

TRIPS, access to medicines and HIV/AIDS in South Africa

**A presentation made at the launch of Oxfam International's
"Rigged Rules and Double Standards: trade, globalisation, and
the fight against poverty" document**

11 April 2002, University of the Witwatersrand

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That the push for and the adoption of an international agreement on intellectual property rights has taken place within the paradigm of free trade is not without great irony and paradox, given that intellectual property, by definition, "is about restricting trade in certain goods."¹ In addition, when looked at from a classic trade perspective, it is clear that countries should not be required to maintain the same level of intellectual property protection.² What constitutes a valuable economic activity to any country depends on circumstances and conditions particular to that country.

A rational intellectual property regime, therefore, would in large part be determined according to a country's comparative advantage—whether in innovation, imitation or adaptation of other innovations. More importantly, a rational policy would also need to consider the interests of consumers and the

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¹ Robert Weissman, "A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining Legal Alternatives Available to Third World Countries" (1996) 17 *U. Pa. J. Int'l Econ. L.* 1069 at 1069.

² See Michael J. Trebilcock and Robert Howse, *The Regulation of International Trade*, 2nd ed. (London: Routledge, 1999) at 307.

public interest more broadly.³ Nowhere is this more clearly evident than in the struggle for access to treatment on a sub-continent ravaged by HIV/AIDS.

But despite the international harmonization of intellectual property law, countries are nevertheless permitted by the Agreement on Trade-Related Aspects of Intellectual Property Rights—or TRIPS—to take certain regulatory steps to ensure the accessibility of essential drugs, which include but are not limited to compulsory licensing, early working provisions and complete exclusions from patentability.⁴

The *Declaration on the TRIPS Agreement and Public Health*, adopted at the World Trade Organisation (WTO) Ministerial Conference in Doha in November 2001, expressly recognizes that TRIPS “does not and should not prevent Members from taking measures to protect public health.” Further, the declaration stresses that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to public health and, in particular, to promote access to medicines for all”, and that member states have the right “to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.” Clearly, the stage has been set for action that may bring welcome relief to Southern Africa.

³ *Ibid.* at 308.

⁴ A compulsory license is an authorization to use a patent without the patent-holder’s permission (Sara M. Ford, “Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents” (2000) 15 *Am. U. Int’l L. Rev.* 941 at 942). In the pharmaceutical sector, a compulsory license would entitle the licensee to manufacture generic versions of a patented drug or to import such products from where they are legally manufactured, either by the licensee itself or by another generic manufacturer. Early working provisions, on the other hand, ensure the introduction of generic products to the marketplace as soon as patent protection expires. Early working provisions permit certain forms of conduct—such as the use of the patented product in satisfying regulatory approval requirements—that would otherwise constitute patent infringement. Finally, excluding an intellectual object from patentability means precluding that object from being granted any form of patent protection.

The *Doha Declaration* followed an intense period of international activism and mobilisation, particularly focused around the case of *The Pharmaceutical Manufacturers' Association and Others v The President of the Republic of South Africa and Others*.⁵ With the abandonment of that case, we were lead to believe that our government would move swiftly to implement the much-needed amendments to the Medicines and Related Substances Control Act. Indeed, draft regulations were published for comment a little over six weeks after Big Pharma capitulated in Pretoria.

In exactly a week from tomorrow, however, we will mark the first anniversary of our historic victory with little to show for it domestically. While almost eight months have passed since the deadline for submissions on the draft regulations, the Act has yet to be promulgated and regulations have yet to be issued. This is despite a press statement issued on 19 April 2001 in which the Minister of Health stated as follows:

“We regard today's settlement as a victory in the sense that it unfreezes our law and restores to us the power to pursue policies that we believe are critical to securing medicines at affordable rates and exercising wise control over them....

Government will now go ahead and promulgate the law and within a few weeks draft regulations relating to various aspects of the Act will be published for public comment.

Certain aspects of the Act ... will kick in automatically with promulgation. In addition, we will move speedily to:

- Set up the Pricing Committee whose job will include the gathering of pharmaceutical intelligence and advising the Minister on a transparent pricing system for medicines.

⁵ Unreported case no: 4183/98, High Court of South Africa (Transvaal Provincial Division) March 2001.

- Activate the system of generic substitution, which will have major benefits for consumers in the private health care sector - and especially medical schemes.”⁶

Not only have we failed to implement the Act, but we have also failed to use or revisit the existing intellectual property framework in any meaningful way. Since 1997, our Patents Act has offered—and continues to offer—TRIPS-plus protections. In addition, our Minister of Health and her trade and industry counterpart have failed to make use of existing TRIPS-compliant mechanisms that will allow for the importation—or better still—domestic production of generic medicines.

It is unclear whether this inertia is driven by an uninformed or misinformed understanding of South Africa’s international obligations under TRIPS, a misplaced fear of having to defend government patent policies before the WTO,⁷ or simply slavish adherence to a neo-liberal agenda coupled with the pursuit of an HIV denialist agenda. In the light of the developments at Doha, the latter seems the most likely of the three scenarios.

Using the mechanisms provided by TRIPS is not without its problems. Some may question the wisdom of engaging a trade regime of questionable legitimacy when engagement may serve to legitimise the system itself. Others rightly point out that the so-called concessions made at Doha are of little consequence in countries without the capacity to manufacture generic

⁶ Dr Manto Tshabalala-Msimang, “Drug Companies Withdraw Case Against SA Government”, online: Unwembi’s Resource of South African Government Information <<http://www.polity.org.za/govdocs/pr/2001/pr0419a.html>> (date accessed: 11 April 2002).

⁷ Since the adoption of the *Doha Declaration* the fear of retaliatory action has been substantially minimised.

drugs or the resources to purchase medicines even at substantially reduced prices.

These are all valid concerns, yet do little to justify our inaction. We are ardent supporters of the trade regime when we seek to export our port, sherry and ouzo. Why should we treat life-saving drugs any differently? In the South Africa of today, we simply have no choice but to take action—not only for ourselves, but also for the region as a whole. While working within the campaign for fair trade and continuing to advance a pro-poor pro-human rights agenda, we need to move swiftly and decidedly in implementing what is possible and permissible today. If world trade is to be harnessed “as a powerful motor for the reduction of poverty”,⁸ we cannot fail to implement the gains already made.

For South Africa this entails both active use of existing provisions within and urgent amendments to the Patents Act to facilitate early generic market entry. In practice, this includes the urgent issuing of compulsory licenses on all essential patented medicines, including antiretrovirals and opportunistic infection treatments, the immediate promulgation of the amendments to the Medicines Act, and the urgent finalisation and promulgation of the regulations. If government and the ruling party are looking for an opportunity to prove that they are indeed “lend[ing] a caring hand of hope”, they would be advised to heed this call.

⁸ Oxfam International, *Rigged Rules and Double Standards: trade, globalisation, and the fight against poverty* (Oxford: Oxfam International, 2002) at 3.