The Issue

- 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 Issue (contd.)

Before

• HIV Medicines not patentable in many developing countries
• Generic competition led to significant fall in price of first line drugs
• People treated in DCs: from under 300,000 to 5 Million in less than a decade
• Over 80% of donor-funded market supplied by Indian generic manufacturers

Now and into the Future

• Widespread patenting of newer HIV medicines in Developing Countries
• Limited generic availability for newer products and limited price reductions
• Differential pricing policies of companies: not same impact on pricing as robust generic competition

In addition

• Formulations/combinations needed in DCs often not developed
• Squeezing budgets for purchase of HIV medicines
• Recommendation to start treating people earlier
• Resistance to 1st line drugs -> need access to 2nd line
The Medicines Patent Pool
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 the Pool Works

Licensor

Patents

Pool

Royalties

Sub-Licensee

Sub-Licensee

Sub-Licensee

Sub-Licensee

Sub-Licensee

Sub-Licensee

Sub-Licensee

Sub-Licensee
**History of the Medicines Patent Pool**

**2006**

**CIPIH 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
Prioritizing ARV products

• Initial prioritization undertaken in 2009 by UNITAID and WHO

• Revised in 2011
  – Joint MPP/UNITAID/WHO Document on Missing Drug Formulations for HIV treatment
  – Submitted in February 2011 to WHO Committee on Selection and Use of Essential Medicines
  – Endorsed by many partners of Treatment 2.0, including Global Fund, PEPFAR, UNAIDS, others...
  – Further prioritization ongoing
• Identification of 69 patents relating to 23 antiretrovirals (current and pipeline) – support from generic companies

• Preliminary search using publicly-available databases

• Where possible, data cross-checked with other sources:
  – Publications (e.g. MSF UTW; I-Mak, others)
  – Local patent attorneys/experts

• WIPO support to validate available data and obtain new data from additional countries

• Wherever discrepancies between sources, reliance on information provided by national patent offices as primary source

• ARV patent status information available on the Pool website before end of the March and to be updated as new information becomes available
1) **Overview of Licence:** A patent family relating to the use of a class of protease inhibitors, including darunavir

2) **Patent Owner:** Research by NIH National Cancer Institute and University of Illinois-Chicago (1999)

3) **Licence Conditions:**
   - Licence text is publicly available
   - Licence to benefit all low- and middle-income countries
   - Royalty-free

4) **Additional Information:**
   - Licence is **not** enough to clear legal path to generic production
   - NIH and the Pool discussing additional licenses
# Current State of Play with Patent Holders

<table>
<thead>
<tr>
<th>Patent Holder</th>
<th>Q4 2010</th>
<th>Q1 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Abbott Laboratories</strong></td>
<td>Sent letter on 1 December</td>
<td>Not currently in negotiations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reply received 26 January</td>
</tr>
<tr>
<td><strong>Boehringer-Ingelheim</strong></td>
<td>Sent letter on 1 December</td>
<td>Not currently in negotiations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reply received 19 January</td>
</tr>
<tr>
<td><strong>Bristol-Myers Squibb</strong></td>
<td>Sent letter on 1 December</td>
<td>Not currently in negotiations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reply received 26 January</td>
</tr>
<tr>
<td><strong>F. Hoffman-La Roche</strong></td>
<td>Sent letter on 1 December</td>
<td>Preparing for negotiations</td>
</tr>
<tr>
<td><strong>Gilead Sciences</strong></td>
<td>Sent letter on 1 December</td>
<td>In negotiations</td>
</tr>
<tr>
<td><strong>Merck &amp; Co.</strong></td>
<td>Sent letter on 1 December</td>
<td>Not currently in negotiations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reply received 28 January</td>
</tr>
<tr>
<td><strong>Sequoia Pharmaceuticals</strong></td>
<td></td>
<td>In negotiations</td>
</tr>
<tr>
<td><strong>Tibotec/Johnson &amp; Johnson</strong></td>
<td>Sent letter on 1 December</td>
<td>Not currently in negotiations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reply received 31 January</td>
</tr>
<tr>
<td><strong>US National Institutes of Health</strong></td>
<td>Licence granted September</td>
<td>In negotiations</td>
</tr>
<tr>
<td><strong>ViiV Healthcare</strong></td>
<td>Sent letter on 1 December</td>
<td>In negotiations</td>
</tr>
</tbody>
</table>
"Support for the Medicines Patent Pool"

"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)

"This licence underlines the U.S. Government’s commitment to the Medicines Patent Pool and its goal to increase the availability of HIV medicines in developing countries. We are now discussing licensing to the Medicines Patent Pool other patents that could have a positive impact on the treatment of HIV/AIDS."

NIH Director Francis S. Collins, M.D., Ph.D.
Thank You!

For more information visit us:

www.medicinespatentpool.org