The Medicines Patent Pool

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Medicines Patent Pool

April 2011

Established in July 2010 with the Support of UNITAID

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 paediatric and heat-stable formulations) by providing access to intellectual property relating to these products
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 drove significant decrease in price
- People treated in DCs: from under 300,000 to 5 Million in less than a decade

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
13 Guiding Principles of the Medicines Patent Pool

1. Public health driven
2. Focus on antiretrovirals
3. Voluntary
4. Developing country focus (low & middle income)
5. Price reductions
6. Enable product development
7. Flexible
8. Quality assurance
9. Efforts at standardising licences
10. Non discriminatory licences
11. Additional / complementary to existing mechanisms
12. Operate within current intellectual property framework
13. Independent entity

Selecting the Target Products

- Initial prioritization undertaken in 2009 by UNITAID and WHO identified target products
- 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
Identifying the Relevant Patents

- **Identification of 69 patents** relating to 23 antiretrovirals (current and pipeline)

- 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** since **yesterday** covering **67 countries!!!**

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**Snapshot of the Pool's Patent Status Database for ARVs**

![Table of Patent Status Database](image_url)
### Obtaining Licenses over Targeted Products

- **First License granted by NIH on Sept 30, 2010**
  - **Overview of Licence**: A patent family relating to the use of a class of protease inhibitors, including darunavir
  - **Licence Conditions**:
    - Licence text is publicly available
    - Licence to benefit all low- and middle-income countries
    - Royalty-free
  - **Additional Information**:
    - Licence is *not* enough to clear legal path to generic production
    - NIH and the Pool discussing additional licenses

### Ongoing Negotiations

- **Formal negotiations** currently ongoing with:
  - Gilead Sciences
  - Viiv Healthcare (GSK + Pfizer)
  - Roche

- **Commitment to negotiate**:
  - NIH (additional patents)
  - Sequoia Pharmaceuticals

- In discussions with additional patent holders of HIV Medicines, including:
  - Johnson and Johnson, Merck, Abbott, Bristol Myers Squibb, Boehringer Ingelheim...
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)

“Médecins Sans Frontières is pleased to see that theWHO/UN Prequalification Programme has taken a significant step forward in its efforts to accelerate access to the latest combination antiretroviral drug therapies. This support for the Medicines Patent Pool is a welcome and important initiative towards achieving universal access to the newer HIV medicines.”

Dr. Francois Chalié, Executive Director
Médecins Sans Frontières

“…..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.

“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)

Thank You!

For more information visit us:

www.medicinespatentpool.org