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Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

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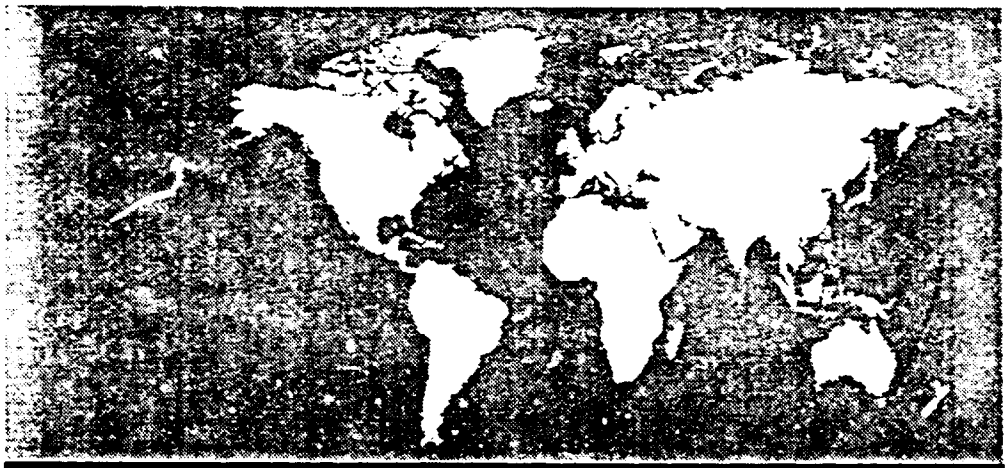

Background Paper

Sectoral impact of the Uruguay Round Agreements on developing countries: Pharmaceutical industry

Prepared by

JAYASHREE WATAL and ANU P. MATHAI

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

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This study was prepared by Jayashree Watal and Anu P. Mathai of the Indian Council for Research on International Economic Relations, New Delhi, India, as consultants.

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Introduction :

The objective of this section is to evaluate the impact of the Agreements emanating from the Uruguay Round of Multilateral Trade Negotiations on the **pharmaceutical sector** in developing countries. For this purpose the pharmaceutical sector is taken to cover all medicinal substances, for humans and animals, including bulk drugs, intermediates and formulations.

Of the substantive Agreements, Understanding, Ministerial Declarations and Decisions adopted in Marrakesh in April 1994 as a part of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, the only one of direct relevance to pharmaceuticals is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

The TRIPs Agreement contains seven parts: Part I contains the general provisions and basic principles which govern the Agreement; Part II, the substantive, minimum standards on seven intellectual property rights (IPRs); Part III, procedures and measures for their enforcement; Part IV, their acquisition and maintenance procedures; Part V, arrangements for the prevention and settlement of disputes; Part VI, transitional arrangements and Part VII, other final provisions for the implementation of the Agreement. The seven IPRs covered are copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits and undisclosed information[1]. Of these, there are mainly three aspects which have a direct impact on

[1]Undisclosed information, including trade secrets, does not strictly fall in the category of IPRs and was opposed by developing countries upto a point. For a detailed description of the contents of the TRIPs Agreement, refer to the UNCTAD Trade and Development Report (1994, Supplement).

pharmaceuticals viz. patents. trademarks and the protection of undisclosed information or trade secrets.

This section deals with the implications of the TRIPS provisions. relevant to pharmaceuticals. on patents. trademarks and trade secrets. Before doing so. an overview of the substantive standards for these IPRs set by TRIPS is given. The economic impact of these changed standards for developing countries is then assessed based on data collected and studies done so far on the subject. Lastly. this section sums up its conclusions with recommendations on the role of international agencies in helping developing countries to adjust to these changes.

Overview of the TRIPS provisions concerning pharmaceuticals :

For the first time there is an international Agreement covering substantive standards on intellectual property rights (IPRs). including frontier areas such as biotechnology and plant variety protection. which is binding on the Members both in terms of containing detailed enforcement procedures as well as in the sense of being subject. in default. to dispute settlement procedures and eventual punitive trade sanctions. This part is confined to an overview of the substantive standards on patents. trademarks and trade secrets.

It is Section 5 on **patents** that makes the most far reaching changes in existing IPR protection in favour of inventors in the pharmaceutical sector. At the start of the round almost 50 countries did not have product patents in the pharmaceutical sector[2]. For the first time in international law. countries are now obliged to provide patent protection to both process and product inventions made in all fields of technology. including pharmaceuticals. subject to the classical criteria of patentability

[2] See World Intellectual Property Organization. Document MTN GNG/NG11/W/24/Rev.1. 15 Sept. 1988

i.e., novelty, non-obviousness (or inventive step) and usefulness (or capability in industrial application)[3]. The only exclusions allowed from patentability, apart from those necessary to protect *ordre public*, morality, environment, life or health[4], are : (i) diagnostic therapeutic and surgical methods of treatment for humans and animals[5]; (ii) plants and animals, other than micro-organisms and essentially biological processes for their production. Also an effective *sui generis* system of protection is obligatory, at the minimum, for plant varieties. These exclusions in biotechnology are subject to a review in 1999[6]. This delicately balanced international consensus on biotechnology inventions primarily benefits inventors in the pharmaceutical sector who now increasingly use biotechnological processes and products.

Article 27 also clarifies that patent rights shall be enjoyed without discrimination as to field of technology. This means that, inspite of the freedom given to Members to specify any grounds for use without the authorisation of the right holder in Article 31, no Member can use compulsory licensing or any other similar provision to discriminate against patentees of the pharmaceutical sector, unless such instruments are equally applicable to all sectors. Similarly, there can be no discrimination between imported or locally produced products. This signifies the end of provisions on "working" the patent locally and the grant of compulsory licences on grounds of failure to work the patents.

Compulsory licensing has been restricted not by imposing limits on the grounds on which such licences can be issued but by subjecting such licences to many restrictive conditions of grant. Of particular interest to the pharmaceutical sector is condition 31 (a) which allows grant of such

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[3] See Article 27 of TRIPS.

[4] The wording for this section has been influenced by the GATT text itself.

[5] This exclusion would not apply to any products used for diagnosis such as "diagnostic kits". See Correa, C.M. 'The Gatt Agreement on Trade Related Aspects of Intellectual Property Rights : New Standards for Patent Protection.' European Intellectual Property Review, Volume 16, 8, August 1994.

[6] This exception resulted from the European Union's hesitation on biotechnological inventions. Subsequently, the European Parliament has turn down the commission draft Directive on biotechnological patents.

licences only after consideration of individual merits. This implies that use of patents without the authorisation of the right holder should be decided on a case by case basis and no across-the-board licenses will be permitted. Some of the more restrictive conditions are that compulsory licences shall be granted for a limited duration, liable to be revoked when the grounds for grant cease to exist; that the patentee must always be approached for voluntary licences first and that such licences shall be issued predominantly to supply the domestic market only. On the issue of dependent patents, Article 31(l) allows compulsory licensing on the first patent only when the second patent represents "an important technical advance of considerable economic significance". Many of these conditions retain a certain degree of ambiguity which will only get clarified in future dispute settlement proceedings.

The provisions of Article 27 are applicable to patent applications for pharmaceutical inventions right from the date of entry into force of the Agreement i.e. 1-1-1995, even though Article 65:4 specifies that developing countries have a further period of five years[*] to delay the application of the provisions on product patents to such areas of technology which were not covered prior to the Agreement. However, these transitional provisions are virtually nullified by Article 70:8 and 9 wherein it is mandatory for Members to accept patent applications for pharmaceutical and agricultural chemical products from 1-1-1995 itself. Such applications are to be provided patent protection after due examination from the date of grant of the patent for the remainder of the patent term of 20 years from the date of application. In addition, such products are to be granted exclusive marketing rights (EMRs) for a period of five years from the date of marketing approval or until the patent is granted or rejected, whichever period is less, provided that a patent application has been

[*] According to Article 65 there is a general period of one year for developed countries and five years for developing countries for the implementation of other provisions of TRIPS.

filed and a patent granted after 1-1-1995 in another Member and marketing approval obtained there. Since EMRs are, for all practical purposes, the same as patent rights[8], this means that in effect not even a day's transitional period has been allowed to developing countries for the introduction of product patents in the pharmaceutical sector[9].

Other provisions which may benefit the pharmaceutical patentees, to the extent that inventions in the pharmaceutical sector relate to processes only, are the rights of process patentees and the reversal of burden of proof. Article 28:1 (b) makes it obligatory to confer on the process patentee not only the right to prevent others from using the process but also all the rights of a product patentee in respect of the product obtained directly by the patented process. Article 34 lays down that in the case of infringement of the rights of process patentees, there shall be a reversal of burden of proof such that it is incumbent on the defendant to prove that the process used to obtain an identical product is different from the patented process. Here Members have a choice of introducing such reversal either when the product obtained by the patented process is new or when there is a substantial likelihood that the identical product was made by the patented process and that the patentee has been unable, inspite of reasonable efforts, to find the actual process used. In the latter case the product need not be new and hence the scope of the provision is wider than in the former case[10].

Under the section on **trademarks**, Article 15 of TRIPS states that "the nature of goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of

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[8] This is because the principal right of a patent is the exclusive right to sell the patented product. However, since the EMR is confined to the domestic market, third parties may be allowed to manufacture for exports only.

[9] The original proposal of the United States was to grant "pipeline" patent protection for all products not yet introduced in the market even if these did not strictly meet the criteria of novelty. See Article 26 in MTN.GNG/NG 11/W/70: Submission of the United States dated 11-5-1990. The present provision is referred to as "mailbox protection", meaning that the application will sit in the mailbox and be processed only when the county confers product patent protection.

[10] This is the interpretation of Correa C.M. (1994), confirmed by the fears of the International Federation of Pharmaceutical Manufacturers Associations that many products of patented biotechnology processes are not new and therefore may be left out in the former option.

trademark". This provision makes it clear that no Member can disallow the registration of trademarks for pharmaceuticals for the purpose of promoting generic names. Article 20 further disallows any unjustifiable encumbrance on the use of trademarks by special requirements, including "use in any manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings". Thus, any requirement to reduce the prominence of the brand name relative to the generic name of pharmaceutical products would run counter to the TRIPS Agreement. The other provisions on trademarks have an indirect effect in that they raise the level of protection to include, *inter alia*, combinations of colours or signs, a distinct advantage for pharmaceutical products. It is of interest to note that the question of parallel imports was not resolved in the TRIPS negotiations, giving scope to Members to design their own regimes for the exhaustion of rights.

The TRIPS provisions on the **protection of undisclosed information** provide the basis for the first international Agreement on the subject. There are two distinct parts to this, viz., protection of trade secrets in general and the protection of test data given for obtaining marketing approvals for pharmaceutical or agricultural chemicals. The first part is important for inventions which can be kept secret. This is not applicable to the pharmaceutical sector where regulatory approvals require "relatively wide dissemination of pharmaceutical research results and production techniques through scientific literature and discussion"[11] leading to a greater reliance on patents rather than trade secrets. The second part of Article 39:3 states that Members must protect undisclosed test or other data, required to be submitted to them as a condition for marketing approvals from unfair commercial use and from unnecessary disclosure. This is meant to give some degree of protection to new

[11] Taken from "Pharmaceutical R&D : Costs, Risks and Rewards" Office of Technology Assessment, US Congress (1993) page 290.

pharmaceutical products, whether non-patentable or patent expired.[12] The final text goes much further than the original demand of the US for payment of reasonable value for the use of such data or a reasonable period, say five years, for the exclusive use of the right holder.

One interpretation of the TRIPS text is that such data is to be protected without any time limit and that competing follow-on products would not be able to rely on such data for obtaining marketing approvals and would either have to buy the data from the originator or duplicate all the tests required themselves. Where the originator wishes to have monopoly rights, no other entrant would be able to obtain marketing approval. In such a case, protecting such undisclosed data, Members would be going further than even patent protection in that such rights would be absolute and with no time limits. It is unlikely that this was the intent as the history of the negotiations shows that this part of the text was deliberately weakened by developed countries to accomodate the interests of developing countries. It is more likely that the obligation is not to use test data submitted by the original applicant to clear marketing approvals for others for a certain period of time. Since this period has been deliberately left undefined, it can be even less than the five year period originally proposed by the US. Recently, New Zealand has amended its law to provide for a protection of five years, from the date of submission of test data, from both unfair commercial use and disclosure[13].

Economic implications of TRIPS on the pharmaceutical sector in developing countries:

A. The Place of Developing Countries in the World's Pharmaceutical Industry :

The world pharmaceutical industry is geographically a highly concentrated one with only a few countries accounting for the bulk of world productioin. Almost 82% of the world production in

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[12] See Cottier .T. "The prospects for Intellectual Property in GATT" CML Rev. 1991 page 409, footnote 86.
[13] See "An Act to amend the Patents Acts, 1953" 9th December 1994.

1990 was in the industrialized countries, with the developing countries accounting for only 18%. The picture has hardly changed since 1975 when the figures were 79.5 and 20.5 respectively (see Table-2 given below). Even amongst the developed countries, almost 75% of world production took place in only 6 countries, and over 50% of the production by market economies was accounted for by only 30 large companies[14]. This contrast is even more marked in the figures for per capita consumption of pharmaceuticals. In developed countries, the figure is estimated at over $88 annually while in developing countries, it is only about US$8.4. More details are given in Table-2 below.

However, the economic costs of even this comparatively low level of consumption, are extremely high, particularly in terms of foreign exchange cost. Many developing countries depend on imports for vitally needed drug supplies, which makes the costs of imported drugs and policies to reduce them, a matter of national concern. Table-1 below shows the proportion of consumption that is met out of national production. In four countries, namely, the Philippines, Nigeria, Taiwan and Thailand, more than 10% of the requirement of pharmaceuticals is imported. This is evidence of the inadequacy of domestic production to meet their requirements. In one estimate, the import bill of developing countries is expected to rise from US$ 3.2 billion in 1978 to US$ 55-60 billion by the end of the century.[15]

However, many other developing countries are self sufficient in their pharmaceutical production. These are Argentina, Mexico, Brazil, South Korea, Egypt, Turkey, Colombia, Indonesia, Chile and Venezuela amongst others. Developing countries like India, China and Singapore even figure amongst the twenty largest pharmaceutical exporters (see Table-3 below). While in the case

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[14] Lall, S. "Economic considerations in the provision and use of medicines", in R. Blum, A. Herxheimer, C. Stenzland and J. Woodcock (eds). 'Pharmaceuticals & Health Policy' (Croom Helm, 1981).

[15] Von Wartensleben, Aurelie, "Major Issues Concerning Pharmaceutical Policies in the Third World", World Development, Vol. 11, No 3, pp 169-175,1983.

of Singapore much of the exports may only be sourced through it. India and China have large domestic production accounted for by local companies. These exports are not only to countries with weak patent protection but also to developed countries, after the date of patent expiry for the exported drugs. Domestic companies will now be prohibited from producing or marketing patented drugs once the TRIPS Agreement comes into force. Unfortunately, there is little serious evidence of the dynamic costs and benefits of this Agreement in terms of future R&D, transfer of technology or foreign direct investment in the pharmaceutical sectors of developing countries.

Table 1

Local Production as a Proportion of the Total Consumption of Pharmaceuticals in Selected Developing Countries

	Ratio of Output to Consumption[b/] (Percentage)	
Country or area	**1975**	**1990**
China	101.1	99.2
Argentina	99.2	99.1
Mexico	101.4	98.1
Brazil	99.7	96.0
India	96.9	118.3
Republic of Korea	100.3	97.9
Turkey	100.0	98.0
Colombia	99.9	98.2
Indonesia	94.6	98.5
Philippines	98.5	89.2
Venezuela	95.6	94.6
Nigeria	46.0	72.7
Taiwan	86.8	85.7
Thailand	71.7	83.8
Chile	95.8	91.2

b/ At current prices

Source : Handbook of Industrial Statistics 1992, UNIDO.

TABLE-2: SELECTED INDICATORS FOR PRODUCTION AND CONSUMPTION OF PHARMACEUTICAL PREPARATIONS, BY COUNTRY GROUP, 1975 AND 1990[a]

Gross output				
	Share in world total (percentage)		Average per-capita consumption (dollars)	
Country/Country group	**1975**	**1990**	**1975**	**1990**
Industrialised Countries	79.5	81.7	48.5	88.3
Eastern Europe and USSR	10.4	8.7	21.8	32.8
EC	29.2	27.4	57.0	101.7
Other Europe	3.1	3.0	51.5	86.6
Japan	14.5	15.5	92.0	170.2
North America	21.0	25.8	58.3	122.4
Others	1.3	1.2	24.4	34.9
Developing Countries	20.5	18.3	5.8	8.4
North Africa	0.4	0.4	7.0	7.3
Other Africa	1.4	0.7	6.6	6.6
Latin America	7.1	5.7	16.7	18.4
South & East Asia excl. China	3.7	4.5	2.8	4.0
China	5.7	5.9	4.3	7.0
Others	2.2	1.1	18.1	43.1

a/ At constant 1980 prices

Source : Handbook of Industrial Statistics 1992, UNIDO.

TABLE-3: THE TWENTY LARGEST EXPORTERS OF PHARMACEUTICAL PREPARATIONS, 1990[a/]

1990			
Rank	**Country or area**	**Share[b/]**	**Exports in output**
1	Germany, Federal Rep. of	15.6	24.3
2	United Kingdom	13.6	42.2
3	Switzerland	13.2	84.4
4	France	12.3	20.1
5	Belgium	5.7	67.2
6	United States	5.7	2.4
7	Sweden	5.5	70.1
8	Netherlands	4.4	73.2
9	Denmark	4.2	81.9
10	Ireland	3.5	103.1
11	Italy	3.3	6.8
12	Yugoslavia	2.0	60.6
13	India	1.8	23.4
14	Austria	1.1	38.7
15	Japan	1.0	0.5
16	Spain	0.9	4.7
17	China	0.8	3.5
18	Singapore	0.5	217.7
19	Canada	0.5	3.3
20	Australia	0.5	10.6

[a/] At current prices.

[b/] In world total exports of pharmaceutical preparations. Eastern Europe countries and USSR were excluded.

Source : Handbook of Industrial Statistics 1992, UNIDO.

The degree of patent protection given to pharmaceutical products seemed, in the past, to be clearly related to the level of development of the domestic pharmaceutical industry[16]. This has changed recently due to bilateral and multilateral initiatives taken by developed countries. In those countries which have a well-developed domestic industry based on imitative R&D, indigenous firms strongly favor a weak system of patent protection for pharmaceutical products. Absence of product patent protection for products makes it easier for the domestic firms to copy the patented drugs on the basis of new processes. This explains why much of the resistance to TRIPS, which continues even after the Agreement, comes from countries such as India and Argentina which have a well-developed pharmaceutical industry.

Not all developing countries, however, succeeded in reducing the dominance of multinational enterprises (MNEs). This is on account of certain characteristics of success in the world pharmaceutical industry such as the requirement for strong research capability with the required capital base and wide international marketing links. The global market is however segmented into national markets on account of differences in country preferences and the importance of local marketing. It is for this reason that MNEs prefer foreign direct investment to trade, atleast in countries with large markets. It is estimated that for the developing countries as a whole, two-thirds of pharmaceutical production comes MNEs[17]. In many cases, market shares held by foreign firms have been higher than 50% and have even reached 80 to 90% in some cases (example in Brazil, Kenya, Mexico, Colombia etc.). Brazil continues to be dominated by MNEs inspite of the absence of both product and process patents for pharmaceutical over the last two decades (See Table 4 below). It can be seen from this table that in two of the developed countries, viz., Canada and Australia, the foreign share is as high as 85%. This is possibly related to the fact that none of the major pharmaceutical MNEs originate in either country.

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[16] See 9, supra.

[17] See Baillance, R. et al, "The World's Pharmaceutical Industries - An International Prospectives on Innovation, Competition and Policy", Edward Elgar, 1992, page 25.

TABLE- 4

Pharmaceutical market shares held by domestic and foreign firms in 25 selected countries, 1975

Country	Domestic share (Percentage)	Foreign share (Percentage)
Saudi Arabia	0	100
Nigeria	3	97
Belgium	10	90
Venezuela	12	88
Canada	15	85
Australia	15	85
Brazil	15	85
Indonesia	15	85
Mexico	18	82
India	25	75
Iran	25	75
Argentina	30	70
Philippines	35	65
Italy[a]	40	60
Netherlands[a]	40	60
South Africa	40	60
United Kingdom[a]	40	60
Sweden[a]	50	50
France[a]	55	45
Spain	55	45
Germany, Federal Republic of[a]	65	35
Switzerland[a]	72	28
United States[a]	85	15
Japan[a]	87	13
USSR	100	0

a/ The home country of at least one of the major pharmaceutical transnational corporations

Source : Leif Schaumann, 1976, Pharmaceutical Indust y Dynamics and Outlook to 1985, table 3, p. 13.

The table shows that the share of the domestic companies exceeds 20% in only three developing countries viz., India, Argentina and the Philippines. However, this data is outdated as it related to the year 1975. The domestic shares have been going up sharply in some of these developing countries; for instance, in 1980 the national companies in Argentina held 47 per cent of

the market while in Chile they held 42 per cent and in India, in 1987, the figure stood at 59 per cent. The place occupied by the leading four domestic companies is another indicator of their importance . ALIFAR, an association of pharmaceutical manufacturers of Latin America, has found that in Argentina, Chile and Venezuela, the four leading domestic companies featured easily amongst the first 25 companies in 1980. In 1987 in India these featured amongst the first 10 itself[18].

Regional Impact of TRIPS on the Pharmaceutical Sector :

It is quite clear from the above facts that only a few developing countries are engaged in the production of basic drugs. They include Argentina, Brazil, China, Egypt, India, Mexico, South Korea, Puerto Rico, Turkey and ex-Yugoslavia. We have seen above that the share of foreign ownership in the pharmaceutical industry differs widely amongst developing countries.

While all developing countries would be adversely affected by TRIPS in as much as they are not inventors of pharmaceutical products or processes, owners of internationally well-known trade marks or originators of test data, some countries belonging to the least developed country (LDCs) group will be the worst affected. This is because these countries are at the very initial stages of industrialisation. They depend heavily on imports of finished products or of penultimate intermediates and merely package or formulate the medicines domestically. In view of the lack of adequate resources, both capital and human, these countries have little hope of been able to benefit from the TRIPS Agreement in this sector. On the other hand, some of the policies that these countries could have followed to moderate high drug prices, such as monopsonistic purchase of

[18] Taken from White, Eduardo "Cooperation among National Drug Manufacturers: ALIFAR" *World Development*, Vol 11, No. 3, pp 271-79., 1983, for Latin America and for India from data given by Operation Research Group, Baroda. December 1987.

medicines by the government from the cheapest international source and compulsory use of generic names is now prohibited by TRIPS. With world-wide patent protection it will become increasingly difficult for these countries to source cheaper drugs during the life time of a patent.

It is only countries like China, India and Argentina who have already begun international patenting of their inventions, albeit in a small way, which can hope to have their own patented products and processes as well as their own brand names in the long run. These countries are expected to intensify domestic R&D efforts either in a consortium of domestic companies or with MNEs. They are also likely to postion themselves as the world's cheapest sources for generic drugs. For this they may need collaborations with MNEs on the international marketing of generics Evidence of these moves by large domestic companies is already available in the case of India.

Given these facts, it would be interesting to examine the economic impact of TRIPS on the pharmaceutical sector of developing countries. We will refer, in passing, to the legislations of developing countries on IPRs prior to TRIPS.

B. Economic Impact of TRIPS on the Pharmaceutical Sector :

PATENTS :

Given the nature and cost of pharmaceutical R&D it is often stated that **patent** protection for pharmaceutical products and processes is an essential incentive to encourage new inventions and to protect the fruits of R&D, an activity of crucial importance to the modern pharmaceutical industry and one on which substantial expenditures are incurred by the leading corporations[19]. Such patents offer the firm the possibility of regulating the use of inventions, charging higher prices and requiring

[19] See for example, Mansfield, E. 1986, "Patents and Innovations : An Empirical Study," *Management Science*, Vol. 32, pp 173-181.

other conditions that a more competitive market situation would not allow.[20] Patent rights facilitate cross-licensing agreements between leading pharmaceutical firms and raise the height of the entry barriers faced by new entrants to particular patented product markets.

The pharmaceutical sector has been at the centre of the debate on patents which is not surprising in the light of studies which have shown that patents are far more important in this sector than in others. In the context of the TRIPS negotiations, much of the lobbying in the North for improved protection emanated from this sector and conversely much of the resistance to change in existing patent regimes in the South came from the same sector.

Not surprisingly, the countries which offered strong patent protection for pharmaceutical products and processes of production, prior to TRIPS, were mostly in the developed world. The trend towards full patentability of pharmaceuticals was completed quite recently even amongst the developed countries. Protection for pharmaceutical products was introduced by France in 1958, the Federal Republic of Germany in 1968 and more recently by Japan in 1976 and Italy in 1978. Spain and Portugal revised their laws only by 1992 as this was a requirement of the European Common Market.

In many developing countries only processes of production could be patented, not products. Pharmaceutical products were excluded from patent protection in as many as 49 countries, both developed and developing. Ten countries excluded both pharmaceutical products and processes from patent protection.[21] These were Argentina, Brazil, Colombia, Malawi, Mexico, New Zealand, the Republic of Korea, Turkey, Zambia and Zimbabwe. It can be seen that with the exception of New

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[20]Chudnovsky, Daniel, "Patents & Trademarks in Pharmaceuticals", World Development, Vol 11, No 3, pp 187-193, 1983.

[21]World Intellectual Property Organization, Document MTN.GNG/NG11/W/24/Rev 1, 15 Sept 1988

Zealand, these are all developing countries. Subsequently, during the course of the TRIPS negotiations, several of these countries have changed their patent laws or are in the process of doing so. Several developing countries initiated the process of changing their patent legislations even before the conclusion of the Uruguay Round, primarily in response to the threat of sanctions under Special 301 provisions of the US trade law. Hence the intended changes in the Uruguay Round have been largely pre-empted through bilateral initiatives, in which the abstention from withdrawal of existing market access concessions appears to have been presented as "compensation".[22] For instance, the Republic of Korea introducted product patents for pharmaceuticals in 1986. Mexico did the same with effect from 1992[23], as did Chile[24], Thailand and Indonesia. Amongst others, India, Brazil, Argentina, Turkey, Uruguay and Colombia have initiated changes, providing for the temporary acceptance of product patent applications as required under TRIPS. The amendments of India and Argentina are, however, yet to be passed by their respective Parliaments as at the time of writing.

The economic studies in the past decades on IPR protection in developing countries by Vaitsos, Penrose, Anderfelt, Greer and Grundmann generally concluded that such protection, particularly for patents, went against their national interests as it only strengthened the market power of multinational enterprises (MNEs) and retarded the industrialization of these countries.

In recent years also theoretical studies have shown that the South stands to gain with weaker IPR protection while the North always benefits from having the patents of its firms respected outside its borders[25]. Some have argued that while the welfare of the inventing country rises with the

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[22] Subramanian, Arvind, "TRIPS and the Paradigm of the GATT : a Tropical, Temperate View", *World Economy*, vol. 13, no. 4, December, 1990

[23] This was done as part of the negotiations on NAFTA

[24] Chile is negotiating to be a part of NAFTA

[25] Chin, J.C., and G.M. Grossman, "Intellectual Property Rights and North-South Trade", in R.W. Jones and A.O. Krueger(eds) "*The Political Economy of International Trade*", Cambridge, M.A., Basil Blackwell, 1991.

extension of patent protection world wide, that of the consuming country falls more and hence world welfare as a whole becomes negative[26]. However, it can also be shown that if there are significant differences in North-South technological preferences, then the South may benefit from higher IPR protection[27].

There have been a few specific studies on the impact of patents on the pharmaceutical sector in developing countries. In one of the earlier studies on the Turkish pharmaceutical industry[28], it was concluded that the empirical evidence does not show any simple or straightforward relationship between patents and industrial development, be it in terms of competition, transfer of technology or local R&D. It was shown that even in the absence of patents, non-use or transfer pricing were both possible. Further, market concentration remained very high and, contrary to expectations, both foreign investment and licensing of technology increased during this period.

Studies on effect of pharmaceutical product patents on prices and welfare :

Recently, three studies have, using the comparative static framework, attempted to quantify the effect of the introduction of patents for the pharmaceutical sector in developing countries in terms of price and welfare changes. The paper by Subramanian[29] estimates changes in prices, profits and social welfare arising from increased patent protection for pharmaceuticals for two developing countries viz. Argentina and India, concluding that these are sensitive to assumptions about pre-patent market structures and price elasticities of demand. Nevertheless a lower and an upper bound figure

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[26] See Deardorff, A.V. "Welfare Effects of Global Patent Protection", *Economica*, vol.59, No.233, Feb.1992, page 35-51.
[27] Diwan, I., and D. Rodrik. "Patents, Appropriate Technology, and North-South Trade", *Journal of International Economics*, 30(1-2), February 1991, pp27-47.
[28] Kirim, A.S. "Reconsidering Patents and Economic Development : A Case Study of the Turkish Pharmaceutical Industry", *World Development* 13, 21, 1985, pp 219-236.
[29] Subramanian, A "Putting some numbers on the TRIPS pharmaceutical debate" *International Journal of Technology Management, vol. 10* (1994), pp 1-17.

have been given for the large country case where price increases could range from (-) 7% to 42% and welfare losses from (-) 27% to 67% and for the small country case where price increases could be 17% to 67% with annual welfare losses ranging from 72% to 75%. The upper bound represents a move from pre-patent perfect competition to monopoly while the lower bound stands for pre-patent duopoly moving to patent monopoly. In a subsequent study[30], the same author makes estimates for several asian developing countries wherein the average price rise for patented drugs ranges from a minimum of 5 per cent to a maximum of 67 per cent. The maximum welfare losses with an assumption of the share of patented drugs at 15%, are US $ 315 million for India, US $ 33 million of Indonesia, US $ 46 million for Pakistan, US $ 59 million for Phillipines and US $ 47 million for Thailand.

Nogues[31] assesses the social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries. His paper studies six developing countries viz. Argentina, Brazil, India, Mexico, Korea and Taiwan. He estimates that consumer misallocation from the introduction of product patents would be the highest in the case of India where this could range from US$ 916 million to US$ 3055 million. The corresponding figure of Subramanian is US$1279 million for India. Nogues does not make any precise estimates on price changes. He, however, recognises that these would depend, to a large extent, on the pre-patent market structures.

An earlier version of Subramanian's paper was expanded upon by Maskus and Konan in their subsequent work on TRIPS[32]. Using simple linear models like Subramanian, they constructed two

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[30] Subramanian A. "Trade Related Intellectual Property Rights and Asian Developing Countries : An Analytical View", prepared for the Asian Development Bank in 1995.

[31] Nogues, Julio J. "Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries", *The Developing Economies XXXI-1*, March 1993, pp 24-53.

[32] Maskus, K.E. and D.E. Konan "Trade-Related Intellectual Property Rights : Issues and Exploratory Results" in *"Analytical and Negotiating Issues in the Global Trading System"*, ed. by A.V. Deardroff and R.M Stern, Ann Arbor : University of Michigan Press, 1994, pp 401-446.

additional pre-patent scenarios viz., one where a domestic pirate-fringe industry with a foreign-owned monopoly becomes a completely foreign-owned monopoly and second, where a domestic pirate-fringe and a legitimate-fringe industry with foreign-owned monopoly becomes only a legitimate fringe industry with foreign-owned monopoly. The upper bound, however, remains the case where perfect competition changes to patent monopoly and hence the maximum welfare losses remain the same as Subramanian estimates.

The data used in all the three studies is given by the US Pharmaceutical Manufacturers' Association (USPMA) as reported in Gadbaw and Richards (1988). Apart from the fact that this data gives only broad aggregates on the size of the total market, patented market and sales by domestic copiers and foreign patent owners, the accuracy of the data is suspect as the motive of the USPMA was to project a high level of losses to the foreign pharmaceutical companies.[33] The analysis of these authors is extremely useful however, as it emphasises the importance of the pre-patent market structures in developing countries in any assessment of the impact of the introduction of product patents in the pharmaceutical sector of these countries. All these studies have pointed to the inadequate empirical research done on the subject and the crucial need for more detailed evidence before any accurate estimates can be made.

Recently, an attempt has been made by the present author to fill this gap, at least in the India context.[34] Using detailed market share data on patentable drug markets for the year 1993, it has been shown that the average price rise resulting from a move from the present oligopolistic market

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[33] It was found in the case of India that the total size of the pharmaceutical market and the patentable segment was less then 25 per cent of that projected by the USPMA even taking the data of 1993.

[34] Watal Jayashree, "Implications of Introducing Product Patents - Case of the Indian Pharmaceutical Sector", mimeo, Institute of Economic Growth, Delhi, December 1993, (revised in 1995).

structures to patent monopoly would be in the range of about 50 per cent, with range from 0 to 75 per cent.

TABLE-5
Comparative Results of Studies on Price and Welfare Changes in India

Authors' Names	Price Rise (%)		Welfare Losses US$Mn	
	Maximum	Minimum	Maximum	Minimum
Nogues 1993	-------	-------	3055.2	916.6
Maskus And Konan 1994	67%	5%	1279	95
Subramanian (Forthcoming)	67%	-7%	1279	- 273
Watal (Unpublished 1995)	75%	0%	------	-----

It can be seen that the price increases with the introduction of product patents in India can be in the maximum range of 70 to 75 per cent. This is far lower than apprehensions, based on newspaper reports in the country, that prices may go up by 1000 per cent. There is much more variability with respect to the welfare losses. This is due to differences in the data and methodology used by the authors. However the concept of welfare losses[35] is of purely academic interest and would not influence policy in any way.

Another econometric study of patentable drug markets in India by the present author[36] concludes, based on data for seven years from 1987 to 1993, that even in the absence of product

[35] Welfare loss is defined as the dead weight loss to consumers from the resulting patent monopoly generally with reference to perfect competition.

[36] Watal, Jayashree, "MNEs, Market Structure and Price Competition in Patentable Drug Markets in India", presented at a Seminar on *Technology and Globalization*, conducted jointly by The Institute of Economic Growth, Delhi and The United Nations University (INTECH), Maastricht, The Netherlands, at Delhi in April, 1995.

patents, such markets are highly concentrated and prices are influenced by MNEs and market concentration variables, the only attenuating factor being the availability of credible substitute drugs. Price competition in these markets seems to be confined only to products of similar quality i.e. the lead products, with first-movers and large-sized firms gaining enormous marketing advantage over others. This shows that the promotion of trademarks and other marketing strategies plays an important role in capturing market power even in the absence of product patents, the difference being that with such patent protection, such power will mostly accrue to MNEs.

Instruments to moderate abuses of patent monopoly:

The question now is whether there are any instruments available under the TRIPS Agreement which can moderate anticipated price increases due to product patents. **Compulsory or non-voluntary licenses** have always been considered by developing countries to be very important deterrent in preventing abuses of patent monopolies and an important instrument for the development of local industry. Although compulsory licences are well recognized even by developed countries to be an important instrument to correct the abuse of patent monopolies and to resolve interdependence of patents[37], those issued on grounds of failure to work the patent locally have been opposed, particularly by the U.S. and are now prohibited under TRIPS. However, both the Paris Convention and the WIPO Model Law allowed the freedom to issue compulsory licenses on grounds of non-working and even eventual revocation of patents as a remedy against this. Canada and U.K. used such licences to effectively control prices of pharmaceutical products in the past. Even the U.S. which has strongly opposed open-ended compulsory licenses, allows them as a remedy in anti-trust cases. Non-

[37] Patents are considered to be interdependent where a later patent cannot be exploited without infringing an earlier patent.

voluntary licenses are also permitted in the field of production or utilization of special nuclear material or atomic energy; or in connection with the implementation of pollution standards.

Further, in most patent laws, including in the U.S., the patented invention may be exploited, even without the agreement of the patent owner, by a government agency or a third person designated by a government authority where the public interest, in particular, national security and the development of vital sectors of the national economy, so requires. It is for this reason that the U.S. incorporated special provisions in Article 31 (b) of the TRIPS Agreement for public non-commercial use. In such cases it is only when the Government or its agent becomes aware without recourse to a patent search, that a patent is being violated, that the patentee needs to be informed.

Similarly, an exception has been made for anti-competitive cases which prescribed compulsory licenses as a punishment such that the conditions on adequate remuneration based on the economic value of the patent and on prior efforts to obtain voluntary licenses have been waived. This exception can now be used by developing countries to incorporate in the national **competition laws**, specific standards of monopoly abuse such as unreasonably high prices. It is for each country to determine nationally the level at which prices become unreasonably high.

The question of what would be the economic impact of these changes on compulsory licenses is hard to answer as there has been no study of this aspect.

Apart from the general provisions on non-voluntary licensing, the TRIPS Agreement allows for the use of **price controls**. Indeed most of the countries in the world have some system of price controls or controls of the profit margins of pharmaceutical companies. Almost all major developing countries imposed direct price controls at the whole sale or retail level or both. For these countries price controls offer a cheaper alternative to subsidising medicines sales or offering extensive social

security schemes. Moreover, developing countries try to use the system to correct for transfer pricing by MNEs, but they do not necessarily succeed in this.It is difficult to determine the costs of intermediates and raw materials sold within the MNE. It is feared that with product patent protection, MNEs may use this only to capture export markets. In this scenario, price controls may not be an effective mechanism as there would be no way of determining a "fair" price.

TRADEMARKS :

Apart from large expenditures devoted to R&D, the pharmaceutical industry is also characterized by one of the highest rates of promotion expenditures per unit of sales.[38] These promotional activities are utilized in order to differentiate the products of pharmaceutical firms, particularly by means of **trademarks**. Trademarks, unlike, patents receive specific legal protection for an unlimited period. Unlike in other industries, in the pharmaceutical industry, the choice of the product is usually made by the doctor, for whom prices are not likely to be the determining factor. Quite often in the developing countries, it is the dispensing pharmacist who selects the particular brand. As a result, a significant proportion of the expenditure on sales promotion is spent in influencing doctors' choice of brands. Since brand specific advertising is an important factor in the creation of market power, prices of branded drugs will be higher, and consequently the profits of the producing firms. These benefits are, however, not passed on to the consumers, the pharmaceutical firms being the main beneficiaries.

While transnational pharmaceutical companies are the ones capitalising on internationally well known trademarks and resorting to brand competition, the large domestic firms have also been

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[38]Chudnovsky, Daniel, "Patents & Trademarks in Pharmaceuticals", World Development, Vol.11, No. 3, 1983.

expending large sums on promotional activities. Therefore unlike patents, trademarks have not been such a controversial issue between foreign and big indigenous firms, or between the North and the South. Moreover, there has been public critisism of this aspect of the industry even in developed countries and now several of the States in U.S. have special laws allowing substitution of brand name prescription by generics[39]. The sales of generic drugs have gone up to about 18 per cent of total prescription sales in the U.S. in 1990. Such a policy was tried successfully in Cuba, Costa Rica and Sri Lanka, but failed in Pakistan.

However, the promotion of generics is not a sufficient condition for achieving lower prices in the consumer industry and improving consumer protection. Without complementary government policies, MNEs, attracted by the expanding world markets for generic drugs, will benefit more than the consumers in developing countries.

In developing countries where there are inadequate facilities for testing the quality of drugs, trademarks may play a marginal role in persuading doctors and pharmacists to prescribe quality drugs. It has been argued that "brand names provide a unique identification of the products ..... linking the manufacturer's name and reputation with his product, and assuring the user that the manufacturer stands behind and accepts responsibility for the quality of his product".[40]

Although TRIPS now prohibits any restrictions on the registration or use of trademarks, policies to encourage the use of generic names can still continue. Such policies, however, should be used in conjunction with other policies as it is R&D and sales promotion which is the main source of market power in the pharmaceutical industry.

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[39] A generic name for a drug applies to all those brands of that drug which contain the same active ingredient, which means that there are fewer generic names than brand names.

[40] Peretz, S.M., "Pharmaceuticals in the Third World : The Problem from the Suppliers' Point of View", *World Development*, Vol.11, No.3, pp. 259-264, 1993.

One such relevant policy is the grant of marketing approval for pharmaceutical products. There have recently been several initiatives to harmonise the procedures for such regulatory approvals amongst certain developed countries and if this is successful, developing countries may also be asked to join the international consensus.

TRADE SECRETS :

Unfortunately, there is hardly any economic literature on **trade secrets** and none on the implications of the protection of undisclosed test data relevant for the pharmaceutical industry, especially in the context of developing countries. Much would depend upon how the developed countries interpret these provisions in the TRIPS Agreement in their own laws by the end of this year 1995. It is important to know whether this would be used to extend monopoly power on patent-expired or non patentable products in developing countries. This is a subject which needs to be studied in some detail urgently before its full implications can be judged.

***Conclusion* :**

The TRIPS Agreement marks a significant turning point in the international law on IPRs. The most far reaching changes in existing IPR protection have been made obligatory under this Agreement., especially in the area of patents. Such changes were motivated, to a large extent, by the multinational pharmaceutical lobbies in developed countries and were resisted by the domestic pharmaceutical interests in developing countries. It is evident that pharmaceutical MNEs in the developed world perceived large gains and domestic companies in developing countries, huge losses from the conclusion of the TRIPS Agreement. It is this perception that has been the subject of recent economic studies.

These studies have shown that developing countries will face price increases of patented pharmaceutical products and also significant welfare losses with the introduction of product patents. However, the dimensions of these price increases are not likely to be as high as was apprehended earlier.

It is clear that while patent monopolies would lead to maximum price increases of the order of 70 to 75 per cent, availability of substitute products in the same therapeutic group would moderate such price increases. On the other hand, market exclusivity under the patent regime could lead to high prices, with the leading brands retaining a large share of the market long after patent expiry. It would be difficult for domestic companies to counter such dominance by MNEs even in the post-patent situation. With product patents being accepted world wide, the question of tempering prices through procurement and import policies, does not rise. Developing countries can only hope to reduce prices by increased product competition which can only come with indigenous R&D.

The strengthening of trademark regimes will help large pharmaceutical MNEs to register and use their trademarks without any fear of restrictions on such use. Governments, however, would be free to promote the use of generic names by 'substitution' laws and other policies as long as they do not restrict registration or use of trademarks.

The effect of the section on protection of undisclosed information, in so far as it concerns the protection of its data from "unfair commercial use", would depend largely on the interpretation of this clause of the TRIPS Agreement. It is as yet unclear as to whether national governments could rely on test data, originated by the first company which requested marketing approval, for clearing the cases of subsequent applicants for the same product. If this is permitted, and is not considered as unfair commercial use, this clause would have no adverse effect on prices of pharmaceutical products. If, however, this is considered as prohibited, it would mean that market exclusivity would be granted to

patent-expired and non-patentable products for an unlimited period, a situation with far graver implications for pharmaceutical prices then has been the case with product patents.

It is felt that in the context of the impact of the TRIPS Agreement on the developing countries, especially in the pharmaceutical sector, international agencies, such as UNIDO, can play a constructive role. Specifically, they can provide technical cooperation and support to the domestic pharmaceutical industry, upgrade quality control standards, promote R&D through tie-ups with international consortia and even help in the formulation of effective responses to changes in the world pharmaceutical market. This could be done through industry associations, individual consultants or through other non-government organizations. With the increasing importance of the private sector in the changed global economic scenario, international agencies could be an effective link between the private sectors of developed and developing countries. It is evident, however, that the success of these efforts would depend, in no mean measure, on the cooperation between the governments of developed and developing countries.