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# Pills, Patents and Profits: The Fight for Affordable Medicines for All

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## 1. Introduction

The issue of public health and patents generated considerable heat at the World Summit on Sustainable Development (WSSD) held in Johannesburg in July/August 2002. Away from public attention, there was a near political setback on the victory gained at the last World Trade Organisation (WTO) Ministerial Conference in Doha with regard to the WTO's intellectual property rights agreement and public health.

The exorbitant prices of branded or patented drugs have captured world attention and triggered a global campaign for access to affordable medicines over the last two years. Prices of branded or patented drugs are often far higher than prices of similar products by alternative or generic sources. When drug companies sell a product in different countries, they often adopt price differentiation, setting price levels according to what the individual market can 'bear'. So, where no alternative is available, the product can be sold at the highest price possible. Where generic alternatives are available, the price of the patented drug drops.

Profit maximisation through elimination of competition and maintenance of market monopoly seems to be the main objective, and patent protection is the most effective tool for international drug companies to keep out competition from generic producers and maintain monopoly control.

It is now recognised that the current regime of patents being 'globalised' by the WTO is one important cause of this problem. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in the WTO obliges all WTO Members to recognise patents in respect of drugs, thereby enlarging and entrenching the rights of patent holders at the expense of consumers. The effect of such all-encompassing patents has been to confer monopoly rights on international drug companies in the production and distribution of their patented drugs. By shutting out competition, TRIPS gives drug companies the ability to charge high monopoly prices for their drugs.

The crux of the issue is how to make medicines more affordable to more people who need them. HIV/AIDS drugs are just one high-profile example. Many other drugs for tuberculosis, malaria, cancer, asthma, diabetes and Parkinson's Disease, among others, are made unaffordable, simply because drug companies have been able to block competition from other firms and products through the use of patents.



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## 2. The Doha Declaration on TRIPS and Public Health

While TRIPS obliges WTO Members to provide patent protection for drugs, it also allows them to take certain measures (e.g., government use of patents, compulsory licensing, parallel importing and exceptions to patent rights) which override or limit patent rights under certain conditions. These measures have, in fact, been introduced by the developed countries as a means of balancing patent rights with the public interest of encouraging competition, consumer protection and, in the case of drugs, access to affordable medicines.

There are many examples of the use of compulsory licensing and government use of patented inventions, on grounds of public interest, in the developed countries, all of which are deemed TRIPS-consistent. In developed countries like the US, Canada, the UK and other EU countries, governments have broad powers to override patent rights, through compulsory licensing, government use and exceptions to patent rights. Parallel importing is also allowed under TRIPS, which states that WTO Members are free to choose their own regime of exhaustion of patent rights. Yet, developing countries have been hesitant to use the same measures.

Through a combination of political pressures, legal challenges and other tactics, the developed countries and the drug company lobby have endeavoured to discourage and prevent developing countries from exercising their rights under TRIPS to use compulsory licensing or parallel import measures.

The public outcry over such moves generated an international debate and led to a worldwide campaign on patents and public health. Developing countries pushed for an interpretation of TRIPS which guaranteed the right of WTO Members to use measures such as compulsory licences and parallel imports. The result is the Ministerial Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Members at the Doha Ministerial Conference in November 2001.

The Doha Declaration states that the TRIPS Agreement 'does not and should not prevent Members from taking measures to protect public health'. It also reaffirms the right of Members to issue compulsory licences (and the freedom to determine the grounds on which the licences are granted) and confirms the right of WTO Members to make use of parallel importing. The Doha Declaration is significant because it recognises the negative impacts of an inflexible implementation of TRIPS, and therefore, the need to balance commercial interests in patent rights with public interest in ensuring access to medicines.

Developing countries in the WTO had fought a hard battle to have recognition of the flexibility in TRIPS which enables Members to take measures to protect public health and promote access to medicines. To preserve this political gain, it was important that the WSSD Plan of Implementation stressed the need for all governments to respect and implement the legal rights affirmed by the Doha Declaration and to build on the political momentum generated by the international campaign on access to medicines.

## 3. Opposing Options

However, some developed countries tried to roll back that step forward by introducing text during the WSSD negotiations that would commit WTO Members to a full implementation of TRIPS rather than reaffirm the right to be flexible, as recognised in the Doha Declaration on TRIPS and Public Health.

In Bali at the last preparatory meeting before the Summit, some developed countries had proposed language 'reiterating our commitment to the WTO/TRIPS Agreement' and to implement the TRIPS Agreement as part of the wider national and international action to address public health problems such as AIDS, TB and malaria (Paragraph 88 of the draft Plan, later to be finalised as Paragraph 94).

This proposed text was the opposite of reality as implementation of TRIPS has led to the escalation of medicine prices. It was precisely this monopolistic control of market prices that led to the battle by developing countries to seek and obtain a WTO ministerial declaration that clarified the issue of the rights of WTO Members.

The G77 thus opposed the language and offered their own formulation, proposing that public health problems should be addressed through 'reaffirming the rights of WTO Members to use to the full the provisions of TRIPS that provide flexibility for this purpose'.

Negotiators were thus faced with basically two options at Johannesburg. One supported and strengthened the spirit and objectives enshrined in the Doha Declaration, and the other sought to limit the political gains obtained in the Doha Declaration.

After prolonged negotiations, the integrity of the Doha Declaration in favour of public health was protected. The final agreed text in Paragraph 94 commits governments to 'Address the public health problems affecting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, while noting the importance of the Doha Declaration on the TRIPS Agreement and Public Health, in which it has been agreed that the TRIPS Agreement does not and should not prevent WTO Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we reaffirm 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.'

## 4. From Political Gain to Reality

The hard-fought victory at Doha, further endorsed at the highest political level at the WSSD, must now be translated into a practical reality in the developing countries. Indeed, the Doha Declaration not only clearly confirms the flexibility available in TRIPS but stresses that countries should implement TRIPS in a manner to promote access to medicines for all.

Implementing the Doha Declaration would involve three key elements:

(a) the need to align national patent legislation to put into effect the rights so recently affirmed at Doha;

(b) the need to assess and determine the appropriate option (or combination thereof) suited to the national situation regarding drugs; and

(c) the need to clarify and establish administrative procedures and practical policies for implementation.

There should be appropriate compulsory licensing, government use and parallel import provisions in the national laws, which should be used. Developing countries that are able to locally manufacture drugs on a viable scale should promote such production. Where necessary, compulsory licences can be issued, or government use made to enable such production. Where production is not possible, the options of parallel importing and compulsory licensing to import a generic equivalent could be employed.

## 5. Local Manufacture and Import

For the local manufacture of the drugs, options include:

- manufacture of drugs that are not under patent locally, where there is no restriction (in terms of the patent laws) on the production of the drugs;

- manufacture through government use, or for public, non-commercial purpose, where a public agency or a government contractor undertakes the production of a patented drug on the ground that such production is required to fulfil a public (and not-for-profit) purpose; and

- manufacture under compulsory licence, where the private and public sector can produce the patented drug on a commercial basis. Manufacture under a compulsory licence can also be done as a joint venture between local and foreign companies. There are, however, limitations on the export of drugs produced under compulsory licence.

For import of drugs, there are a number of options, too:

a) Import under government use, or use for public, non-commercial purposes, where the government or its agent can import generic versions of a patented drug from countries where the product is not under patent, or where the manufacturer has a compulsory licence to produce in its country.

b) Import through compulsory licence, where a compulsory licence can be issued by the government to an applicant (a company, government agency, NGO, etc.) to import generic versions of patented products from other countries where the products are not patented, or where the manufacturer has been given a compulsory licence to produce its own version of the patented product in its country.

c) Import through parallel importing, where a company or NGO or government agency can import a patented drug from another country where the same patented product is sold at a lower price. The importer does not need a compulsory licence to import. The condition is that the importing country must have adopted the appropriate legislation allowing this measure.

In designing a suitable implementation system for these options, the following should be kept in mind:

(i) the system should not be overly legalistic or expensive to administer;

(ii) the provisions for 'government use' and compulsory licence should be strong as TRIPS gives governments broad powers to do so. The provisions in developing countries should not be weaker than the US, UK or other developed-country provisions.

(iii) There should be clear guidelines for fulfilling the conditions for the use of government use and compulsory licences, e.g., for payment of compensation to the patent holder. In some developed countries the compensation is 2% to 8%, and a recent UNDP report had suggested a 4% average.

The experience of the developed countries has shown that measures like compulsory licensing and government use have proved effective in mitigating against monopoly control of the market and in inducing price reductions. The mere existence of the legal provisions may also be sufficient to persuade patent holders to act reasonably, and balance the bargaining positions of the negotiating parties. For instance in Brazil, the fact that the government had enacted compulsory licence laws, and the serious preparations it made to issue compulsory licences contributed to the significant decline in the cost of the relevant patented drugs.

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