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TRIPS and Public Health
What Should African Countries Do?

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Abstract

The purpose of this paper is to discuss the TRIPS Agreement (Agreement on Trade- Related Aspects of Intellectual Property Rights) and public health from an African perspective. Section I of the paper presents a background about the international pharmaceutical market and the situation in Africa, the TRIPS Agreement and patents on drugs, The Doha declaration on TRIPS and public health, examples of flexibility in the TRIPS Agreement, TRIPS Plus, and the arguments for and against the TRIPS Agreement. Section II discusses what should African countries do through presenting some solutions to protect these countries such as compulsory licenses, generic drugs, parallel imports and differential pricing.

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I. Background

This paper discusses the TRIPS Agreement and public health from an African perspective to come out with solutions to protect African countries.

1.1 The International Pharmaceutical Market and the Situation in Africa

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 conglomerates from Developed countries, which are also responsible for the development of new therapies. Another fast- growing sector of the international pharmaceutical industry is that of generic medications. 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 majority of African countries lack research capabilities in diseases that affect their countries, lack administrative and resource capacities to negotiate in international fora, and lack production capacity in modern pharmaceutical industry, however, the pharmaceutical industry in some of these countries has evolved considerably. Often motivated by the industrial politics of the 1950s, many African countries such as Egypt, Morocco, Kenya and South Africa 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 countries' 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, have opened the doors to the multinationals, others like Egypt has preferred to support locally financed enterprises.

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 African 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.

Trade in pharmaceutical products (both in imported products and domestically produced formulations) is at present taking place between some African countries, which are members of regional economic groupings. This trade is however at present relatively small. One of the obstacles to the development of such trade arises from differences in the regulations of these countries relating to manufacture, import, export and distribution of pharmaceutical and health products. There is therefore need for regional trading blocks to collaborate in harmonizing such regulations, because in Africa, even though the proposals for restoring to pooled tenders for obtaining drugs appear to have been discussed for a long time, no significant progress has been made in their practical implementation. The main reasons for this appear to be due to:

- Differences in rules relating to registration and granting of marketing approvals.
- Differences in laws and regulations relating to procurement of goods.
- The absence of a common currency.
- The reluctance of the governments to give up the right for the selection of drugs and for assessment of quality to a regional authority.
- The language barrier hinders trade exchange.
- Limited capacity of production in Southern and Eastern Africa.
- Doubts about quality of generics.
- Differences between standards.
- Lack of harmonization in drug licensing procedures.
- Lack of information on trade opportunities in the region.
- Financing problems.
- Transport difficulties for some African countries.
- Lack of donor funds for the purchase of generics manufactured in Africa.

However Ajanta Mauritius for example has succeeded in selling drugs to countries such as Tanzania, Lesotho, Malawi, and Kenya and to more distant African francophone countries such as Cote d'Ivoire and Senegal. Until recently the Mauritius Pharmaceutical Manufacturing Company limited (MPM) sold drugs to Madagascar, Comoros, Seychelles, Kenya and Malawi.

1.2 The TRIPS Agreement and Patents on Drugs

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 and hence on public health in African countries.

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 to pharmaceutical product and process inventions.

Previously, the question of intellectual property was not really addressed by the General Agreement on Tariffs and Trade (GATT) and countries had adopted various approaches towards drug patents. While some used to grant patents for pharmaceutical product and process inventions, others allowed patent protection only for process inventions. 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, 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.

1.3 The Doha Declaration on TRIPS and Public Health: Patient Rights before Patent Rights

The Doha Declaration on TRIPS and Public Health is an important step towards making the TRIPS Agreement more development friendly. It was significant because for the first time, Developing countries, led by the African group, and others such as Brazil and India decisively negotiated for a development friendly outcome. It has clarified the need to interpret TRIPS from a public health perspective. Specifically, the Declaration states that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. It explicitly recognizes the flexibility within TRIPS to grant compulsory licenses and the right of countries to determine the grounds on which these are granted. Paragraph 6 of the Doha Declaration also recognizes the problems for countries with insufficient or no manufacturing capacity in the pharmaceutical sector and instructs the TRIPS Council to find a solution regarding compulsory licensing for them expeditiously.

The Doha Declaration is an important milestone in the TRIPS debate. It paves the way for more public health- friendly interpretation of TRIPS by explicitly recognizing that intellectual property rights are subservient to public health concerns. It is a political, rather than a legal statement and should be used as a reference point for more public health- friendly interpretations of TRIPS if disputes arise.

1.4 Examples of Flexibility in the TRIPS Agreement

Countries should use the flexibilities available in the TRIPS Agreement to interpret and implement it in a manner that furthers human development goals. Two cases relevant to the use of the flexibility in the TRIPS Agreement have arisen in the WTO so far. One was a dispute between Canada and the European Communities on the so- called "Bolar" exception allowing generic drug manufacturers to produce and/ or import and use quantities necessary of a patented product to conduct tests needed to obtain regulatory approval before the expiry of a patent. Under the TRIPS Agreement, governments can make limited exceptions to patent rights provided certain conditions are met. These exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent and must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interest of third parties (Article 30). A range of exceptions may be covered by this provision. For example, many countries provide for a "research" or "experimental use" exception to allow researchers to use a patented invention more fully. In addition, Article 30 permits countries to allow manufacturers of generic drugs to use patented invention, without the patent owner's permission and before the patent protection expires, for the purpose of obtaining marketing approval from public health authorities. Generic producers are thus able to market their versions almost as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision, and has been upheld as conforming to the TRIPS Agreement in a WTO dispute ruling. In a report adopted on 7 April 2000, a WTO dispute settlement panel stated that Canadian law was consistent with the TRIPS Agreement in allowing manufacturers to do so.

The other case was a dispute brought by the United States about the TRIPS consistency of the Brazilian legal framework for the grant of compulsory licenses. The Brazilian intellectual property law of 1996 (Article 68[1]) requires the patent holder to manufacture the product in Brazil. If this does not happen, the government can issue a compulsory license to another producer, unless the patent holder can show that local production is not feasible. Both these provisions are well within TRIPS parameters. However, the US challenged the provisions of Article (68[1]). The US argued that this provision for the grant of compulsory licenses in the event that a patented invention was not used in domestic production ("local working" requirement) was a protective industrial policy measure and inconsistent with the provisions of the TRIPS Agreement. The Brazilians took the view that this measure was a necessary part of their programme to combat HIV/AIDS and was fully consistent with the TRIPS Agreement, Brazil insisted that the law was central to the country's public health policy and its threat of compulsory licensing has been instrumental in its negotiations with pharmaceutical companies to reduce prices on imported anti-retroviral drugs. On June 25, 2001, the US government withdrew its WTO panel against Brazil and, in turn, Brazil agreed to hold talks with the US before applying Article 68. More recently, Brazil threatened to use the provision when its negotiations with Roche over lowering prices of Nelfinavir (marketed as Viracept by Roche) broke down. Eventually, Roche agreed to lower the price by another 40 percent; Article 68 was not invoked.

Another case concerning access to drugs- not a WTO dispute- that attracted much attention was the challenge in the South African courts by 39 pharmaceutical companies to the South African Medicines and Related Substances Control Amendment Act of 1997. The companies contended that this legislation, which empowered the Minister of Health to authorize and prescribe conditions for the parallel importation of drugs under patent in South Africa, entailed, among other things, a violation of South Africa's obligations under TRIPS. The government argued that its legislation was entirely consistent with the TRIPS Agreement which contains important flexibilities, for instance with regard to parallel importation. No case was brought to the WTO on the grounds that South Africa had breached the TRIPS Agreement. In April 2001, the pharmaceutical companies withdrew their suit, and the South African government pursued the implementation of its regulation, including some that would authorize parallel importation of patented medicines.

1.5 TRIPS Plus

Apart from TRIPS, there are several other regional and bilateral intellectual property agreements that have troubling implications for human development. Many of these agreements are more stringent than the TRIPS Agreement and considerably diminish the room for maneuver for Developing countries. Countries that have signed onto these agreements cannot take advantage of the flexibilities in TRIPS. These agreements go beyond TRIPS in terms of intellectual property rights (IPRs) protection.

The African Intellectual Property Organization has regulated intellectual property in 15 countries of Francophone Africa since the Bangui Agreement in 1977. In 1999, the Bangui Agreement was revised to bring it in line with the TRIPS Agreement. The Bangui Agreement is equivalent to the national patent law in each of these 15 member countries, and in its revised version goes well beyond the TRIPS Agreement. The Bangui Agreement recognizes the regional principle of exhaustion of rights, limiting parallel imports to member countries only. Further, compulsory licenses can no longer be granted if the product can be imported; in other words, the lack of locally available patented products is no longer valid reason for compulsory licenses, licenses to meet special needs can also be granted only for local use and not for imports, leaving unresolved the problem of countries with no production capacity. The revised Bangui Agreement make it harder for these countries to source cheaper generics through imports and to promote generic production domestically, leaving few options for access to cheaper drugs.

Other bilateral agreements that go beyond TRIPS include EU agreements with Morocco, Palestine and South Africa; and the Swiss- Vietnam treaty. These agreements are setting a dangerous precedent. By committing to higher standards of protection than mandated under TRIPS, these countries become unable to take advantage of the flexibilities offered under TRIPS. Any attempt to make TRIPS more human development friendly, therefore, will be meaningless for these countries unless they can ensure that their commitment to TRIPS overrides their bilateral and regional commitments.

As for the US government we notice that it is using bilateral and regional free- trade agreements (FTAs) to impose unnecessarily stringent intellectual property standards on Developing countries that go beyond the requirements of the WTO rules. These new higher standards favor the short- term commercial interests of US pharmaceutical companies, at the expense of public health in Developing countries. The provisions in these agreements go far beyond the obligations required by the TRIPS Agreement.

The Doha Declaration was unanimously agreed by WTO members- including the US- in November 2001. It affirms the right of all WTO members to use the safeguards and flexibilities in TRIPS to promote access to medicines for all and constitutes a commitment to favor public health over patents rights. The US Congress subsequently enshrined the Doha Declaration in the mandate granted to the US Trade Representative (USTR) for negotiating FTAs; the Trade Act of 2002 instructs the USTR to respect the Declaration in all trade negotiations. But none of the FTAs reference the Doha Declaration. All of the bilateral and regional FTAs are TRIPS- plus. The impact will be diminished availability of cheap generic versions of expensive patented medicines, which will further reduce access to medicines, in direct contrast to the Doha aims.

The Doha Declaration was followed by a decision by the WTO in August 30th 2003 to lift TRIPS restrictions on compulsory licensing for export of generic medicines to countries that lack the capacity to manufacture them themselves. The implementation of this decision is facing some difficulties from some developed countries.

1.6 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.

While there is nothing in the TRIPS Agreement that is biased against African countries (firms in all countries are eligible for equal protection in all countries), it is true that currently firms in the Developed

countries own the preponderance of marketable intellectual property. 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.

African countries will be disadvantaged in a number of ways. Firms in these 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 African 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, African 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.

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 African countries by improving the conditions for investment, encouraging the development of local industry, creating jobs, transferring technology, and enabling more goods to be produced. If such a regime is not in place, investors will shy away from investing, research and licensing in these 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. Thus, the 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 the market can bear. A whole economic calculation methodology (pharmacoeconomics) has been developed in the last decade to deal with this. So if, for example, a drug permits savings on hospital costs, it can be sold at a far higher price, and 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 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 African 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.
- Strengthened patent protection is expected to encourage foreign direct investment in African 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.

The Arguments against TRIPS

The arguments against TRIPS can be summarized as follows:

- There is little indication, apart from the Doha Declaration, that TRIPS has really been interpreted in the true spirit of balance between rights holders and users. From a legal perspective, the generalist language employed in TRIPS has worked both ways for Developing countries; it has allowed for flexible interpretation, but also left the text open to dispute. The latitude in the text requires tremendous specialized legal capacity, which most Developing countries lack. Moreover, the experience of Brazil has shown that efforts to use this flexibility provoke strong opposition from the Developed countries.
- A major issue of concern is the incentives for the creation and maintenance of research and development capabilities in African countries. In the absence of TRIPS, firms in these countries have incentives to copy (reverse engineer) products patented in Developed countries in order to produce them locally for sale in the domestic market. African 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 African countries.

- The indigenous capability of the local drug industry in African countries will be hit hard. Consumers will have to pay higher prices. 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 in 2016 for Least- Developed Countries, some African countries which are members of the WTO will no longer be able to protect their pharmaceutical industries, as all discrimination will be 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 African countries. In the field of innovative drugs, Developed countries' industry does not necessarily want to set up shop in African countries, because production costs, in particular manpower, are often a secondary factor when industry determines the price of brand- name drugs.
- Many African countries are careless about patency issues simply for cost reduction purposes. Now, an African 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 African countries lack both.
- Patent systems like TRIPS do not ensure pioneering research into the diseases of the poor, for example, the Global Health Forum (2001) estimates that of the US$ 70 billion spent globally on health research, less than 10 percent is spent on diseases that comprise 90 percent of world's health burden- despite the fact that the most of the poorest countries of Africa have offered patent protection since at least 1984 and, in some cases, since 1977 (The African Intellectual Property Organization's members, comprising 15 countries of Francophone West Africa, have offered a system of pharmaceutical product and process patents since the Bangui Agreement of 1977, and the African Regional Industrial Property Organization's members, comprising 14 Anglophone countries, have offered pharmaceutical patent protection since at least 1984). In the last 25 years, scientists have developed only two new drugs for tuberculosis, while research outlays for malaria are only US$ 100 million.

II. What Should African Countries Do?

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 African countries to complain about the negative aspects of the agreement. All countries 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 African countries do? The answer is to take advantage of the good aspects and introduce policies to minimize the adverse effects of the bad aspects of the agreement. No multilateral intellectual property regime in itself can guarantee that human development objectives will be met. Active government policy intervention is needed in designing national legislation that addresses human development needs in terms of access to health care, and ensuring that products are priced to market and, irrespective of their patent status, are affordable to consumers. The following discussion will present some solutions for African countries.

2.1 Change in African Countries' Strategy and Approach

There should be a change in the African countries' strategy and approach. The current feeling of helplessness that these 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 African countries are in a 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 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.

The effectiveness of the African 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. 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 programs.

The African countries' capacities are limited, 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 these 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. 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 member country or a group of member countries.

In response to many demands for trade- related technical assistance by African governments, the UN Economic Commission for Africa (ECA) established the African Trade Policy Centre (ATPC) in June 2003. The ATPC, which is based in the ECA headquarters in Addis Ababa, was set- up with the financial support of the Canadian government through the Canada Fund for Africa. The broad objective of ATPC is to strengthen the capacity of African governments to formulate, analyze and implement sound trade policies and programmes, and to participate more effectively in bilateral and multilateral trade negotiations with the active involvement of the private sector and civil society. The ATPC is charged with the responsibility of providing independent and Africa- specific research, training, knowledge and tools on trade- related issues. ECA has also established a liaison office in Geneva to respond efficiently and in a timely manner to requests for assistance in trade policy during negotiations at the WTO.

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 an individual country or a group of countries.

The Third World Network, a non- governmental organization, has also been undertaking the work of technical assistance 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 member 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 African countries in the next few years, though each of them constitutes an important contribution in support of these countries. There is a need for a comprehensive assistance program, 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:

- Critical and analytical examination of the current and emerging issues from the perspective of the African countries and their implications for them;

- Assisting African countries in preparing their own proposals in various areas in the WTO;
- Examining the proposals of others with respect to their implications for the African countries, and assisting them countries in preparing their responses; and
- 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 African countries in their preparation and also of regional and group efforts.

2.2 Change in the WTO Negotiating Process

The African 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 these 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. African 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 African 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.

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

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

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:

- 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;
- 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:

- 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 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 "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 State and Government of the Group of Fifteen (G- 15), in Jakarta (30- 31 May 2001), the heads of state and government 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 (for more details see appendix 2).

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 inter- linkages 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.

African countries must note that each provision of the TRIPS Agreement should be read in light of the objectives and principles set in Article 7 and 8. 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 would 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, 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.

2.3 Compulsory Licenses

Compulsory licenses are important to protect public health. Countries 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 in a systematic and efficient way.

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.

Reference should also be made to the provisions of Paris Convention related to compulsory licenses, which have been incorporated into the 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:

- To counter anti- competitive conditions in the country,
- To make products available that otherwise would not be available, and
- To provide for the non- commercial use of the patent for the public good.

In many cases, African countries- particularly Least Developed 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.

The WTO Decision on access to Medicines adopted in August 30th 2003 requires a country importing pharmaceutical products produced by the exporting country under a compulsory license granted in accordance with its terms, to use them exclusively for the treatment of a disease prevailing in its territory. Re- exports of such products to other countries are prohibited. The decision however makes an exception in case of countries, which are members of certain types of regional economic groupings; these countries could re- export the imported product to the countries belonging to the region. This WTO decision as we said before provides that its provisions could be used by countries belonging to regional economic groupings (of which at least half of the members are Least- Developed countries) for developing imports and production on regional basis. At the same time, it calls on these countries to develop "systems for the grant of regional patents". The development of such systems avoids the need on the part of the companies or inventors of having to apply for the registration of patents in each of the countries belonging to the region; acceptance of the application by the regional patent organization could result on the patent being registered in all countries in the region. The practices in this regard could however vary. For instance while the rules of African Regional Intellectual Property Organization (ARIPO) provide its members with the right to reject the patent provisionally approved by it, the Organization of the African Intellectual Property (OAPI), imposes a binding obligation on its member countries to accept and register the regional patents approved by it. The adoption of such regional patents may enable regional intellectual property organizations to issue compulsory licenses for imports (on regional basis) in pursuance of the provisions of the decision, instead of each member country having to issue separate licenses.

The decision also envisages that the flexibility provided by it could be used by the countries with no or insufficient manufacturing capacities for developing gradual production under compulsory licenses. However, one of the major difficulties, which these countries are facing at present, is that because of the small size of the market, there is reluctance on the part of the entrepreneurs to invest in production of pharmaceutical products. To overcome these difficulties, the decision provides that products produced under compulsory licenses by a country belonging to certain types of regional economic groupings could be exported to other countries belonging to such a grouping.

The basic objective of these provisions is to enable countries with no manufacturing capacities "to enhance their purchasing power" by pooling orders on regional basis when products produced under compulsory licenses are to be imported and to provide advantage of "economies of scale" to manufacturers producing under compulsory licenses by providing them a regional market. The flexibility available under the decision could also, in practice, be used to grant compulsory licenses to foreign companies, which are willing to establish manufacturing plants in their territories or to enter into a collaboration arrangement with local companies for the establishment of such plants.

The measures described above, which could be taken for the development of imports, and production are subject to the following conditions:

- Countries belonging to the regional economic groupings of which at least half of the current members are Least- Developed can take advantage of these provisions. Most of the regional economic groupings in Africa [Common Market for Eastern and Southern Africa (COMESA), Southern African Development Community (SADC) and Economic Community of West African States (ECOWAS)] would satisfy these conditions. Those in Asia, Latin America and Caribbean region would not be able to take advantage of the flexibility. The flexibility provided by the Decision which would enable a country to re- export imported pharmaceutical products under compulsory licenses or to export products produced under such licenses can be availed only if the importing country shares the same health problems.
- The territorial nature of the patent must be respected. This condition implies that where the patent relating to the product to be exported is registered in the concerned country, imports would be permitted only if compulsory license to import has been issued.

Which countries can use the system to import?

Patented products produced under compulsory licenses issued in accordance with the terms of the decision can be used only by countries, which are eligible to import such products. For this purpose all Least- Developed countries are treated as "eligible importing countries". Other countries could become eligible countries on notification to the council of TRIPS that it will use the system "as an importer". In such a notification it can, if it so wishes, indicate that it proposes to use the system "in a limited way", for instance, only in the case of national emergency or in cases of public non- commercial use.

Which countries can use the system for exports?

Any WTO member country can use the provisions of the Decision to produce pharmaceutical products solely for exports under compulsory licenses. For instance, Least- Developed countries or countries which have notified to the WTO their intention to use the system as importers, could also use the system as "exporting members" if they have no established manufacturing capacities in certain sectors.

The decision provides that a compulsory license issued by the exporting members must contain the following conditions:

- Only the amount needed by the eligible importing members should be manufactured.
- The entire production produced under compulsory license must be exported.
- Products produced under the license must be clearly identified as being produced under the system set out by the decision through shaping and coloring of the products themselves, and/ or special packaging or labeling.
- The exporting member shall notify to the WTO the name and address of the licensee, the products covered by the license, the quantities for which the products are to be supplied and the duration of the license.

The decision also imposes obligations on the firm to which the compulsory license to produce for export has been issued. The licensed firm is expected to provide on a website the information on the quantities being supplied to each destination, and the distinguishing features of the product. For this purpose the licensed firm may use its own website or a page on the WTO website dedicated to the decision.

Compulsory licensing and government use:

The term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the practice falls under "other use without authorization of the right holder" (Article 31), of which compulsory licensing is only part, since "other use" also includes use by governments for their own purposes.

The TRIPS Agreement does not limit the reasons for which governments may grant compulsory licenses. However, compulsory licensing or government use of a patent without the authorization of the right holder can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder. Article 31 lists a number of provisions that should be respected in such cases. For example, the person or company applying for a license must have first attempted unsuccessfully to obtain a voluntary license from the right holder on reasonable commercial terms. However, for "national emergencies", "other circumstances of extreme urgency", "public non- commercial use" or remedying anti- competitive practices, there is no need to try for a voluntary license. If a compulsory license is issued, adequate remuneration must still be paid to the patent holder, taking into account the economic value of the authorization (Article 31 h). Compulsory licensing must meet several other requirements listed in the same Article. In particular, it cannot take the form of an exclusive license, and "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use" (Article 31 f). This condition need not be applied where such use is permitted to remedy a practice determined after judicial or administrative process to be anti- competitive (Article 31 k).

Compulsory licenses have been used extensively in Canada, Japan, and Europe for a variety of purposes. Canada has the most extensive experience with the use of compulsory licenses for pharmaceutical drugs. Until pressured by the US, as a condition to join NAFTA, to abandon a compulsory licensing approach that was nearly automatic, Canada routinely granted compulsory licenses on pharmaceuticals, with compensation based upon royalties, typically set a 4 percent of the competitor's sales price. 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.

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 to address anti- competitive practices and

for government uses. In several US cases, compensation has been based upon "what the owner has lost, not what the taker has gained", rejecting the argument, by patent owners, that they are entitled to lost profits based upon sales at prevailing commercial market rates.

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. It should be clear that we don't object to profits, but what about profit ceilings?

Despite a public health crisis of enormous proportions for compulsory license for HIV/AIDS, apparently no African country has issued a compulsory license for any medicine. Given the permissive global trade framework for compulsory licensing, one has to wonder why this is so.

The government use provisions should be strong. The rules in the TRIPS give governments very broad powers to authorize use of patents for public non- commercial use, and this is one area where there are many good state practice models to consider. African countries should have strong statutory public use provisions. There is a high variance in national provisions for government or public use of patents. Some are quite permissive, while others are not. The US for example has very broad rights to use patents for public purposes, the government can use patents for any government purpose, and it's not obligated to negotiate for licenses, and does not authorize any injunctive relief to the patent owner, the patent owner is granted compensation, as a government taking under eminent domain laws. In Germany, "a patent shall have no effect where the Federal Government orders that the invention be exploited in the interest of public welfare".

2.4 Generic Drugs

The most common private finance mechanism for health care in the majority of Developing countries is out- of- pocket payment, since governments cannot provide large scale subsidized health care. Out- of- pocket payments in Developing countries exceed 90 percent of total payments, much higher than the 20 percent in Developed countries (WHO, 2000).

Patented drugs are substantially more expensive than generic versions. According to the Federal Trade Commission in the US, generic drugs cost 25 percent less than their patented counterparts and, after two years, the price differential is 60 percent. Several studies for Developing countries have estimated the impact of patents on drug prices (Fink, 2000; Watal, 2000; and Subramanian, 1995). Their estimated increases range from 12 percent to 68 percent once TRIPS is implemented. In the case of anti- retroviral drugs for HIV/AIDS, patented drugs that cost US$ 10,000- $12,000 per patient per year are available for US$ 200- $350 in their generic form.

The term "generic" is actually used to denote versions of products, which are under patents that are produced on the basis of a license granted voluntarily by the patent holder, compulsory license granted by the government, or after the expiry of the duration of the patent period.

The generic versions produced and marketed must be interchangeable with the patented product and among the generic versions of such patented product as doctors often substitute generic version for a patented drug. The patients may also change over to using a generic version, instead of the patented product, particularly where they are substantially cheaper than the patented products. 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.

As the definition of the term "generic version" differs considerably under the national laws of different countries, the WHO refers to such products as Multi- source Products.

In relation to such multi- source products, the producers are required to submit evidence that the multi-source product is "therapeutically equivalent" to the innovative product and has the same standards of quality, efficacy and safety as the innovative product.

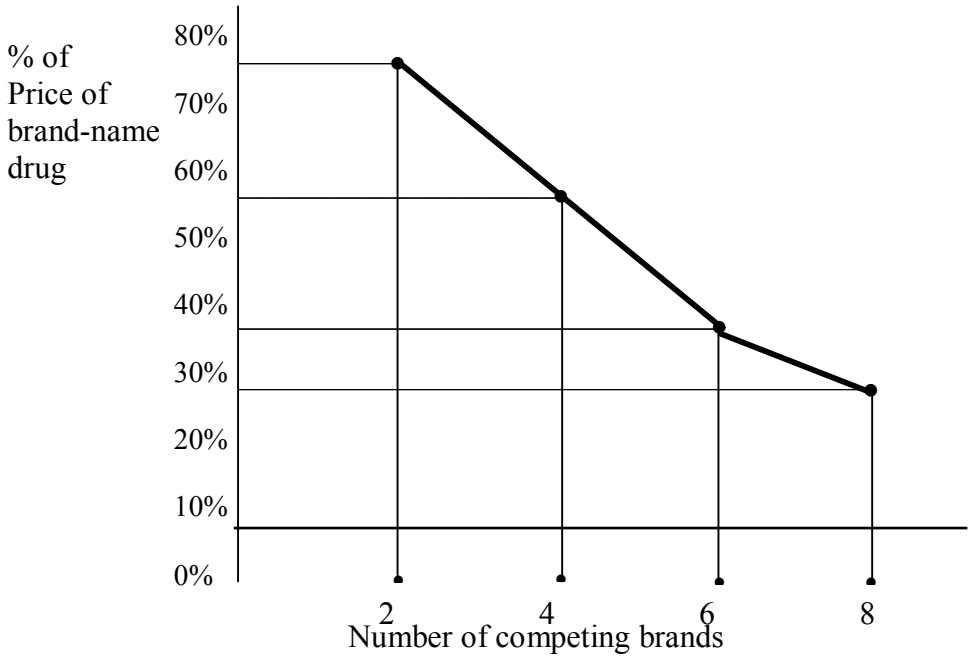
Generic medicines had a role to play in promoting public health in all countries. According to the WHO, more than one third of the world's population lacked regular access to essential drugs. Every year, millions of children and adults in Developing countries around the world still died from diseases that could be readily treated by drug therapies, and more economically treated with generic drugs.

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.

Generic drugs are priced 40- 50 percent lower than their brand- name counterparts. Competition from generics ensures the availability of affordable, 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

African countries under the coordination of the Africa Union should pool their resources and strengthen their capacity to manufacture the needed generic pharmaceutical products. The regional trading blocks such as COMESA, SADC and ECOWAS should share the manufacturing of generic drugs based on their comparative advantages and trade among themselves.

The Africa Union should also network with its members to negotiate bulk procurement of raw materials for generic production since the costs will be lower than what countries are capable of negotiating individually.

2.5 Parallel Imports

Parallel imports (or gray- 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.

In the TRIPS Agreement, parallel importation is regulated by the concept of the "exhaustion" of intellectual property rights. The TRIPS Agreement simply says (Article 6) that none of its provisions, except those dealing with non- discrimination on the basis of nationality (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. 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.

Article 6 of the TRIPS Agreement is extremely relevant for member 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 African 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. 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.

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.

Some practices on exhaustion of Intellectual Property (IP) rights:

The US law provides for national exhaustion of IP rights. The EU system provides for exhaustion of the IP holders rights, Parallel imports from member countries of the Union are permitted, the European Court of Justice has constantly upheld the right to re- sell legitimately procured goods within the community in order to ensure free movement of goods among the member states, parallel imports from countries outside the Union are prohibited. Japanese law provides for international exhaustion and permits parallel imports from outside countries unless such imports are barred by the contract or their original sale was subject to price regulation. Although these countries have adopted the international exhaustion principle, South Africa's attempt to use the principle for parallel imports led to a lawsuit from 39 pharmaceutical companies (later withdrawn) and pressure from the US, illustrating implementation problems under TRIPS.

2.6 Differential Pricing

Where patent protection confers pricing power for drugs of vital public health or life- saving importance, differential pricing is one way of ensuring that prices in poor countries are as low as possible while higher

prices in rich countries continue to provide incentives for R&D. Also called "tiered" or "equity" pricing, differential pricing involves charging lower prices in poorer countries and thus spreading the burden of providing incentives for research and development more equitably. The TRIPS Agreement does not stand in the way of such arrangements.

An example of a differential pricing strategy in action is the voluntary price- cuts by several big drug companies announced in the last few years, in which the price of certain drugs for the treatment of HIV and AIDS was reduced by 90 percent or more. However, even at such reduced prices, the cost may still be prohibitive for the poorest countries.

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. 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.

Conclusions and Recommendations

This papers shows that trade in pharmaceutical products between African countries at present is relatively small. One of the obstacles to the development of such trade arises from differences in the regulations of these countries relating to manufacture, import, export and distribution of pharmaceutical and health products. There is therefore need for regional trading blocks to collaborate in harmonizing such regulations.

The paper confirms that 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 African countries to complain about the negative aspects of the agreement. All countries 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 African countries do is to take advantage of the good aspects and introduce policies to minimize the adverse effects of the bad aspects of the agreement.

The paper suggests some solutions for African countries such as compulsory licensing, and it shows that despite a public health crisis of enormous proportions for compulsory license for HIV/AIDS, apparently no African country has issued a compulsory license for any medicine. Given the permissive global trade framework for compulsory licensing, one has to wonder why this is so.

The paper recommends also the use of generic drugs, thus African countries under the coordination of the Africa Union should pool their resources and strengthen their capacity to manufacture the needed generic pharmaceutical products. The regional trading blocks such as COMESA, SADC and ECOWAS should share the manufacturing of generic drugs based on their comparative advantages and trade among themselves. The Africa Union should also network with its members to negotiate bulk procurement of raw materials for generic production since the costs will be lower than what countries are capable of negotiating individually.

The paper recommends as well the use of parallel importation; it suggests that for African 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. 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.

Finally the paper suggests the use of differential pricing since it can play a relevant role in providing better access to affordable medicines for African countries, and it shows that the TRIPS Agreement does not stand in its way because it is not an intellectual property issue.

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Appendix 1: Some Relevant Articles of the TRIPS Agreement

TRIPS is a broad framework and contains several flexible provisions that Developing countries need to use. At the same time, several challenges remain in ensuring that TRIPS articles are interpreted and implemented in a public health- oriented manner. Some of the relevant articles are illustrated below.

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:

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

b- 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:

a- Authorization of such use shall be considered on its individual merits;

b- 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;

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

d- Such use shall be non- exclusive;

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

f- 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

20/11/2001

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/220/11/2001Declaration on the TRIPS Agreement and Public HealthAdopted 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 licenses and the freedom to determine the grounds upon which such licenses 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. (http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm)

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