Published on *Treatment Action Campaign* (http://tac.org.za/community)

Letter to the High Commissioner for India to South Africa

By *moderator*
Created *2010/07/01 - 8:47pm*
1 July, 2010 - 20:47 ? moderator
Mr R K Bhatia
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23 June 2010
Dear Mr Bhatia

OUR CONCERNS REGARDING INDIAN TRADE NEGOTIATIONS WITH EU

Over a million people with HIV in South Africa are receiving antiretroviral (ARV) treatment. At least 100,000 additional people receive treatment via private or non-profit sources. ARV treatment is saving lives and stemming the decline in life-expectancy that has occurred due to the HIV epidemic.

One of the main reasons this has happened is because the prices of ARV regimens fell from over R3,000 per month in the 1990s to less than R150 per month for a standard first-line regimen used in the public sector today. Even the private sector price of one of the best first-line regimens is R532 including VAT, a fraction of the lowest 1990s prices of far less optimal regimens. If these prices were corrected for inflation, the drop would be even more dramatic. Lower prices have made the HIV treatment programme affordable for the state. Lower prices have also allowed medical schemes and non-profit private organisations to cover HIV treatment, thereby alleviating some of the public sector's treatment burden. Without these massive price reductions, nearly a million additional people would be dead or dying now in South Africa. But these price reductions have benefited people far beyond South Africa's borders; there are programmes in many sub-Saharan African countries providing quality ARV drugs because they are now affordable.

As this letter explains, the prospect of making new ARVs available in South Africa at affordable prices is under threat because of events unfolding in India. In particular, pressure is being applied by the European Union on the Indian government to sign a bilateral trade agreement that will stifle competition on essential medicines still under patent. The problem goes beyond ARVs. It will apply to any new medicine that is developed, whether it be for cancer, diabetes, tuberculosis or a future epidemic. Undoubtedly, this will prove to be detrimental to everyone regardless of social class and geographic location. We should all be concerned.

How ARVs became affordable

Until the early 2000s, each ARV was marketed exclusively by at most one company in South Africa usually under patent or via an exclusive license agreement with the patent-holder. Consequently there was no competition on ARVs. There is a clear chain of causation that led to most of the price reductions. In general:
1. Generic manufacturers based mainly in India (but also in Brazil and elsewhere) produced dramatically cheaper

generic versions of ARVs. They could do so because medicines were not patented in India. Previously, these drugs had not been available in South Africa.

2. Activists in South Africa, the rest of the African continent, and across the world forced patent holders to license generic manufacturers to sell their medicines in sub-Saharan countries and elsewhere. Such activism included protests, successful complaints at the South African Competition Commission and threats of litigation.
3. Following this pressure the companies manufacturing ARVs and other important HIV-related medicines under patent either dropped their prices substantially or allowed generic competition.

Many ARVs manufactured in India are now sold in South Africa at affordable prices. So too are ARVs manufactured in South Africa using active ingredients ordinarily imported from India. They are registered with the Medicines Control Council, the US Food and Drug Administration and approved by the World Health Organisation. Therefore they meet stringent requirements ensuring these are safe, effective and of good quality.

The Indian Patent Act

But in 2005, the Indian government passed legislation that allowed medicines to be patented, as it was required to do in terms of its World Trade Organisation (WTO) obligations. This means that medicines developed since 1995 cannot as easily be produced by generic companies operating in India. This essentially breaks step one in the above chain of causation and makes it much harder to campaign successfully for lower medicine prices. Notwithstanding these new limitations, Indian patent law - as permitted by the WTO - still contains a number of flexibilities that allow for the market entry of generic medicines prior to patent expiry.

Since 2005, the AIDS Law Project (now SECTION27) and TAC have worked closely with civil society organisations in India to ensure the existence and use of such flexibilities. In early 2005, for example, we were part of a group of international activists who met with Indian parliamentarians in New Delhi during final deliberations on the Patents (Amendment) Bill, 2005. Our intervention sought to ensure that India's amended patent legislation took full advantage of the flexibilities permitted under WTO law. In early 2007, we supported an international call on the Swiss-based pharmaceutical company Novartis to drop its High Court challenge to one of the Indian Patents Act's key flexibilities - section 3(d). (See http://www.tac.org.za/community/node/2175). Although the challenge proceeded, it was ultimately unsuccessful, resulting in a key public health safeguard remaining on the statute books.

Despite these flexibilities newer drugs are being patented in India. For example, raltegravir is a relatively new and important ARV, especially for people who are resistant to standard ARV regimens, which has been patented in India. It currently costs R2,396 including VAT monthly. It is priced far too high for the South African public health system or for general use in the private sector. There is no generic equivalent of it in India or anywhere else, nor does it look likely that one will be made in the short-term. This makes it extremely difficult for activists to apply pressure on the pharmaceutical company Merck, which owns the patent on it. With no competition there is no downward pressure on the price, and it is extremely unlikely to be accessible to people in South Africa in the near future.

At least two new tuberculosis drugs are likely to be ready for registration in the next few years. These are urgently needed especially in light of the growing drug-resistant TB epidemic. It is a matter of deep concern that they might not be accessible where they are most needed: in poor countries.

Bilateral trade negotiations with the European Union

This is a bad situation, which is about to get worse. The European Union (EU) is conducting trade negotiations with the Indian government. A leaked draft of the negotiating texts has shown that the EU is pushing for the following in a bilateral trade agreement:

? Data exclusivity: Generic medicines are usually registered by showing that they are bioequivalent to the original

medicine. This is a relatively inexpensive procedure. It means that a generic drug does not have to be put through expensive clinical trials since these were already conducted for the purpose of registering the original version of the drug. The EU however wants a period of data exclusivity to be enforced for new drugs. During this period the Drugs Controller General of India (the equivalent of South Africa's Medicines Control Council) will not be able to rely on available clinical data to register a medicine. Since it would be unethical and too costly to repeat a clinical trial during this period, this condition would essentially block the registration of a generic drug during the original drug's data exclusivity period. The length of the data exclusivity period being negotiated is five to nine years. Of concern is that data exclusivity provisions apply even in cases where patents have not been granted or where licences have been granted to generic manufacturers, undermining the public health flexibilities and safeguards that currently exist in Indian patent law.

? Longer patent periods: Currently patents are granted for 20 years ?at some point before the product is submitted to a drug regulatory authority for registration. The EU is pushing for patent periods to be extended by the length of time the drug regulatory authority takes to examine an application for registration, or by the length of time a patent office takes to examine a patent application.

? Border measures: The EU wants to be able to seize medicines that are in breach of EU patents at EU borders, even if these medicines are in transit on their way to a country outside the EU, such as a sub-Saharan African one, where their use would not infringe any patents. This is not a theoretical possibility. It has already happened where the EU seized a shipment of abacavir sulphate on its way from India to Africa. The shipment was procured by UNITAID and was funded by the Clinton Foundation. 17 such seizures took place until worldwide condemnation for the EU?s actions began. Now the EU wants to legitimise such laws by pushing them into the EU-India FTA. By doing so it threatens to stop at the Indian or EU borders the export of Indian generic medicines that most African countries rely on.

None of these measures are required by the WTO. All will critically hamper the prospects for generic competition on patented ARVs in sub-Saharan Africa.

We ask you to convey our concerns to the Indian government, in particular those responsible for the trade negotiations with the EU. We call on the Indian government not to limit the options available to it under the WTO Trade-Related Aspects of Intellectual Property Rights agreement.

Yours sincerely

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Source URL (retrieved on *2016/12/11 - 2:29am*): http://tac.org.za/community/node/2896