We need the Patent Pool to work

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A Joint Statement by Treatment Action Campaign, Treatment Action Group, HIV i-Base, European AIDS Treatment Group and SECTION27

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The exorbitant price of AIDS medicines, especially antiretrovirals, has been one of the main barriers to people with HIV accessing them, especially in developing countries. As activist organisations we have been at the forefront of many of the struggles to make medicines affordable.

A patent gives a pharmaceutical company the exclusive right to manufacture and market a medicine. The patent lasts for 20 years from the date of filing the patent application. Companies typically patent medicines that they develop, they buy patents from other companies or they enter into exclusive licensing arrangements with universities or small companies that have developed medicines but do not have the capacity to bring them to market.

The purpose of patents is to encourage research and development into new medicines. The problem is that patents ordinarily create monopoly conditions which allow companies to charge exorbitant prices.

Over the last 15 years, some developing world governments and activists have battled pharmaceutical companies to reduce medicine prices. They have won many hard-fought concessions that have brought down the prices of life-saving drugs and allowed millions of people to go onto antiretroviral treatment. But new generation patented drugs that have fewer side effects, are easier to take or offer treatment alternatives to people resistant to current regimens, are mostly unaffordable. Yet they will soon be needed by millions of people. Furthermore, the struggles for lower medicine prices have to a large degree depended on country-specific laws and the capacity of activists in those countries to organise. Crucially, it is not sustainable to fight drug-by-drug, country-by-country for concessions from the pharmaceutical industry.

One of the initiatives that has resulted from these struggles is the Patent Pool. This is an initiative by activists and UNITAID [1] to negotiate concessions from the pharmaceutical companies on an international scale to license their products through the patent pool. Multiple generic producers will then be able to access these licenses, stimulating sufficient competition between generic producers to drive down prices. The pool also aims to spur the production of generic combinations of medicines, where patents on medicines are held by a number of different companies.

There is no guarantee the Patent Pool concept will work. It ultimately depends on pharmaceutical companies entering into voluntary agreements that dilute the monopolies that patents give them. Getting pharmaceutical companies to the negotiating table requires ongoing activist pressure and protests. It requires co-ordinated strategies to monitor prices and patents, pressure governments to use the powers they have under TRIPS [2] to license essential medicines and campaigns to expose profiteering from health.

The Patent Pool has not been without teething problems and this has led to questions and criticism from activists around the world. It needs to improve its consultation mechanisms. We are pleased that it has begun to do so by meeting with key HIV civil society organisations around the world and by putting together an expert advisory group that will recognise the expertise and experience that members of civil society may bring.

So far only one antiretroviral patent-holding company, Gilead has signed an agreement with the Patent Pool. Gilead has agreed that the Patent Pool can license some of its antiretrovirals to generic companies in over 100 countries. The drugs include tenofovir (TDF), cobicistat (COBI), elvitegravir (EVG), and the Quad, a fixed-dose combination of TDF-COBI-EVG-emtricitabine. Gilead has also committed to not enforcing its exclusive rights on emtricitabine (FTC). It will also not stop companies from making fixed-dose combinations involving these compounds. [3]

The Gilead agreement has shortcomings. For example, Brazil, Thailand, China, Botswana, Namibia and Ukraine, all countries with significant numbers of people with HIV, and many other middle-income countries are excluded from part or all the agreement. Botswana, Thailand and Namibia are included in the TDF license, but excluded from the COBI one. The current agreement also unnecessarily restricts the sub-licensees to Indian generic manufacturers only.

Nonetheless these licenses are the most far-reaching of the concessions obtained from pharmaceutical companies on AIDS drugs. Millions of people can benefit and we must keep up pressure to ensure that all people do. That is why we demand that Gilead re-open negotiations with the Patent Pool to extend the licenses to include all the above countries and others in all aspects of the agreement. Also, the excluded countries can still access products produced by licensed companies if they make use of their TRIPS flexibilities; we therefore call upon them to do so.

We also demand that other pharmaceutical companies join the Patent Pool and make their essential HIV medicines available for voluntary licensing. In particular, we call on Viiv, Merck, Johnson & Johnson and Abbott to conclude agreements with the pool so that the antiretrovirals dolutegravir (still in clinical trials), raltegravir, darunavir, etravirine, rilpivirine and lopinavir and ritonavir become more accessible.

If these companies join the Patent Pool, the prices of these drugs are likely to drop substantially. Hundreds of thousands, perhaps millions, more people with HIV will therefore have access to these life-saving medicines.

Today six million people are alive and receiving antiretrovirals. Nine million more are in need. In some countries however, access to treatment is reducing rather than increasing. The unaffordable prices of medicines is one of the reasons for this. We maintain the view that patents should not be used to make essential medicines unaffordable and that governments should play a much greater role in research and development of medicines. Access to essential medicines cannot be left to the market and the private sector; these cannot meet people?s needs

We call on activists globally to unite and once again build powerful campaigns against pharmaceutical company profiteering so that access to antiretrovirals as part of the human right to the highest attainable standard of health, can be universally realised.

Footnotes

1. UNITAID is a WHO initiative. Its mission is "to contribute to scaling up access to treatment for HIV/AIDS, malaria and tuberculosis, primarily for people in low-income countries, by leveraging price reductions for quality diagnostics and medicines and accelerating the pace at which these are made available."

2. The WTO?s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was negotiated in the 1986-94 Uruguay Round. While imposing intellectual property regimes on countries that did not previously have them, it does contain some flexibilities.

3. TDF is an important drug because it can be used for first-line antiretroviral treatment instead of an older drug called stavudine which has much worse side-effects. Cobicistat, which is not yet approved, is potentially important because there is currently only one other drug that serves a similar purpose, i.e. to boost other antiretrovirals. The Quad is a four-in-one once daily pill that is not yet approved, but is hopefully going to be an excellent first-line antiretroviral regimen. Elvitegravir is also being tested. It will likely be useful for people who are resistant to other antiretrovirals.