Access to Medicines For All: A Major Human Rights Issue

By Narenda B. Zaveri

Until the WTO Ministerial Conference met at Doha in November 2001, most Member countries read and applied the TRIPs provisions relating to public health as supportive of a strong product patent regime. This enabled right holders to fix and maintain extremely high prices for life-saving patented drugs, with the result that treatment was denied to millions of people dying and suffering from HIV/AIDS, tuberculosis, malaria and other epidemics. To make matters worse, the patent holding corporations were actively discouraging governments from discharging their basic obligation to protect their citizens from these life-threatening diseases by procuring drugs from generic sources at a small fraction of the patent holders' prices. Human values, reason, world opinion and even considerations of human rights were all ignored by the patent holding firms.

However, the Doha Declaration on the TRIPs Agreement and Public Health affirmed the right of WTO Members 'to protect public health and, in particular, to promote access to medicines for all'. Confirming TRIPs' 'flexibilities for this purpose', the Declaration establishes beyond question the primacy of health care and the powers of WTO members to grant compulsory licenses and to treat HIV/AIDS, tuberculosis, malaria and other epidemics as situations of national emergency.

One of the stumbling blocks is that many developing countries have no pharmaceutical industry with the capacity to manufacture generic drugs. Yet Article 31(f) of TRIPs stipulates that any use of the subject matter of a patent that is not authorised by the holder must be 'predominantly for the supply of the domestic market of the Member authorizing such use'. But realising 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', the Conference instructed the TRIPs Council 'to find an expeditious solution to this problem and to report to the General Council before the end of 2002'.

The Right to Life, Health and Development

Resolving this problem is a matter of life and death for millions of poor people suffering from these diseases. More than a trade related issue, it is a humanitarian and human rights problem; and more than a national anxiety, it is a matter of serious international concern.

The right to life, which includes the right to healthcare and nutrition, is universally accepted as a natural, inalienable and fundamental right of all human beings, and is affirmed in the Universal Declaration of Human Rights, and the International Covenants on Civil and Political Rights and on Economic, Social and Cultural Rights (ICCPR and ICESCR). Specifically, Article 12 of the ICESCR declares that 'The States Parties … recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', and that the steps to be taken to realise this right shall include those necessary for:

- the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
- the prevention, treatment and control of epidemic, endemic, occupational and other diseases; and
- the creation of conditions which would assure to all medical service and medical attention in the event of sickness.'

These international conventions establish the universality of human rights and oblige all member states to respect, promote and protect them. No exception can be claimed or made by reference to nationality, territory or location of individual claiming such protection. It is in assertion of these human rights and obligations that UN members hold the government of any member country accountable for the atrocities or human right violations it commits even on its own citizens within national borders.

Thus, in the context of healthcare requirements, particularly for treating pandemics like HIV/AIDS etc., the government of country A – lacking adequate capacity to produce the generic drugs necessary for its citizens' health – can rightfully claim and require the government of country B, where generic production of the required drugs is available, to permit production and exports of such drugs for treatment of citizens of country A by grant of compulsory licenses. The conventions and treaties cited above oblige the government of country B to issue compulsory licenses permitting such supplies by its generic manufacturers, in order to protect the right to life and healthcare of citizens of country A.

These principles have also been consistently confirmed in the official Declarations or Resolutions adopted at special sessions of the United Nations General Assembly (27 June 2001), the UN Security Council, the UN Economic and Social Council, the World Health Assembly (20 May 2000), the UN Commission on Human Rights (3 April 2002), UNAIDS and other international fora, particularly those dealing with pandemics like HIV/AIDS, tuberculosis and malaria. Actions based thereon have been strongly recommended as part of co-ordinated international action, particularly in the context of public health and the implementation of trade agreements.

Continued on page 18

Global Crisis – Global Action

In the Preamble of the UN General Assembly Declaration of Commitment on HIV/AIDS adopted on 27 June 2001, UN member governments

- recognised that 'the cost, availability and affordability of drugs and related technology are significant factors to be reviewed and addressed in all aspects and that there is a need to reduce the cost of these drugs and technologies in close collaboration with the private sector and pharmaceutical companies';
- recalled 'efforts to make drugs available at low prices for those in need'; and
- welcomed 'the efforts of countries to promote innovation and the development of domestic industries consistent with international law in order to increase access to medicines to protect the health of their populations, and noting that the impact of international trade agreements on access to or local manufacturing of essential drugs and on the development of new drugs needs to be evaluated further'.

Access to Medicines, continued from page 17

The Preamble of the World Health Assembly Resolution is very significant and provides guidance for implementing trade agreements having public health implications. It commends co-operation between: 'international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements'. It also underlines 'the need to advocate respect for human rights in the implementation of all measures to respond to the epidemic'.

The Doha Declaration should not be considered separately from these covenants, declarations and resolutions. Indeed, Paragraph 2 stresses 'the need for TRIPs to be part of the wider national and international action to address these problems'. Having regard to all these considerations, Art 31(f) cannot be interpreted rigidly to restrict the scope of exports. The expression 'predominantly for domestic market' itself is flexible enough to allow for exports when domestic requirements are satisfied. In conclusion, Article 31(f) may be correctly interpreted as allowing for exports to countries granting the compulsory license. Consequently, there is no need to amend the sub-paragraph or to draft an interpretative statement on Article 30 to make such exporting permissible.

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Zimbabwe Declares AIDS Emergency; US and Argentina Settle Patent Dispute

On 24 May, Zimbabwe became the first country to take advantage of the flexibilities confirmed in the Doha Declaration on TRIPs and Public Health. The country's Minister of Justice Patrick Chinamasa declared a six-month period of emergency, effective immediately, 'for the purpose of enabling the State or a person authorised by the Minister under Section 34 of the [Patent] Act

(a) to make or use any patented drug, including any antiretroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions;
(b) to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions.'

This declaration, which effectively frees Zimbabwe from its obligations to rights holders even for medicines that are under patent in the country, reflects the Doha TRIPs Declaration's acknowledgement that

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

TRIPs Article 31(b) allows Members to waive the requirement to seek the patent holder's consent before issuing a compulsory license in cases of 'national emergency or other circumstance of extreme urgency'.

With a quarter of its 13 million citizens estimated HIV positive, Zimbabwe has one of the highest HIV infection rates in the world. During the emergency period, the government is likely to purchase antiretroviral AIDS drugs from India, where a one-day dose of generic Combivir, for instance, sells for 75 US cents (the drug's brandname manufacturer GlaxoSmithKline had offered it to Zimbabwe for US$2 a day). The government will finance the purchase of AIDS drugs from a US$5.3 million grant offered by the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Non-governmental organisations, such as the South African Treatment Action Campaign and the Health GAP, welcomed Zimbabwe's move, but cautioned that six months would not suffice to deal with the problem of access to medicines. Médecins sans Frontières called the Zimbabwean decision a 'model other countries should follow'.

On 31 May, Argentina and the United States notified the WTO that they had reached a mutually agreed solution to the dispute the latter initiated in May 2000 against Argentina's laws on the protection of pharmaceutical patents and test data for agricultural chemicals.

Argentina agreed not to issue compulsory licenses on the basis of a finding of anti-competitive practices, unless the national Commission on the Defence of Competition has first established that the patent holder abuses its dominant position in the market. Insufficient 'working' of a patent would not 'in and of itself warrant an automatic determination that a patent owner is engaging in an "anti-competitive" practice', the two countries agreed.

According to the agreement, Argentine authorities 'shall grant' exclusive marketing rights for a product that has been approved for marketing but whose patent application is pending, either for five years or until the patent is either approved or rejected, on condition that the patent application was filed after 1 January 1995, or that another WTO Member had either granted a patent or marketing approval for it.

The agreement also contains new legal language that will be proposed to the Argentine National Congress to amend or supplement existing provisions on process patent protection and preliminary injunctions to prevent patent infringements. In addition, new legal text would shift the burden of proof in process patent infringement cases from the plaintiff to the defendant.

The US had also challenged Argentina's protection of micro-organisms and chemical compounds (TRIPs Article 27.3(b)), but agreed that the government's October 2001 guidelines about its practices relating to the patentability of micro-organisms responded to this concern.

Finally, the parties agreed that, depending on the outcome of the Argentine legislative process, the US may still request a WTO panel on Argentina's laws protecting undisclosed test data submitted for market approval from unfair commercial use (TRIPs Article 39.3). If Argentina loses the dispute, it will submit a legislative amendment to the National Congress within a year of the adoption of the relevant DSB rulings.

The agreement (WT/DS171/3) is available on the WTO website.