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*Zugang zu Medikamenten für alle*

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***The Medicines Patent Pool***

**An innovative approach to achieving access to medicines for all**

Von Ellen 't Hoen and Suerie Moon

*The UNITAID Executive Board adopted a resolution on December 15 2009 that gave the go ahead for the establishment of a legal entity to house the Medicines Patent Pool. UNITAID has committed to provide funds of up to US\$ 4 million in 2010 for the start up, subject to the approval of the budget. The authors explain, how the pool is working.*

Just five years ago at the UN General Assembly, the world committed to achieving universal access to treatment for HIV/AIDS by 2010 (United Nations General Assembly, 2005; United Nations General Assembly, 2006). The unprecedented mobilization of people living with HIV/AIDS (PLWHA), civil society, governments, donors, and health workers, has resulted in tremendous progress: since 2003, the number of people with access to antiretroviral therapy (ART) has increased over twelve-fold to reach five million people by the end of 2009 (2010). A central enabling factor in this achievement was the availability of low-cost, quality generic antiretroviral drugs (ARVs), whose prices have dropped by over 99% since 2000 (Médecins Sans Frontières (MSF), 2010; Perez-Casas, Mace, Berman, & Double, 2001).

**Patent barriers**

However, we are running far behind in our efforts to achieve universal access, and huge challenges lie ahead. Nine million people are still waiting for lifesaving ART, and many patients currently on first-line treatment will need to transition to second-line drugs that cost three times as much (2010). Newer ARVs are likely to be patented more widely in developing countries – due to implementation of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – and are expected to be more expensive. As a result, developing countries may not have access to affordable generic versions of important new medicines for many years. The introduction of product patents on medicines in India, in particular, is restricting the space for competitive generic production of medicines from the country that currently supplies over 80% of ARVs (by volume) to the developing world (Waning, Diedrichsen, & Moon, forthcoming) . Patent barriers can also make it more

difficult to develop the fixed-dose combinations (FDCs) – two or more medicines combined into one pill – that have become a key tool in facilitating patient adherence to treatment. While needs are great and costs are increasing, funding has been flatlined and is falling far short. Maintaining momentum against the epidemic will require that funders live up to their commitments, and that we find innovative approaches to reducing costs while improving treatment.

For these reasons, UNITAID has supported the creation of the Medicines Patent Pool Foundation (the Pool) (Bermudez & 't Hoen, 2010). UNITAID is a new financing mechanism based on a small solidarity tax on airline tickets supported by 29 countries, the Bill and Melinda Gates Foundation, NGOs, and communities. UNITAID's mission is to increase access to treatment for HIV/AIDS, TB and malaria by making global markets work better for health. UNITAID has raised 1 billion USD, and seeks to be innovative in the way it both raises and deploys its funds – as demonstrated by the Pool.

The objective of the Pool is to reduce prices and ensure the availability of new and improved AIDS medicines. The Pool will initially focus on seeking licenses for newer products that are expensive in developing countries, such as improved first-line treatment regimens or the second- and third-line regimens needed when older products fail. The Pool will also seek licenses for technology that could be used to develop important products that are currently unavailable, such as medicines adapted for children. The Pool will complement the other market-based mechanisms UNITAID uses to stimulate the availability of more appropriate and affordable medicines, such as reliable financing and bulk purchasing.

## Falling prices

What is a patent pool? A patent pool is created when a number of patents held by different owners are brought together (or pooled) via license agreements. The pool can then grant licenses to other parties, such as generic drug manufacturers, in exchange for royalty payments to patent holders. A patent pool can facilitate third-party access to patented technologies, such as medicines.

Patents can restrict access to medicines, partly by keeping prices high and partly by hindering the development of certain products. Patents may result in high prices because patent holders can block other manufacturers from making generic versions of the medicine. With no competitors to threaten sales, medicines can be sold at the highest price the market will bear. Patents can also be a barrier to the development of products such as FDCs – especially when the component drugs are patented by different companies.

A key objective of the Pool is to facilitate robust competition in the production of ARVs. Generic competition has proven to be the most effective way to bring down the price of medicines. After generic versions of medicines become available, prices fall on average between 65 and 80 percent, and sometimes much more, depending on the number of manufacturers

entering the market (Congressional Budget Office (CBO), 1998). For example, as a result of robust generic competition, the price for one year of AIDS medicines fell from more than US\$10,000 per patient to as low as \$80 today.

## Voluntary licenses for key HIV/AIDS medicines patents

Generic versions of a medicine can be made if, for example, a patent has expired or has been revoked, or if a medicine has not been patented in a given country. In addition, companies can obtain licenses to make generic versions of medicines. Patent licenses can be compulsory (issued by a government agency or court) or voluntary (obtained through an agreement with the patent holder) and usually involve the payment of royalties.

The Medicines Patent Pool will obtain voluntary licenses for key HIV/AIDS medicines patents, and then make these licenses available to qualified third parties on a non-exclusive and non-discriminatory basis. To qualify, drug manufacturers will have to meet eligibility criteria such as quality, safety and efficacy requirements. The licenses will be for use in developing countries, and royalties will be paid to patent holders.

The Pool is one possible way to overcome patent barriers to enable the production of affordable versions of new and improved AIDS medicines. By easing access to patent licenses, the Pool will encourage generic competition and bring medicine prices down. It will also facilitate the development of improved products, such as combination pills containing two or more drugs – an innovation that simplifies AIDS treatment and reduces the risk of resistance.

The Pool will benefit all parties involved. More patients in developing countries will gain faster access to better, more affordable medicines. Developing country governments and international donors will be able to provide better treatments to more people for less money. Medicine patent holders will be compensated for the use of their technology. And generic manufacturers will more easily be able to obtain patent licenses allowing them to sell new or improved medicines.

The willingness of patent holders to license their patents to the Pool, and of generic manufacturers to make use of those licenses, is central to the success of the initiative. To date, several key patent holders and generic manufacturers have expressed interest in participating in the Pool. Success will also depend upon continued widespread support among other stakeholders and the public, and the willingness of donors to make sufficient resources available for AIDS treatment on a sustained basis.

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For more information please see <http://www.unitaid.eu/en/Patent-pool-resources.html>

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