

# **Global Challenges Seminar on Patents and the WHO Model List of Essential Medicines**

**April 2016**

**Dr. Peter Beyer  
Dr. Nicola Magrini**



**World Health  
Organization**

# Hepatitis C - Patent Landscapes

Sofosbuvir	Harvoni	Gilead Sciences
Ledipasvir		Gilead Sciences
Daclatasvir		BMS
Dasabuvir	Viekira Pak with ritonavir	AbbVie
Ombitasvir		AbbVie
Paritaprevir		AbbVie
Simeprevir		Janssen

WHO is currently updating these patent reports

Link to reports: [www.who.int/phi/implementation/ip\\_trade/ip\\_patent\\_landscapes/en/](http://www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/)

# The role of intellectual property in local production in developing countries (2016)

## New WHO study that includes patent landscapes of

- **Atazanavir** (antiretroviral drug)
- **Raltegravir** (antiretroviral drug)
- **Imatinib** (cancer drug)
- **Sitagliptin** (antidiabetic drug)
- **Pegylated interferon alfa-2a** (antiviral drug )
- **Gardasil human papillomavirus** (vaccine)



[www.who.int/phi/publications/int\\_prop\\_local\\_prod\\_opportunities\\_challenges/en/](http://www.who.int/phi/publications/int_prop_local_prod_opportunities_challenges/en/)

# UN High-Level Panel on Access to Medicines

WHO submission includes some proposals, including

- calling for transparency of the patent status of all essential medicines worldwide, as this information is not presently easy to obtain. This would allow countries to assess whether they can procure generic copies, or produce them locally
- calling for further expansion of the mandate of the Medicines Patent Pool to all disease areas, and for all patented essential medicines on the WHO Essential Medicines List to be licensed into the Pool



Link to WHO submission: [www.unsgaccessmeds.org/intergovernmental/](http://www.unsgaccessmeds.org/intergovernmental/)

# EML 2015:

## 77 applications and a few big challenges

- New highly effective HCV drugs (new direct antiviral, single agents and combinations, IFN free regimens)
- MDR-TB drugs (4) and 1 for TB prophylaxis
- Cancer drugs: a large comprehensive review was commissioned (29 applications) for 22 new medicines
- New oral anticoagulants (NOACs), polypill, ranibizumab

### Perspectives

#### Tough decisions on essential medicines in 2015

Nicola Magrini,<sup>a</sup> Jane Robertson,<sup>a</sup> Gilles Forte,<sup>a</sup> Bernadette Cappello,<sup>a</sup> Lorenzo P Moja,<sup>a</sup> Kees de Joncheere<sup>a</sup> & Marie-Paule Kieny<sup>a</sup>

# EML 2015: innovative/patented medicines

- New highly effective HCV drugs: a very inclusive approach – all 6 new DAA included to
  - promote competition among available alternatives and
  - allow for the selection of optimal combination treatment regimens, which may or may not be existing fixed-dose combinations
- MDR-TB drugs (4) and one for TB prophylaxis: all included
- Cancer drugs: a very selective approach: “only” 16 new drugs included” out of more than 50 available/approved
- **Rejections:** New oral anticoagulants, polypill, ranibizumab



# EML: next update in 2017

- Expected applications for the inclusion of
  - cancer treatments
  - more of the new hepatitis C treatments
  - antibiotics
  - ... some pending issues
- Application period: currently open for a whole year
- Everybody can submit applications



# Promoting Access to Medical Technologies and Innovation



[www.who.int/phi/promoting\\_access\\_medical\\_innovation/en/](http://www.who.int/phi/promoting_access_medical_innovation/en/)

[www.who.int/phi/publications/category/en/](http://www.who.int/phi/publications/category/en/)

**Dr Peter Beyer**  
**Senior Advisor**  
**World Health Organization**

**[beyerp@who.int](mailto:beyerp@who.int)**

**Tel. +41-22-791 25 07**