Despite recent progress in access to HIV medicines, there is still significant need for additional treatment:

- 5.2 million people in developing countries on ART by end of 2009
- But further 10 million people are in urgent need of treatment as per WHO guidelines
- An additional 18 million people are HIV positive and will need treatment
- 1.2 million new people on treatment in 2009, but 2.6 million new infections

The Context

- Generic competition central to treatment scale-up of past decade
  - Price of 1st line regimen down to under 1% of original price

- Widespread patenting of newer drugs in Developing Countries
  - Limited generic availability and limited price reductions
  - Differential pricing: not same impact on pricing as robust generic competition

- Promising FDCs / formulations often not developed
  - WHO Committee on Essential Medicines has identified opportunities

- Financial crisis
  - Squeezing budgets for purchase of HIV medicines

- Treatment Needs
  - WHO Treatment Guidelines (earlier start; drugs with less side effects)
  - People in developing countries developing resistance to 1st line

The Case of Paediatric HIV/AIDS

- Market for paediatric HIV medicines almost exclusively in developing countries
- 1,200 new paediatric infections every day
- Over 85% of infected children are not treated
- HIV disease progression in children is more rapid than in adults
- Options for treating HIV-infected children more limited than for adults (need for paediatric formulations)
- Approximately 300,000 children on treatment today (80% financed by UNITAID)
Public Health Vision

To improve access to appropriate affordable HIV treatments in developing countries

Medicines Patent Pool Mission

The patent pool will bring down the prices of HIV drugs, facilitate the development and production of improved formulations (e.g., fixed dose combinations and paediatric and heat-stable formulations) by providing access to intellectual property relating to these products

History of the Medicines Patent Pool

2006

CIPHR 2006 recommendation:

"Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries."

MSF and KEI proposed to UNITAID to set up a medicines patent pool.

2008

May 2008

WHO Global Strategy and Plan of Action included Voluntary Patent Pools (upstream and downstream)

July 2008

UNITAID Executive Board

Supports the principle of establishing a patent pool and requests the secretariat to undertake all necessary actions for this establishment.

2009

Broad stakeholder consultation

Developed the implementation plan for the medicines patent pool

Ongoing dialogue with patent holders and with other ARV drug manufacturers

Decision by UNITAID Board to fund

2010

Establishment of the Medicines Patent Pool

Formal licensing negotiations begin

NIH grants first licence to the Pool

UNITAID funds the operations of the Pool under a 5-year MOU
How the Pool Works

Three Main Objectives

• Enable the development of fixed dose combinations (FDCs) of which the patents are held by different entities

• Enable the development of adapted formulations for children or for specific developing country needs (e.g., heat stable)

• Accelerate the availability of generic versions of new ARVs in developing countries
How is it different from existing schemes?

Current landscape of Access programs for ARVs shows a wide variety of different schemes that include:
- Voluntary licenses with widely differing and opaque terms and conditions
- Non-assert declarations
- Differential pricing schemes

Over 60 countries have made use of flexibilities in TRIPS /Doha to access generic ARVs

The Pool would provide:
- A reasonably standardized mechanism for making available voluntary licenses that would significantly facilitate the development of new combinations
- Enhanced credibility of voluntary licenses through terms and conditions negotiated from a public health perspective
- Cooperative platform
- Reduction in transaction costs for all parties involved

Missing ARVs - Priority setting

Patent Pool, UNITAID, WHO HIV/AIDS submitted “Updated List of Missing ARVs” to 19th WHO Expert Committee - endorsed by 10 Tx 2.0 Partners

Next steps:
- Further prioritisation based on needs and opportunities
- Working with UNITAID, WHO, Tx 2.0 partners to determine next steps → roles of various actors to ensure maximum uptake of drug development opportunities created through the Pool
Patent Pool Partnerships

- UNITAID:
  - initiated the Medicines Patent Pool project ’08
  - funds operations of Pool under a 5-year MOU
- WHO:
  - Medicines quality assurance (WHO PQ Department)
  - identification of priority medicines (HIV/AIDS Depart. and Essential Medicines)
  - IP, access and innovation and Health issues (PHI)
- WIPO
  - licensing terms and conditions (co-organization of expert workshop in 2010)
  - patent information
- Many others (WTO, Global Fund, UNAIDS, ANRS, EPO, MSF etc.)

The Market for HIV/AIDS

- Low and middle income countries represent a small proportion of current global sales for HIV/AIDS (a fraction of 6%) and highly concentrated in a handful of countries.
- For 2\textsuperscript{nd} and 3\textsuperscript{rd} line drugs: less than 3%
- Contribution to bottom line of originator companies, even lower
- But over 90% of the disease burden
Support for the Medicines Patent Pool

“One promising initiative that can help decrease the cost of patents for the Index Countries is the patent pool initiative of UNTAID.”

ATM Index 2010 (Engagement with PP included as one of the issues measured in the Index)

“We urge all public institutions and pharmaceutical companies to follow the measures taken by the NIH, and to share without delay their patents on this and other antiretrovirals with the Medicines Patent Pool, in order to facilitate access to these treatments at the lowest possible price for countries in need.”

Prof. Kazatchkine, Executive Director
Global Fund

“We think that the Medicines Patent Pool is an important initiative towards achieving universal access to the newer HIV medicines...At WHO we will be pleased to give priority to any of the newly developed FDCs for assessment by our WHO / UN Prequalification Programme in order to facilitate its rapid uptake by the funding agencies and national governments.”

The World Health Organization (October 2010)

“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 Sidibe, UNAIDS Executive Director (July 2010)

“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”

NIH Director Francis S. Collins, M.D., Ph.D.

Patent Holder Engagement

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<tr>
<th>Patent Holder</th>
<th>Q4 2010</th>
<th>Q1 2011</th>
</tr>
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<tbody>
<tr>
<td>Abbott Laboratories</td>
<td>Sent letter on 1 December</td>
<td>Not currently in negotiations. Reply received 26 January</td>
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<tr>
<td>Boehringer-Ingelheim</td>
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<td>Not currently in negotiations. Reply received 19 January</td>
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<td>Bristol-Myers Squibb</td>
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<td>F. Hoffman-La Roche</td>
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<td>Gilead Sciences</td>
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<td>Merck &amp; Co.</td>
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<td>Sequoia Pharmaceuticals</td>
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<td>Tibotec/Johnson &amp; Johnson</td>
<td>Sent letter on 1 December</td>
<td>Not currently in negotiations. Reply received 31 January</td>
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<tr>
<td>US National Institutes of Health</td>
<td>Licence granted September</td>
<td>In negotiations</td>
</tr>
<tr>
<td>ViIV Healthcare</td>
<td>Sent letter on 1 December</td>
<td>In negotiations</td>
</tr>
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Addressing the Difficult Issues

• Geographical Scope of Licenses:
  – Work with Licensors to achieve as broad a geographical scope as possible given Pool mandate (low and middle income countries)
  – Opportunity for defining royalty levels that benefit all

• Development of Adapted Formulations
  – Innovation: key focus of the Pool
  – Range of opportunities arising as a result of creation of Pool. Discussions ongoing with wide range of partners.

• Quality Control: key concern for all parties
  – In line with international practice, reliance on approval by SRA or WHO PQ.
  – Close collaboration with WHO Prequalification will be central

The Way Forward

• The Pool starts negotiations with five HIV drug patent holders

• Negotiations is no guarantee for success but it is the only way to sort out the differences and create confidence and establish a robust and predictable voluntary licensing system

“... to succeed it is critical to have more companies joining the Pool to scale up HIV Treatment”

(US Government at WHO Executive Board, January 2011)
THANK YOU

www.medicinespatentpool.org