



MSF briefing note

Taking the plunge

The UNITAID Patent Pool – a new tool for achieving access to medicines

The prices of AIDS medicines are on the rise again. At US\$ 600-1000 for one patient's yearly treatment, the improved first-line treatment recommended by the World Health Organization (WHO) costs seven to eleven times as much as the previously recommended regimen.¹ With increasing numbers of AIDS patients failing on their first-line therapy, there is also an urgent need to find affordable second-line treatments.

Furthermore, children's needs continue to be overlooked: of the 22 antiretroviral (ARV) drugs currently available, six are not approved for paediatric use and seven are not available in paediatric formulations.

A patent pool could help make AIDS medicines more affordable and appropriate for patients. For example, it could facilitate the development of fixed-dose combinations (FDC) of first- and second-line regimens for adults and children. By combining multiple drugs into one pill, treatment is easier to take for patients, which can enhance patient adherence, improve health outcomes, and reduce the risk of resistance.

The UNITAID Patent Pool

UNITAID, the international drug purchasing facility, has decided to take steps to create a patent pool for AIDS medicines.² It offers an important and innovative approach to tackling access issues.

Collective management of patents

The idea behind a patent pool is that different patent-holders, such as companies, universities and research institutes, make their patents and other relevant intellectual property available to others on a non-exclusive basis through the pool. Generic manufacturers can access patents in the pool to produce medicines and/or to make further improvements on them. Patent-holders will receive royalties from those who use the patents.

The Pool will be operated by a 'one stop shop' licencing agency that manages licences,

¹ Prices are for fixed-dose combinations (FDC) using originator products. The price of the previously-recommended regimen is US\$87 per patient/year.

² At its July 2008 meeting, the UNITAID Board decided to test out the idea of a patent pool with an initial focus on AIDS medicines.

negotiations and the receipt and payment of royalties. Thus, one of the key benefits is that it will provide an alternative to complex negotiations and litigation over patent rights.

Any qualified company that wants to use the inventions can get a licence from the pool. The UNITAID patent pool will be voluntary, and the resulting medicines are to be available in developing countries only.

Stimulus to innovation

The pool may also lower monopoly-related barriers to innovation. For example, if a company wanted to develop a triple FDC for the treatment of AIDS, currently it would need to obtain licences from at least three different patent-holders to be able to develop, produce and export the FDC. In practice, it has been difficult to get patent-holders to agree to such licences, and any one refusal could jeopardise the entire FDC. If, however, the patent-holders have already agreed to put the patents in the pool, the producer would need to deal only with the pool to get access to all intellectual property needed to develop and produce the FDC.

Reducing the cost of medicines

The pool will also help to accelerate the availability of lower-priced new medicines. Without having to wait for the patents to expire (usually 20-year terms), producers will be able to make generic versions of medicines under pre-determined licencing conditions. These producers will, however, be required to pay royalties to the patent-holders through the pool.

In addition, if the licences are applicable to a large market in the developing world, production would be economically attractive to multiple producers. Competition between multiple producers would bring down drug prices, which in turn, would help to reach greater numbers of patients.

How can we make it work?

The medicines patent pool will be voluntary. Therefore, two elements are crucial for success: first, patent-holders must be willing to put their intellectual property (IP) into the pool, and second, generic producers must be willing to make use of the patents and pay the relevant royalties. For patent-holders, the pool offers a predictable way to address global access issues while minimising the economic and reputational risks of IP-driven controversies and decreasing the transaction costs of negotiating licences.

Summary

The UNITAID patent pool has the potential to accelerate access to more affordable medicines and to stimulate the development of innovative drugs such as FDCs and paediatric formulations. By reducing risks and transaction costs, it offers an attractive alternative to the current system for both patent-holders and medicines producers. All of these factors combined can translate into important benefits for patients through wider access to affordable, appropriate medicines. UNITAID's next steps will be to set up a task force to develop an operational plan for the creation of the patent pool.