



medicines
patent
pool

The Medicines Patent Pool:

Promoting innovation and access through
public health-oriented licences

Chan Park
27 June 2012

WHY DO WE NEED A PATENT POOL FOR HIV MEDICINES?

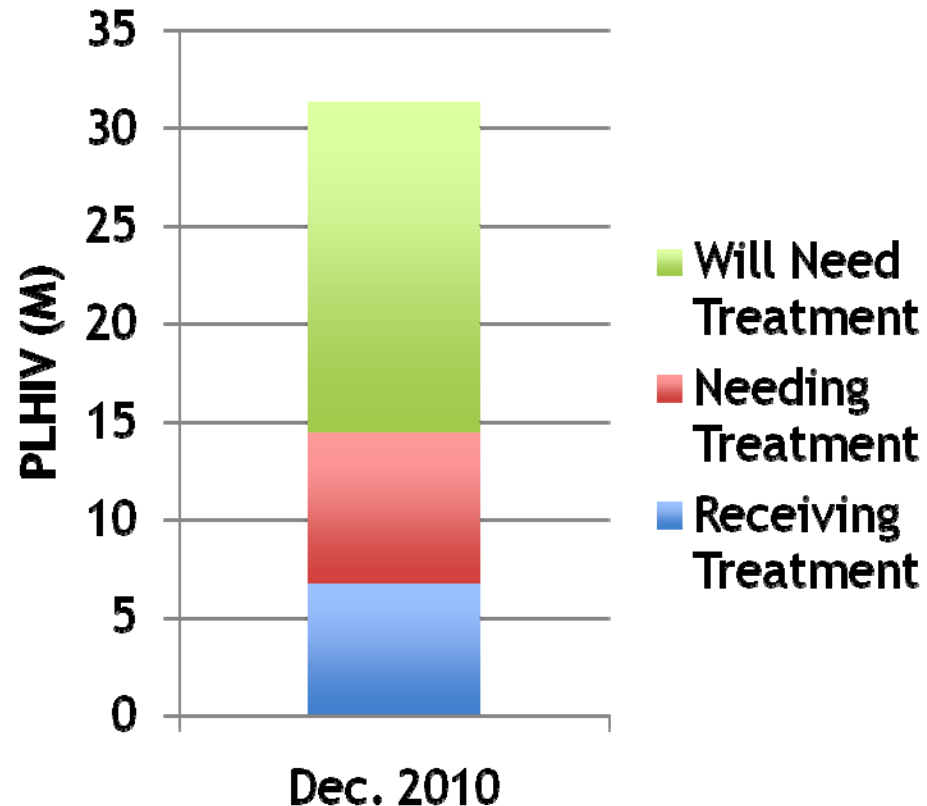


The Context

- Significant HIV treatment needs in developing countries
- International commitment to treat 15 million people by 2015
- Generic competition central to treatment scale-up of past decade
- Patenting of HIV medicines in developing countries
- Important formulations needed in developing countries often not developed or barriers to access



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



- 6.65 million people in developing countries on ART by end of 2010
- But further 7.75 million people are in urgent need of treatment as per WHO guidelines
- Approximately 17 million more people are also HIV positive in developing countries and will need treatment
- 1.45 million new people on treatment in 2010
- New evidence shows huge benefits of early start for treatment

The Context

- Significant HIV treatment needs in developing countries
- International commitment to treat 15 million people by 2015
- Generic competition central to treatment scale-up of past decade
- Newer HIV medicines widely patented in developing countries
- Important formulations needed in developing countries often not developed or barriers to access

UN Political Declaration (2011)



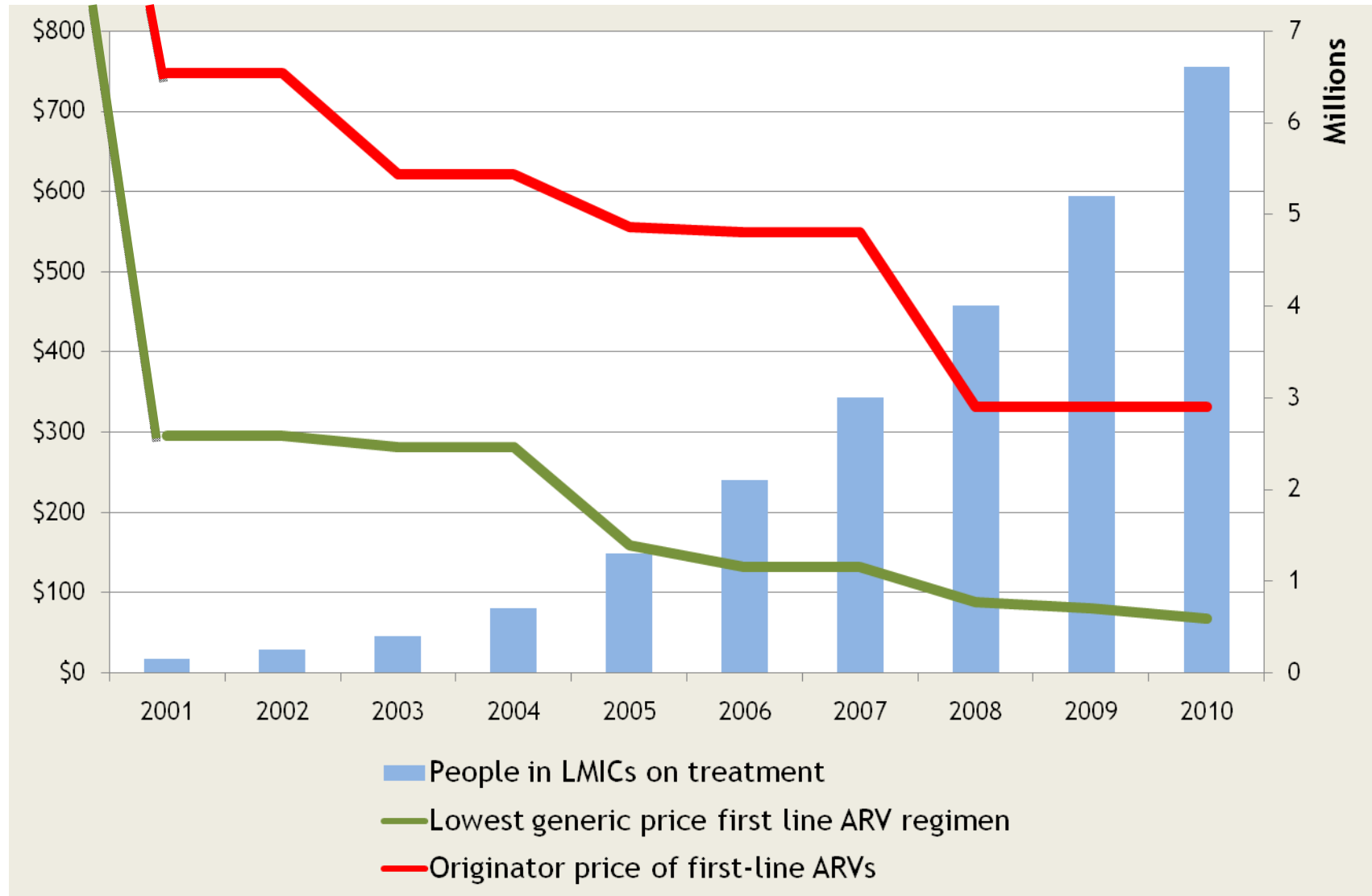
“Commit to accelerate efforts to achieve the goal of universal access to antiretroviral treatment for those eligible based on World Health Organization HIV treatment guidelines... with the target of working towards having 15 million people living with HIV on antiretroviral treatment by 2015”

The Context

- Significant HIV treatment needs in developing countries
- International Commitment to treat 15 million people by 2015
- Generic competition central to treatment scale-up of past decade
- Newer HIV medicines widely patented in developing countries
- Important formulations needed in developing countries often not developed or barriers to access

Generic Competition & Treatment Scale-Up

\$2700 \$10,400



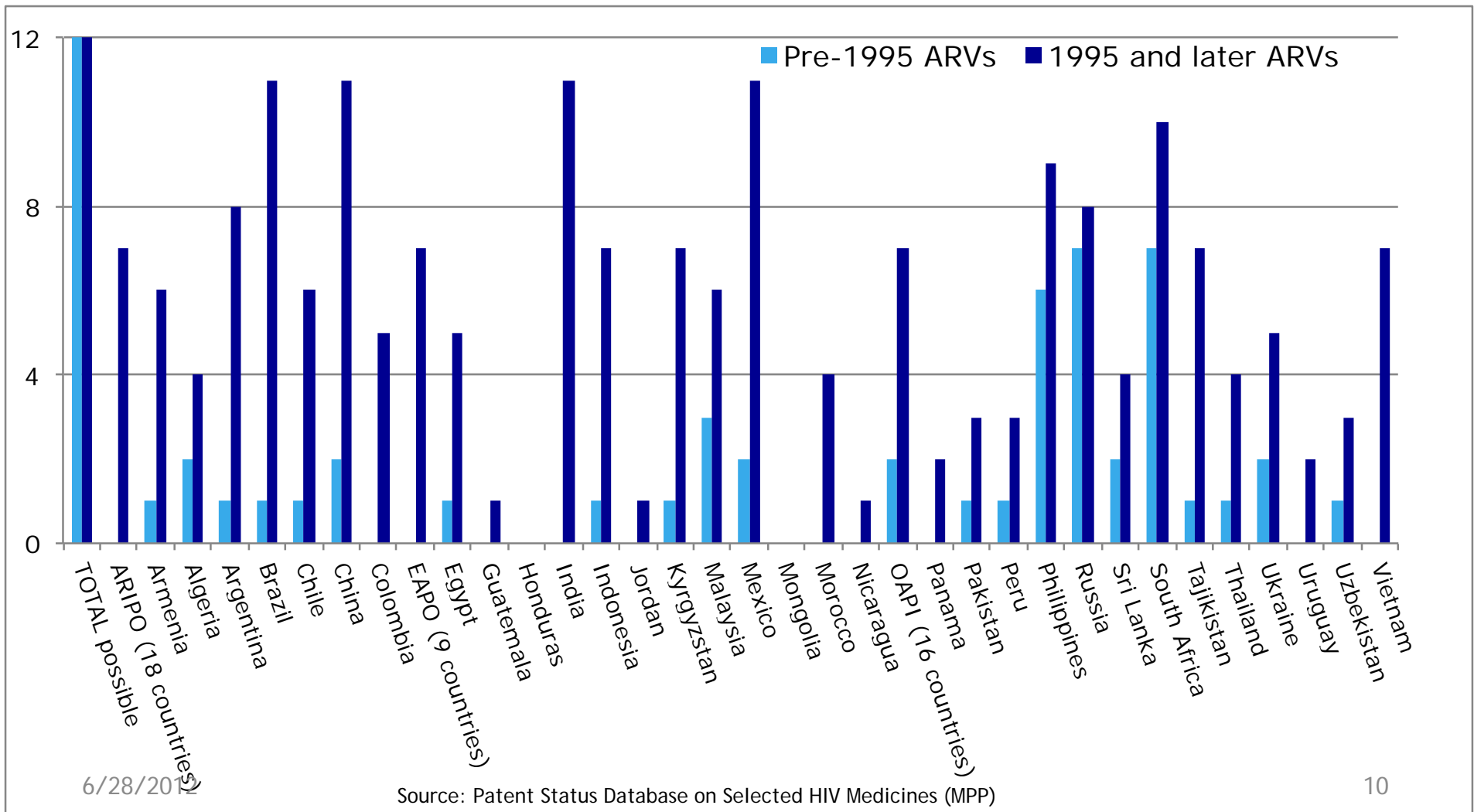
The Context

- Significant HIV treatment needs in developing countries
- International Commitment to treat 15 million people by 2015
- Generic competition central to treatment scale-up of past decade
- Newer HIV medicines widely patented in developing countries
- Important formulations needed in developing countries often not developed or barriers to access

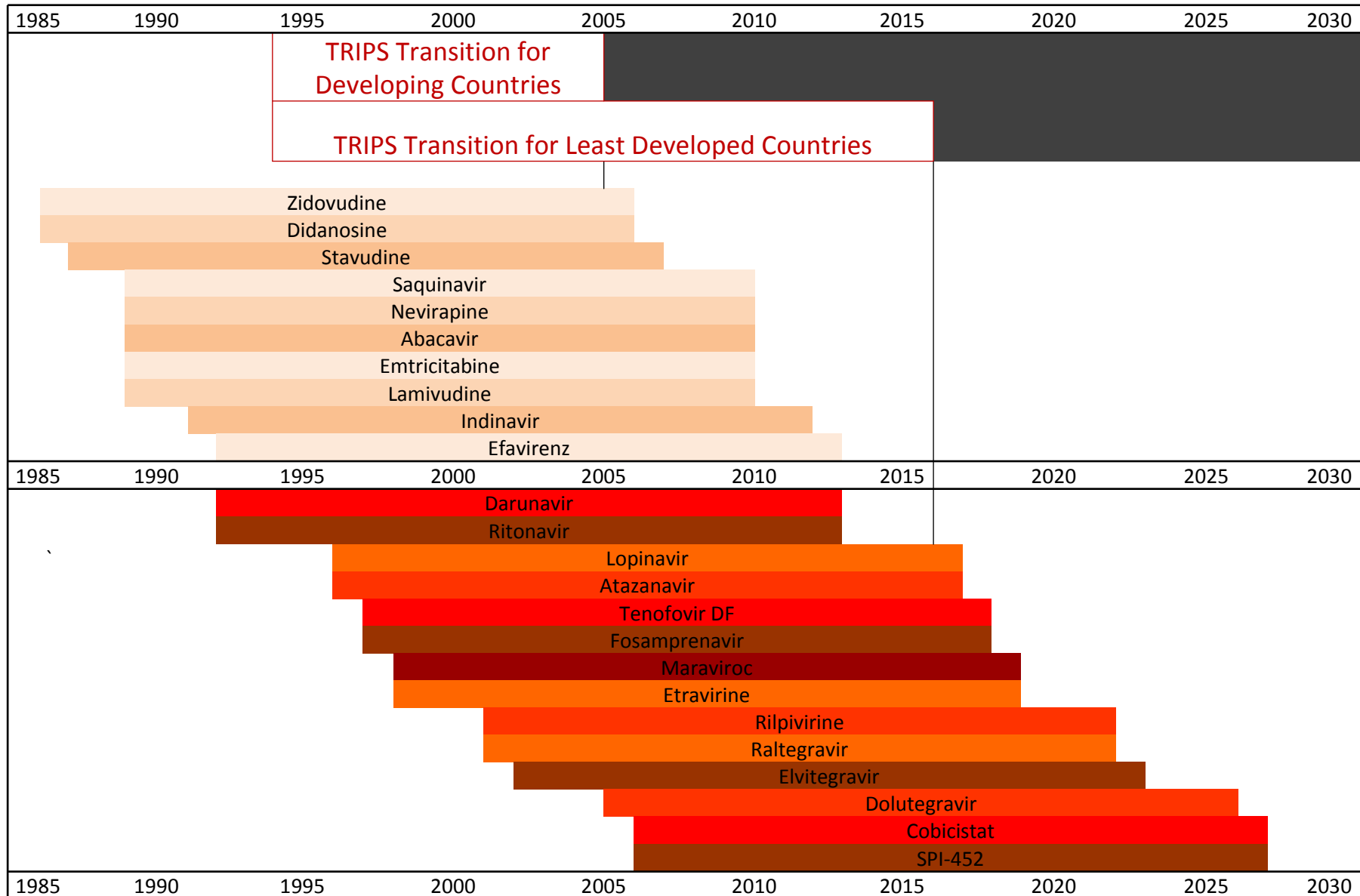


New HIV medicines are more widely patented in developing countries...

Total number of product patents pending or granted, by jurisdiction, for older compounds (pre-1995) and newer compounds (post-1995)*



...and have many years left before expiry



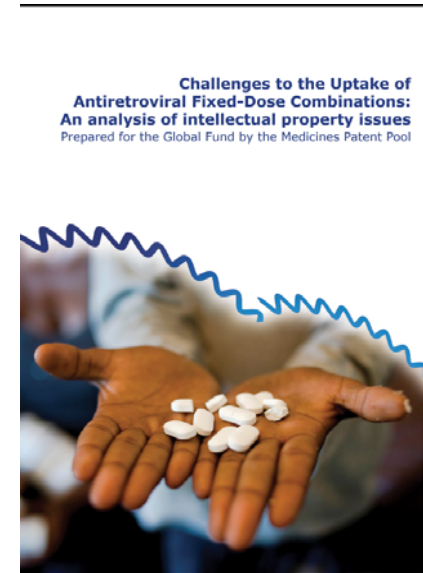


The Context

- Significant HIV treatment needs in developing countries
- International Commitment to treat 15 million people by 2015
- Generic competition central to treatment scale-up of past decade
- Newer HIV medicines widely patented in developing countries
- Important formulations needed in developing countries often not developed or barriers to access

Fixed Dose Combinations (or “three-in-one pills”)

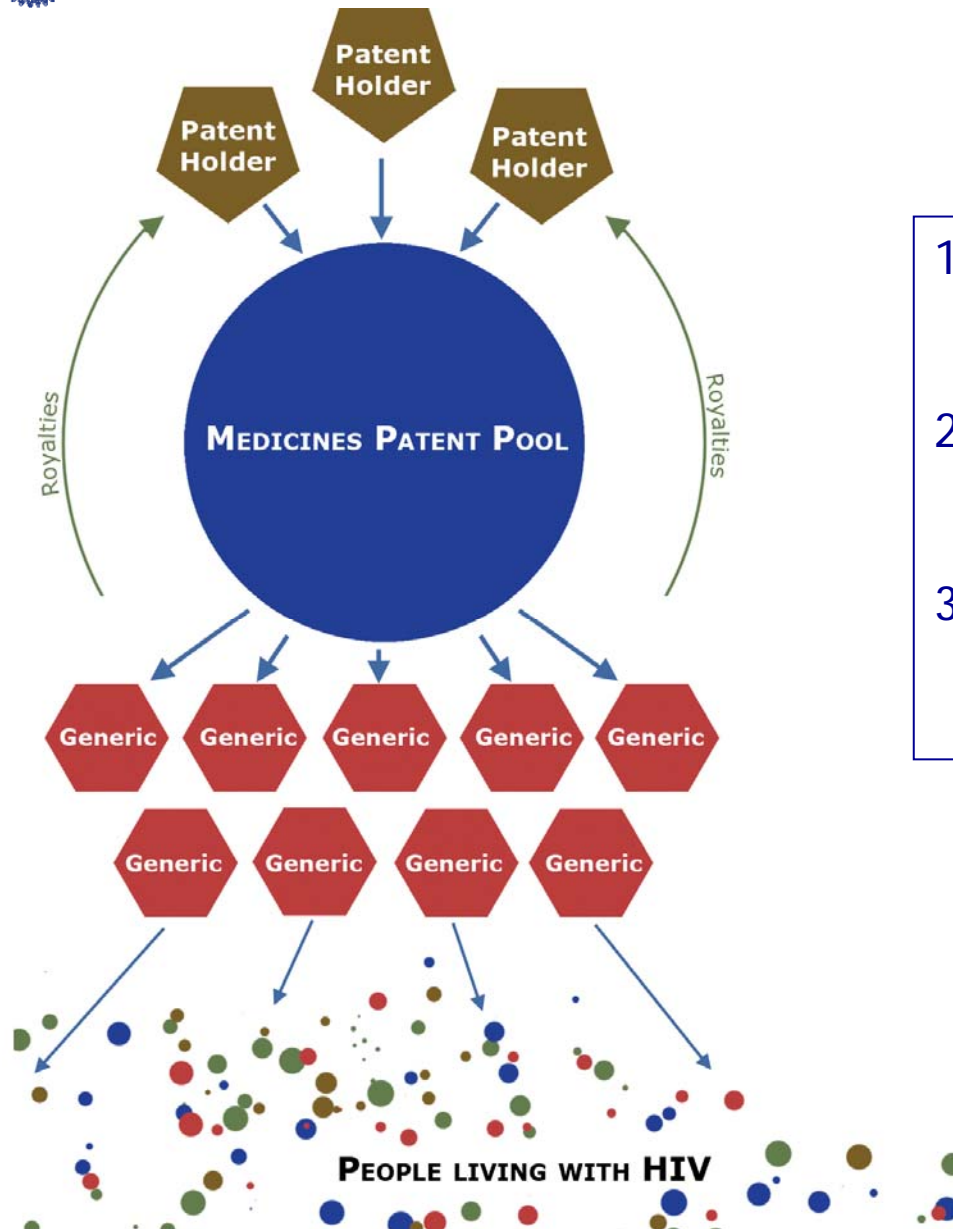
- Analysis of patent-related challenges to the uptake of Fixed Dose Combinations (FDCs) undertaken for the Global Fund Market Dynamics and Commodities ad hoc Committee
- Out of **10 recommended FDCs** with at least one supplier, potential **IP barriers to generic competition for 7** in at least one developing country (greater barriers for 3 FDCs)
- **All 6 FDCs** known to be either in development, or having very recently obtained regulatory approval, **appear to face patent barriers** to generic competition in some developing country jurisdictions



THE MEDICINES PATENT POOL



The Medicines Patent Pool: an Innovative Licensing Mechanism for HIV



1. Enable generics versions of existing compounds
2. Promote Fixed-Dose Combinations
3. Facilitate development of adapted formulations (e.g. paediatrics)

Established in July 2010 with the support of 

How We Work



Based on analysis of medical needs, potential patent barriers

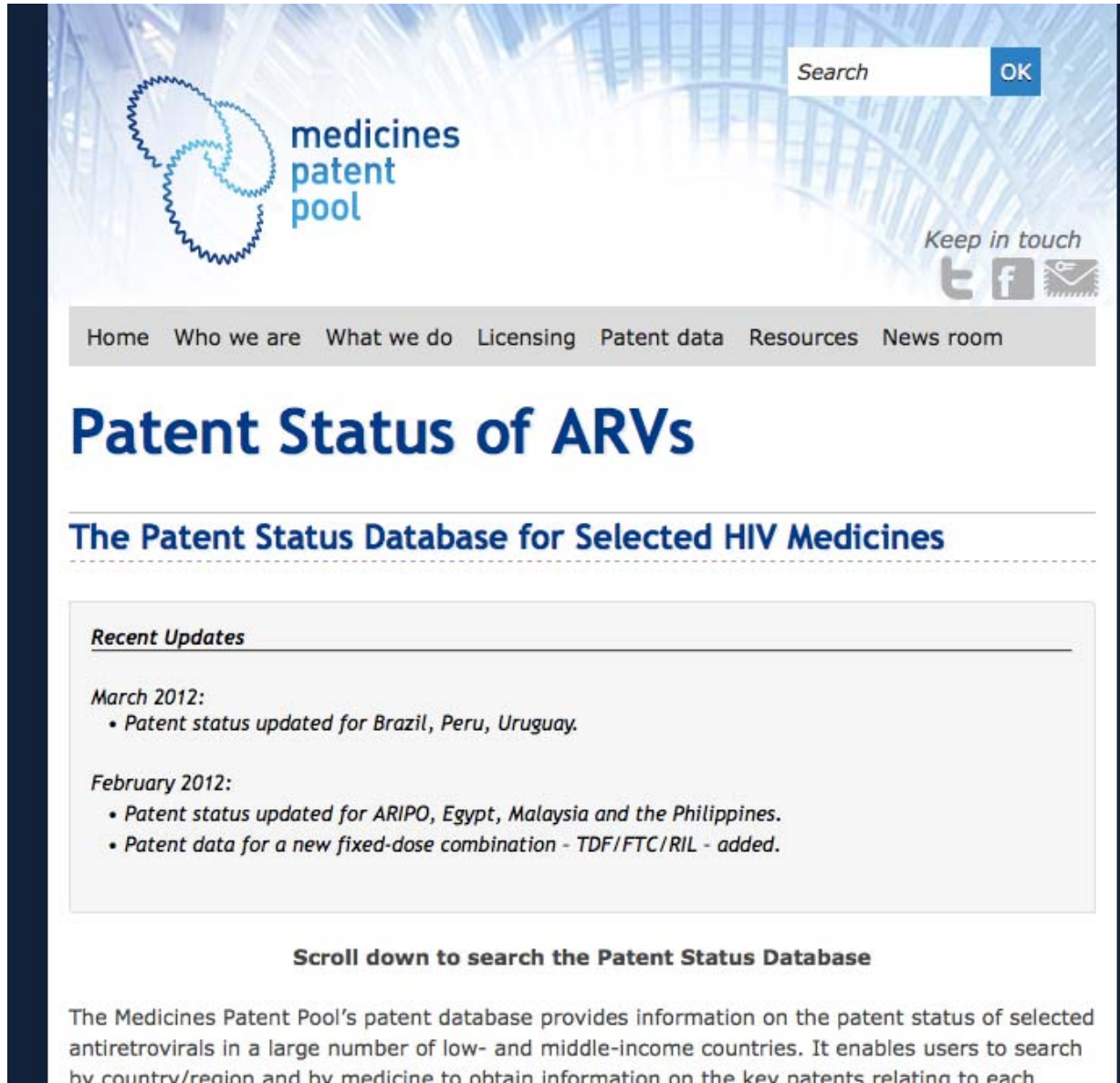
To negotiate licences allowing others to make and sell generic versions of patented medicines in developing countries, or develop adapted formulations

The Pool seeks licences that push the status quo forward, with the aim of ensuring access to medicines for all people living with HIV in developing countries

Licences go to the Pool

And others, such as product development partnerships (PDPs), who are then free to develop, produce and sell medicines in agreed countries under strict quality assurance. Pool staff work with sub-licensees on product development and regulatory approval.

Identification of Patent Status of HIV Medicines



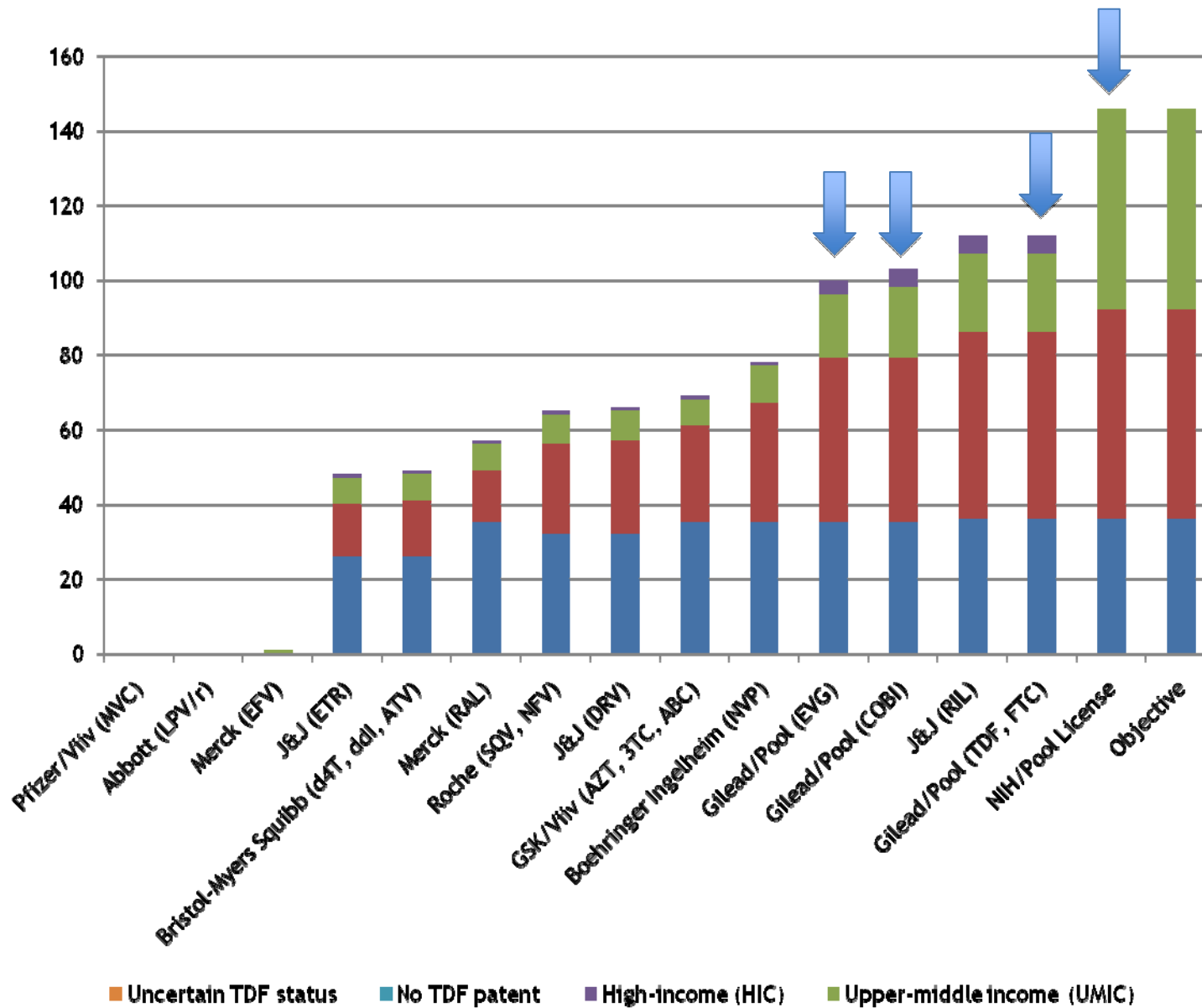
The screenshot shows the Medicines Patent Pool website. At the top left is the logo. To the right is a search bar with a 'Search' button and an 'OK' button. Below the search bar are social media icons for Twitter, Facebook, and Email, with the text 'Keep in touch'. A navigation menu includes: Home, Who we are, What we do, Licensing, Patent data, Resources, News room. The main heading is 'Patent Status of ARVs'. Below this is a sub-heading: 'The Patent Status Database for Selected HIV Medicines'. A section titled 'Recent Updates' lists:

- March 2012:
 - Patent status updated for Brazil, Peru, Uruguay.
- February 2012:
 - Patent status updated for ARIPO, Egypt, Malaysia and the Philippines.
 - Patent data for a new fixed-dose combination - TDF/FTC/RIL - added.

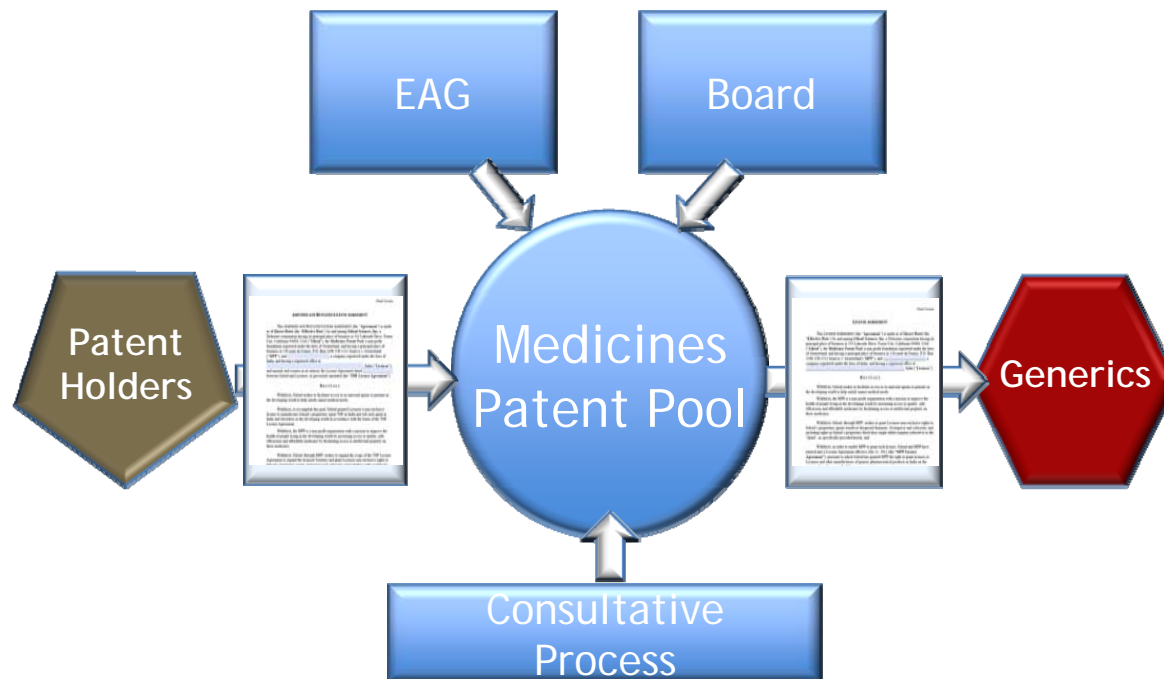
Below the updates is a button that says 'Scroll down to search the Patent Status Database'. At the bottom, a paragraph reads: 'The Medicines Patent Pool's patent database provides information on the patent status of selected antiretrovirals in a large number of low- and middle-income countries. It enables users to search by country/region and by medicine to obtain information on the key patents relating to each'.

- Patent status data collected for 24 HIV compounds in 76 low and middle income countries with support of WIPO and national patent offices
- Provided for the first time a clear understanding of what is patented where
- Included in a searchable database on our website
- Today: most complete single source of patent status data on HIV medicines. Widely used by public health actors.

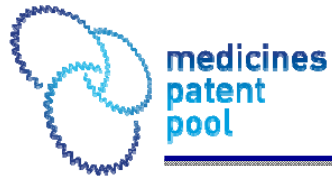
Geographical Scope of Voluntary Licences



Core Principles for Pool Licences



- Licenses are negotiated from a **public health**, pro-access perspective
- Licences are **transparent** - text of licences available on Pool website
- Significant improvement on the pre-existing situation for as many people living with HIV as possible
- Aim to include all **low and middle income countries**, including through the use of differentiated royalties according to income and disease burden
- Ensure that terms and conditions are consistent with the use of **TRIPs flexibilities/Doha Declaration TRIPs and Public Health**
- **Raise the bar** for licensing in the HIV field
- Manage licences with a **public health focus**
- Work with partners to **promote the development** of needed formulations



Supporting Statements



"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, Executive Director, UNAIDS, July 2010



"Encouraging the voluntary use, where appropriate, of new mechanisms such as partnerships, tiered pricing, open-source sharing of patents and patent pools benefiting all developing countries, including through entities such as the Medicines Patent Pool, to help reduce treatment costs and encourage development of new HIV treatment formulations, including HIV medicines and point-of-care diagnostics, in particular for children."

-UN General Assembly Political Declaration on HIV/AIDS



"We welcome the Patent Pool Initiative launched by UNITAID...and we invite the voluntary participation of patent owners, private and public, in the project." - G8 Summit, Deauville, France, May 2011



"Encourage the use of new mechanisms such as the UNITAID Medicines Patent Pool to help reduce treatment costs and promote the development of new treatment formulations, including paediatric formulations and fixed-dose combinations." - Sao Paulo Parliamentary Declaration on Access to Medicines and Other Pharmaceutical Products, Global Fund Partnership Forum, June 2011



I commend UNITAID for taking the initiative to establish the Medicines Patent Pool and commend the companies that are in negotiations with the Patent Pool -Margaret Chan, Director General of WHO, July 2011

THANK YOU

www.medicinespatentpool.org