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Access to Medicines and Public Policy Safeguards under TRIPS

by

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Executive summary

This dialogue is on access to medicines. It needs to be underscored that access to medicines is one of the means to an end and not an end by itself. The end is Health for All. It is therefore very important not to discuss access to medicines in isolation, as an end in itself, but in the wider context of health for all, which is our final goal.

The Doha Declaration is the first Ministerial acceptance of the negative impact of the TRIPS Agreement on public health when the Ministers recognized the concerns about the effect of intellectual property protection on drug prices.

Patents and high prices are among several constraints to access to medicines. Factors affecting access include: a country's wealth, distribution of income within a country, public and private health spending, commitment to national drug policy, national insurance schemes, and price controls.

Selected key indicators of 15 countries in the South and South-East Asia are compared. This region has about 30 percent of the world's population but approximately 50 percent of the world's poor live here.

Poverty is the world's deadliest disease and also the commonest cause of ill-health. Infant, maternal and under-5 mortality rates and prevalence of malnutrition are unacceptably high in the majority of countries. There are at present seven least developed countries. In 1971 when the list was first prepared there were only four. The UN has identified India, Indonesia, Pakistan, Sri Lanka and Viet Nam as countries, which meet some but not all the criteria to be included in the list of LDCs. If the economies of these countries continue to deteriorate, the ranks of LDCs in the region will continue to grow in the next decade.

Poverty eradication measures are the only ways to improve and promote health and to ensure regular access to essential medicines. Public health expenditure is very low. Six countries [40 percent] spend less than one percent of their GDP on public health. Thirteen countries [87 percent] countries spend less than two percent of the GDP on public health. The total health expenditure in 10 countries [67 percent] is less than five percent of the GDP. The very low public health expenditure on health is the major constraint to access. For example in India, where drug prices are the lowest in the world, only 30 percent of the population has access to drugs.
There are no universal national health insurance schemes. Except in India, there is no price control policy.

Empirical data on welfare losses to the country, and increase of drug prices with patent protection are given. The WHO has initiated a collaborative process to monitor and analyse the impact of multilateral trade agreements on access to drugs. This initiative will undertake research to provide answers for four questions:
*How is patenting affecting drug prices?
*How are patents and enhanced intellectual property protections affecting the rate of introduction of generic drugs?
*Are TRIPS and expanded intellectual property protections spurring the development of drugs for neglected diseases?
*Are TRIPS and expanded intellectual property protections contributing to an increase or decrease in transfer of technology and direct foreign investment in developing countries?

The paper reviews the problems and prospects facing developing countries in the immediate follow up of the Doha declaration.

Technical assistance given by WIPO and WTO to developing countries to create national legislation on intellectual property seems to be an instrument of regulatory policy more concerned with how to comply with TRIPS rather than how to best make use of the safeguards provided in TRIPS and to choose the most appropriate strategies within the multilateral framework.

The economic and demographic profiles and the science and technology capacities clearly indicate that a large number of developing countries do not have the resources to implement and enforce an efficient and effective intellectual property regime. Moreover TRIPS is an agreement on a legal framework. Its implications will be decided by settling disputes. That makes case law and the power of the parties involved of great importance. The high costs of disputes with the world's leading nations are very frightening. This discourages developing countries from asserting their rights. For example not a single developing country has included compulsory licensing in its national law since TRIPS. Several industrial countries have included compulsory licensing and parallel importing in their national laws.

Traditional medicine serves the healthcare needs of about 80 percent of the world's population, majority of whom live in South and South-East Asia.

TRIPS Agreement has been developed to meet the needs of inventors engaged in high technology R & D. But traditional healers have entirely different ways of owning and transferring technology related to genetic resources, traditional and community knowledge and expressions of folklore.

But the same framework for intellectual property rights developed for the modern high technology R&D is being applied to genetic resources, traditional and community knowledge and folk medicine. By this process, they are easily patentable, become private property and enrich the new owners who have actually "pirated" them using a legal framework quite irrelevant to what are 'pirated". The world needs an entirely different legal framework to meet the needs of billions of people in developing countries who have been the keepers of genetic resources, traditional and community knowledge.

The paper describes the evolution of the national pharmaceutical industry in developing countries. In the 1960s, the drug prices in India were one of the highest in the world. About two decades later, India had the lowest drug prices. The policy instrument responsible for this was the Indian Patent Law, 1970. This Indian law followed the German system of allowing process patents but not product patents. Protection was granted for seven years.

India has to abandon this law. The Indian Drug Manufacturers' Association has warned of a national health disaster as a result of the implementation of the TRIPS Agreement.
The Doha Declaration gives clarification, which public health groups have been campaigning for. The Declaration enables members to use to the full compulsory licensing and parallel imports. The next step is to turn these provisions into feasible public policy options. This will require a legal structure suited to developing countries. In view of the limited resources in developing countries, a model legislation prepared by knowledgeable persons would serve as a guideline to formulate national legal provisions and procedures on patent and public health. Unfortunately WIPO will not prepare a model legislation on intellectual property system since

countries have different legal systems. Draft provisional legal structures proposed in the Human Development Report 2001, and by an NGO are presented.

The WHO initiative of a collaborative process to assess the impact of TRIPS on access to drugs confirms NGOs' position that the Doha Declaration is just the first short-term step towards countering the negative impact of TRIPS and improving access to medicines. Much more data and analysis are required to find long-term solutions. The long-term sustainable solution to ensure self-reliance and self-sufficiency involves building the pharmaceutical manufacturing capacity in all those developing countries that have adequate resources. This will promote generic manufacture and competition to ensure a truly competitive global market in pharmaceuticals, to serve particularly those smaller countries (about 60 of them) who have no resources to set up national pharmaceutical industry or enact and enforce an efficient intellectual property regime.

Establishing and strengthening the pharmaceutical sector in developing countries will need a supportive patent legislation. In this respect, the Doha Declaration does not address major problems developing countries face. These include:

i. Faulty patent granting systems, which do not meet patentable criteria such as novelty, inventive step, prior art, etc

ii. The inadequate capacity level in developing countries to ensure the application of patent criteria and examination of patent applications

These are issues our negotiators may wish to take into consideration in calling for a review of TRIPS.

In this context, it is encouraging to quote from the opening address to a WHO meeting by Dr.Supachai Panitchpakdi, the Director-General Designate of WTO. He clearly preferred that the review of the TRIPS Agreement commence before the launch of the next Round saying,
"So we are looking at implementation and I am sure that before the next Round which I will call the Development Round we would have some sort of agreement to look into some of the requirements of TRIPS. I am sure that there will be also some review of the requirements connected to patent rights and the protection of patent rights that must have some bearing on certain kinds of essential drugs".

In light of the external perception of the WTO, he emphasized his desire to give it a human face by adding; *"I would like to put a human face on the WTO which has always been called the rich man's club. I have to change that."*

1. THE HEALTH NEEDS OF PEOPLE IN SOUTH AND SOUTH-EAST ASIA

1.1 Poverty and ill-health

This dialogue is on access to medicines. It needs to be underscored that access to medicines is one of the means to an end and not an end by itself. The end is Health for All. It is therefore very important not to discuss access to medicines in isolation, as an end in itself, but in the wider context of health for all, which is our final goal.

The World Health Report 1995 drew attention to the widening gap between the health of the privileged and under-privileged groups and concluded that poverty is the world's deadliest disease. Poverty is in fact, a socio-economic disease. The biological manifestations of this socio-economic disease are referred to as "diseases of poverty" and are the common communicable diseases. Poverty is, therefore, not only the deadliest disease, but also the commonest cause of ill-health in the world.

The consequences are very low standards of health characterized by unacceptably high infant, maternal and under 5 mortality rates and high prevalence of malnutrition of children under five years. A majority of the countries in South and South - East Asia are poverty stricken, as table 1 shows.

Table 1 gives the following selected key indicators in 15 developing countries in South and South - East Asia.

1. Infant mortality rate
2. Maternal mortality rate
3. Under 5 mortality rate
4. Prevalence of malnutrition under 5 years
5. Population below national poverty line
6. Population below $1 a day
7. Per capita GNP US $
8. Ratios of the incomes of the poorest 10% and the richest 10% of population
9. Health expenditure as a percentage of GDP
10. External debt as a percentage of GNP
11. Number of scientists and engineers in R & D per million population

Table 1 – Selected Key Indicators in 15 Developing Countries in South and South-East Asia

Developing Asian Country	Population in million 1999	Infant Mortality Rate 1998	Maternal Mortality Rate 1990 -1998	Under 5 Mortality 1998	Prevalence of Malnutrition % of children under age 5 1992 – 1998	Population below national poverty line % Latest available	Population below $1 a day % Latest available	Per Capita GNP US$ 1999	Ratio of the incomes of the poorest 10% to the richest 10%	Health expenditure as a percentage of GDP		External debt as a percentage of GNP 1998	Number of Scientists and Engineers in R & D per million population 1987 – 1997
										Public 1990– 1998	Private 1998		
Bangladesh	128	73	440	96	56	35.6	29.1	370	1:7	1.6	1.9	22	52
Bhutan	0.78	71	380	n.a	39	30	n.a	390	n.a	5.1	5.5	n.a	n.a
Cambodia	12	102	n.a	143	n.a	36.1	n.a	260	1:12	0.6	6.3	62	n.a
India	998	70	410	83	53	35.0	44.2	450	1:10	0.6	4.2	20	149
Indonesia	207	43	450	52	34	20.3	15.2	580	1:8	0.6	0.8	169	182
Lao PDR	5	96	650	111	40	46.1	n.a	280	1:6	1.2	1.3	92	n.a
Malaysia	23	08	39	12	20	15.5	n.a	3400	1:21	1.3	1.0	69	93
Maldives	0.278	30	202	n.a	56	40	n.a	1080	n.a	5.1	5.5	n.a	n.a
Myanmar	45	78	230	118	43	n.a	n.a	n.a	n.a	0.2	1.6	n.a	n.a
Nepal	23	77	540	107	57	42.0	37.7	220	1:9	1.3	4.2	31	n.a
Pakistan	135	91	n.a	120	38	34.0	31.0	470	1:8	0.9	3.1	41	72
Philippines	77	32	170	40	30	40.6	n.a	1020	1:16	1.7	2.0	66	157
Sri Lanka	19	16	60	18	38	35.3	6.6	820	1:8	1.4	1.7	41	191
Thailand	62	29	44	33	19	13.1	<2	1960	1:12	1.7	4.1	79	103
Vietnam	78	34	160	42	40	50.9	n.a	370	1:8	0.4	4.0	76	n.a

Source (i) World Development Report 2001, World Bank
(ii) Asian Development Bank Key Indicators of Developing Asian and Pacific Countries, 1998, Volume XXIX
(iii) Human Development Report 2001, UNDP.
n.a – not available

A critical analysis of the data in table 1 will enable us to identify the constraints to regular, access of the most needed medicines and basic healthcare to all the people in this region. It needs to be underscored that patents and high prices of essential medicines are among several constraints to access. For example, India does not recognize product patents and drug prices in the country are the lowest in the world. Yet hundreds of million people do not have regular access to even a few essential drugs.

Factors affecting access to essential medicines and basic health care include the following:

- Countries' national income and distribution of income within the country;
- Public and private spending on health;
- Commitment to national drug policies;
- National insurance mechanisms; and
- Regulations and control of drug prices

1.2 National Incomes and Income Distribution

Until the mid 1960s all developing countries were considered as a single homogeneous group. At the first session of the United Nations Conference on Trade and Development (UNCTAD) in 1964 special attention was focused on what were then called the "less developed" among developing countries.

At UNCTAD II in 1968, the first resolution on the least developed countries (LDC) was adopted (1). The General Assembly of the United Nations (UN) in 1971 established the first list of LDCs on the recommendation of the Economic and Social Council (ECOSOC) and on the advice of the Committee for Development Planning (CDP).

In spite of special UN programmes to arrest and reverse the deterioration in the socio-economic situation in LDCs, these countries are lagging further and further behind and in some cases moving backwards. In addition they are growing in numbers. The list began with 24 countries in 1971. The most recent review was done in April 2000. At present there are 49 LDCs with a population of 620 million. The original list in 1971 had four LDCs in South and South – East Asia. They were Bhutan, Lao PDR, Maldives and Nepal. Three more have been downgraded to LDCs. They are Bangladesh, Cambodia and Myanmar. The UN Committee for Development Policy[1] has identified India, Indonesia, Pakistan, Sri Lanka and Vietnam as countries that meet some but not all of the criteria to be included in the list of LDCs. If the economies of these countries continue to deteriorate prompted mostly by rising debt, falling commodity prices and sharp declines in development aid and foreign investments, the ranks of LDCs will continue to grow during the next decade (2). The future, therefore looks very bleak unless realistic poverty eradication measures are put into effect. Unfortunately it would appear that poverty eradication has been given to the rich countries. Although at their summit the G8 governments committed to halving world poverty and reducing child mortality by two thirds by 2015, the reality seems to be different (3). The 2001 Human Development Report warns that the goal of reducing infant and

[1] The UN Committee for Development Planning was subsequently reconstituted as the UN Committee for Development Policy.

maternal mortality is nowhere near the target. Ninety-three countries with almost two thirds of the world's population will miss the target to reduce under 5 mortality by two thirds.

The infant, maternal and under 5 mortality rates are unacceptably high in the majority of countries in the region. (Table 1)

Effective poverty eradication programmes are the only way to improve health standards and lower the three mortality rates. In this context, it is heartening to note that a two-day finance minister's conference on poverty reduction took place in Islamabad, Pakistan recently. Finance and Planning Ministers from the seven–nation South Asian Association for Regional Co-operation (SAARC) have said they expect to evolve a joint strategy to fight poverty in the region where almost half the world's poor live. The meeting unanimously adopted a 16 point plan of actions to eradicate poverty from one of the world's poorest regions. Among others, the Ministers called for flexibility for developing countries in intellectual property rights (4,5).

The data in table 1 confirms the Ministers statement that about 600 million people in the region live below the poverty line. The population in the region is 1735 million and constitutes about 30 percent of the world population but it accounts for approximately 50 percent of the world's poor. The higher incidence of poverty in the region is not only due to low GNP but also to the high maldistribution of income among population sub-groups in these countries. The Human Development Report 2001 states that 9 billionaires in India are worth 23 billion US dollars or five percent of the country's annual GDP, or equivalent to the annual incomes of about 600 million of the lowest income earning Indians. The ratios of the per capita GNP of the poorest 10 percent of the population to the richest 10 percent vary from 1:6 in Lao PDR to 1:21 in Malaysia.

The only source of access to medicines for the poor is the public sector, where medicines are given free. But the public sector health expenditure in countries of the region is very low. The public sector drug budgets are minimal. This is the reason why over two billion people have no regular access to essential medicines.

1.3 Public and Private spending on Health

Table 2 gives the percentage of public, private and total health expenditure as a percentage of the GDP.

Table 2 Health Expenditure as a Percentage of GDP

Health expenditure as a percentage of GDP	Number of Countries		
	Public Sector	Private Sector	Total Health Expenditure
<1.0	6	1	0
>1.0 - 2	7	6	2
>2 - 3	0	0	2
>3 - 4	0	2	4
>4 - 5	0	3	2
>5 - 6	2	2	2
>6 - 7	0	1	1
>7 - 8	0	0	0
>8 - 9	0	0	0
>9 - 10	0	0	0
>10 - 11	0	0	2

Source: Table 1

Table 2 shows that in six out of the 15 countries, the public health expenditure is less than one percent of the GDP; in 13 countries it is less than two percent. Bhutan and Maldives, both LDCs, are the only two countries that spend 5.1 percent of the GDP each on public health.

With very low spending on public health it will be impossible to provide the basic healthcare to all. The World Health Report 1996 was constrained to state that because of the social and economic crisis that still affects many countries, health systems which should offer protection against disease have, in extreme cases, either collapsed or not even been built.

According to Dr Gro Harlem Bruntland, the Director General of WHO, of great concern, was the observation that less than half the world's population had regular access to essential drugs. Medicines are still unavailable or unaffordable for too many people especially the poor and those most in need. (6).

The private health expenditure is more than that of the public in all countries, except Malaysia. Majority of the people in the region have to pay out-of-pocket for their healthcare. The poor who have no money have no access.

In 10 out of the 15 countries, the total health expenditure as a percentage of the GDP is less than five. This is one of the greatest constraints to regular access of essential medicines and basic health care.

1.4 National Drug Policies

According to the WHO nearly 90 countries have national drug policies in place or in preparation. Three out of four countries – over 140 in total, have adopted national essential drug lists. These national lists are widely used for drug purchases, training and public education about medicines. Nearly 100 governments have developed national treatment guidelines. (7).

There seems to be an apparent contradiction between the success of the WHO Essential Drugs Programme and the fact that more than half the world's population has no regular access to essential drugs, and medicines are still unavailable or unaffordable to those most in need.

Table 2 explains the contradiction. Essential drug lists and national drug policies apply only to the public health sector in all developing countries and not to the private sector. Essential drug lists and national drug lists are irrelevant to the private sector, which controls about 50 – 90 percent of the pharmaceutical market in these countries.

Further constraints to regular access to medicines include the following:

- There is no national health insurance system in any of the countries in the region.
- There are no effective price regulatory and control mechanisms for drugs in these countries, except India.

In spite of the constraints to access to drugs in the region listed above, one redeeming feature is the relatively low prices in the region due to the generic manufacture and competitive national drug industry in India (8,9). This is possible because the Indian Patent Law does not provide patent protection for pharmaceutical products. However when India changes its patent law to provide product patents in conformity with the TRIPS Agreement, the national industry may collapse and drug prices will rise depriving still more people from regular access to essential drugs.

2. THE TRIPS AGREEMENT AND PUBLIC HEALTH

Patent protection covers the entire spectrum of innovations. However this paper will focus only on the patent system for pharmaceutical and healthcare inventions.

Several studies based on critical analysis of empirical data have reported on the negative impact of strong pharmaceutical protection on public health particularly on prices of and access to essential medicines.

Today, as signatories to the TRIPS Agreement, developing countries have to implement national systems of intellectual property rights following an agreed set of minimum standards. This includes 20 years product and process patent protection. The LDCs have an extra 11 years to do so.

Of the 15 countries listed in Table 1, all are members of WTO except Bhutan, Cambodia, Lao PDR and Nepal, which are observers. Bhutan is an observer country that had not applied to join the WTO as of April 2001. (10).

Price increases will also depend on the type of market before the implementation of TRIPS. In countries with generic manufacture and a very competitive market, the emergence of a monopoly market with implementation of the TRIPS agreement will cause a steep rise in drug prices. On the other hand in countries without generic manufacture and a competitive market, the price increases will not be as high.

2.1 Impact of Patents on Drug Prices

According to a World Bank economist the minimum welfare loss to a sample of developing countries (Argentina, Brazil, India, Mexico, Korea and Taiwan) would amount to a minimum of US$ 3.5 billion and a maximum of US$ 10.8 billion, while the gains to foreign patent owners would be between US $2.1 billion and US 14.4 billion (11).

A “national health disaster” has been anticipated by the Indian Drug Manufactures Association (IDMA) as a result of the implementation of the TRIPS Agreement in the country, where only 30 percent of the population can afford modern medicines in spite of the fact that drug prices in India are one of the lowest in the world. Comparison of prices of drugs between India and countries where patent protection exists indicate that in some cases they are up to 41 times costlier in countries with patent protection (12).

A study by an IMF economist reported that drug prices in Malaysia, where patents protection existed, were from 20 to 760 percent higher than in India, which reflected a profit maximizing behavior on "what the market" can bear (13).

Further studies by the same author looked at the likely impact of pharmaceutical product patents in small and large countries, in cases where either a perfectly competitive market or a duopolistic market becomes a monopoly under patents. Welfare and price effects were found to be negative for a number of Asian countries. Price increases estimated for patented drugs ranged from five to 67 percent. Annual welfare losses for India ranged between USD 162 million on USD 1,261 million and annual profit transfer to foreign firms between USD 101 million and USD 839 million (14, 15).

Price increases of drugs resulting from the introduction of product patents in Egypt were estimated at five to six folds as compared to non-patented products (16).

A study conducted in Argentina estimated that the introduction of pharmaceutical product patents in the country would imply on annual additional expenditure of USD 194 million with a reduction of 45.5 percent in the consumption of medicines as a result of a price increase of around 270 percent (17).

The January 1999 issue of the SCRIP Magazine carried an article, "Quotable Quotes", where the author highlights important quotes of 1998 related to pharmaceuticals. One of them was attributed to Health Action International (HAI). The quote was, *"Retail drug prices resemble the law of the jungle where right is might"*. This was based on an analysis of empirical data on retail prices of selected essential drugs in a number of countries (18). Table 5 gives the retail prices of 100 tablets of Zantac (generic ranitidine) manufactured and marketed by the same manufacturer and varies from two dollars in India to 183 dollars in Mongolia, a least developed county.

Bangladesh, India and Nepal did not provide product patents. Their prices are the lowest. Australia and New Zealand, the two developed countries regulate and control drug prices. In the other countries there is price discrimination and profit maximization. Prices are determined by what the markets can bear.

Table 3 The retail prices in USD of 100 tablets of 150 mg Zantac (Zinetac in India) in two developed and 12 developing countries in the Asia-Pacific region. Minimum daily wage and per capita GNP in USD are also given.

	Australia	New Zealand	Bangladesh	India	Indonesia	Malaysia	Mongolia	Nepal	Pakistan	Philippines	Sri Lanka	Thailand	Vietnam
Minimum daily wage USD	46	32	2.1	1.3	0.5	n.a	0.8	1.6	2.2	5.0	1.4	2.9	n.a
GNP per Capita USD	18,720	14,340	240	340	980	3890	310	200	460	1050	700	2740	240
100 Zantac tablets 150 mg USD	23	21	9	2	41	55	183	3	22	63	61	37	30

Source K Bala, Dr Oscar Lanza, Shila Rani Kaur, “Retail Drug Prices : The Law of the Jungle” HAI News Number 100, April 1998

2.2 Initiatives by WHO

At a meeting held in Bangkok, Thailand in February 2001, WHO initiated a process to monitor and analyze the impact of multilateral trade agreements on access to drugs in partnership with four WHO collaborating centers in Brazil, Spain, Thailand and the United Kingdom (19). The meeting was in response to the mandate the World Health Assembly gave to WHO in its Resolution WHA 52.19 on the Revised Drug Strategy in May 1999.

The main emphasis of the meeting was to develop a framework of operations for a nascent Network for Monitoring the Impact of Globalization and TRIPS on access to medicines. The meeting established that the network through the individual and collective work of the four collaborating centers would undertake research and shed light on four questions:

- How is patenting affecting drug pricing?
- How are patents and enhanced intellectual property protections affecting the rate of introduction of generic drugs?
- Are TRIPS and expanded intellectual property protections spurring development of drugs for neglected diseases?
- Are TRIPS and expanded intellectual property protections contributing to an increase or decrease in the transfer of technology and direct foreign investment in developing countries?

Developing countries and NGOs will be eagerly waiting for answers to these questions. Critical analysis of all answers to these four questions will hopefully provide adequate justification for a review and revision of the TRIPS Agreement. Dr Supachai Paritchpakdi, the Director–General Designate, World Trade Organization, in his opening address at this meeting stated, among others, “There are a large number of countries around the world who think that we must review the TRIPS Agreement.

2.3 Implementing the TRIPS Agreement and Policy Goals

TRIPS’s minimum standards for intellectual property should be reflected in national legislation. But there is good scope for appropriate national strategies within the multilateral framework. The impact of TRIPS will therefore depend on how individual countries choose the strategies best suited to their technological, commercial and economic development and thereby achieve the country’s policy goals.

The major policy goal in the pharmaceutical sector is to ensure regular access to a selected number of essential drugs to meet the real health needs of all the people.

There are two possible options to ensure regular access:

a. National production by:
   - State – owned firms;
   - National private sector
   - Subsidiaries of foreign companies; and
   - Joint ventures.

b. Imports

These two options are not mutually exclusive. A country's stage of technological development will determine the options. India is the only country in the region, which is self-reliant and can meet the total requirements with national production. The smaller LDCs - Bhutan, Cambodia, Lao PDR and Maldives may have to import their total requirements. All other countries will use both options.

Having selected the policy options, a country needs to create appropriate legal structures and provisions and design administrative measures required to implement the legal provisions taking into account TRIPS's obligations and the clarifications provided in the Doha Declaration.

2.4 Problems and Prospects

The technical assistance given by WIPO and WTO to developing countries with respect to creating national legislation on intellectual property seems to be more concerned with how to comply with the TRIPS Agreement than how to best make use of the safeguards provided in TRIPS and choose the most appropriate strategies within the multilateral framework.

TRIPS like all other WTO agreements is an agreement on a legal framework. Its implications will be decided by resolving disputes. That makes case law and the power of the parties involved of great importance. A single set of minimum rules may seem to create a level playing field, since one set of rules applies to all. But the game is hardly fair when the players are of such unequal strength economically and institutionally. The following data on developing countries will be relevant (20, 21).

a. Demographic patterns; Out of 130 developing countries

- Thirteen countries have populations less than 100,000 each;
- Twenty-nine countries have less than 500,000 each; and
- In 65 countries (or 50 percent) the population is less than five million each.

b. Gross Domestic Product (GDP); Out of 114 developing countries;

- Ten countries have GDPs less than 500 million each;
- Thirty countries have GDPs less than one billion each; and
- Seventy-five countries (or two thirds) have GDPs less than 10 billion each.

c. Science, Technology and R & D

The number of scientist and engineers in research and development (R&D) per million population:

High income countries	3,166
Middle income countries	668
East Asia and the Pacific	492
South Asia	137

The US spends about one billion dollars to maintain its patent office. Even this office had granted patents, which turned out to be faulty and had to be withdrawn. (22).

From the data presented above, it is clear that for a large number of developing countries, enacting, implementing and enforcing an efficient and effective intellectual property regime will put stress and strain on the very limited resources and administrative skills available in them. Moreover, the very high costs of disputes with the world's leading nations, are frightening, discouraging these countries from asserting their rights.

Very few developing countries have enacted appropriate national legislation including the safeguards provided in the TRIPS agreement. There is at preset, very little or no empirical evidence available on the effects of such legislative changes.

Many industrial countries include compulsory licensing and parallel importing in their law and practice as part of their national strategy for using intellectual property rights for achieving their policy goals. Yet under intense pressure from some leading countries to introduce legislation beyond that required by TRIPS, many developing countries have legislated themselves into a disadvantaged position. Since the adoption of the TRIPS Agreement, Canada, Japan, the UK and US have used compulsory licenses for pharmaceuticals. In contrast not one compulsory license has been issued south of the equator. (23)

What South and South East Asia and other developing countries need are alternative legislative models that will avoid emphasis on litigation and create provisions suited to the needs of developing countries.

The Human Development Report 2001 recommends the following in order to create a legal structure to include compulsory licensing suited to developing countries.

- Administrative approach
  The best option is an administrative approach that can be streamlined and procedural. Avoid overly legalistic expensive to administer systems;

- Strong government use provisions
  The TRIPS Agreement gives governments broad powers to authorize the use of patents for public, non-commercial use and this authorization can be fast – tracked without usual negotiations. No developing country should have public use provisions weaker than German, Irish, UK or US law on such practice.

- Allow production for export
  Legislation should permit production for export when lack of competition in a class of drugs has given the producer global market power that impedes access for alternative drugs or when the legitimate interests of the patent owner are protected in the export market – when that market provides reasonable compensation.

- Reliable rates on compensation
  Compensation needs to be predictable and easy to administer; royalty guidelines reduce uncertainty and speed decisions. Germany has used rates from 2 to 10 percent; in Canada, the government used to pay royalties of 4 percent.

  Developing countries could award an extra 1 – 2 percent for products of good therapeutic value and 1 – 2 percent less when R & D has been partly covered by public funds.

- Dispute demands disclosure
  The onus should be on the patent holder to back up claims that the royalty is inadequate. This will promote transparency and discourage intimidating but unjust claims.

At the Third World Network (TWN) – TRIPS and Public Health Workshop in Geneva 29 – 30 March 2002, a draft discussion paper on issues in formulating appropriate national legal provisions and procedures on patents and public health was presented.

The following is a suggested model provision for parallel imports:

It shall not be an infringement of a patent to import, offer for sale, sell or use

(a) any patented product, or
(b) any product obtained directly by means of the patented process or to which the patented process has been applied,

which has been put on the market in any country outside of …….… (name of country), by the patent holder, or with his consent or by another party authorized by a compulsory license given on grounds to correct anticompetitive practice.

2.5 TRIPS and Traditional Medicine

According to the WHO, traditional medicine is believed to serve the healthcare needs of about 80 percent of the world's population. The goal of Health for All (whenever that becomes a reality) cannot be achieved without traditional medicine (24, 25). It is important to study the impact of TRIPS Agreement on traditional medicines, medical practices and conservation of biological diversity.

Genetic resources, traditional and community knowledge, and expressions of folk-lore (folk-medicine) have gained economic value almost as much as patented inventions based on high technology research and development.

The framework for international intellectual property rights in the TRIPS agreement has been developed to meet the needs of inventors engaged in high technology R & D. But the keepers of genetic resources, traditional and community knowledge and expressions of folklore have entirely different ways of owning and transferring them. But the same framework for intellectual property rights used for modern inventions are being applied to traditional and community knowledge and genetic resources and these are easily patentable, become private protected property and enrich the new owners who have actually "pirated"

them using a legal framework quite irrelevant to what have been “pirated”. Well-known examples are the claims on the healing properties of the neem tree and turmeric.

The world needs an entirely different framework to meet the needs of billions of people in the developing countries who have been the keepers of genetic resources, traditional and community knowledge.

The World Intellectual Property Organization (WIPO), based on case studies, fact finding missions and Roundtables on Intellectual Property and Traditional Knowledge, has identified the needs of traditional healers who have been the keepers of all their valuable knowledge and passed it to succeeding generations. (26).

The needs include the following:

- The prevention of the acquisition of intellectual property rights over traditional medicine by its documenting and publication as searchable prior art;

- A re-assessment of what constitutes prior art for purposes of patent examinations;

- The testing of options for the collective management of intellectual property rights by traditional healers associations;

- A study of customary laws which protect traditional medicine in local and traditional communities;

- Testing the applicability of the present intellectual property system for the protection of traditional medicine;

- Facilitating access to intellectual property system for traditional medical practitioners;

- Legal and technical assistance with the documentation of traditional medicine; and

- Awareness raising as to the role of intellectual property protection in relation to traditional medicine.

Recognizing that it is essential to discuss these issues at intergovernmental level, the Member States of WIPO established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Central to the Committee work will be better understanding and managing the relationship between intellectual property and the conservation, use and sharing of benefits from genetic resources, traditional knowledge and folklore. The goal will be to develop internationally acceptable intellectual property standards for regulating access to and sharing the benefits of genetic resources and for protecting traditional knowledge and expressions of folklore. The challenge is to ensure that the international intellectual property system becomes equally relevant to and adequate for all communities.

3. TRIPS AND THE DOMESTIC INDUSTRY

Pharmaceutical technology, and production can be grouped into four stages.

i. Research and development

ii. Production of chemical intermediates from basic chemicals

iii. Production of raw materials (or bulk drugs) from;

   a. Chemical intermediates;
   b. Fermentation; and
   c. Plant sources

iv. Formulation of dosage forms (or finished products) from imported raw materials (or bulk drugs).

Comprehensive research and development to discover and develop new drugs (new chemical entities – NCEs) require human, technological and financial resources, which at present, are available in only 10 advanced industrialized countries.

Production of chemical intermediates from basic chemicals require innovative capabilities. There are only six developing and 12 industrial countries that have such innovative capabilities.

The United Nations Industrial Organization (UNIDO) has classified countries into five groups based on the degree of development of pharmaceutical technology and industrial production. (27).

Table 6 gives a typology of the pharmaceutical industries in South and South East Asia based on UNIDO's classification.

Table 4 – A typology of pharmaceutical industries in South and South – East Asia

Stage of Development	Country
1. Sophisticated vertically integrated pharmaceutical industry with a significant research base	NIL
2. Possessing innovative capabilities. Ability to copy new chemical entities by a process of reverse engineering	India
2. Ability to produce therapeutic ingredients / raw materials from: • Chemical intermediates, • Fermentation and • Plant sources	Bangladesh, Indonesia, Pakistan, Philippines, Thailand
3. Formulating dosage forms from imported raw materials	Malaysia, Myanmar, Nepal, Sri Lanka, Vietnam
4. No pharmaceutical industry	Bhutan, Cambodia, Lao PDR, Maldives

Table 5 gives the pharmaceutical production, consumption, imports and exports in 11 countries in the region. The data is old but has been included to facilitate in assessing the impact of TRIPS Agreement on the domestic industry.

Table 5 – Pharmaceutical production consumption, imports and exports in 11 countries in South and South – East Asia.

	Production as percentage of world total		Consumption per capita USD	Percentage share of					
				Production to consumption		Imports to consumption		Exports production	
	1975	1990	1990	1975	1989	1975	1989	1975	1989
Bangladesh	0.1	0.07	1.1	89.9	83.8	10.4	16.3	0.3	0.2
Bhutan	-	-	1.6	-	-	100	100	-	-
India	0.93	1.29	2.2	96.9	104.3	6.5	5.4	3.5	9.4
Indonesia	0.36	0.46	3.9	94.6	98.8	5.8	2.0	0.4	0.9
Malaysia	0.02	0.04	7.8	27.5	49.5	87.5	62.5	54.4	24.2
Maldives	-	0	2.0	-	-	100	100	-	-
Myanmar	0.02	0.01	0.3	77.5	60.5	23.7	39.7	0	0.4
Pakistan	0.14	0.33	5.1	80.9	79.1	20.5	21.6	1.8	0.9
Philippines	0.39	0.29	7.7	98.5	89.7	1.6	11.3	-	1.2
Sri Lanka	-	-	1.8	25.8	16.7	74.4	84.1	0.8	4.5
Thailand	0.24	0.21	6.6	71.7	87.6	29.0	14.3	1.0	2.1
Total	2.2	2.7							

Source: UNIDO – The Worlds Pharmaceutical Industries; An International Perspective on Innovation, Competition and Policy by Robert Balance, James Pogany and Helmet Forsteiner, 1992

Table 5 correlates well with table 4. In 1989, Bangladesh, India, Indonesia, Pakistan, Philippines and Thailand had manufacturing capacity to meet over 80 percent of their requirements. Myanmar produced 60 percent and Malaysia 50 percent of their consumption. It needs to be noted that only India has an industry with innovative capability to be self-

sufficient. All other countries depend on imports of chemical intermediates and raw materials from the world market.

Before assessing the likely impact of TRIPS implementation on the domestic industry, it will be useful to understand how the industry developed in the region.

All the countries in table 1 except Thailand, Nepal and Bhutan were colonies of Western European countries and the US. After World war two they became independent and became members of the UN and its agencies.

In the 1950s and 1960s there was hardly any national pharmaceutical industry in the region. India with a large population of poor people had some of the highest drug prices in the world (28).

During the 1960s and 1970s developing countries began to ask questions about the international standards of intellectual property that had emerged in the previous decades. Several studies were published which conclusively showed that the then existing international norms and national legislation on patents had an adverse impact on the commercial, economic and technological development of the pharmaceutical sector in developing countries (29, 30, 31, 32). The government of India set up two committees to conduct a review of the Indian Patent System. They concluded that the Indian patent system had failed, " to stimulate inventions among Indians and to encourage the development and exploitation of new inventions" (33).

Developing countries began to react. Over a decade of negotiations took place in UNCTAD. These negotiations resulted in a strong and precise recommendation to revise the Paris Convention. Such a revision should meet the special needs of the developing countries.

Developing countries used the provision in the Paris Convention to enact national legislation on patents as policy instruments to strengthen the technological, commercial and economic development of the pharmaceutical sector (34). The provisions in the national legislations included the following:

- Areas of Patentability: Pharmaceuticals products were excluded from patent protection;

- Duration of patents: Process patents were granted from 7 – 10 years

- Working of patents: The title-holder was obliged to work the patent. This means that the product should be manufactured in the country, which provides patent protection. Imports of finished products do not qualify as working of the patent, and

- Compulsory licensing

India passed its Patent Law in 1970 following the German system of allowing process patents but not product patents. Protection was granted for seven years. This law became the foundation for a highly successful generic industry. A country with some of the highest drug prices became, within about two decades, a country with the lowest drug prices. This was a direct result of the Indian Patent Law.

It was not only developing countries, which refused to grant patent protection. Many of today's advanced economies refused to grant patents throughout the 19th and first of the 20th centuries, or found legal and illegal ways of circumventing them. They formalized and enforced intellectual property rights gradually as they shifted from being net users of intellectual property to being net producers. Several European countries including France, Germany and Switzerland completed what is now standard protection only in the 1960s and 1970s (35).

During the 1970s Brazil, Argentina, Mexico and the Andean pact countries introduced laws with weaker patent protection in the pharmaceutical sector. A study undertaken by WIPO in 1988 for the negotiating group that was dealing with TRIPs in the Uruguay Round revealed that of the 98 Members of the Paris Convention, 49 excluded pharmaceutical products from protection (36).

Developing countries and generic manufacturers became a threat to the western pharmaceutical cartels that had dominated the international pharmaceutical industry.

Following the recommendations by UNCTAD for a revision of the Paris Convention, the revision began in 1980. The fiercest debates took place over revision of compulsory licensing of patented technology (37). Attempts to revise the Paris Convention broke down and the revision was never completed. Intellectual Property Rights negotiation was taken to the GATT in which the US was the single most important player.

The TRIPs Agreement has removed the provisions in the national legislation which enabled the growth and development of the pharmaceutical industry in developing and the now developed countries. These provisions are: non-patentable subject matter, duration of patent protection, definition of working of patents, importation and working of patents, and remedies against non-working of patents.

The environment under which the pharmaceutical industry in developing countries grew is no more available. The TRIPs Agreement imposes on developing countries a patent law, which serves as a tool of regulatory policy and not a policy instrument for strengthening the pharmaceutical industry.

Provisions for compulsory licensing and parallel importing will improve access to drugs but not enable the strengthening of the pharmaceutical industry in developing countries.

4. DOHA DECLARATION AND PUBLIC HEALTH

For the first time, we have in the Doha Declaration a Ministerial acceptance of negative impacts of the TRIPS Agreement on public health in developing countries when the Ministers expressed concerns about its effect on prices. Paragraph 4 states, *inter alia* TRIPs Agreement should not prevent members from taking measures to protect public health. This statement enables Members to use to the full the two provisions – Compulsory Licensing and Parallel Imports, allowed in the agreement.

Paragraph 5 gives clarifications which public health groups have been campaigning for. The task before developing countries is to turn these provisions into feasible public policy options. This will require a legal structure suited to developing countries. In view of the very limited resources available in the majority of developing countries, a model legislation

prepared by experts would serve as a guideline to formulate national legal provisions and procedures on patent and public health. At a recent conference in Geneva, a WIPO spokesperson told the participants that WIPO would not prepare a model legislation on intellectual property system since countries had different legal systems. WIPO provides technical assistance on request to individual member states (38).

Some NGOs have already begun exploring possibilities of developing a model legislation (39). A draft legal structure on compulsory licensing proposed in the Human Development Report quoted earlier in this paper is a useful guide.

A model provision for parallel imports proposed by the Third World Network's TRIPS and Public Health workshop has also been quoted earlier in this paper.

Article 31(f) limits the use of compulsory licensing by developing countries. Very few, not more than 10 developing countries at most, can use compulsory licensing and copy patented products. The restriction imposed by Article 31(f) that the licensee must, " predominantly" supply the local market limits the capacity of members to use this provision. The smaller importing members are limited to the source of products. The few exporting countries are limited in their capacity to establish economies of scale.

It seems to be a difficult task to interpret Article 31(f) in a manner that addresses the problems faced by developing countries. Perhaps one way of solving the problem is to propose amending the TRIPS Agreement to delete 31(f). This would permit compulsory licensing predominantly for export and eliminate the most serious obstacle to manufacture and trade in public health related products. In view of the time constraints, a waiver of Article 31(f) might be adopted pending conclusion of amendment of the TRIPS Agreement.

Compulsory licensing and parallel imports are measures to improve access to essential drugs. But these are not permanent sustainable solutions completely under the control of individual countries. Strengthening the technological, economic and commercial development of the pharmaceutical sector will enable developing countries to build and strengthen their pharmaceutical manufacturing capacities. This is the only way to ensure a truly competitive market for pharmaceuticals. The smaller developing countries, about 60 of them, do not have the resources to set up domestic pharmaceutical industry or to set up an efficient intellectual property office to enact and implement an intellectual property regime to make use of compulsory licensing and parallel importing.

The TRIPS Agreement prevents developing countries from enacting national legislation, which can be policy instruments in developing and strengthening their pharmaceutical industry.

In this respect the Doha Declaration only provides clarification of provisions in the TRIPS Agreement but does not address some of the problems developing countries face. These include:

i. Faulty patent granting systems, which do not meet patentable criteria such as novelty,
inventive step, prior art, etc.

ii. The inadequate capacity level in developing countries to ensure the application of patent criteria and examination of patent applications. Some patent applications disclose their innovations with great obscurity, stretching patent officers capacity to judge and the ability of other researchers to understand. It has been reported that in 2000, WIPO received 30 patent applications over 1000 pages long with several reaching 140,000 pages (40).

iii. Very few developing countries have the necessary resources and capacities to set up and operate a patent office to provide an optimum service. Most that they can do is to function as service providers – accept the patent applications, file them and grant 20 years product and process patents.

These are issues that our negotiators may wish to take into consideration in calling for review of the TRIPS Agreement. In his opening address, the WHO Meeting on TRIPS Agreement in Bangkok, Thailand, February 2001. Dr. Supachai Panitchpakdi, clearly preferred that the review of the TRIPS Agreement commence before the launch of the next Round saying, *"So we are looking at implementation and I am sure that before the next Round, which I will call the Development Round, we would have some sort of agreement to look into some of the requirements of TRIPS. I am sure that there will be also some review of the requirements connected to patent rights and the protection of patent rights that must have some bearing on certain kinds of essential drugs"*. He had also stated, *"I would like to put a human face on the WTO, which has always been called a rich man's club. I have to change that."*(41)

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