UNITAID Mission

UNITAID's Mission
► Scale up access to treatment for HIV/AIDS, malaria and TB
► Leverage price reductions of quality drugs and diagnostics
► Accelerate availability

How
Sustainable, predictable and additional funding to generate a steady demand for drugs and diagnostics

Impact market dynamics to reduce prices and increase availability and supply

Support the Doha Declaration on TRIPS and Public Health

Any other innovative solution that may overcome limitations to market diversification in developing countries will also be pursued
What is a Patent Pool?

Portfolio of patents and other relevant intellectual property held by various actors made available on a non-exclusive basis to third parties, (e.g. generic manufacturers) against the payment of royalties.

➤ Patent Pools come in different shapes and forms and are set up for different purposes

➤ While we learn from existing 'standards' pool, the Medicines Patent Pool Initiative is quite different
**History of 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."

Proposed to UNITAID to set up a medicines patent pool.

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**2008**

May 2008
WHO Global Strategy and Plan of Action included Voluntary Patent Pools

July 2008
UNITAID Executive Board
‘Green light ‘to establish a voluntary medicines patent pool

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**2009**

Broad stakeholder consultation

Developed the implementation plan for the medicines patent pool

Ongoing dialogue on terms and conditions

Public Health Vision

To improve access to appropriate affordable antiretrovirals 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 drugs for children) by providing access to intellectual property relating to these products
### 13 Guiding Principles of the Medicines Patent Pool

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<th>Principle</th>
<th>Details</th>
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<td><strong>1. Public health driven:</strong></td>
<td>The Patent Pool will be driven by public health needs</td>
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<td><strong>2. ARV focus:</strong></td>
<td>The Patent Pool will initially focus on antiretroviral (ARVs) medicines</td>
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<td><strong>3. Voluntary:</strong></td>
<td>The Patent Pool will operate on a voluntary basis</td>
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<td><strong>4. Developing country focus:</strong></td>
<td>The Patent Pool will focus on developing countries (low and middle income countries as classified by the World Bank)</td>
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<td><strong>5. Price reductions:</strong></td>
<td>The Patent Pool will focus on achieving price reductions through increased competition for production &amp; distribution</td>
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<td><strong>6. Enable product development:</strong></td>
<td>The Patent Pool will enable &quot;access to patents&quot; to facilitate the development of appropriate and adapted formulations</td>
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<td><strong>7. Flexible:</strong></td>
<td>The Patent Pool will be sufficiently flexible and innovative to adapt to evolving health needs and opportunities</td>
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<td><strong>8. Quality assurance:</strong></td>
<td>The Patent Pool will leverage existing mechanisms (e.g. WHO pre-qualification, US FDA, EMEA) for quality assurance</td>
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<td><strong>9. Standardized licenses:</strong></td>
<td>Key license terms and conditions will be standardized across all licensees / licensors to ensure efficiency and effectiveness</td>
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<td><strong>10. Non discriminatory licenses:</strong></td>
<td>Licenses will be available on a non-exclusive and non-discriminatory basis in order to enhance competition</td>
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<td><strong>11. Additional:</strong></td>
<td>The Patent Pool will be additional to other mechanisms and measures to promote access to medicines</td>
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<td><strong>12. Intellectual Property:</strong></td>
<td>The Patent pool will operate within the current IP framework. Patent owners will be compensated through royalties as appropriate. The patent pool will manage products rather than specific underlying patents</td>
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<td><strong>13. Independent entity:</strong></td>
<td>The Entity administering the Patent Pool must be independent</td>
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How will the Patent Pool help to address impending patent-related access problems?

- Diversifying supply sources to reduce prices
- Expanding generic market size to reduce prices & expand access
- Facilitating the development of improved formulations (e.g. Fixed Dose Combinations (FDCs), pediatric and heat-stable formulations)
- Increasing legal certainty for generic companies and patent-holders
- Reducing transaction costs for licensing agreements (e.g. FDCs)
How will the Patent Pool operate?

Patent Pool entity works with WHO to identify products of interest in relevant countries

- Patent Pool entity develops standardized licensing agreement with patent holder
- Patent holder licenses product to Patent Pool entity
- Patent Pool entity sublicenses product to licensee
- Licensee produce products for countries in scope
- Licensee produce reports for patent holders and Patent Pool entity regarding products sold, price, country of sale, etc.
- Licensee pays royalties directly to patent holder

Patent Pool entity works with key stakeholder to identify potential incentives necessary to achieve the mission of the patent pool
How will the Patent Pool operate?

Patent Pool negotiates standard license agreements with patent holders. Generic manufacturers interact directly with the patent owners for royalty payments.

*Refer to Appendix for details of the patent pool functions*
Next steps...

➡️ Continued consultations with patent holders to refine the proposed terms and conditions
➡️ Continued engagement with potential sub-licensees
➡️ Establish legal entity for the UNITAID Patent Pool
➡️ Commence formal negotiations
➡️ Conclude agreements
Thank You!