

# UNIVERSAL ACCESS TO TREATMENT FOR HIV/AIDS: DOES AUSTRALIA'S POLICY ON TRADE AND INTELLECTUAL PROPERTY HELP?

By Peter Drahos

The Australian Government has committed itself to expand the treatment of HIV/AIDS 'in line with the goal set at the 2005 UN World Summit to provide as close as possible to universal access to HIV treatment by 2010'. (Commonwealth of Australia, 2006:50) Currently, the World Health Organization (WHO) estimates that in the South East Asia region 14% of those who need antiretroviral (ARV) treatment are receiving it, leaving about 970,000 without treatment. (WHO, 2006:77)

In the Western Pacific region, coverage is 27%, leaving about 150,000 without treatment. Increasing access to treatment in Australia's region is possible because the price of first-line ARVs has come down. For example, in 2005 the average price in low-income countries for the fixed-dose combination of stavudine, lamivudine and nevirapine was US\$148 per person per year and US\$549 for zidovudine, lamivudine and a single dose of efavirenz. (WHO, 2006:29)

The prices for second-line treatments are very different. The second-line regimen of tenofovir, abacavir and lopinavir or ritonavir averaged US\$1,888 in low-income countries. (WHO, 2006:30) Médecins Sans Frontières did some price comparisons of first- and second-line combinations in low-income countries and found that second-line combinations were on average 12 times more expensive. (MSF, 2006:6)

These price differences are a function of the effects of patents and trade agreements on the structure of global pharmaceutical markets. Any commitment to universal access to second-line treatments has potentially massive cost implications. It follows that any government that wishes to improve access to treatment should be following a policy on trade and intellectual property that aims to bring down the cost of treatment. Unfortunately, as we will see, the Australian government seems to be heading in precisely the opposite direction.

## Understanding why there are cost differences between first- and second-line treatments

Antiretrovirals became cheaper by the end of the 1990s because of an interaction between national patent law and trade law. Many of the first-line ARVs such as stavudine and zidovudine had been discovered in the 1980s or even earlier. They had not been patented in India because India's patent law of 1970 did not allow for the patenting of pharmaceutical products. Indian generic companies such as Cipla and Ranbaxy were efficient producers of high-quality medicines for export. Seeing international demand, they began making ARVs at a price that for the first time made it possible to think about treating millions of people.

However, India was a member of the World Trade Organization (WTO) when it came into operation on 1 January 1995. All members of the WTO have to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS obliges

all members to grant patents on pharmaceutical products that meet the criteria of invention. The structural impact of this single change on global pharmaceutical markets is huge. Currently the WTO has 149 members, with another 30 countries or so queuing to join. More importantly, China and India, the two countries most capable of producing low-cost, high-quality generics for global export are both members of the WTO.

Using TRIPS rules, India took maximum advantage of a transition period available to developing countries and only introduced product patents on pharmaceuticals on 1 January 2005. In the period between 1 January 1995 and 1 January 2005, India had to accept patent applications (referred to as mailbox applications) and in some cases offer exclusive marketing rights. The essential point is that multinational pharmaceutical companies can now apply for patents on pharmaceutical products in India. Currently thousands of applications are being received. The Indian patent office is also opening and examining the 9,000 or so mailbox applications it accepted during the transition decade.

In the longer term, it may be hard for India to remain a source of high-quality, low-cost ARVs. Under Indian law a generic company can oppose the grant of a patent before or after it is granted or it may seek the revocation of the patent if it is sued for infringing that patent. It may seek a voluntary licence from the patent owner, but even if such a licence is granted it may be subject to export restrictions. It may also seek approval from a court to use the patent without the permission of the patent owner (known as a compulsory licence) but if successful it will have to pay royalties. The patent environment in India is becoming much more complex. Inevitably patent litigation will increase. This suits pharmaceutical multinationals more than it does Indian generic companies.

As the full implications of the structural change that TRIPS had wrought began to be more widely appreciated, civil society and public healthcare advocates began a campaign aimed at making governments understand that compulsory licensing, the single most important tool for the regulation of patents for public health purposes, was still available to them under TRIPS. One profound achievement of this campaign was that a coalition of developing country governments and civil society actors were able to negotiate in November 2001, as part of the opening of the Doha Round of the WTO, the *Declaration on TRIPS and Public Health*. It recognises what was always the case under TRIPS, namely the right of states to protect public health and 'promote access to medicines for all' (Paragraph 4).

The problem with TRIPS, however, is not that it prohibits this right, but rather that it sets up a structure that strikes at the capacity of developing-country generic producers to achieve economies of scale in global markets. Aside from the product patent rule, Article 31 of TRIPS places restrictions on the use of compulsory licences by states. States can continue

to use compulsory licensing, but if they issue a compulsory licence for the use of a patent, it has to be predominantly for the supply of their domestic market (generally read as requiring more than 50% of production to be for the domestic market).<sup>1</sup>

This rule was clearly aimed at generic exporters, especially Indian producers. The rule also creates a problem for developing countries that want to issue a compulsory licence for a patent as a means of bringing down the price of a pharmaceutical, but do not have generic manufacturers capable of manufacturing under the licence. Countries facing this situation would have to import, but any potential exporting country like India faces the TRIPS restriction on export.

Paragraph 6 of the Doha Declaration recognised the problem and instructed the TRIPS Council to find a solution. The solution adopted by the WTO General Council on 30 August 2003 took the form of waivers of the obligations in Article 31.<sup>2</sup> The waivers would operate only if a number of conditions were met. For present purposes it is sufficient to point out that the six pages of rules that make up the so-called Paragraph 6 solution are procedurally cumbersome and do not deliver the kind of commercial clarity a generic company needs to enter the market. The problem is neatly illustrated by the following comment from a World Bank Working Paper:

[T]his Guide can only provide a starting point. The actual implementation of the Paragraph 6 Decision will take place within the contours of each country's existing legislative and regulatory framework, practice and jurisprudence. The authorities of each country will have to work with their own legal experts to arrive at a solution that is right for their situation. (quoted in Abbott and Van Puymbroeck, 2005:3)

One wonders how developing countries can see other than hypocrisy and deceit in a solution that pushes developing country public health officials onto a battleground of legal rules, a battleground that favours those with large litigation budgets and armies of lawyers.

At the same time as these developments in the WTO, the US has been negotiating with other states free trade agreements (FTAs) that contain intellectual property rules that go beyond TRIPS (known as 'TRIPS-plus'). A recent report by the Committee on Government Reform (2005) in the United States House of Representatives examined a number of these FTAs and came to the conclusion that 'U.S. trade negotiators have repeatedly used the trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices'.

### Australia and the 'Axis of Patents'

During the trade negotiations that led to TRIPS, Australia was a member of the Friends of Intellectual Property Group and essentially supported the US on its agenda for a comprehensive agreement on intellectual property. Australia reasoned that if the US was given TRIPS, it and other agricultural countries would in exchange receive significant concessions in agriculture. This gamble has not paid off.

After TRIPS came into operation, Australia continued to be pressured by the US to move to TRIPS-plus standards. In 1998, Australia caved in to US trade pressure and introduced patent term extension for pharmaceuticals. This hurt Australian generic companies which had been preparing to invest in the production of pharmaceuticals that were due to come off patent. In addition, the Australian government refused to respond to requests from Australian generic companies to be allowed to manufacture pharmaceuticals for export only to those markets where the relevant pharmaceutical had gone off patent even though it remained under patent in Australia. The generic industry argued that such export to the non-patented market would not interfere with the patent owner's Australian patent. A government interested in helping a local generic industry achieve critical economies of scale would have been sympathetic to such a request.

After the Doha Declaration on TRIPS and Public Health in 2001, the Department of Foreign Affairs and Trade took the view that the Doha Declaration struck an appropriate balance between intellectual property rights and public health needs. During the course of the Paragraph 6 negotiations that followed the Doha Declaration Australia supported the US in its efforts to produce a complex and unworkable solution.

A number of states such as Canada and Norway have implemented the Paragraph 6 solution into their national law in an effort to prepare for the possibility that they might receive requests from developing countries for the manufacture and export of needed medicines. It is likely that at some stage the Paragraph 6 solution will attract some symbolic export activity. Certainly the WTO will be hoping so, since its credibility looks increasingly weak as developing countries stay away from using the Paragraph 6 system.

Australia to date has not bothered to implement the Paragraph 6 solution. This perhaps has the virtue of honesty about its worth. In any case, none of the six Australian generic companies that the author interviewed in 2005 reported a desire to manufacture under the solution. Given the treatment of the generic industry by the Australian government this is not especially surprising. Commerce depends on trust in government.

During 2001 there was a welcome initiative by Australia on TRIPS. It offered to provide support to governments in the Asia Pacific region to draft laws that took full advantage of TRIPS flexibilities so that ARVs could be imported with minimum risk from intellectual property restrictions. (Commonwealth of Australia 2004:18) To the author's knowledge, no government in the region has asked for assistance with drafting. Whatever the reason, it is not related to a lack of need for technical drafting assistance. A recent survey by the ASEAN Secretariat (2005) revealed that most ASEAN members have laws that do not take full advantage of TRIPS flexibilities. Many smaller states in Australia's region (for example, the Pacific Island states) lack technical expertise in intellectual property.

<sup>1</sup> This requirement, however, does not apply if the licence relates to a remedy for anticompetitive conduct. Proving anticompetitive conduct requires institutional capacities that developing countries generally lack.

<sup>2</sup> Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003.

On the bilateral trade front a significant change has occurred in Australia's approach since it concluded a free trade agreement with the US that came into operation in 2005. Prior to that, Australia had finished negotiating FTAs with Singapore and Thailand. In both those agreements it agreed to abide by TRIPS standards. The agreement that Australia concluded with the US contains a detailed chapter on intellectual property that goes beyond what is required under TRIPS. For example, it creates a linkage between patent registration and drug registration, something on which TRIPS is silent. Since the US-Australia FTA, Australia has begun negotiating FTAs with Malaysia and China. In both cases, it is seeking TRIPS-plus standards. This suggests that Australia has bought fully into the US agenda of protecting patents first and public health second.

## Conclusions

The recent White Paper on Australia's Aid Program clearly locates HIV/AIDS within Australia's development strategy. The goal of universal access to treatment that is articulated there carries with it cost implications. In a given year, 5% to 10% of a patient group will have to shift from first-line to second-line treatment. (MSF, 2006) The demand for second-line treatment will progressively shift from the tens of thousands into the hundreds of thousands and eventually the millions. For reasons that we have seen, the capacity of Indian and Chinese generic companies to meet this rising demand is being affected by the US-led agenda on trade and intellectual property that is deliberately aimed at making export by generic companies for public health purposes much more difficult.

Australia's support for this US agenda on intellectual property has cost implications for its own regional development strategies for HIV/AIDS, as well as the management of the risks of diseases and pandemics more broadly. In the case of HIV/AIDS, future Australian governments will face a situation in which the costs of second-line treatment remain high. Since most countries in Australia's region will not be able to afford this cost, these Australian governments will be faced with a rising bill for treatment. Investing in prevention remains key, but on any scenario treatment forms an integral part of dealing with HIV/AIDS.

There are also more direct risks to Australia of supporting a US trade strategy that is aimed at protecting the US pharmaceutical industry. The recent case of Roche's inability to supply the drug oseltamivir to meet Australia's demand for stockpiles of the drug illustrates the bigger risks that Australia is taking. Roche was unable to meet worldwide demand for the drug, including demand by countries in the Asia Pacific region which were high-risk countries in terms of a possible outbreak of avian influenza. This was a clear case where countries in the region should have resorted to the coordinated issue of compulsory licences in order to encourage a major Indian generic supplier like Cipla to enter the market. (Lokuge, Drahos and Neville, 2005) Instead, each country ended up managing the patent issue and supply of oseltamivir on its own, often in a confused and sub-optimal way.

From the point of view of managing pandemic risk, as well as other public health risks, Australia needs to encourage the development of smoothly functioning systems of compulsory licensing by countries in its

region. It then needs to lead a regional discussion on the use of these systems in fora such as APEC and the Pacific Island Forum, a discussion that, amongst other things, should be aimed at creating the necessary political confidence in the use of such systems.

Australia must develop a long-term regional strategy for the management of patents that bear on public health risks, a strategy that can harness the export capability of Chinese and Indian generic companies. Encouraging large-scale generic competition and supply is the only sure way in which the price of essential medicines can be brought down.

Australia should repeat its offer of October 2001 to provide technical assistance to Asia Pacific governments on the intellectual property issues, except this time the offer should be to help national public health authorities develop regulatory systems for the management of intellectual property for public health purposes. This kind of regulatory expertise is desperately lacking in the region and it is in Australia's obvious long-term interest to help create it.

Finally, Australia needs to re-think its support for the US trade agenda on intellectual property. US trade bullying on intellectual property has created an atmosphere of fear and self-censorship when it comes to official discussions of patents and medicines in many countries. Public health officials cannot be expected to manage public health risks and crises in such an atmosphere. Australia must develop a deeper vision of trade, intellectual property and development when it comes to public health. The current policies are little better than a gamble, more based on fealty to the US than any rational approach to managing risks.

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