The Future Impact of the TRIPs Agreement on the Pharmaceutical Industry
How Can Developing Countries Deal With it?

Amal Nagah El-Beshbishi(*)

ملخص

الانعكاسات المستقبليه لاتفاقيه التريبس على صناعه الأدويه
كيف تتعامل الدول النامية معها؟

أسفرت جولة أوروجواى عن عدد من الاتفاقيات من بينها اتفاقية هامة أثارت العديد من التساؤلات والتعليقات والانتقادات، هي اتفاقية اوجه حقوق الملكية الفكرية المرتبطة بالتجارة المعروفة باسم TRIPs.

ولقد حظي الدواء في اتفاقية التريبس باهتمام كبير وحدث حوله جدل أكبر طوال السنوات الماضية وذلك للأسباب العديدة التي تخص الدواء من حيث إنه سلعة حساسة يحتاجها الإنسان وهو في أضعف حالاته الصحية والنفسية والاجتماعية وقد تكون الاقتصادية.

ولقد قامت هذه الدراسة باستعراض الحجج المؤيدة لهذه الاتفاقية ومنها أن نظام حماية حقوق الملكية الفكرية يسمح بدعم النشاط العلمي والتكنولوجي، واستقطاب رؤوس الأموال من خلال تهيئة الظروف المواتية للبحث والتطوير، والحجج المعارضة لها ومنها أنها تؤدى إلى ارتفاع تكلفة نقل التكنولوجيا من الدول المتقدمة إلى الدول النامية، وصولاً للتوصيات التي من شأنها حماية مصالح الدول النامية ومن أهمها فرض نظام الترخيص الإجبار إزاء تعسف صاحب براءة الاختراع في تسلم الحقوق المكفولة له أو حال ممارسته لإجراءات غير تنافسية وإنشاء مركز معلومات دولي يرتبط بمراكز المعلومات العالمية، وكذلك إحياء اتفاقية السوق العربية المشتركة كي يمكن الاستفادة من نظام الوزارات الموازية، كما هو الحال في دول الاتحاد الأوربي إلى جانب إعمال نظام الجودة الشاملة ISO 9000 وما يتضمنه من تأكيد الجودة بالنسبة للأدوية.

(*) Department of Economics, College of Commerce, Mansoura University-Egypt

The purpose of this paper is to discuss the future impact of the TRIPs Agreement (Agreement on Trade- Related Aspects of Intellectual Property Rights) on the pharmaceutical industry and how can developing countries especially Egypt deal with it. Section A of the paper presents an introduction, a background about the Uruguay Round and the TRIPs Agreement, the international pharmaceutical market and the situation in Egypt. Section B discusses the arguments for and against the TRIPs agreement. The final section presents the policy recommendations for developing countries.

I. Introduction and Background:

This paper discusses the future impact of the TRIPs Agreement on the pharmaceutical industry in developing countries, and the access of the population of these countries to essential drugs at a reasonable price[1] to come out with what can be recommended to protect such countries in general and Egypt more specifically.

A.1. The Uruguay Round and the TRIPs Agreement:

In 1994, the Uruguay Round negotiations culminated in the signature of an agreement instituting the World Trade Organization (WTO). The Organization came into being on 1 January 1995. In deciding to become members of the WTO, countries undertake to abide by its rules. A certain number of treaties on trade in goods and services are annexed to the WTO convention and are therefore binding on all members. Among these "multilateral" agreements, the TRIPs Agreement will undoubtedly have the most impact on the pharmaceutical industry.

The TRIPs Agreement establishes minimum standards in the field of intellectual property. All member countries have to comply with these standards by modifying their national regulations to accord with the rules of the agreement. The main change with respect to pharmaceuticals is the obligation to grant patent protection[2] to pharmaceutical product and process inventions.

A.1.1. The TRIPs Agreement and Patents on Drugs:

Previously, the question of intellectual property was not really addressed by the General Agreement on Tariffs and Trade (GATT)[3] and countries had adopted various approaches towards drug patents[4]. While some used to grant patents for pharmaceutical product and process inventions, others allowed patent protection only for process inventions. The objective of the latter was to make it possible for companies with limited financial resources to develop new processes for the same active principle as an original drug but more cheaply. Other countries did not grant any form of protection for inventions in the pharmaceutical sector. Moreover, the term of protection conferred by a patent varied greatly between countries.

Under the TRIPs Agreement, member countries have to grant patents for a minimum of 20 years[5], to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness. As soon as the agreement comes into force in a member country, unauthorized copies of patented drugs are prohibited, and countries that break this rule will incur trade sanctions authorized by the WTO.

A.1.2. When Must the Agreement's Rules be Applied?

The TRIPs Agreement allows developing countries a period up to 2005 to amend their patent legislation relating to drugs in accordance with these new rules. Least developed countries are given up to 2006, with a possible extension, to harmonize their regulations with the new international obligations[6]. Hence, the agreement will apply only to new drugs for which a patent application has been made after the entry into force of the WTO agreement.

We should note here that the WTO council responsible for intellectual property, on 27 June 2002, approved a decision extending until 2016 the transition period during which least- developed countries (LDCs) do not have to provide patent protection for pharmaceuticals. It also approved a waiver for LDCs on exclusive marketing rights for any new drugs in the period when they do not provide patent protection.

A.2. The International Pharmaceutical Market and the Situation in Egypt:

A.2.1. The International Pharmaceutical Market:

Today's international pharmaceutical market is comprised of three sectors:

Non- prescription medications; generic prescription drugs; and patented prescription drugs. Of these, the market for patented prescription drugs is the most important economically. This market is dominated by large western conglomerates, which are also responsible for the development of new therapies.

Over the last few years, there have been many mergers between these giant pharmaceutical manufacturers, which have enabled them to reduce costs by eliminating duplication in research, and by jointly marketing their products internationally.

Another fast- growing sector of the international pharmaceutical industry is that of generic medications. Generic medications are copies of brand- name drugs whose particular patents have expired (the trademarks themselves are protected indefinitely). Generic medications began to be developed in industrialized countries in the 1970s as the most profitable patented medications were released into the public domain and manufacturers of generics began a price war amongst themselves and against developers whose drugs were in the public domain. In countries like the US, there are strong incentives to replace patented medications with generics (high prices for patented medications and laws favoring competition) as soon as their patents expire. Generic drugs currently make up half the pharmaceuticals market.

The pharmaceutical industry in the developing countries has also evolved considerably. Often motivated by the industrial politics of the 1950s, many countries began to create national pharmaceutical industries to replace imports as well as to guarantee themselves autonomy in a domain considered strategic, or at the least, symbolic; to reduce expenditures in foreign currencies

by limiting imports of materials, and to supply the country's needs at the lowest prices for social and public health reasons. Essentially, existing medications were produced locally replacing foreign imports. And though certain countries, such as Morocco and Brazil, have opened their doors to the multinationals, others like India and Egypt have preferred to support locally financed enterprises and like most other countries have expressly excluded medications from their national patent legislation (Egypt, India, South Korea, ... etc.)

At first glance, it might seem that because of reduced production costs (most significantly, labor costs) it should be possible to produce medication cheaply in developing countries. However, it is not so simple in countries without industrial or environmental expertise, and it is also difficult for countries that have limited internal markets (those with small and/ or impoverished populations), which cannot benefit from the economies of scale larger countries and multinational companies enjoy.

In addition, developing countries have been compelled to protect their local industry against imports (in particular, to avoid the "dumping" campaigns of the western pharmaceutical laboratories), at least initially. This protection has many side benefits: it supports local producers, keeps the cost to the local consumer down, benefits the local job market, and the currency market, and develops competitiveness in local industry. Such protection can take many forms: import taxes, discounts on prices, or greater ease of registration for medications produced locally, a ban on imports... etc.

Beginning in the 1970s and continuing through the 1990s, the world has seen certain developing countries (such as India) not only refine their manufacturing capacities to enable them to produce more and more sophisticated medications but also conducting their own research. This research often consists of refining a new production process for medications, which are still under patent (reverse engineering) to benefit from international pharmaceutical innovations without paying fees to the companies concerned. Multinationals have accused countries that do not recognize pharmaceutical patents of supporting piracy and counterfeiting.

A.2.2. The Situation in Egypt:

The Arab Republic of Egypt became a contracting party of the original GATT on 9 May 1970 and acceded to membership in the existing WTO effective 30 June 1995[7]. Members of the WTO are bound by treaty obligations to observe the GATT'94/ WTO rules governing international trade in global markets to the extent that, as "developing nations" or "least developed nations", they are eligible for "special or differential treatment" under which they are permitted a longer period of time within which to phase in the implementation of such obligations or, in the case of least developed nations, are exempted entirely from most such obligations while they remain in that category.

Egypt is among a small number of developing countries availing itself to the full transition period for product patent until 1 January 2005 provided in the WTO/ TRIPs Agreement.

Despite the grace period, US multinationals have been pushing Egypt and other developing countries to pass patent legislation sooner, that's why Egypt adopted a new law which is Law 82 in 2002 that replaced Law 132 for the year 1949[8]. Despite these changes, US multinationals successfully lobbied to put the country on the American government's "Priority Watch List"- implying the threat of trade sanctions[9].

TRIPs is highly controversial in Egypt[10]. The Egyptian government has agreed to accept it as an inseparable part of the wider, multilateral GATT trade deal in the belief that staying out would be against the interests of the Egyptian economy as a whole.

The TRIPs Agreement will not have the same influence on all pharmaceutical sectors in Egypt. For example, it is estimated that the multinationals and the joint ventures are those companies that will not be influenced by the agreement since required technologies and researches are provided from their mother companies abroad. In other words, their production costs will not be affected. However, private companies will have to spend more on pharmaceutical research and technology in order to be able to

compete with multinationals and joint ventures. They will have to develop their productive capacity through foreign technology and researches. Companies that belong to the public sector will be exposed to tremendous loss since they will neither get the required technology of R&D nor be able to compete with any of the other sectors.

Thus, in general national companies fear that patent protection will confer a monopoly onto multinationals and result in price explosion. They further maintain that a strong patent act will only benefit international research based companies to the disadvantage of the local pharmaceutical companies.

From the discussion above we can conclude that Egypt under the TRIPs Agreement has an international obligation to bring in legislation giving patent protection to pharmaceutical products and processes and that's what happened exactly in Law 82 for the year 2002 which is compatible with the Doha WTO Ministerial Declaration concerning the TRIPs Agreement and Public Health adopted on November 2001.

For the government, the original purpose of reducing patent protection for pharmaceuticals (through compulsory licensing according to articles 25 and 26 of this new law) was to shield national companies [11] from powerful multinational competitors with what would otherwise have been exclusive patent- protected new drugs. This was thought to encourage the development of the national pharmaceutical industry by opening the door to legalized copying of drugs. Out of this will emerge a strengthened national industry, which will develop export business and, as a result of growing sales and profits, should eventually turn to original research.

II. The Arguments for and against the TRIPs Agreement:

The issues surrounding protection of intellectual property are a double-edged sword. Such protections contribute to world welfare by creating market incentives to reward those who generate new knowledge. The rewards are provided through the granting of monopoly power to the owners of knowledge, enabling them to charge prices above costs for the goods and services containing that knowledge. If such monopoly power were not

granted, the incentives for discovery would be smaller, the volume of resources devoted to research and development would be smaller, and the rate of growth in world knowledge would be slower.

On the other hand, monopoly power is typically granted to owners of knowledge for a long period of time during which competitors are significantly restricted. The market, for knowledge goods and services are distorted, with smaller volumes being produced for consumers and prices are higher. Fewer competitors at the point of market entry provide less competition in the discovery of small innovations and improvements. These factors lessen world welfare(12).

While there is nothing in the TRIPs Agreement that is biased against the developing countries (firms in all countries are eligible for equal protection in all countries), it is true that currently the preponderance of marketable intellectual property is owned by firms in the developed countries. Once the provisions of the TRIPs Agreement have been implemented in all member countries, it will be the owners of existing intellectual property who will be the major beneficiaries. At this point the benefits of the TRIPs Agreement will be skewed decidedly in favor of the firms in developed countries.

The developing countries will be disadvantaged in a number of ways. Firms in developing countries that wish to produce and sell products covered by patents will be forced into a licensing agreement, which, in all likelihood, will involve royalty payments to the owners of the patent. Consumers will be charged higher prices. In some cases, the foreign owner of the patent will choose to serve the markets of developing countries through exports rather than local production; employment opportunities will be lost and the foreign exchange cost of imports will rise. Similar consequences would apply in the case of local firms producing counterfeit goods in violation of trademark provisions. Finally, the developing countries will also be burdened with the costs of legislating laws for the protection of intellectual property and the administrative costs of enforcing those laws.

The following discussion will shed some lights on these points.

B.1. The Arguments for TRIPS:

The arguments for TRIPs can be summarized as follows:

- Strong intellectual property protection not only benefits research- based pharmaceutical companies and the patients they serve. It also helps developing countries by improving the conditions for investment, encouraging the development of local industry, creating jobs, transferring technology, and enabling more goods to be produced [13]. If such a regime is not in place, investors will shy away from investing, research and licensing in developing countries. Why would multinational corporations risk giving their license before there is an improvement in the regulatory and legal framework that encourages innovation and protects proprietary data and products?
- Multinationals would like to see the immediate adoption of patents instead of benefiting from the grace period. They argue that the development of new and improved compounds is not only becoming more costly, but also more difficult. Multinationals argue that high profits are the reward for success in the risky business of pharmaceutical research and development. Abraham Lincoln for example said that patents add "the fuel of interest to the fire of genius".
- Innovative drugs often originate in countries where prices are free, such as the US. Industry sets the price, not on the basis of cost (research and production) to which is added a profit margin, but at a far higher level: that which the (American) market can bear. A whole economic calculation methodology (pharmacoeconomics) has been developed in the last 10 years to deal with this: if, for example, a drug permits savings on hospital costs, it can be sold at a far higher price. If it prolongs the life of Aids patients, there will be almost no limit on its monetary value.
- When the patent expires, the fall in the price of drugs is spectacular, as the generic drugs market is highly competitive.

- In article 66.2 of the TRIPs Agreement, it is obligatory on the developed countries to 'provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least- developed country members in order to enable them to create a sound and viable technological base'.
- Due to fear of piracy and low product prices in developing countries, most multinational companies are reluctant to introduce their top- of- the- line products in these places. Therefore, patients in these countries compulsorily lose out on better treatment options.
- The majority of the multinational companies conduct research on those diseases that affect the population in developed nations while tropical diseases get low priority.
- Strengthened patent protection is expected to encourage foreign direct investment in developing countries. An environment hospitable to foreign innovative technology sets in motion a range of other dynamics such as licensing, co- marketing and joint ventures, generating multiplier effects that benefit local drug manufacturers. Moreover, intellectual property protection is critical to finding solutions to current challenges to world health.

B.2. The Arguments against TRIPS[14]:

The arguments against TRIPs can be summarized as follows:

- A major issue of concern is the incentives for the creation and maintenance of research and development capabilities in developing countries. In the absence of TRIPS, firms in developing countries have incentives to copy (reverse engineer) products patented in developed countries in order to produce them locally for sale in the domestic market. Developing countries benefit from the provision of jobs, local production provides competition with imports that might otherwise be sold at very high monopoly prices, and it reduces the volume of imports thereby saving foreign exchange. Moreover, it creates a research and development

capability and mentality. In the early stages this activity may be limited to rather unsophisticated reverse engineering. However, over time, these capabilities may become more sophisticated and result in product innovations and improvements aimed to develop products more suitable to the demands of local consumers. In some cases, the end result may be research and development capabilities that are truly competitive worldwide. An effective TRIPs will undermine efforts toward the creation and improvement of research and development facilities in developing countries.

- The indigenous capability of the local drug industry in developing countries will be hit hard. Consumers will have to pay higher prices [15]. The infrastructure created by local industry will remain unutilized. Local production will be confined to making age- old drugs, denying the benefits of new drugs and innovation. Local producers will have to wait 20 years for the patent to expire on a new drug, before they can start to manufacture it, by which time a new drug in the market will probably undermine its value.
- When the TRIPs Agreement becomes applicable in full, the developing countries which are members of the WTO will no longer be able to protect their pharmaceutical industries, as all discrimination is now prohibited between local producers and foreign producers on the one hand and between local producers and importers on the other (small duties on imports are still however possible).

The multinationals are promising that the new legislation covering patents will lead them to invest massively in developing countries. In the field of innovative drugs, western industry does not necessarily want to set up shop in developing countries, because production costs, in particular manpower, are often a secondary factor when industry determines the price of brand- name drugs.

- If developing countries could implement the TRIPs as it is, some of the concerns could be minimized[16]. However, this is not so, increasingly they

are facing political pressure and threats particularly from the US government, preventing them from implementing what is legally allowed[17]. For example, South Africa passed legislation to permit generic substitution and parallel imports in pharmaceuticals, a practice common in Europe and allowed under TRIPS. The US government, at the request of the pharmaceutical industry, using trade threats, has asked South Africa to repeal its legislation. Similarly, Thailand that had a statute allowing compulsory licensing, has been threatened by US government and has repealed its own regulation. There are other examples in which the US government is opposing countries trying to enact laws that are identical to US laws. Moreover, the pharmaceutical industry is lobbying the US government to put pressure and possible economic punishment on countries for implementing TRIPs as it is. Eighty percent of the pharmaceutical industry is based in the US and the US government appears to be lobbying for pharmaceutical companies' commercial interests[18].

These developments raise a major question:

Is the TRIPs Agreement going to be used by the powerful to protect corporate profits regardless of the cost in human life?

How the TRIPs Agreement can be used to ensure access to innovation and affordability of pharmaceuticals is the challenge that World Health Organization (WHO), governments, Non- governmental organizations (NGOs), consumers and all people interested in justice face[19].

- Many developing countries are careless about patency issues simply for cost reduction purposes. Now, a developing country should either has the financial capabilities to buy patented drugs from multinational companies, or develop the technological and research capacities that produce its own pharmaceutical products. Unfortunately, most developing countries lack both. Developing countries can have another option which is to make drugs that are free from patents[20], in particular the generics. The prospects for generics in particular look good. Generics have strong

impact on price reduction of brand- name drugs. The former's price reach 40- 50 percent lower than the latter. The patient would rather take a generic drug than buying an expensive brand- name drug that has the same effect. The entrance of each new generic player reduces prices further. The stronger the competition between patents and generic drug manufacturers, the lower the prices of drugs. Developing countries can save a lot of money as a result of purchasing lower cost generic pharmaceuticals in place of their brand- name equivalents. These savings are critically important to their cash strapped health care system; drug expenditures are the fastest growing component of health care costs. The increased prescribing of new and more costly single source drugs which do not have generic competition is a prime cause of the rapid increase in drug costs(21). The potential for generic drugs to continue to bring cost savings to drug purchasers depends critically on government policy and practice including countries' regulatory systems for approving generic drugs. Unfortunately, doctors often prescribe newer and more costly drugs rather than less costly existing alternates. New drugs tend to be more expensive and do not have lower- cost generic alternatives. Recent legislations have extended the period of time during which new drugs are protected from competition from generic substitutes which will accelerate health care problems(22).

- The WTO's fierce defense of intellectual property rights comes at the expense of health and human lives. The organization's support for pharmaceutical companies against governments seeking to protect their people's health has had serious implications for places like Sub- Saharan Africa, where 80% of the world's new AIDS cases are found.

III. Policy Recommendations for Developing Countries:

The TRIPs Agreement is the outgrowth of economic and political forces that have been building up over a number of years. It does no good for the developing countries to complain about the negative aspects of the agreement. All countries, developed and developing, are dissatisfied with certain aspects of the agreement, each country with its own list of dissatisfactions. However, this is the normal outcome of any negotiations. So what should the developing

countries do? The answer is simple. Take advantage of the good aspects and introduce policies to minimize the adverse effects of the bad aspects of the agreement.

To be more specific we should answer the following question:

What can the developing countries do, in light of TRIPS, to minimize the damage caused in their economies and to their capabilities to conduct research and development?

A simple first step is to take advantage of the "compulsory licensing" provisions of the agreement to ensure that patented products are locally produced. The local firms, of necessity, will be knowledgeable of the technical details of the patent and of the technology necessary to apply the patent. Thus, a knowledge base will be created. So firms in developing countries that are producing for local consumption might benefit from TRIPs enforcement that grants "compulsory licensing" to existing firms.

A second strategy is to establish a narrow scope for patents. This would provide a wider scope for improvements that are patentable in their own right. Thus, local firms would have an incentive to license foreign patents and then engage in research and development leading to patentable improvements. Such a strategy would require governments in developing countries to become very familiar with the international norms for administering patent and other intellectual property laws.

A third complementary strategy is to take advantage of the exception for the non- commercial use of intellectual property and provide for the experimental use of patents by universities and other research laboratories. This would also allow local firms to engage in reverse engineering for purposes of discovery and improvement prior to production for sale. So since most intellectual property is owned by firms in developed countries have little opportunity to gain from TRIPS. The only way to gain from TRIPs is to own intellectual property. Support of education and scientific research can be recommended. Government policies that stimulate private research and

development through government subsidies or incentives for investment in research and development would also pay dividends.

The following discussion will present these policy recommendations.

C.1. General Policy Recommendations:

- **Change in Strategy and Approach:**

There should be a change in the developing countries' strategy and approach. The current feeling of helplessness that the developing countries cannot have their say in the WTO should be replaced by a new mood that they can achieve their objectives if a number of them are united and well- prepared. The developing countries are in a very large number in the WTO and even if one does not expect all of them to come together on all the issues, one can at least expect a large number of them to have a common perception and a common stand on a number of subjects.

The current process of being pushed into making one- sided concessions or facing a sudden collapse at the end should naturally be changed to one of engaging in a meaningful negotiation of give and take and insisting on getting commensurate concession from others before finally agreeing to any concession from one's own side.

- **Preparation Process:**

All this needs the support of detailed analytical examination of the issues involved and identification of interests. The developing countries should undertake such examination, but their capacity is limited. They should build up and strengthen their capacity. They should sponsor this work in some of the universities and institutions in their countries. They should also build up a network of institutions in their countries for this purpose. But considering their limited resources and capacity, it is doubtful if they will be able to undertake studies and analyses on their own on a sustained basis. They need assistance.

Earlier, particularly during the Tokyo Round and the Uruguay Round, the United Nations Conference on Trade and Development (UNCTAD)

undertook a massive technical assistance program to help developing countries in the negotiations. It was supported by financing from the United Nations Development Program (UNDP). UNCTAD is still engaged in studying the subjects and issues relating to the WTO. Some other organizations are also engaged in the work of providing assistance to developing countries. The WTO itself has such a program, which is devoted mainly to assistance in implementation of the agreements. Sometimes it prepares analytical papers at the request of a developing country or a group of developing countries.

The Commonwealth Secretariat has been running a program of technical assistance. It is mainly devoted to the preparation of short analytical papers at the request of individual countries or a group of them.

The Third World Network, a non- governmental organization, has also been undertaking the work of technical assistance to developing countries on the WTO issues. It has concentrated on topical subjects under consideration and has prepared analytical and briefing papers. It has organized seminars and workshops for exchange of views and expertise among developing countries on important occasions. It has assisted them in developing cooperation among themselves in the formulation of positions in important areas.

None of these efforts in their present form by itself can satisfy the emerging needs of developing countries in the next few years, though each of them constitutes an important contribution in support of developing countries. There is a need for a comprehensive assistance program. Preferably it could be funded mainly by the developing countries themselves, or at least a large number of them. There could be supplemental funding from other benevolent sources. This program could be located in one of the existing organizations with the appropriate capacity and orientation or could be established as a separate unit. Even if it is located in an existing organization for administrative or accounting purposes, it should work as an independent program and unit.

The main functions of the program could be the following:

(a) critical and analytical examination of the current and emerging issues from the perspective of the developing countries and their implications for them;

(b) assisting developing countries in preparing their own proposals in various areas in the WTO;

(c) examining the proposals of others with respect to their implications for the developing countries, and assisting developing countries in preparing their responses; and

(d) during the intense phase of negotiations, providing quick and prompt assistance in respect of the formulation of and responses to the amended proposals.

Such an assistance program will be supportive of the national efforts of developing countries in their preparation and also of regional and group efforts.

- **Regional and Group Efforts:**

The effectiveness of the developing countries will be enhanced if there is better coordination among them. The exercise of coordination should start right from the stage of identification of interests and formulation of positions and stands. Under the overall umbrella of the informal group of developing countries in the WTO, there may be some smaller groups, based on specific issues and interests, with full transparency and interaction with the other members of the informal group. There may also be burden- sharing in preparations in specific areas and exchange of information, which will avoid duplication of efforts and ensure better utilization of their scarce resources.

There should also be coordination, linkages and networking among the research institutions and universities in these countries engaged in analysis of the issues in the WTO. There could be arrangements for burden- sharing among such institutions. The efforts of these institutions should also be coordinated with those of the multilateral central assistance program proposed above.

- **Change in the WTO Negotiating Process:**

The developing countries have to endeavor to bring in changes in the negotiating process in the WTO so that there is greater transparency and wider participation of developing countries in the negotiations. Discussions in small groups for the purpose of explaining proposals and persuading other countries are a natural process; but for negotiation of the texts of the proposals and agreements, there must be much wider direct participation. There may be difficulties in negotiating the texts in very large groups, but a balance has to be worked out between the need for efficiency and full direct participation of the countries in the negotiating process. Developing countries may deliberate on this issue and make specific proposals for an improved method of negotiations in the WTO.

The WTO agreements and their operation are and will be having a profound impact on the economies of the developing countries. Hence it is imperative that they do not remain indifferent and handicapped, but actively participate in the negotiations and other activities and make themselves effective in its decision-making and operations.

C.2. Specific Policy Recommendations:

Developing countries should note that the WTO has no mandate to establish public health policies(23), which should remain within the mandate of other international bodies, such as the WHO.

They should also note that the TRIPs Agreement does not in any way undermine the legitimate right of WTO members to formulate their own public health policies and implement them by adopting measures to protect public health(24).

In April 2001, the 57th session of the United Nations Commission on Human Rights adopted resolution 2001/33, on "Access to Medication in the Context of Pandemics such as HIV/AIDS", which was approved by the overwhelming majority of its members. The resolution recognizes access to medicines in the context of pandemics as an essential human right. The United

Nations Commission on Human Rights, in this resolution, "calls upon states, at the national level, on a non discriminatory basis for all, to:

(a) refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them;

(b) adopt legislation or other measures, in accordance with applicable international law, including international agreements acceded to, to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties; adopt all appropriate positive measures to the maximum of the resources allocated for this purpose so as to promote effective access to such preventive, curative or palliative pharmaceuticals or medical technologies. Among other actions, the Human Rights Commission also calls upon states, at the international level, to take steps individually and/ or through international cooperation, in accordance with applicable international law, including international agreements acceded to, such as:

(I) to facilitate access in other countries to essential preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common infections that accompany them wherever possible as well as to extend the necessary cooperation wherever possible, especially in times of emergency; and

(II) to ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, efficient and affordable

preventive, curative or palliative pharmaceuticals and medical technologies.

In 21 May 2001, the 54th World Health Assembly approved a resolution relevant to the TRIPs Agreement. The resolution "WHO Medicines Strategy" contains several important elements. The World Health Assembly notes that "the impact of international trade agreements on access to, or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated". Further, the resolution urges members to "cooperate with respect to resolution 2001/33 of the United Nations Commission on Human Rights" and "in order to increase access to medicines, and in accordance with the health needs of people, especially those who can least afford the costs, and recognizing the efforts of member states to expand access to drugs and promote domestic industry, cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes in order to promote innovation and enhance the development of domestic industries".

At the XI Summit of the Heads of States and Governments of the Group of Fifteen (G- 15), in Jakarta (30- 31 May 2001), the heads of states and governments stressed the "urgent need to address pandemic and endemic diseases such as HIV/AIDS, Tuberculosis and Malaria" and stated that "the implementation of the TRIPs Agreement should in no way prevent developing countries from taking measures, such as compulsory licensing and parallel imports to ensure access to life- saving drugs at affordable prices to overcome hazards to public health and nutrition caused by HIV/AIDS and other diseases".

In Doha WTO Ministerial Declaration in November 2001 ministers stressed the importance of the implementation and interpretation of the TRIPs Agreement in a manner supportive of public health by promoting both access to existing medicines and research and development into new medicines, that's why they adopted a separate declaration concerning the TRIPs Agreement and Public Health .

Although there were some conflicting views regarding the conditions under which the flexibility of the TRIPs Agreement could be used, the Doha Declaration on the TRIPs Agreement and Public Health helps clarify this issue. The Declaration was seen as important step to prevent situations where countries have considered themselves under pressure, from industry and/ or foreign governments, not to avail themselves fully of the flexibility provided in the TRIPs Agreement.

The importance of the trade and health interlinkages and the need for greater coherence between trade and health policies received a strong endorsement from the international community at the Doha Ministerial Conference. The Doha Declaration on the TRIPs Agreements and Public Health made clear that WTO rules and health policies can go hand in hand, that public health considerations are important in implementing WTO rules and that trade and health policies can be made mutually supportive.

Now we can say that developing countries must note that each provision of the TRIPs Agreement should be read in light of the objectives and principles set in Articles 7 and 8 [25]. Such an interpretation finds support in the Vienna Convention on the law of Treaties (concluded in Vienna in 23 May 1969), which establishes, in Article 31, that "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".

Article 7 is a key provision that defines the objectives of the TRIPs Agreement. It clearly establishes that the protection and enforcement of intellectual property rights do not exist in a vacuum. They are supposed to benefit society as a whole and do not aim at the mere protection of private rights. Article 7 states that the protection and enforcement of intellectual property rights "should" contribute to the promotion of technological innovation and the transfer and dissemination of technology; the mutual advantage of producers and users of technological knowledge; social and economic welfare; and the balance of rights and obligations. In the context of health policies for instance, patent rights should be exercised coherently with the objectives of mutual advantage of patent holders and the users of patented

medicines, in a manner conductive to social and economic welfare and to a balance of rights and obligations. Where confronted with specific situations where the patent rights over medicines are not exercised in a way that meets the objectives of article 7, members may take measures to ensure that they will be achieved such as the granting of compulsory licenses.

The objective of the promotion of the technological innovation and the transfer and dissemination of technology places the protection and enforcement of intellectual property rights in the context of the interests of society. Such an objective is essential for the promotion of health policies, as it encourages the development of domestic production of pharmaceutical products. Whenever economically feasible, local production of pharmaceutical products is extremely important to ensure that medications are more readily available in the market, and at more affordable prices. Local manufacturing of pharmaceutical products also encourages sustainable access to medication by insulating the price of patented medicines against currency devaluation, as well as supporting the development of local expertise, which is vital in addressing local needs. As mentioned above, these objectives can be obtained by the normal exercise of patent rights. Where the patent holder fails to meet the objectives of the TRIPs Agreement and of public health policies, members may take measures to ensure transfer and dissemination of technology to provide better access to pharmaceuticals.

Also regarding patent protection of pharmaceutical products, the concept of "balance of rights and obligations" and of "mutual advantage of producers and users of technological knowledge" are relevant to ensure that the exercise of the exclusive rights provided by patent rights is subject to limitations, which are expressed in different provisions of TRIPs, such as those relating to compulsory licenses and parallel imports.

In Article 8, the TRIPs Agreement affirms that members may adopt measures to protect public health, among other overarching public policy objectives, such as nutrition and socio- economic and technological development. Any interpretation of the provisions of the agreement should take into account the principles set forth in Article 8.

The reading of such provision should confirm that nothing in the TRIPs Agreement will prevent members from adopting measures to protect public health, as well as from pursuing the overarching policies defined in Article 8.

Article 8.2 allows members to take measures to prevent the abuse of intellectual property rights by right holders or the resort to practices, which unreasonably restrain trade or adversely affect the international transfer of technology. In the implementation of public health, one situation of abuse of rights could be, for instance, the practice of excessively high prices of patented pharmaceutical products. Under normal circumstances, the exercise of patent rights can encourage the creation of new drugs and promote sustainable availability to society, as part of the "balance of interests" foreseen in the objectives of Article 7. Nevertheless, in many instances, the owners of patented pharmaceutical products may abuse their exclusive rights, by selling or offering for sale drugs at prices beyond reasonable margins of profit[26], which prevents adequate access to medications by the general public. Another situation of abuse of rights could occur when the owners of patented pharmaceutical products do not offer their products in sufficient amounts to meet the demands of the market. In such non- exhaustive situations, patent rights are exercised in a way that conflicts with public health policies as they prevent adequate access to medicines.

- **Parallel Imports[27]:**

Article 6 [28] of the TRIPs Agreement is extremely relevant for members, especially developing countries, and particularly the least developed and smaller economies among them. Article 6 provides that members are free to incorporate the principle of international exhaustion of rights in national legislation. Consequently, any member can determine the extent to which the principle of exhaustion of rights is applied in its own jurisdiction, without breaching any obligation under the TRIPs Agreement.

Whenever governments deem it appropriate, adoption of the principle of international exhaustion of rights can be a useful tool for health policies. Where the prices of pharmaceutical products are lower in a foreign market, for

instance, a government may decide to allow importation of such products into the national market, so as to allow offer of drugs at more affordable prices. Such measures may be beneficial to prevent anti- competitive practices on behalf of patent owners who offer their patented products at unreasonably high prices in the domestic market. In this case, patent owners would compete with other legitimate products, given their exclusive rights would be exhausted, the interests of the patent owner would not be damaged.

For developing countries, in particular, least- developed countries and smaller economies, "parallel importation" can be a significant way of increasing access to medications, where the prices charged by patent holders for their products are unaffordable[29]. Moreover, in situations where the local manufacture of the product is not feasible, and therefore compulsory licenses may be ineffective, parallel importation may be a relevant tool to ensure access to drugs[30].

In light of the importance of Article 6 as an instrument for health policies, we consider that Article 6 should be implemented in such a way as to ensure the broadest flexibility for members to resort to parallel imports. Members should therefore confirm their rights of applying regimes of exhaustion of rights in their jurisdiction.

- **Compulsory Licenses[31]:**

Compulsory licenses are important to protect public health. Members should take the view that the TRIPs Agreement in no way stands in the way of public health protection, and therefore that it should provide the broadest flexibility for the use of compulsory licenses.

Compulsory licenses can represent a significant tool for governments to ensure access to pharmaceuticals. Normally, patent owners are expected to provide access to their patented medicines to the market. In specific circumstances, however, governments may deem it necessary to grant compulsory licenses to allow interested third persons to produce medicines, in order to ensure that it will be more readily available, or more affordable to the general public.

Some of the most relevant provisions of the TRIPs Agreement with respect to compulsory licenses are Articles 7, 8, 31 and 40 of TRIPs and Article 5 of the Paris Convention. When read together, such provisions allow scope for members to ensure that regulatory policies can be exercised by governments to promote public health policies. Based on Article 5 A of the Paris Convention and 31 of TRIPS, governments may issue compulsory licenses as a way of ensuring that medicines will be available at more affordable prices.

Article 31 makes specific mention of five possible grounds for the granting of compulsory licenses; that is, in cases of refusal to deal, in situations of national emergency and extreme urgency, to remedy anti-competitive practices, in cases of public non- commercial use and to facilitate the use of dependent patents.

Reference should also be made to the provisions of Paris Convention related to compulsory licenses, which have been incorporated into TRIPs Agreement. The Paris Convention allows countries a wide discretion to issue compulsory licenses "to prevent the abuse, which might result from the exercise of exclusive rights, conferred by the patent". During the Uruguay Round negotiations, efforts were made by a number of developed countries to limit the freedom available to countries under the Paris Convention in the grant of compulsory licenses. However, these efforts failed due to strong resistance from developing countries.

To summarize, the objectives underlying the compulsory licensing provisions include:

(i) to counter anti- competitive conditions in the country,

(ii) to make products available that otherwise would not be available, and

(iii) to provide for the non- commercial use of the patent for the public good.

In many cases, developing countries- particularly least developed countries and smaller economies- have limited industrial capacities and very

small domestic market to manufacture medicines locally in order to ensure adequate access to drugs. In this regard, it should be noted that nothing in the TRIPs Agreement prevents members from granting compulsory licenses for foreign suppliers to provide medicines in the domestic market. In addition, members may adopt regimes of international exhaustion of rights in national legislation to allow parallel imports into the domestic market. In this respect, the reading of Article 31 (f) should confirm that nothing in the TRIPs Agreement will prevent members to grant compulsory licenses to supply foreign markets(32).

- **Differential Pricing(33):**

Given that differential pricing is not an intellectual property issue, we believe that it should not be covered by TRIPS. Differential pricing arrangements can play a relevant role in providing better access to affordable medicines(34). Governments should consider the establishment of global databases on drug prices, which should facilitate decisions related to the establishment of price controls, authorization of parallel imports and granting of compulsory licenses.

We discussed till now some of the specific policy recommendations that have a base in and a support from some international organizations such as the U N, WHO and some other groups such as G- 15. We discussed also some specific policy recommendations that can find support in the TRIPs agreement itself. We showed that the reading and explanation of some articles of the TRIPs Agreement should confirm that nothing in this agreement will prevent members from adopting measures to protect public health.

The remaining policy recommendations can be summarized as follows:

- Responding to the human tragedy of public health problems in developing countries is a task for the global community, including governments, international organizations, NGOs, the business community, and individual citizens. Research- based pharmaceutical industry that will be committed to partnering with governments and other organizations is

needed to breakdown the barriers that slow or prevent delivery of much-needed treatments.

- Countries must devote the proper resources to improve the number and rate of generic drugs approved. These are the products that can bring the most financial relief to the drug bill. The potential for generic drugs to bring even greater cost savings depends in large measure on government policy and practice. The more quickly a generic is added to drug formularies, the more savings can accrue to not only the drug program but to all consumers.

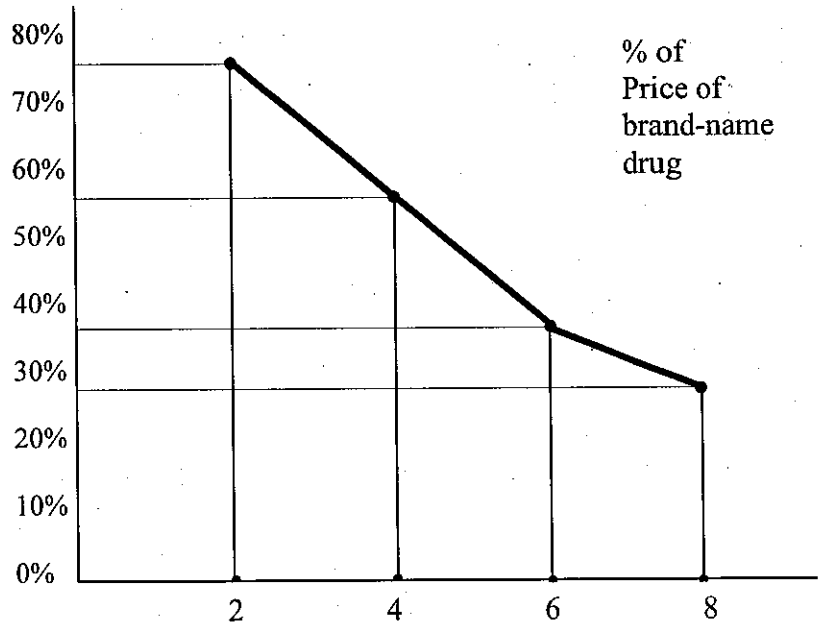
Now we can raise an important question which is:

What are the benefits of generic competition?

To answer this question we can say that on average, generic drugs are priced 40- 50 percent lower than their brand- name counterparts. Competition from generics ensures the availability of affordable and high quality substitutes for expensive brand- name prescription drugs, thereby reducing overall drug costs. When a generic substitute for a brand- name drug enters the market, it does so at a substantially lower price and, as more generic versions of the same drug enter the market, the price drops even further.

The following graph shows that competition substantially reduces the cost of pharmaceutical products. The greater the number of competing brands the lower the price.

The Effect of Generic Competition on Drug Prices



Source: The Impact of Bill C-91 on Canada's Health Care System: A Brief Overview, *Canadian Drug Manufacturers Association,* January 1994, p.4

- Finally we can say that for Egypt it should target its traditional markets of Eastern Europe and the former Soviet Union, The European Union, Africa and the Middle East. Egypt currently exports pharmaceuticals to a number of countries of which the most important in descending order are: Saudia Arabia, Yemen, Kuwait, United Arab Emirates, Iraq, Sudan, Nigeria, Zambia, the Philippines, Korea, Sri Lanka and the European Union. To guarantee a growing share of the export market, local pharmaceutical companies should step up their marketing efforts, integrate within the global sourcing network to supply immediate orders in neighboring markets, raise their expenditure on R&D and reinforce their quality image by obtaining ISO 9000 certification.

Footnotes:

(1) About 14 million people die each year from infectious diseases, many of which preventable or treatable, such as acute respiratory infections, diarrheas diseases, malaria and tuberculosis. Up to 45% of deaths in Africa and Southeast Asia are thought to be due to an infectious disease. The death toll is unacceptably high in developing countries, even as health indicators show improvements in many countries of the world. This health crisis is caused by several inter- linked factors, poverty, lack of access to health services, water and sanitation being some of them. However, a vital factor in the promotion of public health- and very often, a matter of life and death- is the supply of effective and affordable medicines and peoples' access to such medicines and treatments. Many cases of medicines for life- threatening diseases being made unaffordable, simply because companies owning or controlling patents on the medicines have been able to block competition from other firms and other products. Prices of patented medicines are very much linked to the monopolies enjoyed by pharmaceutical companies, protected and maintained by patent rights.

For more details see:

Communicable Diseases 2000- Highlights of Activities in 1999 and Major Challenges for the Future, *World Health Organization,* Geneva, Switzerland, 2000.

, Globalization, TRIPs and Access to Pharmaceuticals, WHO Policy Perspectives on Medicines, No.3, *World Health Organization,* Geneva, Switzerland, March 2001.

(2) Public criticism has been mounting, as are questions about the legitimacy of patents on life- saving medicines. This has led to calls for changes or amendment to the TRIPs Agreement, which many feel, is too heavily in favor of private rights and commercial interests, and against public interests.

(3) GATT has operated since 1947 as both the primary forum for international trade diplomacy and as the basic framework for international rules governing global trade. Concluded in 1947 and signed by its 23 original contracting parties, the GATT was intended as one of the four institutional pillars for the construction of the post- World War II structure for preserving world peace and stimulating economic growth through:

(i) international political consultation (United Nations),

(ii) international monetary cooperation (International Monetary Fund),

(iii) international economic development (World Bank), and

(iv) open markets through global trade liberalization (GATT).

(4) Until the WTO agreements were signed, the organization of international patents was based on the Paris Agreement (1883) and the Stockholm Agreement (1967) which set up the World Intellectual Property Organization (WIPO). These agreements do not make it compulsory to file patents in all technological fields, nor to set a minimum protection time for the patents. The WTO agreement concerning the intellectual property aspects related to trade makes these two points compulsory.

(5) Patents are a trade- off. In exchange for disclosing to the world the research and science underlying an innovation, a patent holder receives the exclusive rights to the patented product or processes for 20 years from the date of the original patent application.

(6) The transitional period is of paramount importance for the industry to adjust in terms of upgrading facilities, training in various areas and overcoming technical and non- technical barriers.

(7) Signatories of the original GATT (1947) were referred to as "Contracting Parties" and the entity of the GATT itself- technically an "agreement" rather than an organization- was referred to as the "Contracting Parties". Countries that subsequently founded or acceded to the Post- Uruguay Round WTO are referred to as "Members".

For more details see:

Development Economic Policy Reform Analysis (DEPRA) Project, Final Report, *Egypt: Obligations and Commitments under the GATT/ WTO Agreements*, prepared for the Government of Egypt- Ministry of Trade and Supply, submitted to US Agency for International Development- Cairo- Egypt, submitted by Nathan Associates Inc. under USAID contract # 263- c- 00- 96- 0001- 00, August 1999.

(8) The old Egyptian Patent Law (Law 132 in 1949) had specific aspects concerning pharmaceuticals. While the basic patent term available in Egypt was 15 years from date of application (with possible extension of up to 20 years), pharmaceuticals, medicines and foodstuffs specifically were excluded from product patentability. Furthermore, while manufacturing processes for pharmaceuticals and medicines were patentable, the term for process patents was only 10 years. Now the period of protection according to the new law is 20 years (Article 10- Law 82 for the year 2002).

(9) Each year since 1997, the US Trade Representative (USTR) has placed Egypt on the Special 301* Priority Watch List because of lack of progress in patent protection. However, with the help of USAID funded project, {Strengthening Intellectual Property Rights in Egypt (SIPRE)},

considerable progress has been made over the past five years in setting up the government institutions necessary for an effective intellectual property rights regime. A modernized (and computerized) patent and trademark office is now capable of processing and ensuring the protection of patent applications. The quality and transparency of the patent and trademark registration system has been vastly improved.

For more details see:

Introduction to Intellectual Property, edited by: Judy Winegar Goans, J.D. Chief of Party, February 28, 1999, Cairo- *SIPRE Project* (SIPRE) is a USAID- funded project of Nathan Associations, Inc.

, Egypt: Country Commercial Guides for Fiscal Year 2000, *Report Prepared by US Embassy*, Cairo, released July 1999, p. 11- 12.

, US Department of Commerce- National Trade Data Bank, *Egypt: National Trade Estimate Report on Foreign Trade Barriers*, May 6, 1999.

, Negad Shaarawi, Intellectual Property Rights- Egypt, *Seminar on the Legal Framework for Technology Transfer*- Cairo, 4 - 5 September 1995.

, ----------, Hopes and Concerns of the Domestic Pharmaceutical Industry, *Seminar on the Legal Framework for Technology Transfer*- Cairo, 4 - 5 September 1995.

* Section 301 is a provision in US trade law (the Trade Act of 1974) that provides authority to the president to enforce US rights under international agreements and to respond to certain unfair trade practices in foreign markets. That is, the emphasis in these cases is on the actions of foreign governments taken in their own markets against US firms. If foreign governments engage in policies or practices that burden, restrict, or discriminate against US Commerce, the United States may impose import restrictions against the products of that country in the event that an agreement cannot be reached to end the offensive practices. The action may be also to impose retaliation by closing US markets to exporters in the foreign country to persuade the country to end its practices.

The office of the US Trade Representative (USTR) administers section 301 cases. USTR is an agency within the executive branch that is charged with advising the president on trade policy matters and coordinating the US government in its trade negotiations.

Section 301 threats are almost always destined to fail. This is because Section 301 is clearly an intrusion by the United States into the policies of other governments. Political leaders may not want to appear to be vulnerable to US threats and may resist mutually beneficial agreements in order to preserve national pride.

Currently the United States imposes severe limits on imports of textiles, steel, and sugar. To the extent that US practices inspire foreign trade barriers, the US negotiation position may be weakened.

For more details see:

Steven Husted, Michael Melvin, *International Economics,* Fourth Edition, 1998, pp. 246- 249.

(10) For the Egyptian government the crux of the problem lies in the matter of pricing. The government is concerned with the socio- economic implications of prices especially in an area as critical as health care.

(11) The TRIPs Agreement is upsetting the relative comfortable situation local firms have been enjoying until now. TRIPs measures concern two aspects:

- the lifting of any possibility of protecting the local production.
- The application and the reinforcement of patents' system (extension of their duration, patents of products and patents of process, reinforced sanctions in case of violation).

(12) With full implementation of the TRIPs Agreement couple of years away, concrete evidence to support either side is not yet available. However, there is already plenty to think about.

(13) Patent protection could improve the quality of medical care in developing countries, as they progress from a copying culture, to one that induces local innovation.

For more details see:

Barfiled, C.E., and Beltz, C., "Balancing and Rebalancing the National Interest in the Patent System", *American Enterprise Institute,* October 1995.

,Boston Consulting Group, *Sustaining Innovation in US Pharmaceuticals: Intellectual Property Protection and the Role of Patents*, January 1996.

,Congress of the United States, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks, Rewards,* February 1993.

,Mansfield, Edwin, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer,* The World Bank, Washington D.C., 1994.

(14) When one estimates the potential consequences of the TRIPs Agreement on the pharmaceutical industries of the developing countries, there is little room for optimism. Medicines and drugs are industrial products in a category of their own. By refusing to recognize this, the TRIPs Agreement could have negative social and health consequences for already fragile populations in developing countries, which is quite unacceptable.

For more details see:

B.K. Keayla, Conquest by Patents, The TRIPs Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All, *Center for Study of Global Trade System and Development*, New Delhi, India, 1998.

,Zafar Mirza, 'WTO/ TRIPs, Pharmaceuticals and Health: Impacts and Strategies', *The Network's Drug Bulletin*, Association for Rational Use of Medication in Pakistan, Vol. 8, No. 5/6, September/ December 1999.

(15) The local pharmaceutical industry ensures that essential drugs at affordable prices are available to the vast population. However, the new 'trade' rules of the WTO now pose a serious threat to the industry and to the millions who are dependent on it for their health and livelihood. Local producers will be pushed out of the market and multinational suppliers are going to dominate the market with far higher prices.

(16) There should be a commitment by all WTO members that they will not pursue strategies of pressure or intimidation against countries that take measures to protect public health and promote access to drugs. Any attempt to coerce developing countries into foregoing their rights under the TRIPs Agreement would deal a serious blow to the credibility and legitimacy of the TRIPs Agreement and the WTO.

For more details see:

Eva Ombaka, Trade- Related Aspects of Intellectual Property Rights (TRIPs) and Pharmaceuticals, *The Pharmaceutical Program*, Nairobi, Kenya, April 2002, pp.1-2.

(17) Developed countries have largely relied on compulsory licenses, as a tool to limit exclusive rights and prevent or remedy abusive practices. Recent legislative changes in developed countries prove that compulsory license system is still much in use. The grounds and conditions on which compulsory licenses have been regulated and granted in developed countries illustrate the flexibility and potential of the compulsory licensing system to address a multiplicity of public interests and concerns. Such evidence indicates that arguments- voiced by developed countries governments and industry- against compulsory licenses as a deviation from acceptable standards for intellectual property rights are not reflected in the policies actually applied in such countries. In so doing, they practice double standard, denying developing countries the use of effective policy mechanisms that they themselves have used and continue to use.

For more details see:

C. Correa, "The Uruguay Round and Drugs", *World Health Organization*, Geneva, Switzerland, 1997.

(18) The US, like most developed countries, provides for compulsory licensing in its national laws. The US also grants perhaps the largest numbers of compulsory licenses (more than a hundred such licenses have been granted) to address anti- competitive practices and for government uses. It would appear that in the battle between the right to health and the right to monopolies and profits, the battle lines have been drawn between countries of the South on one side and the Northern governments and their industrial lobbies on the other.

For more details see:

Cecilia Oh, TRIPs and Pharmaceuticals: A Case of Corporate Profits over Public Health, *Third World Network*, August- September 2000, pp.1-7.

(19) Civil society groups and NGOs have called for amendment of the TRIPs Agreement so as to ensure a proper balance between the protection of private rights and corporate interests, and the promotion of public interests in socio- economic technological development of member countries, including that of public health. Public criticism is mounting, as are questions about the legitimacy of patents on life saving drugs and the global monopolies provided to pharmaceutical companies by such patents. There is increasing public opinion that the present model for intellectual property rights protection advocated by TRIPs is too heavily tilted in favor of private right holders and against the public interest.

For more details see:

The TRIPs Agreement and Developing Countries, *UNCTAD*, New York and Geneva, 1996.

(20) Not only are the brand- name prices of the older drugs less expensive than the prices of newer drugs, but older drugs are also the ones for which generic alternatives exist. These generic drugs are priced much lower than

their brand- name equivalents. Low prices make generics an attractive option for buyers keen to reduce their health care expenditures.

For more details see:

Generic Drugs, 'Savings to Canada's Health Care System'- *Canadian Drug Manufacturers Association*, September 1995.

(21) The government can ban the practice of manufacturers offering economic incentives to doctors who prescribe their products. We have also to resist and find a solution for the "blackmailing" of patients by some doctors who allegedly coax them into buying expensive imported medicines.

(22) Developing countries' health care systems are facing the dual crisis of soaring costs and diminishing public resources. One of the biggest threats is coming from the skyrocketing costs of prescription drugs.

(23) Article 1 is important to ensure the freedom of governments on the means of implementation of the minimum standards of the TRIPs Agreement in national legislation. In many cases, more extensive protection in national legislation than is required by the TRIPs Agreement may result in limitations for the implementation of health policies. Members should be free to implement the TRIPs agreement in ways that best accommodate the protection of health policies in national legislation.

(24) It is vital that interpretations allow full flexibility for developing countries to exercise their rights to provide affordable medicines to their people, rather than interpretations that may restrict the scope and ability of developing country members to adopt measures to ensure access to medicines.

(25) We should note that for a number of developing countries, the interpretation and implementation of the TRIPs Agreement requires resources and capacity in excess of those already existing. Developing countries should note that the TRIPs Agreement, in its present form, contains certain provisions that can be used to limit patent rights. These

limitations or exceptions are to be effected through national legislation, in order to curb abuses of intellectual property rights and anti- competitive practices, and generally, to offset the negative impact of patent monopolies.

(26) We don't object to profits, but what about profit ceilings?

(27) Parallel imports (or grey- market imports) involve the import and resale in a country, without the consent of the patent holder, of a patented product that was put on the market of the exporting country by the patent holder. The practice of parallel importation is driven by the disparity between prices for goods, between markets. Parallel imports are generally exported from a low- price market for resale at a higher price in the importing country. The underlying concept for parallel imports is based on the principle of exhaustion of rights. This principle is premised on the fact that where the patent holder has been rewarded through the first sale or distribution of the product, he/ she no longer has the right to control the use or resale of the product.

Parallel imports are of particular importance for public health interests, since the pharmaceutical industry generally sets prices differently throughout the world for the same medicines. Parallel imports would prevent market segmentation and price discrimination by patent holders on a regional or international scale. Parallel importation of a patented medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to the medicines. Such measure would also not prevent the patent owner from receiving remuneration for the patented invention in the country where the product is first sold. In this regard, parallel importation must be regarded as a legitimate measure, which WTO members are permitted to adopt to protect public health and nutrition as is provided for in Article 8 of the TRIPs Agreement.

The TRIPs Agreement simply says that none of its provisions, except those dealing with non- discrimination ("national treatment" and "most-

favored- nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that might violate the TRIPs Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non- discrimination are involved.

For more details see:

C. Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries, *South Center,* Geneva, Switzerland, 2000

,TRIPS and pharmaceutical patents, WTO OMC, Fact Sheet, April 2001

(28) Article 6 allows each member country the freedom to incorporate the principle of international exhaustion of rights- the underlying justification for parallel imports- in its national legislation. It further states that members are not subject to the WTO dispute settlement system for disputes relating to exhaustion of rights.

In light of TRIPs Article 6, the TRIPs council should confirm the unconditional right of members to determine the way in which exhaustion of rights regimes are applied in their jurisdiction.

(29) The EU does allow for the free movement of goods among its member countries. Thus pharmaceuticals do, for example, move from Greece to Finland or Germany, as parallel traders purchase lower- priced pharmaceuticals in Greece and sell them for a higher price in the more affluent EU countries. Arab countries can benefit from this idea, especially after activating the Arab Common Market.

For more details see:

Claude E. Barfield and Mark A. Groombridge, Parallel Trade in the Pharmaceutical Industry, *Fordham Intellectual Property, Media and Entertainment Law Journal,* Autumn 1999.

(30) In order to avoid a possible discrimination complaint under Article 27.1 and benefit all sectors of the economy, it is recommended that

parallel importing should be permitted within national legislation, for patented goods in all fields of technology, and not only for health- related inventions.

(31) Compulsory licensing enables a government to issue a license to a third party,

Whether a private company or a government agency, for the right to use or exploit a patent without the patent holder's consent, compulsory licensees generally compensate the patent holder through payment of remuneration. In the context of pharmaceutical patents, such licenses constitute an important tool to promote competition and increase the affordability of drugs, without depriving the patent holder from reasonable compensation.

For more details:

Cecilia Oh and Martin Khor, TRIPS, Patents and Access to Medicines: Proposals for Clarification and Reform, *Third World Network Briefing Paper,* June 2001, P.8

(32) The TRIPs agreement stipulates that a compulsory license must be "predominantly" for the supply of the domestic market. Therefore, exports are possible, although they should not constitute the main activity of the licensee with regard to the licensed product.

Since Article 31 does not lay down an exhaustive list of grounds for the issuance of licenses, members should be free to determine further grounds for the issuance of compulsory licenses. Therefore, the TRIPs agreement does not limit the right of countries to establish compulsory licenses on other grounds not explicitly mentioned.

For more details see:

C. Correa, Intellectual Property Rights, the WTO and Developing Countries- the TRIPs Agreement and Policy Options, *Third World Network,* Malaysia, 2000

(33) Drug prices vary from country to country for a number of reasons including patent regulations, government controls, income differences, currency exchange fluctuations... etc.

(34) When a drug company sells the same product in different countries, it adopts a policy of price differentiation, setting price levels "according to what the market can bear".

In a country where alternative or generic medicines are available, a company's branded product is usually priced lower due to the competition it faces from lower- priced alternatives. The same brand may be sold at higher prices in other countries where there is no competition from generic producers.

For more details see:

Cecilia Oh and Matin Khor, Op. Cit., P.8

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Arlene Wilson. (1995). The GATT and the WTO: An Overview, CRS Report for Congress, *Congressional Research Service,* March 27, 1995.

Boston Consulting Group. (1996). *Sustaining Innovation in US Pharmaceuticals: Intellectual Property Protection and the Role of Patents,* January 1996.

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Appendix 1: Some Relevant Articles of the TRIPs Agreement

Article 1.1

Nature and Scope of Obligations

Members shall give effect to the provisions of this agreement. Members may, but shall not be obliged to, implement in their domestic law more extensive protection than is required by this agreement. Members shall be free to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice.

Article 6

Exhaustion

For the purposes of dispute settlement under this agreement, subject to the provisions of Articles 3 and 4 nothing in this agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge in a manner conductive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1- Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio- economic and technological development, provided that such measures are consistent with the provisions of this agreement.

2- Appropriate measures, provided that they are consistent with the provisions of this agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices, which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 27

Patentable Subject Matter

1- Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of article 65, paragraph 8 of article 70 and paragraph 3 of this article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2- Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3- Members may also exclude from patentability:

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

ii- plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provision

of this sub- paragraph shall be reviewed four years after the entry into force of the WTO Agreement.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

i- authorization of such use shall be considered on its individual merits;

ii- such use may also be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non- commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non- commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

iii- the scope and duration of such use shall be limited to the purpose for which it was authorized;

iv- such use shall be non- exclusive;

v- such use shall be non- assignable, except with that part of the enterprise or good which will enjoy such use;

vi- any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use.

Article 40

Control of Anti- Competitive Practices in Contractual Licenses

1- Members agree that some licensing practices or conditions pertaining to intellectual property rights, which restrain competition, may have adverse effects on trade and may impede the transfer and dissemination of technology.

2- Nothing in this agreement shall prevent members from specifying in their national legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a member may adopt, consistently with the other provisions of this agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing in the light of the relevant laws and regulations of that member.

3- Each member shall enter, upon request, into consultations with any other member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the member to which the request for consultations has been addressed is undertaking practices in violation of the requesting member's laws and regulations on the subject matter of this section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either member. The member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting member, and shall co-operate through supply of publicly available non- confidential information of relevance to the matter in question and of other information available to the member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting member.

4- A member whose nationals or domiciliaries are subject to proceedings in another member concerning alleged violation of that other member's laws and regulations on the subject matter of this section shall, upon request, be granted an opportunity for consultations by the other member under the same conditions as those foreseen in paragraph 3.

Article 66

Least- Developed Country Members

1- In view of the special needs and requirements of least- developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPs shall, upon duly motivated request by a least developed country Member, accord extensions of this period.

2- Developed country members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least- developed country members in order to enable them to create a sound and viable technological base.

For more details see:

The Results of the Uruguay Round of Multilateral Trade Negotiations- the Legal Texts, Published by the GATT Secretariat, Geneva, Switzerland, 1995. Annex 1C. Agreement on Trade- Related Aspects of Intellectual Property Rights, pp.365-403.

Appendix 2: DOHA WTO MINISTERIAL Declaration 2001

WT/MIN(01)/DEC/1
20 November 2001
Ministerial declaration
Adopted on 14 November 2001

Trade-related aspects of intellectual property rights

"17. We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration."

DOHA WTO MINISTERIAL 2001: TRIPs

WT/MIN(01)/DEC/2
20 November 2001
Declaration on the TRIPs agreement and public health

Adopted on 14 November 2001

"1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPs Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPs Agreement. We instruct the Council for TRIPs to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPs Agreement."

We notice that in this declaration, ministers stress that it is important to implement and interpret the TRIPs Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.

The separate declaration on TRIPs and public health is designed to respond to concerns about the possible implications of the TRIPs Agreement for access to medicines.

It emphasizes that the TRIPs Agreement does not and should not prevent member governments from acting to protect public health. It affirms governments' right to use the agreement's flexibilities in order to avoid any reticence the governments may feel.

It states that the agreement should be interpreted in a way that supports governments' right to protect public health. This provides guidance to individual members and to dispute settlement rulings.

The separate declaration clarifies some of the forms of flexibility available, in particular compulsory licensing and parallel importing.

As far as the Doha agenda is concerned, this separate declaration sets two specific tasks. The TRIPs Council has to find a solution to the problems countries may face in making use of compulsory licensing if they have too little or no pharmaceutical manufacturing capacity, reporting to the General Council on this by the end of 2002. The declaration also extends the deadline for least-developed countries to apply provisions on pharmaceutical patents until 1 January 2016.

For the first task we can say that Director- General Supachai Panitchpakdi, on 20 December 2002, expressed disappointment over the failure by WTO member governments to meet the year- end deadlines for agreement in negotiations on special and differential treatment for developing countries and access to essential medicines for poor countries lacking capacity to manufacture drugs themselves.

As for the second task we can say that the WTO council responsible for intellectual property, on 27 June 2002, approved a decision extending until 2016 the transition period during which least- developed countries (LDCs) do not have to provide patent protection for pharmaceuticals. It also approved a waiver for LDCs on exclusive marketing rights for any new drugs in the period when they do not provide patent protection.