## Hepatitis C - Patent Landscapes

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand Name</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir</td>
<td>Harvoni</td>
<td>Gilead Sciences</td>
</tr>
<tr>
<td>Ledipasvir</td>
<td></td>
<td>Gilead Sciences</td>
</tr>
<tr>
<td>Daclatasvir</td>
<td></td>
<td>BMS</td>
</tr>
<tr>
<td>Dasabuvir</td>
<td>Viekira Pak with ritonavir</td>
<td>AbbVie</td>
</tr>
<tr>
<td>Ombitasvir</td>
<td></td>
<td>AbbVie</td>
</tr>
<tr>
<td>Paritaprevir</td>
<td></td>
<td>AbbVie</td>
</tr>
<tr>
<td>Simeprevir</td>
<td></td>
<td>Janssen</td>
</tr>
</tbody>
</table>

**WHO is currently updating these patent reports**

**Link to reports:** [www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/](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/
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/
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

Tough decisions on essential medicines in 2015
Nicola Magrini, Jane Robertson, Gilles Forte, Bernadette Cappello, Lorenzo P Moja, Kees de Joncheere & Marie-Paule Kienny

In 1977, the World Health Organization (WHO) published its first Model List of Essential Medicines. This year, the issues of budget impact or affordability of a medicine. Experience suggests that in the absence of competition, options for medicines for cancer, given the small gains in life expectancy offered by some new and expensive treatments.
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/

www.who.int/phi/publications/category/en/

Dr Peter Beyer  
Senior Advisor  
World Health Organization  
beyp@who.int  
Tel. +41-22-791 25 07