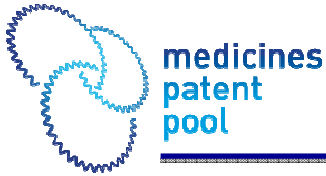


## The Medicines Patent Pool

# Understanding the Patent Status of Antiretroviral Drugs

Ellen 't Hoen  
Medicines Patent Pool

WHO-WIPO-WTO Symposium  
February 18, 2011



# The International Context

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## WTO Doha Declaration (2001):

*“We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics*

*(...) We also recognize the concerns about its [intellectual property protection] effects on prices.*

*(...) the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.*

## WIPO Development Agenda (2007):

*19. To initiate discussions on how, within WIPO's mandate, to further facilitate access to knowledge and technology for developing countries and LDCs to foster creativity and innovation*

*25. To explore intellectual property -related policies and initiatives necessary to promote the transfer and dissemination of technology, to the benefit of developing countries...*

*36. To exchange experiences on open collaborative projects such as the Human Genome Project as well as on intellectual property models.*

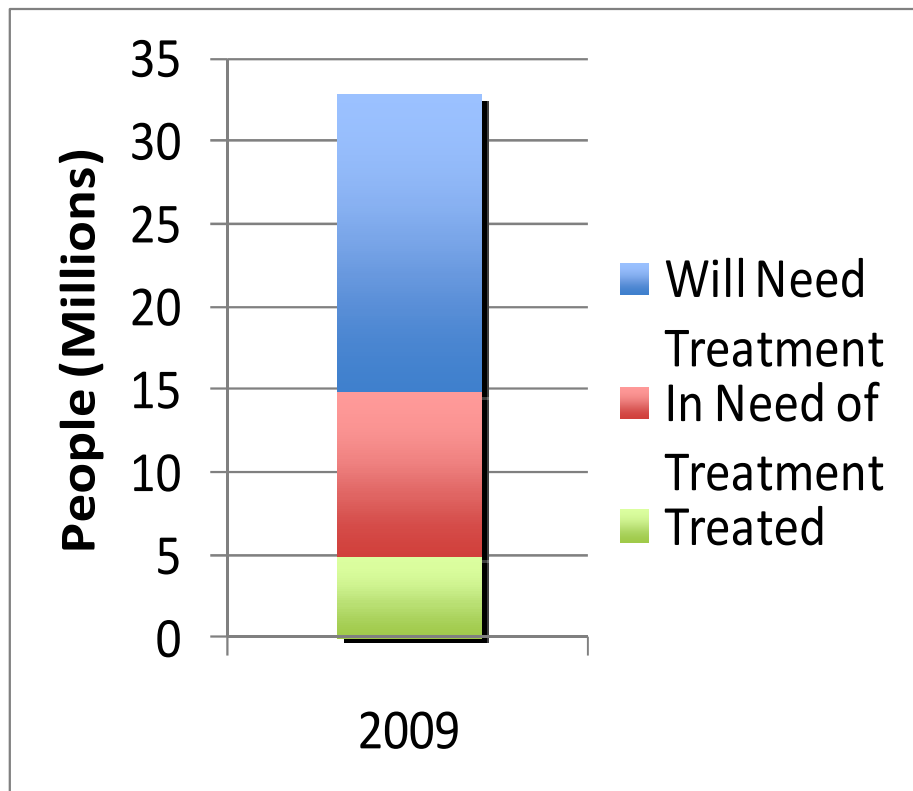
## WHO Global Strategy and Plan of Action on PH, Innovation and IP (2008):

*“The actions to be taken in relation to this element [Technology Transfer] are as follows:*

*(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies:*

*(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices*

# 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.)

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### Before

- HIV Medicines not patentable in many developing countries
- Generic competition led to 99% fall in price of first line drugs
- People treated in DCs: from under 300,000 to 5 Million in less than a decade

### Now

- Widespread patenting of newer HIV medicines in Developing Countries
- Limited generic availability 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 1<sup>st</sup> line drugs -> need access to 2<sup>nd</sup> line

# The Medicines Patent Pool

## Three Main Objectives

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- 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



# 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

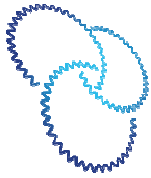


## 2010

Establishment of the Medicines Patent Pool

Formal licensing negotiations begin

NIH grants first licence to the Pool



medicines  
patent  
pool

# 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 UNITAID"*

**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**



*"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.**



*"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."*

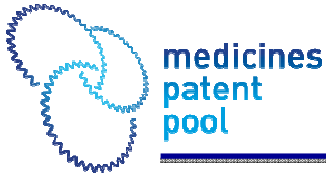
**The World Health Organization (October 2010)**



*"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)**





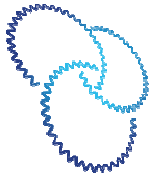
# Patent Pool Partnerships

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- 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.)



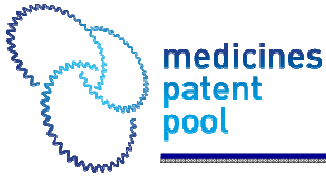




medicines  
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# The Medicines Patent Pool And Patent Information



# Patent Information Needs of the Pool

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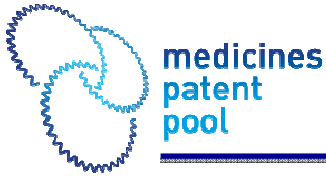
- Which patents are relevant for the Pool to achieve its objectives?
- **More specifically:**
  - What are the main patent families covering the targeted products?
  - Who holds such patents?
  - What aspects of those products are covered by those patents?
  - In which countries were such patents filed/granted?
  - What is the current legal status of those patents?
    - Is the patent still valid? Have maintenance fees been paid? Is it the subject of pre- or post- grant opposition? Has it been abandoned/withdrawn?

# Challenges

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## *What are the main challenges in obtaining patent information?*

- **Complexity:** Difficult to identify which patents are relevant to a given product
  - FDA Orange Book a good starting point, but not comprehensive and does not cover pipeline products
- **Accessibility:** Many national/regional patent collections can only be consulted on-site
- **Timeliness:** Information often not updated with the necessary frequency
- **Comprehensiveness:** Legal status information particularly difficult to retrieve
- **Logistics:** Language barriers, high costs

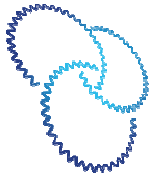


# Legal Status Project

## Pool/WIPO Collaboration

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- Identification of **69 patents** relating to the 19 targeted products
- 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:
  - Information provided to WIPO by national/regional patent offices
  - Validated data from 11 countries plus ARIPO (covering 17 countries)
  - Ongoing attempts to obtain validated data from other countries
- Wherever discrepancies between sources, **reliance on information provided by national patent offices** as primary source.



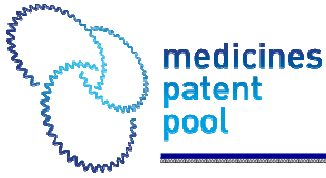
# Access to Information

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- ARV patent status information available on the Pool website in **March** and to be updated as new information becomes available
- **Significant source of publicly available patent information on antiretrovirals in DCs in one central location**
- **Important Caveats:**
  - Still many empty slots in table – invite corrections/additional info
  - Table is illustrative, not exhaustive (e.g. there may be other important patents not covered)
  - Information becomes rapidly outdated
  - To be used with caution

# Illustration of Results

INN	Patent holder	Int. patent application or patent of reference	Priority Nb	Expected date of expiration (20 years from filing date)	ARIPO (as of June 2010)	COLOMBIA (as of Jan. 2010)	INDIA (as of Jan. 2011)	SOUTH AFRICA (as of Dec. 2010)
<b>Abacavir sulfate (ABC)</b>  new intermediates  hemisulfate salt  composition for ped.use	Wellcome (GSK)	WO9100282 EP0434450	US 1989 371789 US1989 0455201	June/Dec. 2010	Expired	No	No	Filed
		WO9521161	GB 1994 9402161.5	2015	No	No	NA	Granted
		WO9852949	GB 1997 9709945.1	2018	Granted	Rejected	Withdrawn after opposition	Granted
		WO9939691	GB 1998 9802472.2	2019	Granted	Granted	Granted	Granted
<b>Cobicistat (GS-9350)</b>	Gilead	WO2008010921	US 2006 60/819,315 US 2006 60/832,371 US 2007 60/903,228	2027	Filed	No	Filed	Designated in int. applic.
		WO2008103949	US 2007 60/903,228 US 2007 60/958,716	2028	Filed	No	Filed	Designated in int. applic.
		WO2009008989	US 2007 60/958,716	2028	No	No	Filed	Designated in int. applic.
<b>Rilpivirine (TMC 278)</b>	Tibotec	WO03016306	EP 2001 01203090.4 EP 2002 02077748.8	2022	Granted	No	Granted	Granted
<b>Raltegravir (RAL)</b>  Potassium salt	Institute for Research in Mol. Biology, Italy, MSD	WO03035077	US 2001 60/339,568 US 2002 60/362,191 US 2004 60/633,132	2022	No	Granted	Granted	Granted
		WO2006060712 WO2006060730	US 2004 60/633,132	2025	No	Filed	Filed	Granted



# Patent Landscapes

Pool/WIPO collaboration

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- Under **Development Agenda Project**, WIPO committed to undertake 12 patent landscape reports
- Treatment of HIV/AIDS selected as a theme of interest
- Consultation with **UNITAID / Medicines Patent Pool**
- Decision to undertake patent landscapes on two antiretrovirals of key interest:
  - atazanavir (recommended by WHO for 2<sup>nd</sup> line treatment)
  - ritonavir (only available pharmacokinetic enhancer required for boosting protease inhibitors)

# Objectives

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## Main objectives:

- Identify all patent families that claim inventions involving Ritonavir
- Provide a detailed analysis of the patent families
- Identify and analyze innovation tracks relating to Ritonavir

## The Landscapes should also provide:

- An instructive example of how pharmaceutical compounds can be researched in patent databases
- A comprehensive explanation of the applied search strategy and well documented and repeatable search queries

Under development – first draft expected for April 2011



# The Way Forward

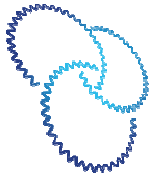
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- Patent status searches and landscapes very useful but provide **snapshot**
- Information becomes rapidly **outdated**
- Important that the necessary patent information becomes:
  - More easily **accessible**, including legal status
  - From **as many countries as possible** (role of National IP offices)
  - Systematically **updated**
  - In a way that is usable by those taking decisions relating to public health
- **Disclosure function of patents** critical and often overlooked
- Discussions ongoing with WIPO, EPO and others to find ways to do this
- EPO's classification system for climate change technologies, if adapted to pharmaceutical field, could facilitate search and retrieval of patents

# Conclusion

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- Medicines patent status information should be publicly available and accessible
- Medicines Patent Pool committed to sharing Patent Status information
- Technical barriers can be overcome
- Requires:
  - **Commitment** from all parties (at national, regional and international levels)
  - Relevant **technical expertise**
  - **Leadership** (key role for IGOs)



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Thank You!

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**[www.medicinespatentpool.org](http://www.medicinespatentpool.org)**