

A PATENT POOL FOR MEDICINES

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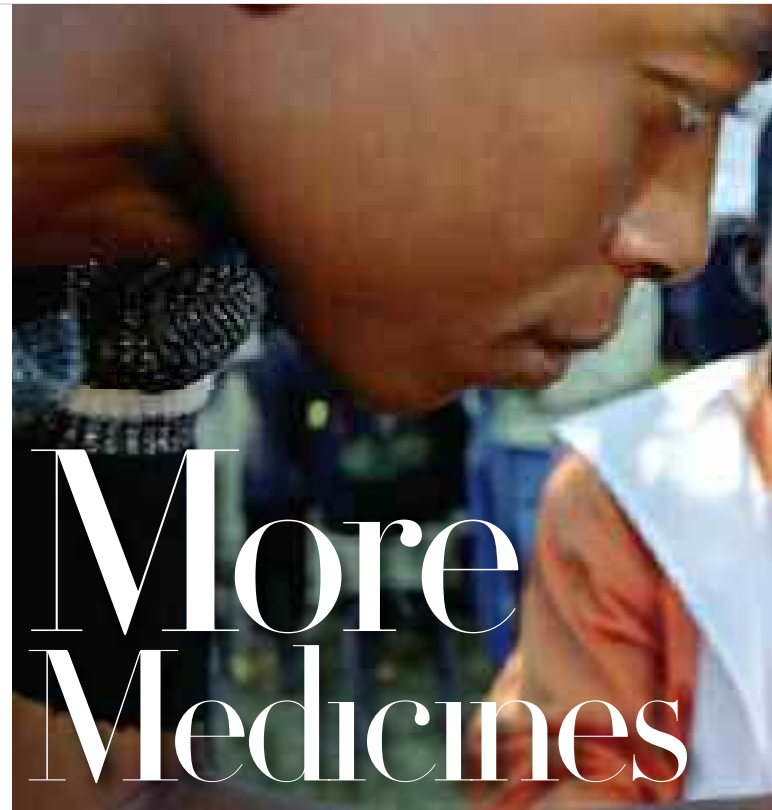
Around three million people living with AIDS in developing countries have access to treatment, a ten-fold increase in just a few years. A key factor in this dramatic achievement was the availability of low-cost drugs produced in India, the pharmacy of the developing world. Companies there could produce AIDS drugs generically because the country did not grant medicine patents until 2005. However, this is now changing. India has begun granting patents on medicines to meet its obligations under the 1994 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The prices of newer essential medicines are likely to rise, threatening the viability of many AIDS treatment programmes – and access to medicines more broadly. An international patent pool for essential medicines could help address this looming crisis.

tHE IDEA BEHIND A PATENT POOL IS THAT different patent-holders, such as companies, universities and research institutes, would make their patents available to others on a non-exclusive basis through the pool. Generic manufacturers could then access patents in the pool to produce medicines, and to make further improvements to them. Patent holders would receive royalties from those using the patents.

Recently UNITAID, a new multilateral financing mechanism for the purchase of medicines, has taken the initiative to develop an international medicines patent pool through which medicine patents could be made available to produce generic versions of AIDS drugs. It could also ease the development of adapted formulations such as three-in-one combination pills and medicines for children.

Any qualified company that wanted to use the inventions could get a licence from the pool. The UNITAID pool would be voluntary, and the resulting medicines would be available only in developing countries.

Under the scheme the products cannot 'leak' into western markets because they are produced by a third company under its own name and possibly brand. Such a company would have



to ask for marketing authorisation in countries where the products are under patent and where the pool licenses would not be valid. If they did this they would immediately be confronted with legal action by the patent holder. This is why today, for example, you do not see Indian generic antiretrovirals in Europe or the US. The same would be the case for the generics produced under pool licences.

WHY IS A POOL NECESSARY?

Many patients need access to newer AIDS medicines, either because they are safer treatment options, or because drug resistance renders older drugs less effective. However, newer drugs are widely patented, including in key producing countries such as India.

As a result, the prices of AIDS medicines are on the rise again. At \$600-1000 per patient per year, using originator products, the improved first-line treatment recommended by the World Health Organization (WHO) costs six to ten times as much as the currently most widely used regimen. Furthermore, children's needs continue to be overlooked: of the 22 antiretrovirals available, nine are not approved for paediatric use and seventeen are not available in paediatric formulations.

The high cost of newer AIDS drugs has led to trade disputes when countries have decided to set patents aside through compulsory licensing to access lower cost generic drugs. High-profile political conflicts over intellectual property rights involving the United States, the European Union and patent-holding pharmaceutical companies on one side, and Thailand, Brazil, South Africa or other developing countries on the other, have drawn attention to this issue in recent years.

The patent pool would provide a more predictable way of

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managing medicines-related intellectual property by easing the licensing process to achieve two main objectives: to lower the price of medicines by encouraging competitive production, and to stimulate development of combination pills that can be more easily taken by the patient.

REDUCING COST

The pool would be operated by a one-stop shop licensing agency that manages licences, negotiations and the receipt and payment of royalties. Thus, one of the key benefits is that it would provide an alternative to complex negotiations and litigation over patent rights.

The pool would help to accelerate the availability of lower-priced new medicines. Without having to wait for the patents to expire – usually twenty years – producers would be able to make generic versions under pre-determined licensing conditions. These producers would be required to pay royalties to patent-owners through the pool.

In addition, making the licenses applicable to a large market in the developing world would make production 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.

STIMULATING DEVELOPMENT

The pool could also help overcome some barriers to innovation that patents can pose. An area where the establishment of a patent pool would have immediate and obvious advantages is in the development of fixed-dose combinations of the newly WHO-recommended first-line AIDS treatment. This treatment consists of three drugs: tenofovir,

lamivudine and either nevirapine or efavirenz. A fixed-dose combination reduces the daily number of pills and makes it much easier for patients to take their medication regularly.

The patents on every compound in this triple-therapy are held by a different company. A generic company seeking voluntary licences for the development and production of these drugs would have to obtain licences from four different patent holders. In India, a patent application is pending for tenofovir; if granted, it would threaten the ability of generic producers to market the combination.

However, if these patents could be combined in a patent pool, a generic company wishing to develop, produce and market the combination would only have to deal with the pool, which would also be responsible for the collection and payment of royalties.

A pool may be an attractive way for patent-holding companies to avoid the proliferation of compulsory licences and the associated public relations problems from intellectual property conflicts, to get access to new markets through the licensee, and improve the company's overall public image.

The medicines patent pool will be voluntary. Therefore, two elements are crucial for success: first, patent-holders must be willing to put their patents into the pool, and second, generic producers must be willing to use the patents and pay royalties.

For patent-holders, the pool offers a predictable way to address global access issues while minimising the risk of intellectual property-driven controversies. The pool can function without any fundamental changes to the existing medicines patent system. It would give patent-holding drug companies a very visible way of showing commitment to access to medicines which will produce significant public relations benefits. Their products will become available to groups that would not be able to afford them at monopoly-price levels.

A pool could also provide opportunities for collaboration between different patent holders to develop desirable combination products. For generic producers, it offers predictability with regard to what products they can develop, produce and market, and reduces the risk associated with negotiating multiple licenses with multiple patent-holders, while opening up larger global markets. Both patent holding and generic pharmaceutical industries have welcomed the UNITAID initiative.

POOL POTENTIAL

The UNITAID patent pool has the potential to accelerate access to more affordable medicines and stimulate the development of innovative drugs such as fixed-dose combinations 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 these factors combined can translate into important benefits for patients through wider access to affordable, appropriate medicines. While the UNITAID pool will initially focus on AIDS medicines, if successful, the model could also help improve access to the many other treatments urgently needed in developing countries.

