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Trade Related Aspects of Intellectual Property Rights (TRIPs)
Agreement and Access to Drugs

by
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For

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Introduction

The world we are living in today has no global government accountable to the people of every country to oversee the globalisation process. Rather what we have is a system that might be called *global governance without global government* (Stiglitz, 2002). A few institutions – the World Bank, the International Monetary Fund (IMF), the World Trade Organisation (WTO) and other players like multinational corporations dominate the scene, but in which many of those affected by their decisions are left almost voiceless, powerless and impoverished.

In 1994 the Uruguay Round trade negotiations culminated in the signature of an agreement instituting the World Trade Organisation (WTO). In deciding to become members of the WTO, states undertook to abide by its rules. A certain number of treaties on trade in goods and services were also annexed to the WTO Convention and are therefore binding on all members. Among these multilateral agreements is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), which has so far proved to have the most impact on the pharmaceutical sector.

The TRIPs Agreement sets out minimum levels of standards concerning patents, copyrights, trademarks, industrial designs, geographical indications, layout designs of integrated circuits and trade secrets (undisclosed information). All member states have to comply with these standards by modifying their national regulations to accord with the rules of the Agreement.

It is worth noting that Intellectual Property Rights (IPRs) were brought into GATT Uruguay Round Agenda in the late 1980s through direct pressure by US pharmaceutical companies. They were complaining that since numerous countries did not provide adequate patent protection for drugs, they were being denied potential royalty payments. Quick to take up their cause, the US government bemoaned that their top 200 companies were losing \$24 billion per year to such “piracy”. Developing countries resisted the introduction of IPRs into GATT, but they lacked the critical mass to block it. However, as a compromise only the trade aspects of IPRs were included hence the name. The thinking was that this could only cover matters related to trade.

There are fundamental flaws in the whole idea of including IPRs in the WTO regime. The TRIPs Agreement itself does not focus on trade issues (e.g. dismantling of barriers). Instead, what it does is sets standards for the protection of IPR. And it does so under false pretences: ***baseless promises of investment and technology transfer to developing countries***. It is often said that countries providing strong intellectual property protection will attract greater inflows of foreign investment and technology, but there is no empirical evidence to back this up.

Transitional Arrangements

The TRIPs Agreement gives all WTO members transitional periods to ensure that their laws and practices conform to the Agreement. The transitional periods depend on the level of development of the each country.

- 1 January 1996: Developed country members
- 1 January 2000: Developing countries and economies in transformation
- 1 January 2006: Least developed countries

Other provisions

- **non-backsliding provision**

The non-backsliding clause in Article 65.5 forbids countries from using the transition period to reduce the level of protection of intellectual property in a way which would result in a lesser degree of consistency with the requirements of the Agreement.

- **Special transitional arrangements in certain cases**

These special arrangements apply in the situation where a developing country does not provide product patent protection in a given area of technology, especially to pharmaceutical or agricultural chemical inventions on the general date of application (2000). The Agreement says such a developing country may delay the application of the TRIPs obligations on product patents to that area of technology for an additional five years (year 2005) and 2011 for least developed countries (which was later revised to 2016 by the Doha Declaration).

Drugs and patents

Patenting means giving legal monopoly or certain rights to inventors over an invention for a specific period of time, usually 20 years. This means patent holders have the rights to licence anyone who uses their inventions for a fee or even the right not to give anyone the permission to use their “intellectual knowledge.”

Patents can only be granted nationally and there are three basic criteria for patents worldwide: novelty (new), utility (usefulness) and inventiveness.

There are two basic principles of TRIPs to keep in mind: everything must be patentable (save for a few exceptions) and foreigners must get the same treatment as nationals (Most Favoured Nation and National Treatment principles of WTO). This is crucial for the biotech industry, which needs to capture Third World markets. As it is, industrialised countries hold over 97% of all patents in the world and are the ones most likely to benefit from a universalised patent regime.

From the above it can be observed that the Uruguay Round served as a framework for the negotiation of a global agreement on intellectual property rights. My presentation is going to focus on patents as these have the greatest repercussions on the production and access to drugs for public health issues.

The TRIPs Agreement requires Member States to grant patents, for a minimum of 20 years to any inventions of a pharmaceutical product or process that fulfils the above mentioned criteria. Unauthorised copies of patented drugs are prohibited, and countries which break this rule will incur trade sanctions authorised by the WTO. But patenting anything entails setting the environment for financial rewards or incentives for the time and effort one would have spent working on producing the product. Monopoly granted to patents allows the patent holder to charge high prices, depriving many, especially the poor of an essential product or technology (in this case drugs).

The globalisation of production and marketing of drugs and health services is going to impact heavily on developing countries, as these are not at the same level of development with other industrialised nations. Consequently, the patent system works very well in industrialised countries where the burden of health care (on both governments and individuals) is relatively low and ensures the continuing development of new drugs. But in poor countries, where the burden of health care is very high, the patent system has failed to provide an adequate response to many prevalent diseases and has restricted access to cheaper drugs. This issue became a contentious issue within the WTO and particularly between the North and the South ever since the TRIPs Agreement came into effect.

Drugs are a critical factor in the cost of healthcare and in many developing countries they form a higher proportion of the total health bill. More than 70% per cent of health expenditure in Sub-Saharan Africa (Zimbabwe included) goes on medicines as compared to only 7.4% in developed countries. Where incomes are low – below one US\$ per day – even the cheapest medicines are out of reach. A third of the world’s population has no access to essential drugs, a figure that rises to half the population in the poorest countries of Africa and Asia. Unfortunately it is these countries that are most affected by diseases.

The Argument: The Genesis of the Conflict and Implications for Developing Countries (Zimbabwe)

Since TRIPs was enacted, it has received a growing level of criticism from developing countries, academics and civil society organisations. The most visible conflict has been over access to drugs in Africa and the rest of the developing world. Despite the indefensible role which patents have played in undermining public health programs across Africa, this controversy has not led to any revisions of TRIPs. Instead, an interpretive statement, which emanated from the 4th WTO Ministerial Conference in Doha, Qatar was issued in November 2001, which indicated that TRIPs should not prevent states from dealing with public health crises.

Significant progress was made at this Doha Ministerial Conference regarding pharmaceutical patents and public health. By virtue of a well protracted process and pressure exerted by developing countries, the declaration on TRIPs and Public Health ensured that the implementation of the TRIPs Agreement should be done in a way compatible with public health interests of those countries, whether in the case of increasing access to medicines or in actually creating new drugs.

The Doha declaration on TRIPs and Public Health stipulated that:

- The declaration must not prevent member nations from adopting measures to protect their public health interests
- As mentioned in the TRIPs Agreement itself, member nations are permitted to use measures such as compulsory licences and parallel importation. However 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.

At the core of the matter was the openly declared need of developing countries to break the patents on various medicines in order to reduce the cost of treating serious illnesses (such as HIV/AIDS, malaria and tuberculosis), a step that was opposed by nations such as the US which were concerned with looking after the interests of their major pharmaceutical companies.

The Doha Ministerial Conference, however, was unable to reach a decision regarding the most controversial question: how would it be possible to permit nations that did not possess the means to produce their own medicines to import generic copies, produced through the breaking of patents in other countries (the so-called paragraph 6 of the declaration)? As a result the TRIPs Council was instructed to find an expeditious solution to the problem by the end of December 2002.

Progress on the issue was slow as proposals from members had sharp differences in their interpretation of the Doha Declaration. After consultations with various members, the Chairman of the TRIPs Council then, Ambassador Perez Motta of Mexico came up with a draft on the 16 December 2002, the so called December 16 Motta Text.

The text was rejected by both developing and developed countries for different reasons; hence the 31 December deadline was missed.

The Africa Group of countries was not comfortable with the statement, particularly with the understanding that the Motta text solution for Paragraph 6 was “essentially designed to address national emergencies and other circumstances of extreme urgency”. Members in the Group, that included Zimbabwe, drafted an amendment to the understanding, to the effect that references to national emergencies and extreme urgency circumstances have been replaced with language as found in the Doha Declaration. That is, the amendment would have Members understand that the Motta text solution for Paragraph 6 was “essentially designed to address public health problems affecting developing countries with insufficient or no manufacturing capacity in the pharmaceutical sector, as called for in the Doha Declaration”.

The US on the other hand rejected the solution due to concerns over the scope of diseases covered. The Motta text applied to all “products from the pharmaceutical sector” and this formed the basis upon which the US rejected the text, among other reasons. The US suggested the inclusion of a footnote that would expand its previously proposed three-listed diseases to 23. This proposal, as rejected by developing countries, would restrict the mandate given by the Doha declaration, which refers more generally to measures to protect public health.

Japan, on one hand, which is also part of the Group of 8 like the US, proposed for the removal of vaccines from the list of diseases. Their argument was that vaccines were not technically pharmaceuticals. *Yet they play an important role in potential public health problems*, as understood by developing countries.

Implementation of Paragraph 6 of the Doha Declaration on TRIPs and Public Health: The WTO August 30 2003 decision

A temporary agreement to the long standing implementation of the Doha Declaration on TRIPs and Public health was finally signed on August 30 2003 in Geneva, just two weeks before the 5th WTO Ministerial Conference in Cancun, Mexico. The Agreement authorises any member nation of the WTO to export generic copies produced under compulsory licensing. All members may also import these medicines, although 23 listed developed nations made a commitment not to do so. 12 more members indicated that they would use the decision only in circumstances of extreme urgency and emergency situations.

The solution agreed to allows members to import generic copies of the patented drugs only for public health reasons and for the domestic market and not for industrial or commercial interests. The objective, of course was to prevent important markets in either developed or developing countries being flooded by these medicines, the consequence of which would obviously be a reduction in the profits of the pharmaceutical conglomerates.

While this deal was well accepted by many members of the WTO, it will present some technical problems in its implementation. Some of these include:

- Issuance of two compulsory licenses
- Competition and drug prices
- The involvement of the WTO in the process

For example there is a **new** drug that treats malaria and is manufactured by a company in South Africa. The drug is patented globally and is sold for R20 000 for a year’s supply. The government of Zimbabwe lacks manufacturing capacity and decides to issue a compulsory licence for the manufacture of the drug notifies the WTO of its intention and issues the compulsory licence. In the process Zimbabwe must specify the product and its distinguishing features, quantity and identify the licensee.

Now where are the problems?

- Difficulty in identifying the generic manufacturer. In some countries e.g. the USA a generic manufacturer has to wait five years after the registration of the patent before they can access data, test and begin registration of the generic version of the drug. In others like the EU, the wait is longer (10 years).
- If the generic manufacture can be found, Zimbabwe must ask South Africa to issue a compulsory licence for the drug to be produced on its territory. South Africa must then specify the manufacturer, product quantities and the destination for which the licence has been issued
- The generic manufacturer, who would like to produce the drug after the data exclusivity period ends, might find that investing in the production of the drug is costly when the market to be supplied is small.

Despite these inadequacies, Zimbabwe must fully exploit the flexibilities in the TRIPs Agreement and the August 30 decision to provide affordable medicines to the public until the TRIPs Agreement is amended next year.

Zimbabwe and the Declaration of a Period of Emergency

On the 27th May 2002, the Government declared a Period of Emergency for six months in view of the rapid spread of HIV/AIDS among the population in Zimbabwe. This declaration was for the purpose of enabling the State or any person authorised by the government to:

- Make or use any patented drug, including any anti-retroviral drugs used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions
- Import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions

This announcement marked the first time that a government has gone beyond using the threat of compulsory licensing as a negotiating tool, and actually declared that it will override patents to increase access to needed medicines when the prices are too high as a result of patent protection.

Although the declaration was initially for six months (which has now been extended to five years and has incorporated other diseases) it was difficult to measure the impact in such a short period of time. But certainly it will go a long way in reducing the prices of drugs and increasing their accessibility. However, we have our own problems locally that militate against us and render all these efforts ineffectual e.g. the shortage of foreign currency. But in a normal situation prices of drugs should stabilise.

Way Forward

As alluded to earlier on, the year 2005 is going to be the year when our own patent legislation, with regards to pharmaceuticals, should conform to the provisions of the TRIPs Agreement. The transition period is going to expire and as a country who is a signatory to the TRIPs Agreement, we have to abide by the rules. In the process of amending our Patent Act, as parliamentarians, we should take cognisance of the following broad environment:

- Examine the implementation of the Doha Declaration on TRIPs and Public Health, the August 30 Solution and the Declaration of a period of Emergency here in Zimbabwe and see how these would have benefited us in the process
- TRIPs Agreement will be amended in 2004 and this again should help us in coming up with our own legislation that takes public health interests first before patents

Once the situational analysis is carried out, then you need to undertake an urgent review of the patent Act or any other TRIPs – compliant legislation to ensure that it takes full advantage of the mechanisms in the agreement to increase access to essential drugs and support public health.

You should be able to question the Health Policy of this country in relation to:

- The budget spent on drugs (both branded and generic) in public and private institutions
- The use of compulsory licenses. Whether they are being adequately used and review their effectiveness

- The types of drugs mostly used (procured) in relation to the burden of disease in the country
- Domestic cost of drugs in the country as compared to other countries in the region
- Are efforts being made to check the efficacy of drugs (that is, are drugs being sold to the public because they are new or because of their clinical effectiveness)
- After implementation of the August 30 Solution is there any improvement in the local or regional production of drugs
- Are any TNCs seeking to patent local remedies or herbs

At a workshop organised by equinet, the Global Equity Gauge Alliance and SADC Parliamentary forum in South Africa in August, Parliamentary Alliances for Equity in Health in Southern Africa recommended that:

- Governments assert their rights under the Doha Declaration on TRIPs and Public Health to define what constitutes a Public Health Problem
- Governments strengthen their efforts to take full advantage of the flexibilities and policy measures allowed in TRIPs to access cheaper medicines and protect indigenous knowledge systems
- Governments ensure that national laws and regional policies provide for compulsory licensing, parallel importation, 'government use', and production of generic drugs;
- Given the central role of nutrition and food security in public health, countries retain the right to raise tariffs and demand elimination of subsidies on exports to protect food sovereignty in agricultural production; The Parliamentary Alliances for Equity in Health in Southern

Negotiations at the multilateral level seem to have taken a back slide after the break down of talks in Cancun. As we have already started noticing, there is intensification in bilateral and regional negotiations with the ACP-EU negotiations being an example. We urge you, as Parliamentarians, and you the stakeholders in the health sector to ensure that Zimbabwe resists implementation of the so-called TRIPs Plus obligations in regional or bilateral trade agreements. If the framework imposed on countries by the WTO cannot be used effectively to promote public health and access to medicines for all, then poor countries (including Zimbabwe) should not be obligated to issue patents on medicines.

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