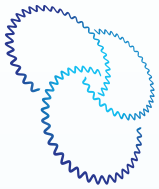

medicines
patent
pool

STIMULATING INNOVATION
EXPANDING ACCESS
IMPROVING HEALTH

ANNUAL REPORT
2010-2011

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ACRONYMS

AIDS Acquired Immune Deficiency Syndrome
ARV Antiretroviral
FDC Fixed-dose combination
HIV Human Immunodeficiency Virus
NIH US National Institutes of Health
TRIPS Trade-Related Aspects of Intellectual Property Rights Agreement
UNAIDS Joint United Nations Programme on HIV/AIDS
WHO World Health Organization
WIPO World Intellectual Property Organization
WTO World Trade Organization

OUR MISSION

To bring down the prices of HIV medicines and facilitate development of better-adapted HIV medicines, such as fixed-dose combinations and special formulations for children, by **creating a pool of relevant patents** for licensing to generic manufacturers and product development partnerships.

OUR GOAL

To increase access to quality, safe, effective, appropriate and affordable treatment for HIV in developing countries through voluntary licensing of patents on key HIV medicines.

OUR ORIGINS

The Medicines Patent Pool was established as an independent foundation in July 2010. It is based in Geneva, Switzerland. Created with the support of UNITAID, an innovative financing mechanism for improving access to treatment, the Pool represents a novel and unprecedented response to the rising global need for affordable, appropriate HIV medicines in low- and middle-income countries.

A LETTER FROM
THE EXECUTIVE DIRECTOR
AND THE
CHAIR OF THE BOARD:

Access to HIV medicines around the world is at a critical juncture. On the one hand, global efforts to increase the availability of affordable medicines have allowed 6.6 million people to live longer, healthier lives and helped stem the further spread of HIV. On the other hand, 8 million people still wait for treatment. The patent status of medicines, particularly for newer treatments, is one factor hindering their ability to get it – as well as delaying the development of new formulations designed for the particular needs of resource-poor settings, such as medicines for children, heat-stable formulations and fixed-dose combinations.

The Medicines Patent Pool is a unique initiative designed to help improve access to affordable, appropriate medicines for people living with HIV in low- and middle-income countries through the voluntary licensing of HIV medicines patents.

In its first year and a half of existence, the Pool has come a long way: it has been recognised by the international community at the United Nations General Assembly and at the World Health Organization as a key part of the solution to increasing access to HIV medicines, has signed two licensing agreements covering 6 treatments, and has launched a patent status database to help share information on what HIV medicines are patented in which countries.

Innovative financing mechanism UNITAID, which helped found and provides funding to the Pool, decided in December 2011 to confirm its support for another four years. UNITAID's renewed commitment is an important endorsement, and UNITAID's continued partnership will help inform and guide the Pool's work in the future.

The Pool is prepared to take its first-year successes forward. At the end of 2011, the Medicines Patent Pool was in negotiations with a five additional medicines patent holders. The value of the Pool as a "one-stop shop" to aid innovation and access increases with every new licence agreement it signs.

The Pool is also putting into place a new consultative process to aid interaction with civil society, communities of people living with HIV and other experts whose input and support has brought the Pool this far today.

A year and half ago the Pool embarked on a mission to help make patents work for public health as well as for pharmaceutical innovators. So far it has made important progress, and the continued support of all of its stakeholders will help the Pool take that progress forward towards meeting its full potential.

Charles Clift
Chair, Medicines Patent Pool Board

Ellen 't Hoen
Executive Director, Medicines Patent Pool

A LETTER FROM

THE CHAIR OF THE EXECUTIVE BOARD AT UNITAID:

UNITAID is an innovative financing mechanism dedicated to scaling up treatment on three diseases whose impact on global public health has been particularly devastating: HIV, tuberculosis, and malaria.

The effect of these three diseases has been particularly profound in resource-poor settings, where needed treatments do not exist or are priced out of reach, and access to health services is limited. UNITAID aims to change that through strategic interventions in markets, with the aim of ensuring more medicines are available for the people who need them. UNITAID raises funds from sustainable and predictable sources, primarily through a small tax on airline tickets. It uses these funds to support creative market-based initiatives that incentivise manufacturers to make needed treatments at affordable prices.

The creation of the Medicines Patent Pool is one of UNITAID's successes.

The unprecedented global need for HIV medicines demanded innovative responses. Robust generic competition had in the past dramatically brought down the price of needed drugs and encouraged innovation in medicines adapted for resource-limited settings, making treatments available that now keep millions of people with HIV alive, and healthier.

The promise of an HIV patent pool attracted UNITAID from the early days. I asked the UNITAID secretariat to look into the possibility of creating such a pool following meetings with the president of Médecins Sans Frontières, and after seeing an early proposal by Knowledge Ecology International. UNITAID decided in 2008 to begin working to set up the Medicines Patent Pool.

A successful pool can ensure the generic competition that helped bring prices down in the past will continue into the future, even in the face of changing intellectual property laws that currently threaten to limit it. It can also help spark innovation on needed new drugs.

The intervention appealed to UNITAID because it is an innovative approach that works for everyone: a successful pool can allow for an increase in the availability of life-saving medicines at prices that would allow treatment programmes on limited budgets to meet rising needs for HIV medicines. It can allow originator pharmaceutical companies to keep their patent-based business models in developed countries, while giving them a way to concretely contribute to global public health by allowing free use of their patents in countries where there is great need for HIV medicine. And it can ensure people living with HIV have access to the medicines they need to survive.

Watching this seed of an idea grow into the Medicines Patent Pool, which now has two licensing agreements and a series of on-going negotiations with key HIV patent holders, has been inspiring. UNITAID maintains a good relationship with the Medicines Patent Pool and I have been consistently impressed by the work of Ellen 't Hoen and her team as well as the work of UNITAID's secretariat in supporting the Pool's activities. UNITAID is proud of the role it has played in launching the Patent Pool and looks forward to its continued success.

Philippe Douste-Blazy
Chair, UNITAID Executive Board


Vitamin C
SCORVITEX
Tinizol 500
CO-TRIMOXAZOLE
1000

HIGHLIGHTS:
JULY 2010 TO DECEMBER 2011

Increasing access to HIV treatment through strategic use of intellectual property

The Medicines Patent Pool's goal is to increase access to affordable, appropriate HIV medicines in developing countries. It does this by negotiating with patent holders for permission (in the form of licences) for other manufacturers to produce their patented drugs at lower cost for use in developing countries. It was founded in July 2010 with the support of UNITAID, an innovative financing mechanism for improving access to medicines for HIV, tuberculosis and malaria.

Why licensing matters

Patents can sometimes act as a barrier to producing medicines at affordable prices. Where there are patent barriers, licences are needed to allow manufacturers to produce quality, low-cost generic versions of patented HIV medicines. Changing patent laws around the world are making the existence of barriers more and more likely. Licences are therefore crucial if affordable, appropriate HIV treatments are to continue to be available for people who most need them.

Robust generic competition both lowers prices and facilitates the development of drugs better adapted for poorer countries, such as medicines that do not require refrigeration, special formulations for children, and fixed-dose combinations that simplify treatment by combining several medicines into one pill.

Where the Pool can help

The Pool acts as a "one-stop shop" for patent licences, making it easier for generic manufacturers to get the licences needed to enter the market and produce lower-cost HIV medicines, known as antiretrovirals (ARVs). The Pool thus makes patents work for public health while ensuring that patent holders can be compensated for sharing their patents.

Key achievements

In its first 18 months, the Medicines Patent Pool has progressed from a newly minted start-up to an organisation with growing momentum that has already begun to change the way intellectual property is managed for public health.

BY THE END OF 2011, THE POOL:

- had developed a working paper prioritising antiretrovirals for inclusion in the Pool, based on medical needs and IP barriers.

- had used the working paper to identify ten holders of relevant ARV patents, who were invited to negotiate with the Pool;

- had concluded two licensing agreements covering six products with Gilead Sciences and the US National Institutes of Health;

- was in formal negotiations with a further five companies — Boehringer-Ingelheim, Bristol-Myers Squibb, F. Hoffman-La Roche, Sequoia Pharmaceuticals and ViiV Healthcare, a joint venture of GlaxoSmithKline and Pfizer; and was in discussions with Abbott Laboratories and Merck & Company;[1]

- had sub-licensed the Gilead patents to two generic companies, Aurobindo Pharma and Medchem International, allowing them to make lower-cost versions of new HIV treatments for use in developing countries;

- had received the support of the international community for its work;

- had begun developing a consultation process to improve feedback on its work from civil society, communities of people living with HIV, and other stakeholders;

- and had developed the world's most comprehensive open access database on patents for HIV medicines, which it regularly updates and publishes on its website.

"The Medicines Patent Pool is a means to enhance availability and facilitate the development of new fixed-dose combinations and adapted formulations, such as paediatric formulations, through voluntary licence agreements."

– WHO HIV/AIDS Strategy for 2011-2015, adopted by the World Health Assembly, May 2011[2]

Milestone-setting licensing agreements

In its first 18 months, the Pool concluded two milestone-setting licensing agreements covering six products: First with the United States National Institutes of Health (NIH) and then Gilead Sciences. The Gilead agreement set new public-health standards, beyond any previous voluntary licensing agreement with a pharmaceutical company. These include:

Transparency – the Pool has published the complete terms and conditions of the agreement on its website, for anyone to read and comment on;

Geographical scope – the licences cover 100-12 countries, an unprecedented number that represents 83-88% of people living with HIV in low- and middle-income countries;

Pipeline products – the licences include four new products that are still in development, which will speed their availability in developing countries;

Flexibility – the licences are "unbundled," meaning that users can "pick and choose" which products they take licences for; they can also terminate licences for individual products at will, without – as otherwise – jeopardising their licences to make other products.

The NIH licence, from the world's biggest funder of biomedical research, will have a lesser commercial impact than the Gilead licences. However, it is an important demonstration of political support for the Pool from the world's largest funder of biomedical research, as well as from the United States, home to most of the major HIV patent holders. The licence covers all low- and middle-income countries without restriction, a reflection of the NIH's recognition of the need for HIV medicines throughout the world.

Generic producers have begun to take up the licences negotiated by the Pool. In 2011, the Pool sub-licensed the Gilead patents to two generic companies: established HIV medicine producer Aurobindo Pharma, and Medchem International, a new entrant to the market for HIV medicines. Aurobindo took advantage of the "unbundling" provision of the Gilead licences by choosing not to take a licence on tenofovir, enabling it to sell an inexpensive generic version of this key HIV medicine to more countries than it was able to before.[3]

By the end of 2011, negotiations with other patent holders were well under way and a number of generic pharmaceutical manufacturers had shown interest in acquiring sub-licences from the Pool.

Endorsement by the international community

The potential public health benefits of the Medicines Patent Pool have been recognised by the international community. The Pool is part of the World Health Organization HIV/AIDS strategy for 2011-2015, adopted by the World Health Assembly in May 2011. The Pool was also endorsed as a promising innovative approach to improve access to HIV medicines by the Group of Eight[4] (G8) largest industrialised countries at their summit in France in May 2011, and by the more than 190 United Nations member states at the UN High Level Meeting on AIDS held in New York in June 2011. Government statements at the High Level Meeting noted the Pool's potential to stimulate needed research and development and increase access to the resulting new drugs through generic production and price competition.

Looking forward

In December 2011, UNITAID committed to support the Medicines Patent Pool for a further four years. The Pool will continue to seek more licences for patents on needed HIV medicines and encourage generic manufacturers to take them up. The Pool's successful negotiation of licences has already begun to lay the foundations for increased generic competition, and therefore greater access to affordable and appropriate HIV medicines in the future. Licensing of products that are still in the development pipeline will help close the often years-long gap between when new drugs come on the market in developed countries and when they finally become available for people living with HIV in developing countries. Thus, the Gilead licences are expected to lead to faster development of cheaper versions of new medicines for people living with HIV, once quality-assured manufacturing facilities are in place and approval by drug regulatory authorities has been obtained.

THE MEDICINES PATENT POOL:

IMPROVING ACCESS, STIMULATING INNOVATION

Who we are

The Medicines Patent Pool negotiates voluntary licence agreements for HIV medicines patents. Its licences are geared towards addressing public health needs. They are non-exclusive and non-discriminatory, and aim ultimately to lower HIV medicines prices through increased generic competition.

In an environment of rising drug costs, constrained financial resources and the broader global reach of pharmaceutical patents, the Pool can play a role in maximising the impact of every dollar spent on drugs. In particular, the high prices of newer generation antiretroviral (ARV) medicines reinforce the need for innovative approaches that can help make them more widely available and affordable for people in the developing world.

The Pool, the first patent pool for HIV medicines, acts as a "one-stop shop" for pharmaceutical companies, which can voluntarily contribute patents to the Pool, and for manufacturers of generics, which can then acquire the rights to produce inexpensive drugs for poorer countries.

Because licences from different companies are pooled together, generic companies and other organisations engaged in research and development can access patents needed to develop new formulations or make generic versions of existing drugs, in one place. The resulting simplicity reduces transaction costs for all the parties involved, as the licences are negotiated and handled by a single entity *(see "Without the Pool/ With the Pool" diagram, page 13).*

Why we are needed

Over the past decade, the cost of first-generation HIV medicines fell by more than 99 per cent, from over US$10,000 per person per year in 2000 to less than $70 in some countries today. This precipitous decline was driven by competition among generic drug manufacturers, especially from India, where there were no patents on medical products before 2005. India remains the main supplier of generic first-generation HIV medicines that currently keep alive 6.6 million people infected with HIV in developing countries.

However, changing patent laws around the world limit generic competition for the newer generations of HIV medicines that are increasingly needed *(see "Patenting of HIV Medicines," page 14).*

Fewer than half the 14.2 million people requiring treatment for HIV/AIDS now have access even to first-generation drugs. And the World Health Organization has recommended that people in

"We need the Patent Pool to work. 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."

– Treatment Action Campaign, Treatment Action Group, HIV i-Base, European AIDS Treatment Group and Section 27, December 2011[5]

developing countries receive newer, better-tolerated HIV medicines at an earlier stage of the disease progression, as happens in wealthy countries.

In addition, there is a growing need for second- and third-line treatments as people develop resistance to earlier medicines and need access to new ones in order to stay alive. These newer medicines are often patented, giving the patent holder a monopoly on production and sales that keeps prices out of reach for people living with HIV in poor countries.

Even the most affordable second-line drug combination costs US$465 per person per year (and is not available at that price in many countries), more than twice as much as the US$176 price tag for the WHO-recommended first-line combination. And this in turn costs more than twice the most commonly used combination that includes stavudine, a drug that the WHO recommends phasing out because of its significant side-effects. For people living with HIV who show signs of treatment failure on a second-line regimen, the cost of medicines can cost US$3,200 a year, or more.

Increased patenting of antiretrovirals, spurred by the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at the World Trade Organization, has been particularly dramatic in important generic producing nations such as India, which currently supply 80% of donor-funded ARVs available in developing countries.[6]

Even though the rate of new infections is declining, the future needs of people living with HIV threaten to overwhelm the resources available to treat them, especially if increased patenting of needed drugs causes treatment costs to rise. By the end of 2010, 34 million people were infected with HIV, most living in the developing world, and by 2030 this number could rise to 50 million, according to UNAIDS.[7] It is essential both to increase the number of manufacturers of HIV medicines and to ensure that people being treated have access to affordable new HIV drugs when the old ones no longer work.

Evidence that treatment can prevent new infections provides the hope that affordable medicines will not only save lives but play a central role in halting the spread of the HIV epidemic. A 2011 study by the US National Institutes of Health[8] found that early antiretroviral treatment for HIV can reduce the likelihood of transmission by 96%.

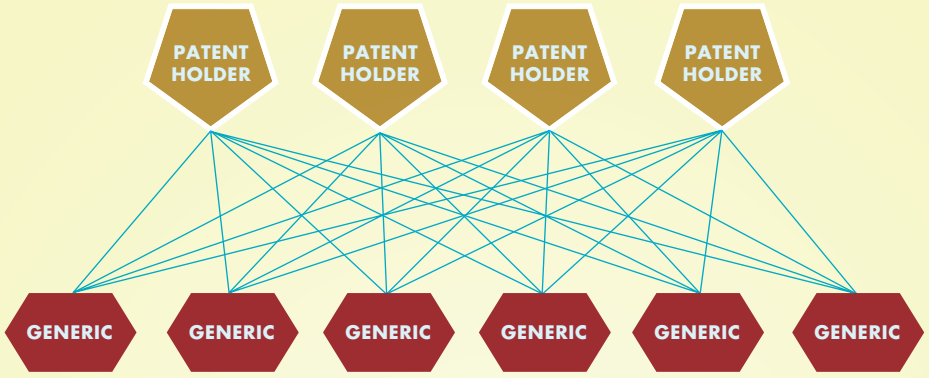
There is also a need for medicines better adapted for use in developing countries (heat-stable formulations, for example), or for specific groups, such as children. The success of strategies to prevent transmission of HIV from mother to child at birth means that almost no children are infected with HIV in wealthy countries. As a result, the pharmaceutical industry has little economic incentive to develop medicines tailored to their needs. Yet an estimated 2.5 million children are living with HIV in developing countries, most in sub-Saharan Africa, and 390,000 babies became newly infected in 2010.[9] Only about half a million children with HIV are on treatment, a lower proportion than of adults, in large part due to the lack of suitable medicines. Some drugs do not have paediatric formulations at all, while others come in a form such as foul-tasting syrups that are difficult to administer.

Furthermore, patents on individual medicines can hinder the combination of multiple medicines into one pill. These fixed-dose combinations (FDCs) simplify treatment for people living with HIV and have been instrumental in helping to scale up treatment for both children and adults in poor countries.

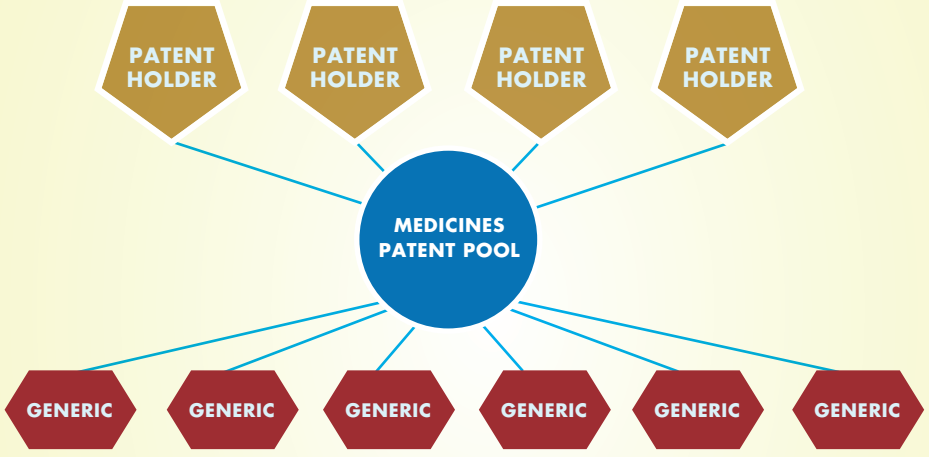
"A successful patent pool will help in accelerating the scaling up of access to care and treatment and will reduce the risk of stock-out of medicines in the developing world."

– Michel Sidibé, Executive Director, UNAIDS, July 2010

WITHOUT THE POOL



WITH THE POOL



The Patent Pool dramatically simplifies interactions between patent holders and generics, lowering transaction costs for all involved

WHAT IS A PATENT POOL?

A patent is a right granted to an inventor by a government that allows the inventor to prevent anyone else from making the invention for a set period of time, typically 20 years. To obtain a patent, an invention must be shown to be new, inventive and useful. Patent holders for pharmaceuticals commonly include companies, researchers, universities and government agencies.

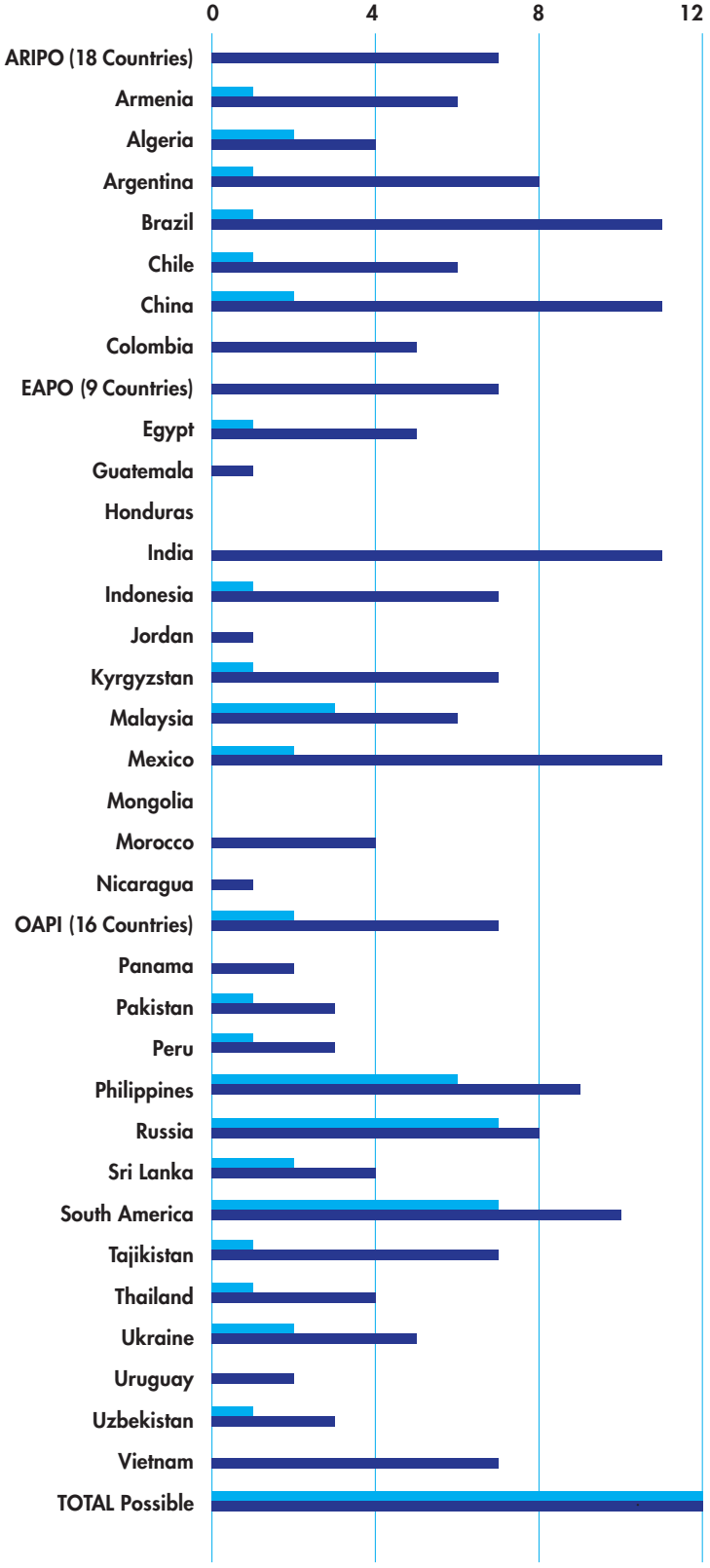
A voluntary patent pool provides a way for two or more patent holders to share their inventions, with each other or with third parties. Instead of negotiating individually with potential makers of their invention on licence terms, including royalties, patent holders negotiate standard licences with the pool. The pool then makes the licences available to others.

The World Health Organization (WHO) has identified patent pools as one way to increase access to essential medicines in developing countries, by making it easier for companies interested in producing lower-cost generic versions of needed treatments to obtain the required licences. The Medicines Patent Pool is the first patent pool for HIV medicines and was endorsed by name in the WHO HIV/AIDS strategy for 2011-2015.

PATENTING OF HIV MEDICINES

Before 1995 (when the World Trade Organization, and with it the world's first international enforceable agreement on intellectual property went into effect), many developing countries did not provide patents on medical products. There are few patents or patent applications on key HIV medicines developed before 1995.

After 1995, this situation changed in many developing countries, and there has been a marked increase in the number of compound patents and patent applications on new HIV medicines.



■ Pre-1995 ARVs

■ 1995 and later ARVs

Source: The Patent Status Database for HIV Medicines
www.medicinespatentpool.org/patent-status-of-arvs

How we can help

The Medicines Patent Pool aims to address these challenges and boost access to HIV treatment by:

- Clearing the path for the development of newer, affordable generic HIV medicines;
- Bringing down medicines prices by facilitating generic competition; and
- Fostering development of better-adapted formulations for developing country contexts, including medicines for children.

The idea behind the Pool is that patent holders – companies, researchers, universities and governments – voluntarily license their patents to the Pool under certain conditions. The Pool then makes licences available to qualified third parties, such as generic drug manufacturers or product development partnerships,[10] which may pay small royalties to the patent holders on the sale of the medicines.

The Pool will particularly ease the development and production of fixed-dose combination (FDC) drugs that simplify treatment regimens and facilitate the scaling up of treatment in developing countries. Although there are FDCs for older HIV medicines, there is an urgent need for FDCs that include newer drugs, which are patented in many developing countries.

A company wishing to develop a fixed-dose combination might need to obtain licences from multiple patent holders to be able to develop, produce, export and sell the product. By providing a "one-stop shop" for all the parties involved, the Pool streamlines the legal and administrative processes involved in obtaining licences, reduces expenses and increases access to essential patents.

The Pool will also help to speed up the availability of lower-priced newer medicines in developing countries because generic manufacturers will not have to wait out the 20-year patent term. Moreover, since the Pool seeks to have its licences cover middle-income countries as well as poorer ones, the size of the market should be large enough to encourage multiple producers to compete and sustainably drive down prices.

The Pool thus offers a win-win-win model that works for everybody.

It works for patent holders, as it may assure them a fair royalty and gives them a concrete, visible way to contribute to global health.

It works for generic companies, sparing them the uncertainty and complexity of having to negotiate with several patent holders for the right to produce a particular medicine and making it easier and faster for them to enter the market, and for innovators focused on developing countries by making it easier to access the patents needed to develop new products.

Most importantly, ***it works for people living with HIV*** by bringing down prices to affordable levels and helping to provide the missing adapted and safe medicines they need to survive.

HOW WE WORK

PRIORITISE HIV MEDICINES

based on analysis of medical needs, potential patent barriers.

INVITE RELEVANT PATENT HOLDERS

to negotiate licences allowing others to make and sell generic versions of patented medicines in developing countries, or develop adapted formulations.

NEGOTIATE PUBLIC HEALTH-ORIENTED LICENCES:

The Pool seeks licences that push the status quo forward, with the aim of ensuring access to medicines for all people living with HIV in developing countries.

SIGN AGREEMENTS;

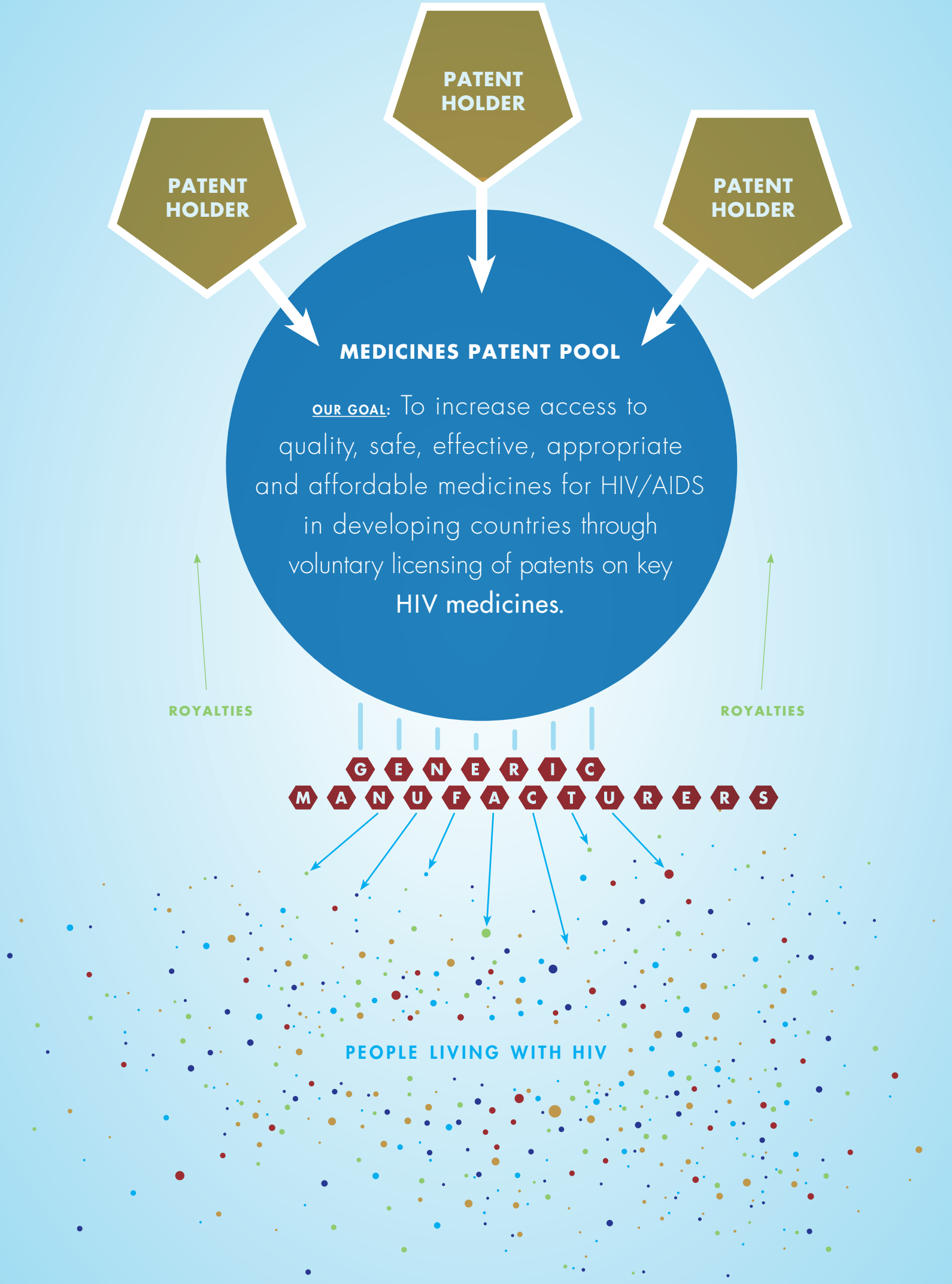
licences go into the Pool.

SUB-LICENSE TO GENERICS

and others, such as product development partnerships (PDPs), who are then free to develop, produce and sell medicines in agreed countries under strict quality assurance. Pool staff work with sub-licensees on product development and regulatory approval.

BRING DOWN PRICES, ENSURE ACCESS:

Once manufacture has begun, robust competition ensures lower prices. This means more people can be treated with the same amount of money, crucial in a climate of increasing need and funding challenges. Patent holders may get a small royalty on medicines sales, and people living with HIV can access the affordable, adapted treatment they need at prices they can afford.


PATENT HOLDER
PATENT HOLDER
PATENT HOLDER
MEDICINES PATENT POOL
OUR GOAL: To increase access to quality, safe, effective, appropriate and affordable medicines for HIV/AIDS in developing countries through voluntary licensing of patents on key HIV medicines.
ROYALTIES
ROYALTIES
GENERIC MANUFACTURERS
PEOPLE LIVING WITH HIV

HOW DOES THE PATENT POOL INCREASE ACCESS TO HIV MEDICINES?

The Medicines Patent Pool works by gathering multiple patents related to HIV in one place, and licensing them out from the same place. This 'pooling' allows patented HIV drugs to be more easily produced as generics, long before their 20-year patent terms run out. Generic competition has been shown to bring down prices and help spur innovation.

HIV medicines best suited for resource-limited settings often carry many patents. Just one patent in either the country of manufacture or the country where the medicine is to be sold can be sufficient to block generic manufacture.

Generic companies therefore must negotiate with the patent holder of every patent they wish to license, and patent holders must negotiate with each potential generic manufacturer. Each negotiation carries cost and uncertainty risks.

A successful Pool could change this situation by dramatically simplifying the interaction between patent holders and generic producers, and acting as a central repository for all patents needed.

"We call on all patent-holders, including pharmaceutical companies, governments, universities and research institutions to: License their patents with the UNITAID Medicines Patent Pool to facilitate the production of affordable medicines and the development of needed formulations for all developing countries."

– São Paulo Parliamentary Declaration on Access to Medicines and Other Pharmaceutical Products, Global Fund Partnership Forum, Sao Paulo, Brazil, 27 June 2011

Key features of the Medicines Patent Pool are:

It focuses on HIV medicines – the Pool focuses on HIV products for which prices are too high and/or suppliers too few (such as newer HIV medicines), on products that have not yet been developed (such as paediatric and heat-stable formulations), and on new HIV medicines in the development pipeline.

It is a voluntary mechanism – the willingness of pharmaceutical patent holders to participate and license their patents to the Pool is critical.

It targets developing countries – licence agreements aim to make HIV medicines available to people in low- and middle-income countries, to meet the need for more affordable and adapted medicines and to ensure that markets for generic products are large enough to achieve economies of scale and generate price reductions.

It requires quality assurance – producers obtaining licences from the Pool must meet agreed quality standards (through the WHO Prequalification of Medicines Programme or other stringent quality assurance mechanisms).[11]

It offers benefits to everyone involved – HIV medicine patent holders can be compensated for the use of their technology; generic pharmaceutical companies are able to obtain licences more easily to produce and sell medicines; and people in developing countries get faster access to better, more affordable treatments.

KEY ACHIEVEMENTS

JULY 2010 – DECEMBER 2011

As of December 2011, the Medicines Patent Pool has progressed from a newly minted start-up to an organisation with growing momentum that has already begun to change the way intellectual property is managed for public health. Below are some of its key achievements.

Engaging with licensors

In its first 18 months, the Pool signed licences covering six products and had concluded or was in formal negotiations with seven patent holders.

In September 2010, the Pool signed its first licence agreement with the US National Institutes of Health (NIH) for a suite of patents related to the protease inhibitor darunavir. The agreement, the full text of which was published on the Pool's website, was noteworthy in covering all low- and middle-income countries and in foregoing royalties.

It was also a strong early signal of support from the world's single largest funder of biomedical research and a major stakeholder, the United States government. It symbolised the importance of making the fruits of publicly funded research broadly available, and aimed to set a standard for ARV licensing clearly oriented to public health. Many key breakthroughs in HIV medicines research have been made by public research organisations. However, Tibotec/Johnson & Johnson, which owns patents in force in some developing countries relating to the manufacture and sale of darunavir, has not yet licensed its patents through the Pool. This will limit the ability of generic companies to make low-cost versions of this drug.

The Pool signed its second licence agreement with Gilead Sciences in July 2011. The licences cover the manufacture of tenofovir, emtricitabine, cobicistat, elvitegravir and the combination of all of these products into a single pill known as the "Quad." The licences also permit development and manufacture of other combinations that include these medicines. Tenofovir and emtricitabine are listed in the WHO List of Essential Medicines. Cobicistat, elvitegravir and the Quad are pipeline drugs in late-stage development.

In November 2011, the Pool and Gilead Sciences signed a set of amendments clarifying issues raised by certain members of civil society after the licences were announced in July 2011.

The agreement with Gilead improves on existing licence agreements in several ways.

"Without the new paradigm which the Medicines Patent Pool offers to make new treatments available rapidly and affordably, expanding treatment access in the future in a sustainable way for the predicted 50 million people who will need these medicines by 2030 will be very difficult to achieve."

– David Deakin, chair of Access to Treatment Working Group, Ecumenical Advocacy Alliance, 23 November 2011[12]

Transparency: The terms and conditions of most privately negotiated licences are not known. In a move unprecedented in the pharmaceutical field, the Pool published the entire text of the agreement on its website.[13] This allows generic companies and product development partnerships to understand exactly what rights and obligations are contained in Pool licences. It also allows stakeholders in the public health community to provide feedback on the licences and make suggestions for improvement.

Waiver of data exclusivity rights: Any applicable data or regulatory exclusivity rights are explicitly waived, removing an important additional intellectual property barrier to access to medicines. It means that generic manufacturers can have access to the results of clinical trials and testing, including those required for regulatory approval. This removes the need for them to conduct their own trials, which can be prohibitively expensive.

Public health focus: The Pool has negotiated the licences so that critical public health safeguards are not compromised. For instance, the agreement expressly ensures that generic companies will be able to supply countries outside the licensed territory if their governments issue compulsory licences.

Pipeline products: It is rare for a commercial research-based company to license products still in clinical development to generic companies for use in resource-limited settings. By allowing access to pipeline medicines, the licences will speed the arrival of new HIV drugs to people living with HIV in developing countries, making the drugs available soon after their launch in developed country markets.

Special provisions for paediatric formulations: Royalties of 3-5% of generic sales will be waived for any new paediatric formulations, and there are provisions for medicines for children under 12 to be made available outside the licensed territory.

Expansion of geographical scope: The number of countries in the licensed territory is greater than in any previous Gilead licence or in any other company's voluntary licences, though the licences do not include all developing countries. The new tenofovir and emtricitabine licences cover 112 countries, the cobicistat licence covers 103 countries and the elvitegravir and Quad licences cover 100 countries.

Use of tenofovir for hepatitis B: Previous voluntary licences have only allowed the use of tenofovir in the treatment and prevention of HIV. The Pool's licences also allow for its use in the treatment of hepatitis B, which is a significant health problem in developing countries that the WHO estimates kills 600,000 people a year.

Termination clauses: Previous licences did not allow for the licensee to terminate without cause. The Pool licences allow licensees to terminate for any reason and on a drug-by-drug basis. That is, they can terminate the licence for one medicine while retaining licences to produce the others, a procedure known as "unbundling."

NEGOTIATING WITH PATENT HOLDERS

On World Aids Day in December 2010, the Pool sent letters inviting pharmaceutical companies holding key ARV patents to enter into formal negotiations. It subsequently held briefing meetings and conference calls with these potential licensors to explain the Pool further and understand patent holders' concerns. As a result of these efforts, six of nine identified pharmaceutical companies entered into formal negotiations with the Pool to license their intellectual property. Apart from Gilead Sciences, they are Boehringer-Ingelheim, Bristol-Myers Squibb, F. Hoffman-La Roche, Sequoia Pharmaceuticals and ViiV Healthcare, a GlaxoSmithKline and Pfizer joint venture. A tenth patent holder, the US National Institutes of Health, also entered into formal negotiations with the Pool.

The Gilead licences are a critical first step in changing norms on voluntary licensing in the direction of greater transparency and public health focus. However, they should be seen as a starting point. In particular, the Pool will work with companies to address shortcomings in these and future new licences by:

- Continuing to strive for a further expanded geographic scope;
- Removing limitations on sourcing of active pharmaceutical ingredients;
- Removing limitations on manufacturing location, currently confined to India in the Gilead agreement.

The Pool will also aim to ensure that key public health safeguards that are in the licences with Gilead are also included in licences with other pharmaceutical companies.

Engaging with sub-licensees

While negotiating licences with patent holders is crucial, so too is ensuring generic manufacturers take up these licences to expand their production of ARVs. In the 18 months to end-December 2011, two generic pharmaceutical companies, Aurobindo Pharma and Medchem International, signed sub-licences with the Medicines Patent Pool.

Aurobindo Pharma, an important manufacturer of generic ARVs, signed an agreement in October 2011 to manufacture several HIV medicines based on products licensed to the Pool by Gilead – emtricitabine, cobicistat, elvitegravir and the fixed-dose combination of these medicines alongside tenofovir known as the "Quad." Aurobindo has an established record in producing quality generic drugs for HIV, including fixed-dose combinations and paediatric formulations.

Aurobindo also took advantage of a key provision negotiated by the Pool, enabling it to sell tenofovir to a larger number of countries without paying royalties. The Gilead licence is "unbundled," which means that a generic manufacturer can elect to take licences on a product-by-product basis. Aurobindo chose not to take a licence on tenofovir, on which there is currently no product patent in India (only a patent on one process for making it). This means it is free to sell tenofovir made by a different process to any country where the drug is not patented, including several middle-income countries excluded from Aurobindo's previous licence with Gilead such as Argentina, Brazil, Chile, Colombia, Malaysia, the Philippines, Ukraine and Uruguay.

Generic manufacturer Medchem International, a new player in the HIV field, has also signed sub-licences with the Pool to produce all five products included in the Gilead licences. Attracting generic producers will help increase production capacity, which is needed to meet treatment goals.

The Pool has engaged and continues to engage with a wide range of potential licensees, through meetings worldwide and conference calls. These interactions are aimed at building relationships, introducing generic manufacturers to the Pool, obtaining feedback on potential terms and conditions and, most recently, discussing out-licensing.

"Voluntary use, where appropriate, of… patent pools benefiting all developing countries, including through entities such as the Medicines Patent Pool, [is encouraged] to help reduce treatment costs and encourage development of new HIV treatment formulations, including HIV medicines and point-of-care diagnostics, in particular for children."

– United Nations General Assembly Political Declaration on HIV/AIDS, June 2011

Resources and technical work

In addition to licensing activities, the Pool undertakes technical and research projects that help support its core licensing work.

Medicines targeted for inclusion in the Pool are chosen based on analysis conducted by the Pool with the help of HIV experts. In September 2011, the Pool published a new priority list of antiretroviral medicines,[14] for comment and input. It takes into account the available clinical evidence as well as market information and patent status. Preliminary results of the prioritisation exercise were presented at the conference of the International AIDS Society in July 2011, and the document was finalised following comments from a wide range of experts, including the WHO *(see "Current Target Products and Formulations," Page 24).*

Reliable patent status information is often difficult to find, and confusion over who is legally able to manufacture or import medicines in what country can delay needed affordable treatments in places where there are in fact no legal barriers, or where these barriers can be overcome. In April 2011, the Pool launched its Patent Status Database for HIV Medicines, which is available on the website and regularly updated. Created in collaboration with national patent offices and the World Intellectual Property Organization (WIPO), the database now covers 71 countries and 24 antiretrovirals. The database is the most complete single source of open access information about critical HIV-related patents in developing countries.[15] It is being widely used by a range of public health actors, including UN agencies and civil society organisations.

The Pool also worked with WHO and UNAIDS to identify missing medicines considered most essential to the health of people living with HIV in low- and middle-income countries, including needed fixed-dose combinations and other formulations, and a joint document was submitted to the WHO Expert Committee on the Selection and Use of Essential Medicines in February 2011, and endorsed by many partners' of the WHO/UNAIDS Treatment 2.0 initiative for meeting current and future needs of people living with HIV.

With UNITAID, the WHO and Chatham House in London, the Pool co-organised a meeting in July 2011 on Innovation in Antiretrovirals to Meet Developing Country Needs, intended to explore opportunities for innovation in antiretroviral treatment arising from the Pool's work. The meeting was attended by selected experts representing a wide range of stakeholders involved in HIV-related innovation and treatment. Coming a few weeks after the international community set new targets at the UN High-Level Meeting on HIV, in particular to have 15 million people on treatment by 2015, the meeting focused on what medicines would be required to achieve such targets, how to ensure they were developed, and how better to integrate the needs of poorer countries into HIV research agendas.

The Pool also prepared a report for the Global Fund to Fight AIDS, Tuberculosis and Malaria on the extent to which patents could pose a challenge to the greater use of fixed-dose combinations in antiretroviral therapy. The report, Challenges to the Uptake of Antiretroviral Fixed-Dose Combinations: An analysis of intellectual property issues, will be published in 2012. It concludes that patents could potentially inhibit uptake and development of FDCs but that various mechanisms exist to prevent or overcome patent barriers. The recommendations to the Global Fund include helping grant recipients to use these mechanisms and encouraging patent holders to negotiate licences with the Pool.

The Pool has also published its own contributions to the literature on HIV treatment and intellectual property, with articles in the Journal of the International AIDS Society[16] and WIPO Magazine.[17]

CURRENT TARGET PRODUCTS AND FORMULATIONS

Compound	Clinical Priority	Market/IP Priority	Main Patent Holder
Level 1 Priorities (medium or high priority under both criteria)			
Lopinavir (LPV)	High	High	Abbott Laboratories
Ritonavir (r)	High	High	Abbott Laboratories
Atazanavir (ATV)	High	High	Bristol-Myers Squibb
Cobicistat (COB)	High	High	Gilead Sciences
Elvitegravir	High	High	Gilead Sciences
Tenofovir (TDF)	High	Medium	Gilead Sciences
Darunavir**	Medium	Medium	Johnson & Johnson/Tibotec
Etravirine (ETV)	Medium	High	Johnson & Johnson/Tibotec
Rilpivirine (RIL)	High	High	Johnson & Johnson/Tibotec
Efavirenz (EFV)	High	Medium	Merck & Co
Raltegravir (RAL)	Medium	High	Merck & Co
Abacavir (ABC)	Medium	Medium	Viiv Healthcare [GlaxoSmithKline/Pfizer]
Dolutegravir (DLG)	High	High	Viiv Healthcare [GlaxoSmithKline/Pfizer]
Level 2 Priorities (medium or high for clinical and low for market/IP)			
Nevirapine (NVP)	High	Low	Boehringer-Ingelheim
Stavudine (d4T)	Medium	Low	Bristol-Myers Squibb
Emtricitabine (FTC)	High	Low	Gilead Sciences
Lamivudine (3TC)	High	Low	Viiv Healthcare [GlaxoSmithKline/Pfizer]
Zidovudine (AZT/ZDV)	High	Low	Viiv Healthcare [GlaxoSmithKline/Pfizer]
Level 3 Priorities (medium or high for market/IP and low for clinical)			
Didanosine (ddI)	Low	High	Bristol-Myers Squibb
Saquinavir (SQV)	Low	Medium	F. Hoffman La-Roche
Fosamprenavir (FPV)	Low	High	Viiv Healthcare [GlaxoSmithKline/Pfizer]
Maraviroc (MVC)	Low	High	Viiv Healthcare [GlaxoSmithKline/Pfizer]

The Pool decides on target medicines based on two criteria: the medicine's clinical importance (determined with the aid of medical and public health experts) and the existence of market and/or patent barriers that might prevent access to it. Each drug gets a ranking within each criterion of high, medium, or low.

The drug is then assigned a priority level of 1, 2 or 3. Level one priorities were ranked "medium" or "high" for both criteria. Level 2 priorities were ranked "medium" or "high" for clinical and "low" for market/patent barriers. Level 3 priorities were ranked "low" for clinical and "medium" or "high" for market/patent barriers.

The Pool has concluded licence agreements for compounds in dark blue.

The Pool is in negotiations for compounds in light blue.

** The Pool has signed a licensing agreement covering darunavir patents with the US National Institutes of Health. However, in order to allow for the manufacture of darunavir, patents are still needed from Johnson & Johnson/Tibotec.

Governance

The Medicines Patent Pool Foundation was established as an independent legal entity in July 2010 with the support of UNITAID, and has been fully operational since November 2010. It is based in Geneva, Switzerland, close to UNITAID, the World Health Organization, UNAIDS, and other global health actors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. UNITAID is providing the funding for the Pool under a five-year Memorandum of Understanding.[18]

The Pool has two primary governing bodies – a Governance Board and an Expert Advisory Group. The Governance Board has the highest authority for making decisions, according to its statutes.[19] It sets policies and strategies for the Pool, oversees its work plan and financial matters, and monitors and evaluates the Pool's performance. It also appoints the Executive Director and Governance Board members, who serve in their personal capacities. The Governance Board may include up to seven voting members, plus up to two non-voting participants, one of which is the chair of the Expert Advisory Group. The Executive Director of the Pool attends Governance Board meetings ex-officio.

The Governance Board meets at least twice a year to discuss the work of the Pool. Additional meetings are convened to review potential licence agreements and address other urgent matters as required. The Board also takes the final decision on which licences to sign and when to sign, after consultation with the Expert Advisory Group.

The Expert Advisory Group is composed of experts in various key disciplines such as public health, law (including pharmaceutical patents), economics, management and pharmaceutical science, with a broad geographical spread. The Group makes recommendations to the Governance Board on draft licence agreements during the final stages of negotiation and advises both the Governance Board and the Pool on other matters of strategy and policy.

The Group, which met for the first time in New York in November 2011, will meet at least once a year and will hold additional meetings as required to review and advise on potential licensing agreements. An ad hoc Expert Advisory Group was convened in March 2011 to advise the Pool on the Gilead licensing agreement.

The Pool has also received pro bono legal assistance from some leading law firms as well as in-kind services from the World Intellectual Property Organization (WIPO) and national patent offices.

At its meeting in December 2011, the Governance Board decided to add a Board member representing communities of people living with HIV and to expand the Expert Advisory Group to include two experts drawn from organisations representing these communities. The Board also discussed how the Pool could expand and formalise its consultative mechanisms to improve feedback on its work from civil society and other stakeholders. In the 18 months to end-2011, the Pool had calls, briefings, consultations and/or meetings with more than 160 civil society organisations from all over the world. In 2012, the Pool plans to launch a consultative process to further improve interactions with civil society stakeholders.

Collaboration with UNITAID

UNITAID is a global health initiative established in 2006 to increase access to quality-assured treatments for HIV, malaria and tuberculosis through sustainable financing and market interventions. It raises funds from predictable sources, primarily through a small tax on airline tickets. UNITAID then uses these funds strategically, through international global health partners, to support creative market-based initiatives that incentivise manufacturers to make needed treatments at affordable prices. Incentives often include bulk purchasing of drugs or diagnostics, which pushes down prices through economies of scale and also helps create markets for medicines that might not otherwise be manufactured.

UNITAID developed the concept of the Medicines Patent Pool as part of its market strategy, which is to stimulate market competition, ramp up production and increase availability of newer and better medicines at affordable prices.

In December 2009, the UNITAID Executive Board voted in principle to create the Medicines Patent Pool, which became a separate legal entity in July 2010. UNITAID is funding the Pool for its first five years of operation under a joint Memorandum of Understanding signed in 2010. At a meeting in Paris on 12-13 December 2011, UNITAID renewed its support for the Pool and reaffirmed its decision to fund Pool's work for the next four years, an important endorsement of the Pool's success in its first 18 months of existence.

UNITAID and the Pool maintain a close working relationship and regularly organise joint events or meetings, including technical briefings and press conferences. Two major co-organised events in 2011 were a side event at the UN High Level Meeting on HIV in June, and a joint event in July with the WHO and Chatham House on Innovation in Antiretrovirals to Meet Developing Country Needs.

END NOTES

[1] The tenth company, Tibotec/Johnson & Johnson, announced in December 2011 that it was not ready to license its patents on HIV medicines through the Pool at that time. The Pool has called on J&J to revisit this decision, remains engaged with J&J in active discussions, and views the door as still open for the company to come to the negotiating table.

[2] http://www.who.int/hiv/pub/hiv_strategy/en/index.html

[3] The Pool negotiated for its licences with Gilead to be "unbundled" - this means a generic manufacturer can elect to uptake licences on a product-by-product basis. The Gilead agreement includes licences for 5 products: emtricitabine, cobicistat, elvitegravir, tenofovir, and a fixed-dose combination of these 4 drugs called the "Quad." Aurobindo chose to take licences covering emtricitabine, cobicistat, elvitegravir and the Quad, but not to take a licence on tenofovir, on which there is currently no product patent in India. This means that Aurobindo should be able to sell tenofovir to a larger number of countries than it was able to sell to before, when it was restricted by an earlier tenofovir licence.

[4] Canada, France, Germany, Italy, Japan, Russia, United Kingdom and United States of America.

[5] http://www.tac.org.za/community/node/3199

[6] Waning, Brenda, Ellen Diedrichsen and Suerie Moon. A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. Journal of the International AIDS Society, September 2010. Available here: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944814/

[7] UNAIDS: 2011 World AIDS Day Report. Available here: http://www.un.org/en/events/aidsday/2011/report.shtml

[8] http://www.nih.gov/news/health/dec2011/niaid-22.htm

[9] UNAIDS: 2011 World AIDS Day Report. Available here: http://www.un.org/en/events/aidsday/2011/report.shtml

[10] Product development partnerships, such as the Drugs for Neglected Diseases Initiative (DNDi), are public–private partnerships formed to develop new medicines needed in developing countries.

[11] A primer on the work of the Pool with the WHO Prequalification Programme is available here: http://apps.who.int/prequal/info_general/documents/FAQ/PQ_PatentPool.pdf

[12] http://www.e-alliance.ch/en/s/news/single/article/2011/11/23/press-release-aids-report-responses-showing-results-need-strengthened-support/

[13] The full texts of all Pool licences are available here: http://www.medicinespatentpool.org/current-licences/

[14] ARV Priority List for the Medicines Patent Pool, Working Paper, September 2011. Available here: http://www.medicinespatentpool.org/target-medicines/

[15] In order to provide a more in-depth understanding of the patents on two specific antiretrovirals, ritonavir and atazanavir, WIPO also commissioned two "patent landscapes" at the request of the Pool and UNITAID.

[16] Ellen 't Hoen, Jonathan Berger, Alexandra Calmy and Suerie Moon: Driving a decade of change: HIV/AIDS, patents and access to medicines for all, Journal of the International AIDS Society 2011, 14:15, 27 March 2011. Available here: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078828/

[17] Ellen 't Hoen, Esteban Burrone and Kaitlin Mara: Medicines Patent Pool: Facilitating Access to HIV Treatment, WIPO Magazine, June 2011. Available here: http://www.wipo.int/wipo_magazine/en/2011/03/article_0005.html

[18] http://www.medicinespatentpool.org/wp-content/uploads/Medicines-Patent-Pool-UNITAID-Memorandum-of-Understanding.pdf

[19] http://www.medicinespatentpool.org/wp-content/uploads/STATUTES-ENG-FR-Medicines-Patent-Pool.pdf

Members of Governance Board as of 31 December 2011

Charles Clift (Chair)	*United Kingdom*
Precious Matsoso	*South Africa*
Sigrun Møgedal	*Norway*
Bernard Pécoul	*France*
Paulo Teixeira	*Brazil*

Members of Expert Advisory Group as of 31 December 2011

Maximilliano Santa Cruz (Chair)	*Chile*
Labeeb Abboud	*USA*
Jonathan Berger	*South Africa*
Alexandra Calmy	*Switzerland*
Shing Chang	*USA*
Carlos Correa	*Argentina*
Eun-Joo Min	*Republic of Korea*
Lita Nelsen	*USA*
Nelson Juma Otwoma	*Kenya*
Achal Prabhala	*India*

Law Firms Providing Pro Bono Assistance

Bird & Bird	*London*
Dechert	*Paris*
Katten Muchin Rosenman	*New York*
Rajeshwari & Associates	*India*
Wilson Sonsini Goodrich & Rosati	*New York*

Medicines Patent Pool Staff as of December 2011

Ellen 't Hoen	*Executive Director*
Sandeep Juneja	*Business Development Director*
Chan Park	*General Counsel*
Esteban Burrone	*Policy Advisor*
Kaitlin Mara	*Communications Manager*
José Imbernon	*Finance and Resources Manager*
Esperanza Suarez	*Finance and Administrative Officer*
Shamsa Abdulrasak	*Executive Assistant*


30 Tablets
Efavirenz Tablets IP
600
600
Each film-coated tablet contains
Efavirenz IP ..... 600 mg
Dosage:
As directed by the physician
Colours:
Yellow Oxide of Iron &
Titanium Dioxide
Store in a cool dry place
away from moisture
Keep the container tightly closed
KEEP OUT OF REACH OF CHILDREN

FINANCIAL STATEMENTS 2011

MEDICINES PATENT POOL FOUNDATION, GENEVA

REPORT OF THE STATUTORY AUDITORS TO THE BOARD

ON THE FINANCIAL STATEMENTS 2011

Financial Report

In the Memorandum of Understanding between UNITAID and the Medicines Patent Pool, signed 14 September 2010, UNITAID endowed the Pool with grants totalling USD 4,852,951 for the period from July 2010 to December 2011. The Medicines Patent Pool Governance Board appointed PricewaterhouseCoopers (PWC) to conduct a limited audit of the Medicines Patent Pool's accounts for this period; PWC released their report on 12 April 2012, which can be found on pages 29-34.

In December 2011, the UNITAID Executive Board committed additional funds up to USD 26,298,170 to support the Pool's activities from 2012-2015.

pwc

Report of the statutory auditors
on the limited statutory examination
to the Board of
Medicines Patent Pool Foundation
Geneva

As statutory auditors, we have examined the financial statements of Medicines Patent Pool Foundation, which comprise the balance sheet, operating statement, statement of changes in equity and notes (pages 30 to 34) for the year ended December 31, 2011. As permitted by Swiss GAAP FER 21 the information in the performance report is not required to be subject to the statutory auditors' examination.

These financial statements are the responsibility of the Board. Our responsibility is to perform a limited statutory examination on these financial statements. We confirm that we meet the licensing and independence requirements as stipulated by Swiss law.

We conducted our examination in accordance with the Swiss Standard on Limited Statutory Examination. This standard requires that we plan and perform a limited statutory examination to identify material misstatements in the financial statements. A limited statutory examination consists primarily of inquiries of foundation personnel and analytical procedures as well as detailed tests of foundation documents as considered appropriate in the circumstances. However, the testing of the operational processes and the internal control system, as well as inquiries and further testing procedures to detect fraud or other legal violations, are not within the scope of this examination.

Based on our limited statutory examination, nothing has come to our attention that causes us to believe that the financial statements do not give a true and fair view of the financial position, the results of operations in accordance with Swiss GAAP FER 21. Furthermore, nothing has come to our attention that causes us to believe that the financial statements do not comply with Swiss law and the foundation's deed and internal regulations.

PricewaterhouseCoopers AG

Marcel Aeberhard
Audit expert
Auditor in charge

Stéphanie Huet D'Amour

Zürich, April 12, 2012

Enclosure:

- Financial statements (balance sheet, operating statement, statement of changes in equity and notes)

BALANCE SHEET
AS OF DECEMBER 31, 2011

	NOTES	2011 USD	2011 CHF
ASSETS			
CURRENT ASSETS			
Cash and bank		702'830	660'590
Prepaid expenses		6'148	5'779
Other receivables	3d	3'917	3'682
Total Current Assets		712'895	670'051
NON-CURRENT ASSETS			
Fixed assets			
Tangible fixed assets (net)	3b/4	77'160	72'522
Total fixed assets		77'160	72'522
Total Non-Current Assets		77'160	72'522
TOTAL ASSETS		790'055	742'573
LIABILITIES, FUNDS AND CAPITAL			
LIABILITIES			
Current liabilities			
Salaries and social charges		36'598	34'399
Accrued liabilities	3c	267'027	250'978
Other liabilities		22'545	21'190
Total current liabilities		326'170	306'567
Total Liabilities		326'170	306'567
RESTRICTED FUNDS			
Restricted Fund UNITAID	3a	415'152	386'006
Total Restricted Funds		415'152	386'006
CAPITAL			
Paid-in capital	3a	48'733	50'000
Total Capital		48'733	50'000
TOTAL LIABILITIES, FUNDS AND CAPITAL		790'055	742'573

STATEMENT OF OPERATIONS

FOR THE PERIOD FROM JULY 16TH, 2010 TO DECEMBER 31, 2011

	NOTES	2011 USD	2011 CHF
INCOME			
Donations			
Donations	3a	4'752'147	4'367'698
Total Donations		4'752'147	4'367'698
Other Incomes			
Revenue on IP advise		22'580	20'753
Other incomes		5'458	5'017
Total Other Incomes		28'038	25'770
TOTAL INCOME		4'780'185	4'393'468
EXPENSES			
Personnel Costs			
Personnel costs and social charges		1'996'956	1'835'402
Other personnel costs		328'566	301'984
Total Personnel Costs		2'325'522	2'137'386
Administrative Expenditure			
Professional fees		1'078'791	991'517
Rent		145'463	133'695
Taxes		26'226	24'104
General and administrative expenses		105'048	96'550
IT services and maintenance		147'097	135'197
Marketing and Advertising		20'926	19'234
Travel and representation costs		757'351	696'081
Depreciation of tangible assets		22'742	20'902
Total Administrative Expenditure		2'303'644	2'117'280
Net financial income/(loss)	5/2	264'133	247'204
Operating Surplus/(deficit)		415'152	386'006
Net Surplus/Deficit for the Year Prior to Allocations		415'152	386'006
(Allocation to)/Withdrawal from restricted capital funds		–415'152	–386'006
Total (allocations)/withdrawal		–415'152	–386'006
Net surplus/deficit for the year after allocations		0	0

STATEMENT OF CHANGES IN CAPITAL

FOR THE PERIOD ENDING DECEMBER 31, 2011

	Beginning of the Period 16.07.2010	Allocation of the Funds	Use of the Funds	Revaluation	End of the Period 31.12.2011
Restricted Fund UNITAID	–	4'640'672	–4'254'666	–	386'006

	Beginning of the Period 16.07.2010	External Withdrawl	Internal Fund Transfers	Allocation to Capital	End of the Period 31.12.2011
Internally generated funds					
Paid-in capital	–	–	–	50'000	50'000
Internally generated unrestricted capital					
Surplus/(deficit) for the year	–	–	–		
Capital of the organisation	**–**	**–**	**–**	**50'000**	**50'000**
Total restricted funds and internally generated funds	**–**	**4'640'672**	**–4'254'666**	**50'000**	**436'006**

NOTES TO THE FINANCIAL STATEMENTS
AT 31.12.2011

Appendix 1 : Presentation

The financial statements are in compliance with Swiss GAAP FER 21 and the Swiss Law.

The Balance Sheet positions are valued at historical cost of acquisition.

The financial statements are based on the assumptions that the going concern is possible for the foreseeable future. They comply with the criterias of reliability and true and fair view.

The financial statements are for a period of 18 months (first year of operation)

The USD currency is disclosed on the financial statement only for information purposes.

Appendix 2 : Accounting principles and allowed valuation principles for assets and liabilities

Conversion of annual accounts:
For this first year, the accounts were held in USD dollars. In accordance with the Swiss law, the accounts of the Foundation are converted into Swiss francs at 31 December 2011 using the following method:

Assets and liabilities: Closing rates
Equity: Historical rates
Incomes and expenses : Average monthy rates.

Exchange differences arising from this translation are included in the net income for the year.

Starting 1st of January 2012, the accounts currency basis will change from USD into CHF. The CHF audited balances at December 31, 2011 will be taken as opening balances for the year starting January 1st, 2012.

Translation of operations in foreign currency
Transactions in currencies other than USD are converted as follows:

Assets and liabilities : Closing rates
Incomes and expenses : Average monthy rates.

Appendix 3 : Accounting principles and allowed valuation principles for assets and liabilities

a – UNITAID

The Medicines Patent Pool Foundation ("the Pool") was established as an independent legal entity on 16 July 2010 with the support of UNITAID, which remains the Pool's sole donor.

UNITAID and the Medicines Patent Pool have maintained a close working relationship since the Pool was established as an independent entity.

Per the Pool's statutes the majority of the Pool's third party funding (excluding royalty payments, if any) shall come from sources of public and/or non-profit nature.

b – Fixed Assets

The tangible fixed assets are valued at historical cost of acquisition, less the accumulated depreciation. The depreciation is recognised on the straight-line method over the useful life, as follows:

Category of fixed assets	*Useful life (years)*
Office equipment	8 years
IT infrastructure	3 years

c – Accrued Liabilities

This position includes the charges related to the current exercice, but will be paid the following exercice.

d – Pension Fund

As of December 31, 2011, the Company has no liabilities due to the pension fund.

e – Taxes

The Foundation is not subject to taxes.

NOTES TO THE FINANCIAL STATEMENTS
AT 31.12.2011

Appendix 4 : Fixed assets

	OFFICE EQUIPMENT	IT INFRASTRUCTURE	TOTAL
Net carrying amount 16.07.2010			**0**
Accumulated gross values of cost			
Beginning of the period 16.07.2010	0	0	0
Additions	53'158	39'655	92'813
Change in the actual values	0	0	0
Disposals	0	0	0
Reclassifications	0	0	0
End of the period 31.12.2011	53'158	39'655	92'813
Accumulated depreciation			
Beginning of the period 01.01.2011	0	0	0
Systematic depreciation–	7'060	–13'231	–20'291
Impairment	0	0	0
Disposals			0
Reclassifications	0	0	0
End of the period 31.12.2011	–7'060	–13'231	–20'291
Net carrying amounts 31.12.2011	46'098	26'424	72'522

Appendix 5 : Net financial result

The financial income and costs are the following

	2011 CHF
Exchange gain/(loss), net	243'613
Translation gain	4'439
Bank interest income/(loss)	2'417
Others, net	–3'265
TOTAL	**247'204**

Appendix 6 : Pro-Bono Agreements

In the collection of patent information, the Pool benefitted from in-kind contributions from a large number of national and regional patent offices and from WIPO.

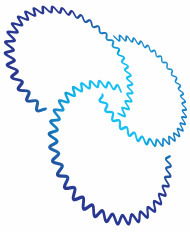
The Pool also received significant pro bono legal services from a number of law firms.

The valuation of such donated services for the period from July 16th, 2010 to December 31, 2011 amounts to CHF 264'205 (USD 287'461). This figure is a composite of the actual market value of pro bono legal services received, as well as an estimate of the value of the collection of patent information from WIPO and national and regional patent offices.

The latter represents a conservative estimate of the value of such data if it had had to obtain it.

Appendix 7 : Other disclosures

Remuneration of the Governing Bodies of the Foundation
The members of the Governing Bodies of the Foundation – the Governance Board and the Expert Advisory Group do not receive any remuneration in respect of their activities within the Foundation.



medicines
patent
pool

MedicinesPatentPool.org