GLOBAL INSIGHT
a focus on current issues
Institute for Global Dialogue
Issue 60 / June 2006

Trade-related intellectual property rights and health treatment access:

a South African government response

Riaz K Tayob

Riaz K Tayob is a researcher at SEATINI, the Southern and East African Trade Institute. This paper is written in his personal capacity.

The agreement on trade-related intellectual property rights (TRIPS) of the World Trade Organisation (WTO) makes it compulsory for countries to protect patent rights, with a few exceptions. Patented drugs, in particular, are used in the treatment of HIV/AIDS because new treatments are generally protected by the 20-year monopoly granted to innovators of new drugs. The monopoly right allows the patent holder to charge any price it wishes. Since both the cost of and access to medicines can be a matter of life and death, developing countries negotiated in the TRIPS agreement some flexibilities to promote access to needed drugs. Using these flexibilities has proven to be a major problem, especially in South Africa where, according to Dr Olive Shisana (2006), HIV/AIDS is of epidemic proportions. The Treatment Action Campaign (TAC), which was nominated for a Nobel peace prize in 2004, states that of the half a million South Africans that need treatment, fewer than 1 per cent receive it, and most of these are in the private sector (TAC nd). While price still remains a major obstacle to access for those in need, health system problems also raise a number of issues. The global and local context of treatment access is complex, and solutions have to be sophisticated.

The TAC has experienced a chequered relationship with the department of health (DOH). On the one hand, for instance, they participated in a collaborative court case in 1999 against Big Pharma (multinational pharmaceutical companies), and on the other there is the recent impasse on whether the TAC will be on the South African delegation to the special session on HIV/AIDS hosted by the UN. The relationship between the TAC and the South African government is indicative of the lack of cohesiveness in official measures to address health systems issues.

Context

Overall, the role of the South African government in facilitating treatment access has been both positive and negative. A simple scorecard on treatment access is not possible because of the complexity of the challenges, but it suffices to state that, with 5 million South Africans infected with HIV/AIDS, and major challenges to public and private health systems, the situation remains alarming. Lack of access to medicines, especially new drugs, is a key impediment to improving our population's health status, and the problem goes beyond HIV/AIDS. The predatory practices of Big Pharma were highlighted by Oxfam, showing how the prices of patented drugs are set to maximise

Global Insight is aimed at providing members of the policy community with concise but trenchant analyses of topical issues. Comments and suggestions are invited.

profit rather than facilitate access – or even be reflective of cost. In 2001, fluconazole was available at US$8,25 in South Africa, US$10,50 in Kenya, and US$27,00 in Guatemala, compared to US$0,29 in Thailand and US$0,64 in India (Oh 2001). Competition from generic producers in India and Thailand intimates a link with cheaper drugs. Médecins Sans Frontières (MSF) reports that for anti-retroviral therapy, generic competition resulted in prices dropping from US$10 000 to US$150 in 2005 (MSF 2005). With these kinds of margins it is no surprise that Big Pharma companies post some of the highest profits compared to other sectors (and, incidentally, are also among the largest political campaign contributors in some industrialised countries). Even the much-publicised World Health Organisation (WHO) programme to get 3 million people on treatment by 2005 ('3 by 5') failed to achieve its target by more than half, indicating a common global inability to meet basic health needs (WHO 2006). This resulted in a WHO commission requesting companies not to register patents on drugs needed in poor countries, or calling on them not to enforce them (Boseley 2006). Implicitly, the WHO recognises that the current system of intellectual property rights registration is inappropriate to meet poor-country needs.

South Africa's contested terrain

South Africa has implemented a number of measures that take a health-systems approach to the complex challenges. Civil society movements have launched various campaigns to deal with their needs. The trouble with single-issue civil society campaigns is that they draw attention to a particular problem, while the state has to deal with that plus many other problems. South Africa has taken some steps towards addressing the issue, such as the new pro-equity National Health Act, which deals in part with the geographic spread of health professionals and services, and the pharmaceutical pricing regulation that implemented price controls on medicines.

Some of these measures have upset some sectors of society, and it has not been an easy road for the DOH to walk by any means. But its difficulties have not been helped by a highly defensive, and at times aggressive, communications campaign that failed at minimum to harness the support of the intended beneficiaries of the programme. To be fair, other stakeholders have also not been as proactive as they should have been. For instance, a ten-year incubation period for the National Health Act provided many opportunities for interaction. Yet some of the equity-based critiques of government policy have come from marginal quarters, and have not been taken as seriously as they should. For example, implementing private wards in public hospitals has certainly helped retain health professionals, but implementing them in hospitals with inadequate or no cost-accounting management systems is problematic, to say the least.

South Africa and the global TRIPS negotiations

Besides the health system issues, the DOH and the department of trade and industry (DTI) share responsibility for our international obligations that affect treatment access, particularly TRIPS under the WTO. The DOH has backed down on its 1999 attempt to make use of perfectly legal flexibilities to produce and import cheaper copies of patented medicines (generics) under the TRIPS agreement. Big Pharma alleged that undermining patent rights was illegal under the WTO, and this position was translated into a political impasse at the world body's highest levels. Consequently, at the 2001 Doha WTO ministerial conference, the controversy resulted in a restatement of the rights that developing countries already enjoyed, that is, to issue compulsory licenses for generic production or parallel importation (Oh 2001). Many civil society organisations claimed this as a success for the public health movement, but it was pyrrhic victory.

Even so, many African countries still had problems. With no or limited production capacity, access to adequate quantities of generic drugs was limited by the TRIPS agreement. A country producing a generic version of a patented drug could only produce primarily for domestic production. This has been interpreted to mean that only 49 per cent of the generic production was legally exportable. Africa was at a crossroads, whether to pursue further negotiations under TRIPS article 31, or to use article 30.[1] Some Latin American and Asian countries preferred the use of article 30, because it offered greater flexibilities. African countries, however, chose to pursue article 31 flexibilities. This effectively stifled exploration on article 30, in part because Africa's development priorities were deferred to by other developing countries. Prior to the Cancun ministerial conference on 31 August 2003, a temporary waiver agreement was reached to allow countries

with limited or no production capacity to import drugs, and to allow generics manufacturers to export more than 49 per cent. At the time of concluding the waiver agreement, the chairman of the committee read out a statement which suggested additional limitations, but this did not form part of the signed agreement.

The waiver agreement was tedious and no country used it. Upon its expiry, it was extended pending renegotiation. The Africa group collectively sought to make the agreement more user-friendly and practical, and submitted a formal proposal to the WTO. The United States tabled its own proposal to lock the waiver agreement in, and sought to include the restrictive chairman's statement as part of the final agreement. This statement was not regarded as part of the waiver agreement by the Africa group and other WTO members, but the partisan WTO secretariat changed the signed waiver agreement by including a footnote making reference to the chairman's statement. This favoured United States negotiators, while further disadvantaging Africa and developing countries in the negotiations. Consequently, the waiver agreement, minus the chairman's statement, was made permanent prior to the 2005 Hong Kong WTO ministerial conference. The global treatment access movement has not sufficiently interrogated the WTO secretariat's role in the negotiations.

What is worrying about the South African role in these negotiations is the lack of coherence, transparency, and concern for other African countries' needs. In 2005, while negotiations were still under way on the waiver agreement, South Africa, together with a small number of other countries, deliberately undermined the Africa group proposal on TRIPS during the African Union's second extraordinary session of trade ministers in Arusha. Their carefully orchestrated series of interventions resulted in a de facto withdrawal of the Africa group proposal, paving the way for the temporary waiver agreement to become permanent. The DTI negotiators in Arusha also undermined the Southern African Development Community (SADC) health ministers' declaration calling for no impediments to treatment access. Inexplicably, a month earlier, during the South African civil society consultation on the then upcoming WTO Hong Kong ministerial, the DTI made it clear it was fully supportive of the Africa group proposal. The removal of the more practical Africa group proposal retarded greater flexibility for treatment access, and now implies a disproportionately greater impact on other African countries.

Conclusions

The DOH has not been as vigilant as it ought to have been on trade issues, while trying to address systemic issues. Failing to use policy flexibilities to improve treatment access, and to use opportunities to expand these policy flexibilities, it has allowed Big Pharma, which enjoys monopoly patent rights, to escape regulatory control at the WTO. The flexibilities include the TRIPS-compliant regulations for generics – which to date have not been passed. There is also no plan for drugs to be produced by public entities, as happens in Brazil and Thailand. Instead, the department has tackled retail pharmacists and their pricing strategies, almost as a cop-out for failing to deal with predatory pricing of Big Pharma. While the important international political moments have been lost, the DOH should take a greater interest in international trade negotiations handled by the DTI, and ensure that its policies are not rendered useless or even illegal.

Studies by the South African Municipal Workers Union (SAMWU) (Sinclair 2005) and the Regional Network on Equity in Health in Southern Africa (EQUINET)[2] indicate that the pharmaceutical pricing and the infamous 'certificate of need' measures in the National Health Act are inconsistent with our obligations under the WTO's General Agreement on Trade in Services (GATS). These 'illegalities' show blind spots in co-ordination between departments, and in their appreciation of international restraints on domestic policy flexibility. To compound this lack of coherence, the DTI has indicated that it will studiously not conduct regulatory impact assessments of the new GATS offers it intends to make.

In conclusion, South Africa has been unable to deal adequately with the international challenges affecting treatment access, while at the same time taking some bold steps to address systemic health issues. For South Africa to make progress, greater co-ordination is required between government departments to ensure policy coherence to meet its population health needs. As a principle, it needs to protect its sovereign rights to regulate and take measures in the public interest. Among civil society, greater vigilance is required to put a stop to the one-step-forward, three-steps-back routine of the under-capacitated state by monitoring and analysing the actions of both the DTI and the DOH.

References

Boseley S. 2006. WHO plea to drugs companies. *The Guardian*. 4 April. www.guardian.co.uk.

MSF. 2005. Prices of AIDS medicines in developing countries continue to be a concern. http://www.msf.org/msfinternational/invoke.cfm?objectid=CCE6C685-E018-0C72-09FDD632034EA020&component=toolkit.pressrelease&method=full_html.

Oh C. 2001. *TRIPs, drugs and public health: issues and proposals*. Malaysia: Third World Network.

Shisana O. 2006. How we know there is an HIV epidemic in South Africa. TAC Equal Treatment. March. http://www.tac.org.za/Documents/EqualTreatment/ET19.pdf.

Sinclair S. 2005. The GATS and South Africa's National Health Act: a cautionary tale. Canadian Centre for Policy Alternatives. November. http://www.policyalternatives.ca/documents/National_Office_Pubs/2005/South_Africa_and_GATS.pdf.

TAC. nd. You can save a life. http://www.tactp.org.za/. Accessed 30 April 2006.

WHO. 2006. Progress on global access to HIV antiretroviral therapy: a report on 3 by 5 and beyond. March. www.who.int.

Endnotes

1 Article 30: 'Exceptions to rights conferred'; article 31: 'Other use without the authorization of the right holder.' At http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

2 Generally, see publications at www.equinetafrica.org.

Institute for Global Dialogue

Block 12, Thornhill Office Park, Bekker Street,
Vorna Valley, Midrand, South Africa
PO Box 32571, Braamfontein 2017, South Africa
Tel +2711 315 1299
Fax +2711 315 2149
Email info@igd.org.za · Web www.igd.org.za

ISSN 1607 2375
Produced by Acumen Publishing Solutions