions would have meant a serious setback to the availability of seeds. Indian agriculture would have suffered beyond repair. The introduction of new varieties would have got slowed down in India. Furthermore, this protection would have also implied a heavy foreign exchange burden because the breeders have been forced to go to foreign property owners to obtain licenses against high royalties .

In the area of micro organisms, we would have been faced with very similar problems. In the case of micro organisms no written descriptions are possible. This means that the provision replacing disclosure is also violated. We would have also paved the way for the introduction of reversal of burden of proof through back door in the Indian Patent Act.

Secondly, an imposition of this agreement would have implied the giving up of license of right and compulsory licensing. A set of extremely weak provisions relating to the grant of non voluntary licenses and the control of restrictive business practices would have taken the place of the current rights relating to revocation of patentee's rights, compulsory licensing and license of right. These rights have been enshrined in the Indian Patent Act, 1970 with the aim to protect the interests of self reliance and development in our country. We would have been forced to accept much higher obligations arising out of uniform substantive norms and standards on IPRs. Across the board this would have resulted in adverse consequences for the access to and diffusion of foreign technologies . The agreement would have meant increase in the cost of production and importation of goods on account of lesser competition in technology market.

Comparing the latest text with the proposals of industrialized countries, it emerges that the principal concession made to developing countries is the provision on transitional arrangements . This is a time bound mechanism aimed at allowing governments to bring their nation laws in to conformity with a TRIPS agreement. It does not there fore correspond to any form of special and differential treatment for developing countries in view of their low level of technological development. Developing countries must be exempted from the higher obligations arising out of upward harmonization.

At the moment the chairperson has accepted to refer only two issues for political decision to the ministerial green room, that is the gattability of TRIPS agreement and the exclusion in respect of protectable subject matters. Proposals by 14 developing countries on crucial issues have been totally ignored. These issues include: preservation of Berne convention in its entirety, protection of computer programmes by a special regime, exclusion of certain subject matters form patentability, compulsory licensing in the case of abuse of patent rights, determination of duration of patent protection by national laws,protection of layout designs on the basis of Washington Convention, exclusion of trade secrets from TRIPS agreement, control of restrictive practices arising from IPRs, and recognition of the limited financial and resource capabilities of developing countries in respect of enforcement.

FINAL ACT

A number of issues relating to Final Act of the Uruguay Round Negotiations are left unresolved. It is yet to be decided whether or not the various agreements on trade in goods, Trade in Services, Trade related intellectual property Rights (TRIPS) will be separate instruments or those in goods and on TRIPS would be combined in to one and automatically lodged in the GATT.

It remains also unresolved whether GATT should be created to deal with and administer all Uruguay Round agreements? Should that organisation deal with trade and development issues or these issues should be dealt with in the GATT?

Lastly, it has to be decided whether the outcomes are going to be incorporated in to a single legal instrument forcing everyone to sign and accept the entire package of results or whether the principles of international law for negotiating and concluding treaties and amendments should continue to prevail.

The proposal to conclude the Uruguay Round with a single protocol must be squarely rejected as the rights of national legislature would be unacceptably restricted. National parliaments must retain the full rights to ratify the agreements being drawn up in the Uruguay Round Negotiations.

Part II

Non-governmental organisations from 27 developing and developed countries participated in the conference "Bringing GATT out of the Shadows", held in Brussels from November 28 to Dec. 2, 1990. I participated on the behalf of National Working Group on Patent Laws, India. The list of names of delegates and countries is enclosed as annexure I.

On the opening day of this conference, there were presentations by the members of the European Community Liaison Committee and Novib. The Novib representative gave an overview of proceedings of the seminar "GATT, Uruguay Round and Development", held in the Hague in June 1990. The EC representative explained the latest position of the EC.

On the first day, the introductory session was followed by a round table on the agenda and perspective of NGOs on the Uruguay Round. There was considerable debate on the issue of the negotiation rights of the governments which do not have legitimate power to govern their own countries in the eyes of NGOs. This led the discussions to the areas such as sovereignty of nation states, multilateralism, natural justice, people's interests and internationalism. The round table provided a good scope for the delegates to learn from each other about their perspective.

On the second day, the discussions moved into the phase of topic based deliberations. The sectoral discussions covered agriculture, services, TRIPS, TRIMS, functioning of the GATT system, Textiles and Manufactured Goods and Environment. It can be seen that the subject of Environment which is not accorded the status of a separate topic in GATT, was accorded due place by the NGOs. Several NGOs present in the conference were specialists in the area of environment. It was also evident that the NGOs felt that the world division of labour must undergo a radical change and provide opportunities to developing countries to diversify their export baskets. This led the working group on textiles to expand its scope to include manufactured goods. The sectoral statements are enclosed as annexure II.

On the third day, the conference met again in plenary session to finalize the statements. In addition to the sectoral statements, the conference adopted a general declaration entitled " A People"s GATT FOR WORLD DEVELOPMENT. The general declaration has two parts: Preamble and ten Demands. A copy of this declaration is enclosed as annexure III.

On the fourth day, the conference deliberated on the strategy for lobbying and the long term action plan of NGOs on the issue of the Uruguay Round Negotiations.

During the negotiations, between december 3-8, the activities consisted of both meetings with the public as well as press briefings. Round table discussions on the topics of Uruguay

Round were held at Hotel Fimotle. An alternative press centre had been created at the same hotel to provide opportunity to progressive journalists to cover the proceedings of the GATT conference. Several press interviews had also been organized for the Southern delegates. The Southern delegates were asked to participate in many of the public debates. I, myself participated in the debate on " Democracy, Sovereignty and Development at stake" and in the round table on " Intellectual property, gene patenting". In these public debates, the delegates from farmers organisations, church, green movement and other progressive NGOs of the North also participated. The public debate and the lobby work were quite successful in achieving their purpose.

The official delegations of several developing countries were approached in particular to disseminate NGO viewpoint. It may be mentioned that the Indian delegation was quite receptive to the viewpoint of NGOs. The Secretary, Commerce as well as the Minister of Commerce, were quite accessible to the NGOs. An observation is here in order about the expansion and continuity of the team selected for the Indian delegation. The official team should be technically strengthened . And in particular its technical leadership must be provided continuity to ensure smooth functioning in the Geneva negotiations which start now from Jan. 15, 1991/

The long term strategy of NGOs is as follows :

a. integrate the future interventions with the work on UNCTAD VIII and World Environment Conference.

b. share information among the participants.

c. disseminate the general declaration and sectoral statements to the fellow citizens of their respective countries.

It was decided to meet on December 8, 1990 to chalk out international co-ordination. Unfortunately, I could not be present as I had to leave for Delhi on 7th forenoon. The proposals from National Working Group on Patent Laws on international co-ordination to the organizers were as follows:

a. act as a clearing house of information on the Round for developing countries.

b. get this general declaration signed by other NGOs and eminent personalities.

c. organize joint protest actions on declared days in the respective countries.

National Working Group on Patent Laws (India) : National Agenda on WTO Issues

I

The World Trade Organisation (WTO) has been in operation for more than three years. The balance-sheet of its working has only confirmed the reservations and apprehensions expressed from time to time by the National Working Group on Patent Laws (NWGPL). [NWGPL has been analysing GATT/WTO issues for the last 10 years.] The unequal nature of the WTO Agreements has been aggravated by the built-in biases in its functioning. At its very first Ministerial Conference held in Singapore in December, 1996, industrialised countries succeeded in imposing the investment issue on its agenda. The USA chose to withhold application of the Most Favoured Nation (MFN) clause in the General Agreement on Trade in Services (GATS) for over three years and wrested additional concessions from developing countries in the process. Pressures were brought on developing countries to **amend their intellectual property laws much in advance** of the time-frame mutually agreed and incorporated in the 'transitional arrangements' of TRIPs Agreement. The dispute settlement mechanism, which was looked upon as a strong and favourable feature of the multilateral system from the viewpoint of developing countries, has come to be used more as an instrument of pressuring developing countries into submission. The disputes raised by USA and EU against India in regard to implementation of transitional arrangements on product patents and exclusive marketing rights are a case in point. The findings of the dispute settlement body have introduced unwarranted and subjective elements such as the panellists' interpretation of "negotiating history" and "balance of advantages". What is worse, the findings virtually prescribe a specific course of action for the sovereign Indian Parliament to follow, on the ground of providing "legal security" to foreign monopolists. Initiatives have also been taken by lobbies of vested interests to extend the copyrights to databases, to multilateralise UPOV and to legitimise MNCs' continuing bio-piracy of rich and diverse biological resources of developing countries. More important, industrial countries are practising unilateral exclusionary regimes banning the transfer of technology in the name of preventing proliferation of the so-called "dual use" technologies. On top of all this, industrialised countries have not relented their pressure on bringing in "new issues" under different pretexts ranging from environment and child labour to human rights and good governance.

II

The challenges posed by the WTO to the autonomous management of national economy have been compounded by two other features of the process of globalisation. First, enormous pressure is being brought on the developing countries to pare down and restrict the role of the state to its law and order functions only. The economic activities, particularly those of interventionist and directional nature intended to promote socio-economic goals that have their foundation outside the profit maximisation calculus, are required to be shed in the name of promoting efficiency and productivity. The chief instrument used for the purpose is the narrowly defined fiscal discipline based on the arbitrary premise that all government expenditure is, by definition, profligate and, conversely, all release of resources in favour of the private sector is efficient.

Second, a virtually independent global regime of international finance has come into existence. It is characterised by enormous movements of finance

capital across the national borders, not easily amenable to influence or control of even the most powerful central banks and the International Monetary Fund. This has resulted in severe diminution, if not virtual eclipse, of the autonomy of financial management, as far as the nation states of the developing world are concerned. The recent events in the South Asian countries have dramatically demonstrated the plight of the "tiger" economies in the face of the onslaught of the international finance capital.

III

The national agenda on WTO issues has to be formulated in this wider context. The major task facing us in the economic sphere is to make a determined and concerted bid to restore a measure of autonomy in the management of the national economy. A comprehensive initiative will have to be developed in regard to our stand on the host of issues that are confronting us in the forum of WTO. They fall under five headings: **"Investment", "Technology", "Services", "Trade",** and **"New Issues".** NWGPL propose the basic elements of such an initiative under each of the headings in the section that follows.

Considering the seriousness of the challenge facing us, NWGPL believes that a national consensus, cutting across political parties, should be built along these lines. Furthermore, it is imperative to garner support of other developing countries to the thrust of our stand as elaborated here. **Recent events in South East Asia have created a more receptive environment for re-energising cooperation among developing countries.**

The Second Ministerial Conference of WTO will be due in less than a year's time. WTO Agreements such as TRIPs, TRIMs, Trade in Agriculture, have built-in provisions for a review process which will form an integral part of the agenda of the conference. Pressures will start building up on developing countries to fall in line with the formulations whose content and directions would have been predetermined by the industrialised countries. It is all the more necessary, therefore, **that we loste no time in launching the national as well as the international initiatives in this regard.**

IV

INVESTMENT

A far-reaching move on establishing a multilateral regime on investment is the top priority of the industrial countries. It should be remembered that while negotiating the General Agreement on Trade in Services industrialised countries did not succeed in building in an unqualified 'right to establish'. Such a right will constitute the cornerstone of the multilateral discipline on investment which the industrialised countries would like to establish. The regime may cover foreign direct investment as well as portfolio investment. All regulation of such investment, which is currently an integral part of the exercise of the sovereign economic power of the nation states, will have to be brought in conformity with the multilateral discipline. In the scheme of things of the impending multilateral discipline, such regulations will be treated as simply the barriers to be negotiated away. In our context, this will eventually necessitate drastic amendment of national laws such as ID&R Act, FERA, MRTP, Company Law, and Taxation Laws.

Unrestricted inward and outward movement of portfolio investment, free access to international borrowing, full freedom for investors to channel their funds into profitable opportunities including speculative and unproductive ones, - all these have been responsible for the collapse of the capital markets and currencies in the South East Asian countries. The limitations of the policies and instrumentalities at the disposal of the International Monetary Fund stand exposed. More disconcerting, the system as it functions today has little to offer except deeper embroilment and even greater dependence. **Mexico, Thailand, South Korea, Indonesia - all present agonising proof of the serious shortcomings and dangerous implications of the market-based approach to the question of capital flows.** Unfortunately, however, the protagonists of a

multilateral discipline on investment in the WTO are unrepentant.

It is of utmost importance to counter this move strongly in the WTO. This will have to be complemented by resisting further moves for liberalising financial services in the context of the negotiations in GATS.

SERVICES

This Agreement provides a permanent forum for liberalisation of trade in services. We have so far resisted the pressures to provide large-scale openings across-the-board. In the first three years of operation of this agreement, the pressure was relatively not too heavy as the United States themselves were holding back the MFN application. They have since agreed to take on the MFN obligation and in the process, have extracted additional concessions mainly from South Asian countries. We have been able to get away somewhat lightly by only marginally enhancing our offer. However, pressures for further opening up will mount continually and more so, in the run-up to the second Ministerial Conference. In the light of the experience of South East Asian countries, **we must halt the process of integration of the national financial sector with the global financial network**. No further move to liberalise financial services should be allowed. We must **retain the authority to regulate foreign portfolio investment through measures such as differential capital gains taxation and prescribing lock-in periods so as to minimise the destabilising effects of these speculative capital movements.** We must retain the authority to closely **monitor foreign borrowing and curb the tendency to substitute domestic savings by foreign savings**. We must not facilitate the easy option of excessive dependence on foreign funding for the long gestation infrastructural investment through opening up of the insurance and pension funds sectors. **We must also continue with the selective approach to direct foreign investment.** Last, but not the least, we must recognise that maintaining controls on capital account is a necessary condition of preserving a degree of autonomy of our national financial management.

TRADE

There are two areas which will require urgent attention. **First, our subsisting right under Article XVIIIB of GATT must be preserved without any further dilution**. As it is, the understandings reached in 1979 and 1994 have already circumscribed this right substantially. Our trading partners have forced on us a short time span for removal of quantitative restrictions on all imports, including all kinds of consumer and other goods now being produced in the small, cottage and household sectors. We are also under pressure to reduce our customs tariffs to the levels obtaining in industrialised countries. In the coming three to five years, we will experience the disrupting effects on production and employment in these sectors. While this is serious enough, a more serious threat is impending. **We will be asked to renounce our right to impose quantiative controls in order to safeguard our external financial position.** In concert with other developing countries, we must resist these pressures and protect our right under GATT. We must also **seek modification of the existing understandings under this Article so as to enable us to reimpose quantitative controls as necessary, at short notice, and without first resorting to less effective price-based measures**. Second, as the Agreement on Trade in Agriculture comes in for review, industrialised countries who are large exporters of agricultural commodities will target their moves on the Indian market, as they did on the Japanese and Korean markets during the Uruguay Round. Our productivity in agriculture is low and with such productivity we cannot hope to compete successfully in many products in the world markets. In the medium run, we are likely to face severe competition not only from developed countries but also from our neighbours in Asia. **The levels of subsidisation and protection continue to remain high in developed countries and their capacity to subsidise agriculture is much greater**. Progressive integration with the world market in agricultural commodities will have varying impacts on different regions of the country and poorer regions may suffer while richer regions may gain. Our agricultural trade policy, therefore, will

have to be devised carefully. **We will have to safeguard our autonomy in formulating support policies for agriculture. Similarly, a degree of flexibility in devising an appropriate border regime in terms of tariffs as well as quantitative measures will have to be retained**. More important, the objective of **ensuring food security** cannot be allowed to be compromised or diluted.

TECHNOLOGY

The theme of technology covers the whole area of **new international regimes on intellectual property protection,** including the protection of plant varieties, the patenting of life forms and micro organisms, the protection of the database and the larger question of conservation of bio-diversity, recognition of the contribution of traditional communities to knowledge and technology and prevention of bio-piracy. Effects of the demanding global regimes on intellectual property protection are already making themselves felt. The legislation that has served the country well in the regime of industrial patents has been questioned and pressures are being exercised for its revision to suit the interests of the big multinationals. **Under such regimes, the Research & Development (R&D) activity may become largely subordinate to the priorities of the multinationals**. As in the case of software, low wages of our intellectual workers may attract the attention of the big business in the industrial R&D. But that will not necessarily strengthen the national research base, nor will it make the R&D activity, part of the national vision and plan of development. The net result of these regimes will be to make access to new knowledge, technologies, skills and databases more expensive, if not unattainable. It is argued that aggressive "promotion of patent literacy" may enable us to meet the challenge. But the enormous lags from which we suffer in many areas of research and development expose the gross inadequacy aspect. The unilateral exclusionary regimes that some of the industrialised countries are practising in the name of preventing the proliferation of the so-called "dual use" only lay bare the desire to dominate that is at the root of the initiative to forge new international regimes in the vital areas of technology, information and knowledge.

We will have to resist the revision of **our patent laws under pressure. More important, our patent regime will have to be appropriately strengthened to escape through the scissor blades of the omnibus patent protection demanded by the TRIPs discipline,** on the one hand, and the unilateral denial practised by industrial countries under their exclusionary national legislation, on the other.

The TRIPs Agreement requires that the signatory countries should establish protection for plant varieties either by providing a patent protection or by instituting an effective 'sui generis' system or by combination thereof. There is nothing in the provisions of this agreement which requires us to become a party to an existing international regime such as the UPOV Convention. **Nevertheless, strong pressures are building up to make India sign the UPOV Convention. We must resist these pressures.**

The UPOV is essentially a system evolved by the breeders of plant varieties in the industrialised countries. These breeders are not farmers of our conception. These breeders represent essentially half-a-dozen multinational conglomerates who have acquired oligopolistic control on the crucial part of agri-business. It is their rights which are sought to be protected by the UPOV Convention. For industrialised countries where, either the contribution of agriculture to GDP or the proportion of the workforce dependent on agriculture, expressed in percentage terms, rarely exceeds a single digit figure, **protection of rights of this kind of breeders is an understandable proposition**. For India, where one-third of GDP comes from agriculture and two-thirds of workforce is dependent on agriculture, **rights of the farmers as breeders are far more important. The UPOV does not recognise the rights of the farmer-breeder of this type.**

Research in India on breeding plant varieties has taken place almost entirely in public institutions like agricultural Universities and Indian Council of

Agricultural Research. Commendable successes have been achieved by this setup in the past, without our having been a signatory to a system of protection of breeder's rights as contained in UPOV.

The focus of Indian research in agriculture has to be on the requirements and the problems of a vast number of resource-poor, marginal and subsistence farmers. Moreover, the research has to respond to the varying agro-climatic conditions and vast areas of rain-fed agriculture and dry farming. The direction of private sector research the world over has been towards promoting cash crops benefiting resource-rich farmers for whom agriculture is more like an industry. It is this market which assures good returns for investments by the private sector breeders and researchers. **Largely, the requirements of Indian agriculture will have to be met by research conducted by public institutions not looking for profits.**

Equally, **the low-cost diffusion of better varieties is crucial for development of Indian agriculture and for promoting food security**. The emergence of a few hundred small seed companies who engage mainly in multiplication of seeds and diffusion of new varieties has played a crucial role in this regard. Their rights to multiply improved seeds and sell them need to be protected and not restricted by creating a system of protection of the so-called breeders' rights.

Above all, **the rights of farmers as breeders need to be protected in any 'sui generis' system designed to respond to our needs**. Equally, the cumulative and collective contribution of generations of farming communities in evolving a whole range of different varieties responding to the different agro-climatic conditions, needs and tastes also will have to be recognised in such a system. Last, but not the least, the system that we evolve should be such that it preserves and strengthens the gains made by developing countries in the negotiations on the Convention on Biological Diversity and not in the opposite direction.

The subject of national legislation on bio-diversity in the context of the International Convention on Biological Diversity (CBD) is of great importance. Historically, it should be remembered that the negotiations on the CBD and the negotiations on the WTO Agreement, including the Agreement on TRIPs, were somewhat parallel. The Uruguay Round negotiations were dominated by the ideology of the so-called and 'free' market operations. The thrust and emphasis of those negotiations was removal of 'distortions' to trade. Developing countries yielded considerable ground in these negotiations due to this overwhelming thrust of the industrialised countries. In areas like intellectual property protection, this amounted to substantial erosion of autonomous decision-making for developing countries.

In the light of this experience, developing countries tried to build in some concepts in the negotiations on CBD, partly to effect some retrieval and partly to put up some counter positions. In this, they achieved a partial success. Thus, in striking contrast to the WTO Agreements, CBD explicitly asserts sovereign right of the nation state on its biological resources. Similarly, while dealing with access to genetic resources and access to transfer of technology, developing countries sought to achieve a kind of balance of mutual advantages by linking the two concepts. Again, recognising the possible conflict between the intellectual property rites regime under TRIPs and the objectives and provisions of the CBD, it was laid down that patents and other intellectual property rights should be made supportive of and should not be allowed to run counter to the objectives of the CBD. The primacy of the objective of avoiding damage to biological diversity has been recognised in the context of the relationship of the CBD with other International Conventions.

One important innovation introduced by CBD is that it explicilty recognises the close and traditional dependence of local communities embodying traditional lifestyles on biological resources and the desirability of sharing equitably benefits arising from the use of the traditional knowledge, innovations and practices.

Our national legislation on conserving biological diversity must necessarily internalise the strong points and opportunities provided by the CBD, particularly keeping in view the constricting effects of the TRIPs regime and the urgent need to counter them. Most important, the national legislation should not merely facilitate foreigners' access to our biological resources. In other words, it should not merely serve the objective of bio-prospecting. It should **reassert the national sovereignty on biological resources; recognise the role of local communities; provide some counter weight to adverse effects of TRIPs Agreement** and incorporate explicit provisions recognising a **nexus between transfer of technology and access to resources.**

NEW ISSUES

We will have to resist the introduction of themes like social clause, human rights and good governance in the context of the trade negotiations. More important, we will have to bring on the agenda some of the untenable [s. 301 of U.S. trade law] and exclusionary [ban on the transfer of technology on the ground of the so-called 'dual use'] laws and practices of the industrial nations. We will have to table our own new issues, e.g., free movement of natural persons from labour surplus countries to labour deficit countries; non-discriminatory treatment in regard to sharing the burden of social security; abrogation of national laws having extraterritorial implications; international regulation of the conduct of the transnational corporations.

Last, but not the least, we have to place our agenda on the WTO issues in the wider perspective of the universal goal of creating a world order which is more equitable, humane and free of exploitation. To this end, we should try to build a parallel system of international trade and economic cooperation through an expanded Global System of Trade Preferences among developing countries (GSTP). A call to strengthen the regional cooperation and **to revive the international cooperation among the developing countries** should form an integral part of our agenda.

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

B.K. Keayla*

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 indicate the time lag between the introduction of new drug in the world market and its introduction in India after the domestic enterprises have developed technologies to manufacture the products. 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.

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(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.

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: Introduction 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

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 depicted in **Table 3.**

(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)."**

– 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 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 purpose without any condition or restriction, this article provides absolute monopoly to the patent holder. Even the authrization 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 possiblity 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 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.

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 transitional arrangements. Developing countries are entitled to delay the application of the TRIPs Agreement by five years as against one year for the 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 Organisation 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 pharmaceutical 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**

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 drug 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.**

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 is 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 on '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 is exchange for the implementation of 'US-style' patent laws have never materialized, the Chilean representatives maintained. The Argentinian government 'should look at its neighbors, 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

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

(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 immedediate 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 their 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 monopolise 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 profits 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 thus virtually no comparison.

The profitability of the Indian industry for various reasons is also quite low. In the past, it has been

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Parliament approves Patents Bill amidst protests

March 14, 1999 -- The controversial Patents (Amendment) Bill 1998, was passed by Parliament when Rajya Sabha approved the legislation on Saturday though opposition opted for a walkout and Congress alleged that the provision of the Bill would be detrimental to the National interests.

When Deputy Chairman Najma Heptulla asked Mr. Gurudas Dasgupta (CPI) after industry minister had replied whether CPI was withdrawing its statutory resolution opposing the Bill CPI members first pressed for a division and then the opposition members walked out of the House while BJP and Congress voted together to ensure the smooth passage of the Bill which was earlier passed by the lower house on Thursday. Opposition walked out alleging that the government had kept the house in dark about the recommendation of the Law Commission, which said that the provisions of the Bill were detrimental to national interest.

Industry minister Mr. Bakht observed that the Government had to secure the passage of the Bill to meet its obligations under the World Trade Organisation but national interest are supreme. Under this Bill the India pharmaceuticals companies would have to restructure themselves but have time till 2005 when a new legislation would have to be brought forward to give effect to the countries international obligations in the pharmaceuticals sector. He said that objections raised by the Law Commission had already been attended and various doubts raised have been answered. But Left party members in Rajya Sabha vehemently opposed the Patents (Amendment) Bill warning it would adversely affect the national interest.

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THURSDAY,
JULY 29, 1999

Patents Act changes soon to protect traditional remedies

Calcutta, July 28: India will soon amend 'grey areas' of its Patents Act to safeguard traditional knowledge as the international agreement on Trade Related Intellectual Property Rights (TRIPS) is against the country's interest, a Union Industry Ministry official said here on Wednesday.

"The Indian patents act needs to be more flexible so as not to let another 'haldi', 'karela' or 'jamun' fiasco happen," Joint Secretary of Ministry A Ahmed told an interactive session to collate views for amendment of the law.

Ahmed said the Ministry will hold about 20 sessions in various cities all over the country to generate opinions of eminent scientists, academicians, industrialists, chambers of commerce and NGOs to influence policy-level decision making for the amendment.

"The ministry is seeking to balance India's international obligations with the imperatives of public and national interests," he said.

The sessions also assume importance in the context of the recent amendments to the Patents Act approved by Parliament in the last session to comply with certain obligations under the TRIPS agreement, he said.

The ministry will receive suggestions and opinions on the issue of proposed amendments to the act at its website http://www.Nic.In/did and a mailbox did@ub.Nic till August, 1999, he said.

He said disputes with the USA and EC over the last set of amendments to the act before the WTO had been recently resolved in consonance with Indian concerns of public interest and national security • PTI

PATENTS - A DESIGN FOR DISASTER

Disease controlled by Amelioration of diseases depends upon medical personnel, health infrastructure and pharmaceutical industry. In India we have a good infrastructure of pharmaceutical industry. Our pharmaceutical industry produces most of the basic drugs in bulk and has brought self reliance in drugs. This is due to the provisions of Indian Patents Act, 1970.

Now, drugs are going to come under a new Patent regime. This patent regime is being forced on many developing countries and India also. Now health aspects of the drugs become secondary to trading aspect of drugs.

Five decades back, it was felt that there is a need for all the countries of the world to have a fair trade in consumer goods, food products, industrial component parts etc. A good intention indeed ! The discussion was initiated and one of its aim was to assist the third world countries to improve their trade and economy. Several rounds of trade negotiations were held in various countries. Eighth round of negotiations was held in Uruguay. The negotiations were dragged on for more than six years. Before the negotiations were concluded, Dunkel, the Director of General Agreement on Tarrifs and Trade (GATT) presented a draft known as Dunkel Draft Treaty (DDT) in 1991 and asked all the partners either to accept or reject and there was no scope for negotiations. The contents of DDT was in favour of developed countries, a definate deviation from the original goal ! The discussion was held in the background of globalisation a warning of disaster to come. The real actors on whose behalf this was done were the MNC's, whose global expansion can take place only by limiting the soverignity of nations.

Meanwhile the third world countries had received a lot of loan from international agencies (IMF, WB) supported by developed countries. It was possible to pressurise because the US became dominant after the collaps of the Soviet Union and East European countries. The developed countries mainly the US used this opportunity to bring pressuse on the third world countries to accept DDT. Remember that India opposed the move in the beginning but later accepted. It can be concluded that there was change in the stage of the play from United Nations to trinity of GATT, IMF & WB. There are various issues in GATT.

Lets discuss the issue of patents in relation to Pharmaceuticals.

Patent issue along with other eight issues are discussed under intellectual property rights.

Patent is a recognition given, right granted by the government to investors for a specific period to exclude other individuals and enterprises from infringing a patented product or process or both. Patents are granted to encourage invention and to secure that invention worked on commercial scale to the fullest extent, to benefit mankind.

In India, the patent regime is there since 1856. A very favourable patent system evolved only after independence, after indepth studies and debates, leading to Indian Patents Act, 1970. It became effective in 1972.

The salient features of IPA 70 are :

Product patent is granted to all except for food, medicines, substances produced by chemical processes.

Process patent is given to food, medicines and substances produced by chemical processess.

Inventions relating to atomic energy, agriculture and horticultural products are not patentable.

Patents last for 10-14 years. For food, drugs and substances produced by chemical processes it lasts for 7 years from the date of application or 5 years from the date of securing a patent, whichever is earlier.

The Indian Patents Act gave boost to Indian Pharmaceutical Industry. As a result, we could achieve self sufficiency in medicine. We could produce 100 basic drugs, 65 - 70 % of the bulk drugs needed for our country were manufactured in India. We entered international market. New drugs were produced in 3-4 years after the drug was released elsewhere, by innovative processes. The prices were once highest in India, before IPA 70 and reduced drastically and were the lowest.

We have exported about 640 crores of drugs to other countries in 1989-90 and today the export is worth 2000 crores.

Exploitation by the MNC's was kept low.
A good achievement indeed !

The IPA 70 protects the interests of both investors and consumers. National interest is given priority, over the interests of the patentee and it helped India develop novel processes in drug production.

The aim of the DDT is to reverse the IPA. DDT demand that there be no restriction on foreign equity participation, no restriction in the area of investment, no licensing system, no export obligation and DDT wants foreign investments to be treated at par with investment of the domestic companies.

This helps global planning through conditionalities of TRIMS.

Richer nations will be given the freedom to exploit the resources and market of poorer nations. The developed nation will find a free access to the resources of raw materials in the developed nationa

As a result, the cost of the drugs in developing countries will go up, adding misery to the lives of common man. it may result in closure of industrial units of Indian origin leading to unemployment. Developed countries will get huge royalty out of patents as the control on product patents will remain with developed countries. Now WTO replaces GATT and India has subscribed to it in 1994. Citing the dangers of WTO "The Tentacles of WTO reach every nook and corner of public life. It regulates industrial products, trade related investment and intelletual property matters. It has complete control over the agricultural services sector and telecommunication and information technology. It is aimed to convert all human life into a big market all human values into exchange commodities".

Twisting of the Patents issue is part of the globalisation, privatisation strategy. The western world with its surpluses is looking towards less developed world and its aim is not only selling their goodw but also stop other countries use S & T and become dependent. It is a blueprint for a vicious economic recolonisation of the third world and redivision of the world by the advanced capatalist countries. The proponents of new patents are telling that there is no alternative. Such lies can convince the common man

It is not for promoting development, co-operation and accomodating the entry of developing countries on the world stage. Instead, it aims at establishing insidious control over the decision making process on the countries of the South. The recommendations go far beyond the perview of trade and infact the draft comes as a blatant attach on our economy and political soverignity.

Patents bill was hurriedly presented in the parliament. External compulsion being the main reason - WTO, WB and the pressure of the US government.

The need of the hour is for every Indian to register the protest, otherwise the dangers of neocolonisation will not be far off to see.

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Outcomes of Copenhagen+5 and their implications for WHO

The Twenty-fourth Special Session of the General Assembly entitled "World Summit for Social Development and beyond: achieving social development for all in a globalizing world" (Copenhagen + 5) was held in Geneva from 26 to 30 June 2000. It brought together senior representatives of the Member States including around 30 Heads of State and Government to discuss the progress in achieving targets set at the Copenhagen Summit five years ago. It set a new action plan and refined targets for implementing the Copenhagen Declaration and Programme of Action.

Since the Copenhagen summit the world has changed. A rapid globalization process has posed new challenges to social and economic development. However, international understanding of the issues of poverty reduction, employment, social protection, health, education and their linkages with economic growth have been further advanced. The growing awareness of the positive impact of effective social policies, including policies in health, education, social protection, etc., on economic and social development has created the imperative of reassessing priorities for creating a more enabling environment for full social development.

"Copenhagen+5" responded to the advances in development thinking by recognizing that effective social policies themselves can largely determine the success of economic policies (in this case, "success" to mean equitable distribution of benefits of economic growth); by acknowledging the need for strengthening developing countries' and disadvantaged societies' capacities to harness benefits of globalization and mitigate its negative effects; by underscoring the importance of full employment including occupational health and safety; by emphasizing the issue of gender equality and the rights of indigenous population, by endorsing the need for urgent actions against HIV/AIDS, malaria, tuberculosis, and other endemic, communicable and chronic diseases that inhibit social and economic development; and by calling for intersectoral approaches and a closer partnership among the international development agencies, governments, civil society groups and the private sector.

The outcomes of "Copenhagen+5" contain a lot of positive and challenging implications for WHO. The political declaration mentions health twice. Paragraph 7 of the Political Declaration reads: *"...We are convinced that universal access to high quality education, ...health and other basic social services ...are essential for the achievement of the objectives of the Copenhagen Declaration and Programme of Action"*. Paragraph 7 bis continues: *"We affirm our pledge to place particular focus on and give priority attention to the fight against the world-wide conditions that pose severe threats to the health, safety, peace, security and the well-being of our people. Among this conditions are: chronic hunger, malnutrition ... endemic, communicable and chronic diseases, in particular HIV/AIDS, malaria and tuberculosis"*.

The final Outcomes document mentions WHO seven times in various contexts. The most significant results from a strategic point of view include the following:

1. That health is no longer confined to the narrow issue of delivery of basic services (Commitment 6) but is now seen as a key component of poverty reduction

strategies (Commitment 2) as well as strategies for promoting full employment (Commitment 3). In fact, WHO's poverty and health strategy is specifically specified as the model to be followed.

2. That "organizations of the United Nations system" (i.e. including Bretton Woods) are specifically requested to work with WHO "to integrate the health dimension into their policies and programmes". A very specific list of economic, environmental and social issues is listed (para 83). (See below)

3. That WHO is mandated to undertake a range of measures related to the implications of trade in health goods and services to meet the needs of poor people. In addition para 80 also agrees the right of countries to "protect and advance access to life-saving, essential medicines "through the exercise of options available under international agreements.

The table below quotes some paragraphs from the final outcomes document (10 commitments), which have most significance for WHO and offer opportunities for the organization to pursue its corporate strategy with much wider scopes.

Commitment	WHO-relevant Paragraphs
1. *To create an economic, political, social, cultural and legal environment that will enable people to achieve social development* The commitment places primary responsibility on governments for creating conducive social, economic and political environments for "people-centred development". It recognises the need for the reduction of negative impacts of international financial turbulence on social and economic development, correctly acknowledges the positive interaction among environmental, economic, and social policies, and recommends more cross-sectoral approaches.	10 (c) bis *"Reduce negative impacts of international financial turbulence on social and economic development, inter alia, through ... taking measures to protect basic social services, in particular education and health, in the policies and programmes adopted by countries when dealing with international financial crises";* 16 (a) *"Promoting increased corporate awareness of the inter-relationship between social development and economic growth.*
2. *To eradicate poverty in the world, through decisive national actions and international cooperation, as an ethical, social, political and economic imperative of humankind.* The commitment urges countries to incorporate concrete poverty reduction targets and relevant strategies in their national policies, employ multi-sectoral approaches to poverty, give priority to	27bis "*In the context of comprehensive national strategies on poverty eradication, integrate policies at all levels including .... Giving priority to investments in education and health, social protection and basic social services...* " 27 bis (u) "*Using health policies as an instrument for poverty eradication, along the lines of the* ***World Health Organization (WHO)*** *strategy on*

investments in health and education, and use health policies as a means for poverty reduction.	*poverty and health, develop sustainable and effectively managed pro-poor health systems which focus on the major diseases and health problems affecting the poor, achieving greater equity in health financing, and take also into account the provision of and universal access to high quality primary health care throughout the life cycle, including sexual and reproductive health care, not later than 2015, as well as health education programmes, clean water and safe sanitation, nutrition, food security and immunisation programmes"*
3. *To promote the goal of full employment as a basic priority of our economic and social policies, and to enable all men and women to attain secure and sustainable livelihoods through freely chosen productive employment and work.* The main focus of commitment 3 is on the issue of child labour, women's employment, and most importantly for WHO, employability and a safe work environment. The commitment puts significant attention on work-related injuries and occupational diseases, and their economic implications for individuals and the entire health systems. It is quite remarkable that the need for changing policy regarding full employment is justified on the grounds of excess health care costs caused by occupational diseases and work-related injuries.	*36. "Expand opportunities for productive employment, including self-employment ... by investing in the development of human resources ... and employability, especially through education ... occupational safety and health".* *38 (d) "Promoting safe and healthy settings at work in order to improve working conditions and to reduce the impact on individuals* ***and health care systems*** *of occupational accidents and diseases".*
4. *Promote social integration by fostering societies that are stable, safe and just and that are based on the promotion and protection of all human rights, as well as on non-discrimination, tolerance, respect for diversity, equality of opportunity, solidarity, and participation of all people, including disadvantaged and vulnerable groups and persons.* The main issues of the commitment are the rights of the disabled, indigenous people and migrants, gender issues, and ageing.	21bis "*Recognize the contribution of indigenous people to society, promote ways of giving them greater responsibility for their own affairs through, inter alia:* *(a)Seeking means of giving them effective voice in decisions directly affecting them;* *(b)Encouraging United Nations agencies within their respective mandates to take effective programmatic measures for engaging indigenous people in matters relevant to their interests and concerns".* 60. "*Exchange views and information on national experience and best practices in designing and*

	implementing policies and programmes on ageing". 61. *"Empower persons with disabilities to play their full role in society. Special attention should be given to women and children with disabilities and to persons with developmental, mental and psychiatric disabilities".* 61bis *"Ensure access to employment for persons with disabilities through the organization and design of the workplace environment and improve their employability through measures which enhance education and acquisition of skills; through rehabilitation within the community wherever possible; and other direct measures, which may include incentives to enterprises to employ people with disabilities".*
5. *To promote full respect for human dignity and to achieve equality and equity between women and men and to recognize and enhance the participation and leadership roles of women in political, civil, economic, social and cultural life and in development.* The commitment calls for building capacities at different levels for gender analysis, evaluation of program and policy outcomes from a gender perspective, and producing gender desegregated statistics. It talks about the importance of health services for safe motherhood, and stresses gender aspect of HIV/AIDS.	72. "*Ensure gender mainstreaming in the implementation of each of the further initiatives related to each of the commitments made at the Summit, considering the specific roles and needs of women in all areas of social development, by, inter alia, evaluating the gender implications of proposals and taking action to correct situations in which women are disadvantaged. The use of positive or affirmative action and empowerment programmes is commended to both Governments and international organizations".* 73bis."*Increased efforts are needed to provide equal access to education, health, and social services and to ensure women's and girls' rights to education and the enjoyment of the highest attainable standard of physical and mental health and well-being throughout the life cycle, as well as adequate, affordable and universally accessible health care and services including sexual and reproductive health, particularly in the face of the HIV/AIDS pandemic; they are also necessary with regard to the growing proportion of older women".* 73ter."*Ensure that the reduction of maternal morbidity and mortality is a health sector priority and that women have ready access to essential obstetric care, well equipped and adequately staffed maternal health care services, skilled*

	attendants at delivery, emergency obstetric care, effective referral and transport to higher levels of care when necessary, post-partum care and family planning in order to, inter alia, promote safe motherhood, and give priority attention to measures to prevent, detect and treat breast, cervical and ovarian cancer and osteoporosis, and sexually-transmitted infections, including HIV/AIDS".
6. *To promote and attain the goals of universal and equitable access to quality education, the highest attainable standard of physical and mental health, and the access of all to primary health care, making particular efforts to rectify inequalities relating to social conditions and without distinction as to race, national origin, gender, age or disability; respecting and promoting our common and particular cultures; striving to strengthen the role of culture in development; preserving the essential bases of people-centred sustainable development; and contributing to the full development of human resources and to social development, with the purpose of eradicating poverty, promoting full and productive employment and fostering social integration.* The commitment calls governments to ensure provision of and access to basic social services for all, develop pro-poor health systems, improve their performance, and combat those major infectious and non-communicable diseases that inhibit economic and social development. The commitment pays significant attention to the issue of HIV/AIDS. It suggests strengthening political commitment and efforts at the international and national levels against HIV/AIDS, with a focus on developing countries. The major attention is on the prevention of the infection's transmission. The commitment encourages WHO to foster partnership with the private sector, particularly pharmaceutical industry, to increase investment in finding remedies for the diseases of developing countries, and for making medicines more easily available to poor countries. The attention is	73bis. *"Ensure appropriate and effective expenditure of resources for universal access to basic education and primary health care, within the country context, in recognition of the positive impact this can have on economic and social development, with particular efforts to target the special needs of vulnerable and disadvantaged groups".* 74. *"Recognize Governments' primary responsibility for providing or ensuring access to basic social services for all; develop sustainable, pro-poor health and education systems by promoting community participation in planning and managing basic social services, including health promotion and disease prevention; diversify approaches to meet local needs, to the extent possible utilising local skills and resources".* 74bis. *"Improve the performance of health care systems, in particular at the primary health care level, by broadening access to health care".* 75. *"Take all appropriate measures to ensure that infectious and parasitic diseases, such as malaria, tuberculosis, leprosy and schistosomiasis, neither continue to take their devastating toll nor impede economic and social progress; and strengthen national and international efforts to combat these diseases, inter alia, through capacity building in the developing countries with the cooperation of the* ***World Health Organization*** *including support for research centres".* 78. *"Encourage, at all levels, arrangements and incentives to mobilize commercial enterprises, especially in pharmaceuticals, to invest in research aimed at finding remedies that can be*

focused on the essential medicines and the role of intellectual property rights for promoting further research. The commitment contains very significant messages for WHO regarding its role in the globalization process. Such role is seen as building capacities at different levels in analyzing health consequences of international agreements and in designing appropriate policy responses to them. The most important message for WHO is that the commitment urges other UN organisations to establish a closer cooperation and partnership with WHO, in order to incorporate health dimensions into their sectoral policies and programmes, and to support countries to do the same.	*provided at affordable prices for diseases that particularly afflict people in developing countries, and invite the* ***World Health Organization*** *to consider improving partnerships between the public and private sectors in the area of health research".* 82. *"Invite the* ***World Health Organization****, in collaboration with UNCTAD, the World Trade Organization and other concerned agencies, to help strengthen the capacities of developing countries, particularly the least developed countries to analyze the consequences of agreements on trade in health services for health equity and the ability to meet the health needs of people living in poverty, and to develop policies to ensure the promotion and protection of national health services".* 82bis. *"Invite the* ***World Health Organization*** *to cooperate with Governments, at their request, and with international organizations in monitoring and analyzing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Governments can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements".* 83. *"Invite the organizations of the United Nations system to cooperate with* ***the World Health Organization*** *to integrate the health dimension into their policies and programmes, in view of the close interdependence between health and other fields and the fact that solutions to good health may often be found outside of the health sector itself; such cooperation may build on initiatives undertaken in one or more of the following areas: health and employment, health and education, health and macroeconomic policy, health and environment, health and transport, health and nutrition, health and food security, health and housing, development of more equitable health financing systems and trade in health goods and services".*

	83bis *"Invite the United Nations system to support national efforts, where appropriate, to build on initiatives undertaken in one or more of the above-mentioned fields".*
7. *To accelerate the economic, social and human resource development of Africa and the least developed countries.* In this commitment, the most relevant theme for WHO is the issue of HIV/AIDS and socio-economic development in Africa. The commitments pay a special attention to the problem of AIDS among youth, and suggest some concrete targets for reducing the prevalence and the rate of the infection. Prevention of the transmission of HIV is seen as a priority.	97bis "*Support the recommendations contained in the Report of the Secretary-General (A/52/871-S/1998/318) and in that context await the outcome of the open-ended ad hoc working group on the causes of conflict and promotion of durable peace and sustainable development in Africa".* 98. *"Support African Governments in expanding and strengthening programmes related to young people and HIV/AIDS through developing a collective strategy with the donor community, international organizations and non-governmental organizations, facilitated by the establishment of national young people's task forces, in order to ensure the necessary multi-sectoral response and the interventions to raise the awareness and address the needs of young people, as well as the needs of those living with HIV/AIDS and children orphaned by AIDS".* 99d. "*Develop a core set of indicators and tools to monitor implementation of youth programmes and progress towards achievement of the target to reduce infection levels in young people by 25% by 2005".*
8. *To ensure that when structural adjustment programmes are agreed to they* include social development goals, in particular eradicating poverty, promoting full and productive employment, and enhancing social integration The commitment calls for establishing participatory mechanisms for the assessment of social impacts of adjustment policies. The commitment invites United Nations system to cooperate with Bretton Woods Institutions in this area. For WHO this means more active participation in the PRSP and debt relief process, which are the subject of the main focus of commitment 8.	106. "*Establish participatory mechanisms to undertake assessment of the social impact of structural adjustment programmes and reform packages before, during and after the implementation process with a view to mitigating their negative impact and developing policies to improve their positive impact on social development goals. Such assessments might involve the support and cooperation of the United Nations system, including the Bretton Woods institutions, regional development banks and organizations of civil society".*

WTO/TRIPS Agreement, the Doha Declaration and the Intellectual Property Bill 2003, Sri Lanka

By Dr K Balasubramaniam

"No one should be fooled by the festive atmosphere of these celebrations. Outside there is anguish and fear, insecurity about jobs and what Thoreau described as a 'life of quiet desperation'".

This statement was made by the Secretary General of United Nations Conference on Trade and Development (UNCTAD). The festive atmosphere was a party in Geneva May 1998. The Trade Ministers were toasting fifty years of free trade. But the UN building where the celebration was taking place had to be surrounded by heavily armed security personnel to protect the revellers from people all over the world who had assembled in Geneva to protest against the World Trade Organisation (WTO).

Why this fear and anguish, insecurity about jobs and life of quiet desperation? The answer is globalization and liberalization and multilateral trade agreements which represent an unprecedented, transfer of power over economic functioning from the heads of Nation – States to the dominant actors in the market place namely the Transnational Corporations (TNCs).

While thousands of people were expressing their fear and anguish in Geneva, nearly a million people worldwide from all social sectors including farmers, indigenous people, workers, women, ethnic groups and the unemployed were expressing their rejection of WTO, the multilateral trading system and neoliberal policies. They were participating in the first international action of People's Global Action (PGA) against 'free' trade and WTO. Global street parties were celebrated in 35 cities all over the world, including Geneva, Birmingham, Sydney, Toronto and Prague, with several thousand people in each city against the WTO and their neoliberal policies.

On May 18, 1998, 23 regional conferences against the WTO were held in India. On May 1, 1998 hundreds of thousands of peasants and workers, participating in a massive national rally, called upon the Indian government to withdraw from the WTO. People's Global Action, a worldwide alliance of organizations and grassroots movements from 56 countries of all continents was formed in February 1998. The manifesto is available at ww.agp.org.

The WTO, WB and IMF are three neocolonialist international agencies used and controlled by the rich industrialized nations particularly G7 to continue the agenda of the colonialists.

People from developed and developing countries have repeatedly assembled at the meetings of WTO, WB/IMF and G8. These included massive protests in Geneva, Seattle, Toronto, Washington, Prague, Davos, Genova and recently Evian.

When fifty to hundred thousands of people assemble together, it is possible that a section of the protestors become violent. Unfortunately the main stream media coverage was corporate led and therefore concentrated on the sensationalism of the violent aspects of the protest without looking into examining and analyzing the real issues. The protestors' message is to show their concerns that globalization and

To Dr TN/CMF -1-
All the material from Dr Balasubramaniam
on WTO/TRIPS/SRILANKA BILL & CAMPAIGN
RN PHM-Sec
31/7/03

liberalization focus on economic growth and do not accommodate public health principles, social values, nor do they address issues of social development and equity essential to human development.

Doha Declaration on the TRIPS Agreement and Public Health

The Seattle WTO Ministerial Conference seems to have been a turning point for developing countries. Since then, there has been an organized and sustained campaign by developing countries supported by NGOs including the Third World Network (TWN) Health Action International (HAI) Consumer Project on Technology (CPT) OXFAM, Medecins sans Frontieres (MSF) to solve the conflicts and controversies and clarify that the TRIPS Agreement should not prevent governments from taking measures in favour of public health.

This process, initiated by the Africa Group of countries with active support from the majority of the developing countries including India and Sri Lanka, saw the developing countries demanding a common understanding on the TRIPS Agreement. This common understanding was that the Agreement allowed the degree of flexibility necessary to meet public health objectives, particularly in relation to compulsory licenses, parallel importation and exceptions to patent rights. This was thought necessary, not so much because the TRIPS Agreement lacked clarity, but more because of the political obstacles that were put in their way in attempting to put into effect the inherent flexibility of the TRIPS Agreement at the national level. The developing countries were moved to take this action in order to give effect to the conviction that the TRIPS Agreement and its provisions should not prevent WTO Members from adopting measures necessary to protect public health, including measures to ensure access to affordable medicines.

At the Fourth WTO Ministerial Conference (9-14 November 2001) held in Doha, Qatar, WTO Members took the unprecedented step of adopting a special declaration on issues related to the TRIPS Agreement and Public Health.

The Doha Declaration thus represents a political victory for developing countries including Sri Lanka and India. It is a strong, political statement, which provides a degree of security and acts as a sheet anchor for developing countries in adopting national level measures necessary to meet public health objectives against the fear of very costly legal battles. However, the Declaration was only the first step. The real test of the success of the Declaration rests at the national level whether or not developing countries will proceed to take the necessary measures at the national level to put into effect public health safeguards provided for in the TRIPS Agreement and reiterated and recognized in the Doha Declaration. Why did India not take any of these necessary measures?[1] Indian consumers need an answer.

The Intellectual Property Bill 2003, Sri Lanka

The Intellectual Property Bill 2003 Sri Lanka was placed on the order paper of Parliament 21st May 2003. The Supreme Court assembled on 6th June to hear three petitions and to determine whether the Intellectual Property Bill 2003 or any provision thereof was inconsistent with the Constitution of Sri Lanka.

The petitioners' contention was chiefly based on the position that the mitigatory features which were incorporated in the TRIPS Agreement have not been included in the Bill.

[1] Doha to Delhi – a retreat on healthcare. Having fought and won at Doha will India surrender at Delhi? by NB Zaveri.

The petitioners cited three examples as important issues that should have been taken into consideration.

a. Articles 30 & 31 of the TRIPS Agreement which provide for a State to make provision for the use of the subject matter of a patent for the domestic market without the prior authorization of the patent holder in certain situations such as national emergencies.
b. The Doha Declaration on the TRIPS Agreement and Public Health which makes provisions for compulsory licensing and parallel importing of pharmaceuticals to meet national health emergencies.
c. The TRIPS Agreement includes several other mitigatory measures which are allowed under the agreement.

The judges noted that none of these measures have been incorporated in the Bill. They added that these provisions were specifically included so that TRIPS consistent public health safeguards can be provided for in national intellectual property bills. The judges determined that several clauses in the Intellectual Property Bill 2003 were inconsistent with the Article 12 (1) of the constitution.

The present Bill, therefore, needs to be amended to include public health safeguards provided for in the TRIPS Agreement and underscored in the Doha Declaration. These safeguards include government use, parallel imports and compulsory licensing.

In order to examine and analyze the present scenario related to Intellectual Property Bill 2003 and to propose appropriate amendments to the Bill, the Ministry of Health, Nutrition and Welfare and the Department of Commerce, Ministry of Commerce and Consumer Affairs requested Health Action International Asia – Pacific to organize a National Seminar on "The TRIPS Agreement, the Intellectual Property Bill and Public Health". This was convened on 4th July 2003 in Colombo.

All stakeholders in the health and pharmaceutical fields were invited. The 76 participants included:

1. Officials from the
   - Ministry of Health, Nutrition and Welfare
   - Ministry of Commerce and Consumer affairs
   - Legal Division, Ministry of Foreign Affairs
   - Customs Department
   - Attorney General's Department
2. The Director, National Intellectual Property Office
3. A member of the Intellectual Property Advisory Commission
4. Senior staff members from the Departments of Pharmacology, Faculties of Medicine
5. Representatives from
   - Research Institutes
   - NGOs
   - Pharmaceutical Manufacturer's Associations
   - Media
6. Health activists

Reports of the proceedings of the seminar and issues related to the Intellectual Property bill were carried in the Sri Lankan media.[2]

The objective of the seminar was to propose appropriate policy options & TRIPS consistent safeguards including provisions for government use, parallel imports and compulsory licensing and to present them to the government for consideration by the drafters of the amendments. One resource person presented a paper entitled "TRIPS Consistent Provisions to Safeguard the Public Health Objectives of the Government". This was discussed by a panel of seven resource persons and later submitted to the Ministry of Health for follow-up.

I take this opportunity to give you good news.

Patent-free innovation possible

A group of top scientists, economists and NGOs (including HAIAP) sent a letter on 7th July to Kamal Idiris, Director General of the World Intellectual Property Organization (WIPO) asking him to promote "open", models of innovation that do not rely on patents.

The response was swift and very positive. WIPO Assistant Director General and Legal Council Francis Gurry issued a statement which appeared in Nature Vol. 424, 10th July 2003 that read as follows:

"The use of open and collaborative development models for research and innovation is a very important and interesting development, especially in areas where technology approaches the domain of basic science and scientific discovery. The Director General of WIPO looks forward with enthusiasm to taking up the invitation to organize a conference to explore the scope and application of these models as vehicles for encouraging innovation".

We were surprised at how fast they responded. We are not aware of any other cases where WIPO has agreed to hold a meeting that will explore the benefits of no Intellectual Property (IP) or weak IP in the context of development of public goods.

It is relevant to note that WIPO is the UN agency mandated to implement the Paris Convention on Protection of Intellectual Property till the WTO was established on 1st January 1995.

This is a very promising initiative to solve the controversy of patents, commercial R & D and financial incentives.

2

i. Patents Bill: Patents to get priority in new draft – Daily Mirror 4th July 2003
ii. Patents Rights in New Bill by Kishani S Fernando – Daily Mirror 5th July 2003
iii. IP Bill: Narrow Escape from a National Disaster by Dilshani Samaraweera – The Business Standard 11th July 2003
iv. Access to Drugs – a human right; Supreme Court Judgment gives hope to poor patients by Kishanie, S Fernando – Daily Mirror 11 July 2003

http://www.cptech.org/ip/wipo/kamil-idris-7july2003.pdf

7 July 2003

Director General
Dr. Kamil Idris, Director General
World Intellectual Property Organization
Geneva, Switzerland

Dear Dr. Idris:

In recent years there has been an explosion of open and collaborative projects to create public goods. These projects are extremely important, and they raise profound questions regarding appropriate intellectual property policies. They also provide evidence that one can achieve a high level of innovation in some areas of the modern economy without intellectual property protection, and indeed excessive, unbalanced, or poorly designed intellectual property protections may be counter-productive. We ask that the World Intellectual Property Organization convene a meeting in calendar year 2004 to examine these new open collaborative development models, and to discuss their

7/8/2003

relevance for public policy. (See Appendix following signatures for examples of open collaborative projects to create public goods).

Sincerely,

(in alphabetical order)

Alan Asher
Consumers Association
London, UK

Dr. K. Balasubramaniam
Co-ordinator of Health Action International, Asia Pacific
Columbo, Sri Lanka

Konrad Becker, Director
Institute for New Culture Technologies /t0
Vienna, Austria

Yochai Benkler
Professor of Law
Yale Law School
New Haven, CT USA

Jonathan Berger
Law and Treatment Access Unit
AIDS Law Project
University of the Witwatersrand
South Africa

James Boyle
Professor of Law
Duke Law School
Durham, NC USA

Diane Cabell
Director, Clinical Programs, Berkman Center for Internet & Society
Harvard Law School
Cambridge, MA, USA

Darius Cuplinskas
Director, Information Program
Open Society Institute
Budapest, Hungary

Marie de Cenival
Chargée de mission ETAPSUD
Agence Nationale de Recherches sur le Sida (A.N.R.S.)
INSERM 379 "Epidémiologie et Sciences Sociales appliquées à l'innovation médicale"
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Cape Town, South Africa

Gwen Hinze
Staff Lawyer
Electronic Frontier Foundation
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Ellen F.M. 't Hoen LL.M.
Medecins sans Frontieres
Access to Essential Medicines Campaign
Paris, France

Jeanette Hofmann
Nexus & Social Science Research Center
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Aidan Hollis
Associate Professor, Department of Economics,
University of Calgary, and
JD MacDonald Chair in Industrial Economics
Competition Bureau, Industry Canada
Gatineau, Quebec Canada

Dr Tim Hubbard
Head of Human Genome Analysis
Wellcome Trust Sanger Institute
Cambridge, UK

Nobuo Ikeda
Senior Fellow, Research Institute of Economy, Trade and Industry
Tokyo, Japan

Professor Wilmot James
Chair, Africa Genome Initiative
Social Cohesion & Integration Research Programme
Human Sciences Research Council
Cape Town, South Africa

Niyada Kiatying-Angsulee, Ph.D.
Drug Study Group
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Philippa Lawson
Senior Counsel, Public Interest Advocacy Centre
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Lawrence Lessig
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Eben Moglen
Professor of Law & Legal History
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General Counsel, Free Software Foundation
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Hee-Seob Nam, Patent Attorney
Intellectual Property Left
Korea Progressive Network JINBONET
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Greg Pomerantz,
Fellow, Information Law Institute, New York University
New York, NY USA

Laurie Racine
President, Center for the Public Domain
Durham, NC USA

Eric S. Raymond
President, Open Source Initiative
USA

Juan Rovira
Senior Health Economist
The World Bank

Frederic M. Scherer
Emeritus, John F. Kennedy School, Harvard University
Cambridge, MA USA

Mark Silbergeld
Consumer Federation of America

Committee on intellectual property
The Hague, the Netherlands

Victoria Villamar
le Bureau Européen des Unions de Consommateurs/
European Consumers' Organisation
Brussels, Belgium

Robert Weissman
Essential Action
Washington, DC USA

Professor Jonathan Zittrain
Co-Director, Berkman Center for Internet & Society
Harvard Law School
Cambridge MA USA

APPENDIX
Open collaborative projects to create public goods

These are some of the projects that could be discussed:

1. The IETF and Open Network Protocols.

The Internet Engineering Task Force has worked for years to develop the public domain protocols that are essential for the operation of the Internet, an open network that has replaced a number of proprietary alternatives. It is important that WIPO acknowledge the success and importance of the Internet, and appreciate and understand the way the IETF functions.

The IETF is currently struggling with problems setting open standards. When the IETF seeks to adopt a standard, there is uncertainty if anyone will later claim the standard infringes a patent. One suggestion to address this problem is to create a system whereby a standards organization could announce an intention to adopt a standard, and after a reasonable period for disclosure, prevent parties from later enforcing non-disclosed infringement claims.

2. Development of Free and Open Software

This movement is highly decentralized, competitive, entrepreneurial, heterogeneous, and devoted to the publishing of software that is freely distributed and open. It includes projects that embrace the GNU General Public License (GPL), which uses copyright licenses to require that modified versions also be free software, and projects such as FreeBSD, which use minimal licensing restrictions and permit anyone to make non-free modified versions, as well as projects such as MySQL, which

digital copyright regimes permit such practices as hypertext linking, the use of materials in search engines such as Google, and liberal views toward fair use.

4. The Human Genome Project (HGP).

In an April 14, 2003 state, the heads of state for the France, the US, the UK, Germany, Japan and China issued a statement, which noted that: "Scientists from six countries have completed the essential sequence of three billion base pairs of DNA of the human genome, the molecular instruction book of human life. . . This information is now freely available to the world without constraints via public databases on the World Wide Web."

If Presidents Jacques Chirac and George Bush, Prime Ministers Tony Blair and Junichiro Koizumi, Chancellor Gerhard Schroeder and Premier WEN Jiabao can collaborate on a statement to herald efforts to create a public domain database, free from intellectual property claims, it is time for the World Intellectual Property Organization to better appreciate why these governments did not want the Human Genome patented.

5. The SNP Consortium

A different example of a project to create a public domain database involves single nucleotide polymorphisms (SNPs), which are thought to have great significance in biomedical research. In 1999, the SNP Consortium was organized as a non-profit foundation to provide public data on SNPs. The SNP Consortium is composed of the Wellcome Trust and 11 pharmaceutical and technological companies including Amersham Biosciences, AstraZeneca, Aventis, Bayer, Bristol-Myers Squibb Company, Hoffmann-LaRoche, GSK, IBM, Motorola, Novartis, Pfizer and Searle. The work was preformed by the Stanford Human Genome Centerm, Washington University School of Medicine (St. Louis), the Sanger Centre and the Whitehead Institute for Biomedical Research. The mission of the SNP consortium was to develop up to 300,000 SNPs distributed evenly throughout the human genome and to make the information related to these SNPs available to the public without intellectual property restrictions.

By 2001 it had exceeded expectations, and more than 1.5 million SNPs were discovered and made available to researchers worldwide. The SNPs consortium, the HGP and other similar projects represent different notions regarding the intellectual property rules for databases, and more information about these projects would be useful in evaluating assumptions and informing debates in the WIPO Standing Committee on Copyright as it considers current proposals to convene a diplomatic conference to adopt a treaty on new sui generis intellectual property rules for databases.

6. Open Academic and Scientific Journals

the new jobs created, and the increased safety and efficiency for services more than outweighed the money we would get from charging -- especially when you consider the additional bureaucracy that would be needed to manage cost recovery. We think that judgement has proven valid, as the world-wide market for GPS applications and services now exceeds $8 billion annually."

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Friday July 11, 2003 Daily

How TNCs have taken over national economies

By Dr K Balasubramaniam
(Advisor and Co-ordinator, Health Action International Asia - Pacific)

At a recent seminar and elsewhere it was clear that many health officials and others involved in drafting relevant laws are not quite clear with TRIPS agreement provisions which are vital if millions of people in Sri Lanka are to have regular access to quality drugs at affordable prices. Health Action thus invited Dr. Balasubramaniam to explain the TRIPS provisions relating to patent rights and patient rights. Dr. Balasubramaniam is widely regarded as world expert on drug pricing and national drug policies.

Health Action
Conducted by
Dr. Koththamalli

The General Agreement on Tariffs and Trade (GATT) came into force in the mid 1940s. A new round of negotiations on GATT began in Uruguay in South America on September 20, 1986. The GATT Agreement was confined to goods only. But the developed countries wanted to enlarge the scope of GATT to several other areas besides goods in the new round which came to be known as the Uruguay Round of Negotiations. These negotiations went on till 1994 in Geneva.

There was initial unity of opposition by G77 (Group of Developing Countries) led by Brazil and India when the major trading powers, at the start of the negotiations in 1986, attempted to enlarge the scope of GATT to include services, intellectual property and investment in addition to goods. A compromise was reached.

It was agreed that negotiators' relating to services were to be conducted outside the jurisdictional framework of GATT. These negotiations would be guided by the objective of development of developing countries and not just be concerned with liberalization and dismantling the existing regulatory structures. National regulatory frameworks were to be respected.

It was also agreed that negotiations on Intellectual Property Rights (IPRs) should follow the approach already contained in Article 1 of the GATT Treaty which ensured that every Member State had the freedom to pursue its own regime of protection of intellectual property and which merely required that no Member State may use this freedom arbitrarily and in a discriminatory manner against the products or goods imported from another country. The developing countries were satisfied with this arrangement and formal talks started in January 1987. Little did the G77 know what was to follow; how a master plan would unfold - deception by design - the great betrayal - broken promise.

In June 1988, the Association of Transnational Corporations (TNCs) of the US, Europe and Japan submitted a joint paper to GATT on IPRs. The Association, not a member of GATT, first placed IPRs on the GATT Agenda.

Within two months, in August 1988, US President Ronald Reagan signed the Omnibus Trade and Competitiveness Act of 1988. This Act created two provisions: Super 301 and Special 301.

These provisions strengthened the ability of the United States Trade Representative (USTR) to retaliate against countries for 'unfair trade practices including alleged inadequate protection of IPRs'.

Special 301 requires the USTR to investigate and retaliate against countries which allegedly deny "adequate and effective protection of IPRs". Super 301 mandated the USTR to retaliate against foreign practices which are unjustifiable and burden or restrict US commerce. The US is one of the major trading partners of most developing countries.

The stage was now set for arm-twisting, to force countries to change their national legislation on patents and to bring recalcitrant countries back to talks.There was hardly any 'negotiations' in the real sense of the word.

The negotiators for the developed countries had with them teams comprising hundreds of experts and specialists who were very knowledgeable in the issues under discussion. Developing countries, on the other hand, sent a senior official of the Trade Ministry. There was no technical support. Several small developing countries were represented by the Trade Counsellor of the country's Permanent Mission to the UN in Geneva. It is not unusual to see some of these Trade Counsellors in Geneva being driven from one committee meeting to another. How can a single 'negotiator' deal with teams of specialists and experts? The issues under 'negotiations' were extremely complex in nature. And there was no coordination among developing countries. The result of the asymmetry was that the so-called 'negotiating process' did not involve give and take.

It was give and give all the way for developing countries. Heads I win : Tails you lose as far as the developed countries were concerned.

Developing countries made several concessions, in terms of agreeing to the higher levels of protection of IPRs demanded by industrialized countries but in return got little by way of tariff reductions in agriculture and textiles.

Adding more confusion to the asymmetry of the 'negotiating process' was the fact that no record of the TRIPS discussions was made, in line with the general practice within GATT. Proposals have no recognized source and only those who participated, if they can yet remember, will know why certain provisions were adopted.

There is no background material that will be vital to interpret the various rules that have been written into the Agreement or at least to find out the premises and intent of the adopted texts.

Further asymmetry: The composition of each working group was determined at the presiding officer's direction and not as a result of a consensus or of a search for a balanced representation of countries at different levels of development.

The entire Uruguay Round of 'negotiations' were withheld from public scrutiny and were kept as a secret preserve for trade officials. Not only the public but even other Ministries or departments in the national governments were not aware of the proceedings. For example, the Health Ministers or even the World Health Organization did not know about the TRIPS Agreement till it was finalized.

The impact of the Agreement would affect each and every consumer in the world. However, consumers were left out.

In view of how the so-called 'negotiations' took place and the Agreement was arrived at, the Final Act has been described as the most non-transparent, non-accountable, anti-people and pro-TNC Agreement in the history of international negotiations and agreements.

The TRIPS Agreement, in particular, will deny billions of poor men, women and children all over the world access to even a limited number of basic essential drugs for the treatment of common illnesses.

There was massive opposition in several member countries to the Final Act when it was concluded. Expressions like 'GATT-strophe', 'recolonisation', 'design for disaster', 'conquest by patent' and 'patent folly' to describe the Final Act gained currency.

The Final Act is not limited to interborder trade issues but the very functioning of national economies and their accessibility to TNCs in terms of financing productive infrastructure and market outlets.

It sets forth rules governing:

- Intellectual Property Rights;
- Foreign Investment;
- Infrastructural Services - Telecommunication, Air Transport, Banking, Finance and Insurance;
- Professional Services;
- Health and Safety Standards; and
- Entire Trade in Goods

The rules are all designed to allow maximum freedom for corporate decision-making and to minimize the role of national governments in the economy.

In short, the Final Act represents an unprecedented transfer of power over economic functioning from the heads of nation-states to the dominant actors in the international market place, namely the transnational corporations.

(To be continued)

Patients' rights in new Bill

By Kishanie S. Fernando

With the Supreme Court striking down several patent rights provisions in the abortive Intellectual Property Bill as a violation of the people's fundamental rights, top officials and health activists met yesterday to discuss proposals for a new Bill.

The aim was to ensure that millions of Sri Lankans would be able to obtain safe and efficacious drugs at affordable prices and that the rights of patients were given priority over the patent rights of global companies.

This came after the Supreme Court in a powerful act of judicial activism reminded government officials that their main duty was to protect the rights of the people and not of global companies.

Ministry Officials, doctors, pharmacists, local manufacturers, lawyers, and health activists took part in yesterday's motivating dialogue at the BMICH, with the focus on the "TRIPS Agreement, the Intellectual Property Bill and Public Health.

The driving force behind the move to put patients rights before patent rights was Dr. K. Balasubramaniam, Advisor and Coordinator of Health Action International Asia Pacific. He said the long term objective of the seminar was to ensure that Sri Lanka had regular access to quality medicines which were safe and effective at prices consumers in Sri Lanka could afford.

However this is dependent on the National Patent Law which is the policy instrument to make available low cost quality drugs and also develop the national pharmaceutical industry. The Intellectual Property Bill 2003 including the patent laws was introduced to meet Sri Lanka's international obligations under various conventions and the World Trade Organisation (WTO) agreement on the Trade Related aspects of Intellectual Property Rights (TRIPS).

Attorney M. Sumathiran discussed the Supreme Court's June 17 decision which struck down the Intellectual Property Bill as inconsistent with the Constitution of Sri Lanka. The judges determined that several clauses of the Bill dealing with patents were inconsistent with Article 12 (1), which guaranteed equal rights as well as equal protection. Therefore the provisions of the TRIPS agreement cannot be applicable to developed and developing countries equally.

The Judges said there could not be equality among those who were unequal pointing out at there was no level playing field when powerful multi-national companies were pitted against defenceless people.

It was observed that although the TRIPS agreement strengthens the position of the patent holders, who are predominantly based in developed countries, it also provides for mitigatory measures to ensure patients are treated in a more 'equitable' manner.

These measures were deliberately included in the TRIPS agreement to minimise abuse of the monopoly rights granted under a patent and to ensure that the needs of public health are met.

While these measures are widely prevalent in other countries, Sri Lanka has failed to fulfill its international obligations and the health needs of the public, by not incorporating these mitigatory measures into the final Draft Bill.

Dr. D. M. Karunaratne, Director of the National Intellectual Property Office replying to the allegations that the provision for compulsory licensing was removed at the last minute from the Bill said in 1998 the Committee on Intellectual Property removed it because it could be a deterrent to foreign investment.

Attorney Sharmila Anthony of the Centre for Policy Alternatives said the whole process of presenting the Bill lacked in transparency.

She said although the Bill was published in the gazette on April 25 this year, and despite repeated inquiries and requests, it was only made available to the public on May 26, leaving just two days for the public to examine the Bill and to challenge it for any inconsistencies with the Constitution.

Rohan Edirisinghe of the Centre for Policy Alternatives reiterating the position said a mere publication of an advertisement in the paper calling for suggestions for the draft Bill was not adequate notice. The final version of the Bill should have been made available for public scrutiny.

He also said that the State had an obligation under International law, TRIPs and the Constitution. The Attorney Generals Department in particular has a responsibility to ensure that the state obligations under human rights are protected in draft legislation of this kind.

Gothami Indikadahena, Deputy Director of Commerce made a presentation on TRIPS consistent provisions to safe guard public health objectives of the Government including some proposed amendments in conformity with the decision of the Supreme Court.

Prof. Tuly de Silva, Past President of the Pharmaceutical Society of Sri Lanka said if the new Bill with TRIPS consistent provisions on parallel importing and compulsory licensing becomes law, health professionals and consumers need to be assured that the drugs that are put on the market are of good quality safe and effective He stressed that quality control should be sustained at the point of manufacture, transport and sale. This cannot be done by Drug control authorities due to the lack of qualified graduate pharmacists and also due to some 8,000 varieties of drugs being imported. (According to Professor Senaka Bibile only 300-400 varieties would be sufficient). He stressed that public health protection should not be guided by multi nationals. Sri Lanka cannot afford to go to international courts to protect its rights and as such all measures should be taken for protection in the new laws.

The seminar was organized by the Ministry of Health in collaboration with the Department of Commerce and HAIAP with the support of the South East Asia Regional Office of the World Health Organisation.

Commuter complaints

National Intellectual Property Office says the next draft of the Bill would incorporate compulsory licensing and parallel importing

IP Bill: Narrow escape from a national disaster

By Dilshani Samaraweera

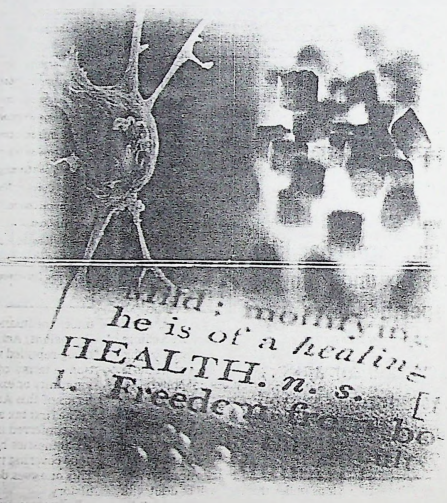
The Ministry of Health called for a hasty meeting last week of the local health sector. Organised by Health Action International on behalf of the Ministry Health, the event assembled the various stakeholders of the health sector ranging from consumer groups to doctors to local and international manufacturers of pharmaceuticals to various local authorities. This came fast in the heels of the Intellectual Property (IP) Bill unveiled by the Ministry of Commerce and Consumer Affairs.

Not surprisingly, the general attitude towards the fate of the IP Bill - struck down unceremoniously as violating fundamental rights by the Supreme Court - was one of relief.

As a representative from the Action Committee on Justice for Patients put it "What if this Bill actually went as it is? How many people in this country would have been able to afford medication?"

The gentleman, like many others, was referring to the tight *patent protection* awarded by the IP Bill of 2003 to both products and processes while being extremely relaxed in alleviating provisos.

For instance the Bill makes no mention of compulsory licensing and allowances made for parallel importing was deemed inadequate. Nevertheless, they are the most basic of public health defences granted to World Trade Organisation (WTO) member states by the TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights) agreement.



"How is it that a Bill - judged unconstitutional and violating Fundamental Rights -could have made its way to the threshold of Parliament in spite of both the Legal Draftsman's office and the Attorney General's office?"

The right of compulsory licensing is an escape valve for Governments from patent obligations. It can be invoked at times of national health crisis or anti-competitive practices by patent holders. Resorting to it a Government can compulsorily licence - even without the patent holder's permission - a third party to manufacture patented drugs.

The catch here is that drugs manufactured through compulsory license must be predominantly sold locally. This limits the option of manufacture for export. TRIPS also does not specify whether a country without the required expertise could award a compulsory licence to a third party, based in another country, to manufacture the needed drugs.

This ambiguity leaves less developed and developing countries at a disadvantage - they cannot manufacture at home and it is unclear whether another country can do so on their behalf. Therefore the subject of compulsory licensing has been under constant debate. However, local WTO Committee sources from the Department of Commerce are confident that a resolution favourable to less developed countries can be expected by September at the WTO ministerial meeting in Cancun.

The second provision of parallel importing slackens patent grip over a country by widening purchase choice. It capitalises on different prices, set by drug manufacturers for the same drug, in different parts of the world. Resorting to this provision Governments can import the same drugs from other parts of the world priced lower than at home.

In context of the local health system, the concerns were with regard to accessibility and availability of medicinal drugs. The IP Bill's unreserved patent protection, for a period of 20 years on both products and processes, effectively cuts off access to generic drugs.

Because once patent protection is obtained for an item - in this case a particular drug - only the patent holder would have the right to manufacture, sell, import and export the item during the patent period. Which means both the generation and sale of cheaper generics would be outlawed.

Currently Sri Lanka is hugely dependent on India for generics, but once these drugs are patented in Sri Lanka the importation of generics would be illegal.

The fear is that without generics to hold down prices, the retail prices of drugs would sky rocket. Medical sources stress that even limited access to generics and cheaper drugs is a necessity in Sri Lanka, as a majority of the population cannot afford branded patent protected drugs. They point out that if an IP regime does not incorporate adequate safety measures to enable access to cheap drugs. Sri Lanka's 19 million population would be left to the tender mercies of international pharmaceutical corporations in the event of a health crisis.

"Despite repeated requests we could not obtain a copy of the Bill. When we finally got the Bill we had less than a day to read the bill and lodge an entry with the Supreme Court."

The all-pervading question therefore was why the proposed IP Bill did not make use of the two basic measures advocated in TRIPS on behalf of public welfare? Particularly since even the developed west, including those with highly advanced domestic pharmaceutical industries, have pounced on these safety provisions to pillow their publics.

Dr. K. Balasubramaniam of Heath Action International pointed out that the US Government - the strongest lobbyist at the WTO in favour of patent rights - itself controlled private sector dictated drug prices by threatening compulsory licensing during nothing more devastating than 10 reported cases of anthrax.

The IP Bill also came under fire from various other quarters. On top of accusations of being biased in favour of corporate rights, the Centre for Policy Alternatives (CPA) charged lack of transparency in drafting the Bill.

M. Sumanthiran, Attorney-at-Law, CPA, said "Despite repeated requests we could not obtain a copy of the Bill. When we finally got the Bill we had less than a day to read the bill and lodge an entry with the Supreme Court."

Why is it, queries the CPA, that the Bill was not freely available for public scrutiny? And how is it that a Bill - judged unconstitutional and violating Fundamental Rights of citizens of this country - could have made its way to the threshold of Parliament in spite of both the Legal Draftsman's office and the Attorney General's office?

"These days even the President is having trouble getting at the Government Printer. You should have contacted your MP."

The State - represented by Dr. D. M. Karunaratne, the Director of Intellectual Property, President's Counsel Ben Eliyathamby, Member of the Intellectual Property Advisory Commission and State Counsel N. Wigneswaran - maintained that there was no secrecy in drafting the Bill.

In reply to the difficulty of obtaining a copy of the Bill, Mr. Eliyathamby laughingly pointed out that "These days even the President is having trouble getting at the Government Printer. You should have contacted your MP."

While this did raise a laugh, many including local manufacturers of medicinal drugs and consumers seem to view the shot down IP Bill as a narrow escape from a national disaster.

The gathering broke up with assurances from the National Intellectual Property Office that the next draft of the IP Bill would incorporate the suggested safeguards of compulsory licensing and parallel importing.

TRIPS and Patents: effects on medicinal drugs

Many argue that patenting causes price increases of drugs. An International Monetary Fund research by A. Subramanian shows that drug prices in Malaysia - where patent protection exists - are 20% to 760% higher than in India - where patent protection is limited and generics compete with branded drugs. In Egypt, with the introduction of product patents, prices of drugs increased between five and six times.

TRIPS or the Agreement on Trade Related Aspects of Intellectual Property Rights is one of the most contentious international treaties of all time. It came into force in 1995 and aims at awarding the same level of protection to Intellectual Property as to any other product traded among the World Trade Organisation (WTO) membership.

Therefore the concepts of National Treatment and Most Favoured Nation Treatment are applicable towards Intellectual Property as well. As a result member states are bound to treat nationals of other member states the same as ones own nationals when it comes to Intellectual Property rights and any advantages, favours, privileges or immunity granted to one must be extended to all.

Sri Lanka signed the General Agreement on Tariffs and Trade (GATT) in 1994 along with another 124 nations.

In 1995 GATT transformed into the present WTO. As a founder member of GATT Sri Lanka became a member of the WTO while still bound by the requirements of GATT. These include the TRIPS agreement and the implementation of the TRIPS advocated Intellectual Property (IP) regime.

Patent protection, like other Intellectual Property Rights, is expected to boost creativity and encourage innovation through legal protection provided to inventions and the guarantee of commercial returns to inventors. However, the enforcement of IP rights in various degrees among different WTO countries indicates a shift in resultant benefits in favour of the technologically advanced countries. This is particularly acute where essential items like medicinal drugs are concerned.

A recent World Bank study shows the gainers and the losers in dollars. The minimum welfare loss to a sample of developing countries (Argentina, Brazil, India, Mexico, Korea and Taiwan) due to patents on medicinal drugs, was between US$ 3.5 billion - US$ 10.8 billion. Meanwhile the income gains by foreign patent owners were between US$ 2.1 billion - US$ 14.4 billion.

WB study on gainers/losers in US$ (medicinal drugs)	
The minimum welfare loss due to patents	US$ 3.5 billion - US$ 10.8 billion.
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Many also argue that patenting causes price increases of drugs. An International Monetary Fund research by A Subramanian shows that drug prices in Malaysia - where patent protection exists - are 20% to 760% higher than in India - where patent protection is limited and generics compete with branded drugs. In Egypt, with the introduction of product patents, prices of drugs increased between five and six times.

This rise in pricing is due to two reasons. Patenting stops the creation of generics. Patenting also creates drug monopolies. These two reasons block competition on price. Measures like parallel importing rights and compulsory licensing were adopted to counter these unfair and even anti-competitive advantages transmitted to patent holders through patent rights.

Those in favour of patent rights argue that the minimum patent period of 20 years does not mean 20 years of commercial opportunity.

This is because the patent rights are calculated from the time of patent application. The activities of actually obtaining the patent, and in the case of drugs, the clinical trials and various other legal barriers, are time consuming but are taken off the granted 20-year period. These processes limit the actual sales period when the drug is in the market, to around eight years from the allocated 20. Given the huge costs of research and development, drug manufacturers say, patent protection is essential for cost recovery.

Therefore WTO negotiations have aimed at achieving a degree of balance between profit and public welfare. As it currently stands TRIPS allows patent rights to manufacturers while also ensuring that Governments can revoke or over-ride patent rights in certain specified situations in the public interest.

The deadline to provide patent protection to pharmaceutical products is January 2005.-DS

fasttrack

In favour of Patent Rights

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Oxfam India
Health Action International (Asia-Pacific)
People's Health Movement

PRESS RELEASE URGENT

'WTO, together with the World Bank and International Monetary Fund, is the greatest threat for public health' says former UN advisor. 'They should be held responsible for the human suffering caused due to high cost of essential medicines'

Bangalore (India), 29th July 2003: Over two billion people have no access to essential and life saving medicines worldwide. WTO allows Multi National drug Companies to place profits above people.

HIV/AIDS took 3.1 million lives in 2002. High costs of anti-retroviral drugs (used for the treatment of HIV/ AIDS) are perhaps one of the key reasons why poor people worldwide can't buy those medicines. WTO allows drug companies to profit from this 'mass murder'.

"WTO, together with the World Bank (WB) and International Monetary Fund (IMF) is the greatest threat for public health," said Dr. K Balasubramaniam, former Senior Pharmaceutical Advisor, United Nations Conference on Trade and Development (UNCTAD), Geneva. "They (WTO, WB and IMF) should be held responsible for the human suffering caused due to high cost of essential medicines" said Dr. Balasubramaniam while delivering an ***Oxfam India Public Lecture*** on ***'WTO/TRIPS Agreement, the Doha Declaration and the Intellectual Property Bill 2003, Sri Lanka'.***

"Public interest groups have just challenged the SriLankan Intellectual Property Bill 2003," said Dr. Bala, Colombo based advisor and Co-ordinator for Health Action International Asia – Pacific, a policy and advocacy network that works for the cause of access to essential drugs and intellectual property rights issues.

The Sri Lankan Bill was placed in the SriLankan Parliament on 21st May 2003. However, three petitions have challenged the bill arguing that the bill was inconsistent with the Constitution of Sri Lanka. The petitioners' contention was chiefly based on the position that the mitigatory features, which were incorporated in the TRIPS Agreement, have not been included in the Bill.

"We will step up efforts to challenge the WTO in various forums," said Dr. Ravi Narayan of the People's Health Movement (PHM). PHM, a grass root movement spread across the globe, reiterated their solidarity for pro-justice movements who have been calling global attention on the anti-poor and anti-people policies of the WTO through their protests in Seattle, Prague, Davos, Genova and recently Evian.

The Doha Declaration can be a reality only if there are political commitments from individual countries. Developing countries like India must start taking necessary steps at the national level to put into effect public health safeguards provided in the TRIPS Agreement and reiterated and recognized in the Doha Declaration. "It is time to act on the Doha declaration," said Mr. G Sri Ramappa, director of Oxfam India, an Indian development and humanitarian agency.

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July - 4th 2003

Patents Bill: Patients to get priority in new draft

The Supreme Court in one of its most powerful acts of judicial activism and involvement for the well-being of the people, recently struck down virtually all clauses relating to pharmaceutical patents in the proposed Intellectual Property Bill.

Before sending the ruling to the President and the Speaker Chief Justice Sarath N. Silva reminded the government it was elected in trust to protect the rights of the people and not the patent rights of global companies.

Acting fast on the Supreme Court ruling, the Health Ministry in consultation with the Trade Ministry and the people's rights group Health Action International has arranged a seminar and panel discussion today to draft a new Bill giving priority to the rights and well-being of the people.

The seminar to be held at the BMICH Committee room E, will be addressed by top Health and Commerce officials, patients, rights activists and lawyers.

The national seminar focussing on the TRIPS Agreement, the Intellectual Property Bill and Public Health will take place from 8.30 a.m. - 5.30 p.m.

This seminar is a follow up to the Regional Consultation on the "WTO/TRIPS Agreement and Access to Medicines - Appropriate Policy Changes" hosted by the Ministry of Health and organized by Health Action International Asia Pacific (HAIAP) and the Third World Network in collaboration with the World Health Organization. The Colombo Consultation in April was attended by participants from eighteen countries in the Asia Pacific region, including senior officials from Health and Trade Ministries, representatives from health-related NGOs and social movements, international experts and resource persons. One of the recommendations of that consultation was that developing countries should enact national legislation on patents with TRIPS consistent provisions for compulsory licensing and parallel imports. This will enable these countries to have regular access to affordable essential drugs.

Today's seminar has been convened to examine, identify and propose TRIPs consistent provisions that can be included in the Sri Lankan Intellectual Property Bill.

The earlier Intellectual Property Bill was presented in Parliament recently. The Bill was challenged in the Supreme Court by three petitioners on the grounds that the Bill violated fundamental rights. The Supreme Court accepted the petitioners claim and ruled that certain provisions in the Bill violated fundamental rights.

The violations were related to the section in the Bill dealing with patents including the absence of effective provisions for parallel importing and compulsory licensing.

The Bill needs to be revised and amended in accordance with the judgment of the Supreme Court. The seminar will examine appropriate policy options and TRIPS consistent provisions on compulsory licensing, parallel importing and government use.

- The agenda lists the resource persons who will present papers and sit on the panel. There will be about 75 participants from the Ministry of Health, Ministry of Commerce and Consumer Affairs, Research Institutes, Professional Associations, Non Governmental organizations (NGO's) and Pharmaceutical Manufactures' Associations.

A limited number of seats will be available for interested members of the public.

The agenda for today's seminar is as follows:

8.30 a.m. Registration

9.00 - 9.30 a.m. Welcome Address

-Dr. H.A.P.Kahandliyanga (Director General, Health Services)

-Mrs. Manuri de Silva (Acting Director General of Commerce, Department of Com merce)

-Dr. Joel Fernando (Member of Governing Council, Health Action International Asia Pacific).

9.30 - 9.45 a.m. Objective of the Seminar

-Dr. K.Balasubramaniam (Advisor/Coordinator Health Action International Asia Pacific).

10.15 - 10.45 a.m Evolution of National Laws on Patents in Sri Lanka

-Dr. D.M.Karunaratne (Director of Intellectual Property, National Intellectual Property Office of Sri Lanka)

10.45 - 11.15 a.m Tea

11.15 - 11.45 a.m. Quality, Safety and Efficacy of Drugs in the Market

-Prof. Tuly de Silva (Immediate Past President and Patron, Pharmaceutical Society of Sri Lanka.

11.45 - 12.15 a.m Impact of pharmaceutical patents on prices of and access to medicines.

-Dr. K.Balasubramaniam (Advisor / Coordinator Health Action International Asia Pacific)

12.15 - 1.00 p.m TRIPS consistent provision to safeguard the public health objective of the Government.

Ms. Gothami Indikadahena, (Deputy Director of Commerce)

1.00 - 2.30 p.m. Lunch

2.30 - 4.00 p.m. Panel Discussion - "The TRIPS Agreement, Intellectual Property Bill and Public Health"

(Moderator Dr. K.Balasubramaniam)

Panelists

Ms. Sharmila Anthony (Attorney at law, Centre for Policy Alternatives).

Prof. Tuly de Silva (Immediate Past President and Patron, Pharmaceutical Society of Sri Lanka)

Mr. D.A.P.Domingo (Assistant Director, Customs)

Mr. Ben Eliyathamby PC (Member Intellectual Property Advisory Commission)

Ms. Gothami Indikadahena (Deputy Director of Commerce)

- Dr. H.A.P.Kahandaliyanage (Director General, Health Service)

Dr. D.M.Karunarante (Director of Intellectual Property, National Intellectual Property Office of Sri Lanka)

Mr. Saleem Marsoof (Additional Solicitor - General Attorney General's Department)

4.00 - 4.30 p.m. Tea

4.30 - 5.00 p.m. Closing Ceremony

Health Action

Conducted by

Dr. Koththamalli