Introduction to the world of patents
(and a few other things)

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WHO 2e Fair Pricing Forum, Johannesburg,
South Africa, 11-13 April 2019
Function of patents

... to encourage inventors to make an investment in time and money in research and development by providing exclusive rights for a limited time in exchange for an early public disclosure of the invention.

Patent system is a social policy tool meant to create benefits for society.
But it comes at a cost.
### Cost of production and price
**New WHO Essential Medicines**

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Originator price intro US</th>
<th>Cost of production¹</th>
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<tbody>
<tr>
<td>bedaquiline</td>
<td>$30,000 (6 month)</td>
<td>$48 -101</td>
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<tr>
<td>sofosbuvir (SOF)</td>
<td>$84,000 (12 week)</td>
<td>$68 -136</td>
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<tr>
<td>SOF+ledipasvir</td>
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<td>simeprevir</td>
<td>$66,360 (12 weeks)</td>
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<tr>
<td>daclatasvir</td>
<td>$63,000 (12 weeks)</td>
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<td>imatinib</td>
<td>$30,000 - &gt;$100,000 (1y)</td>
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<td>trastuzumab</td>
<td>$54,000 (1 y)</td>
<td>$242</td>
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</table>

¹. [http://cid.oxfordjournals.org/content/early/2014/02/13/cid.ciu012.full](http://cid.oxfordjournals.org/content/early/2014/02/13/cid.ciu012.full) (cost of production of HCV medicines)

### References
- Hill A. et al., Target prices for mass production of Tyrosine Kinase Inhibitors (TKIs) for global cancer treatment access - Presented at 18th ECCO - 40th ESMO European Cancer Congress, 27th September 2015, Vienna, Austria [abstract number: 1203]

[www.medicineslawandpolicy.org](http://www.medicineslawandpolicy.org)
Global rules on Intellectual Property

- 1995 World Trade Organization Agreement on Trade related aspects of intellectual property rights (TRIPS Agreement)
- Mandates granting min. 20 year patents for WTO Members
- Contains important flexibilities.
Patents on HIV Medicines
2001 WTO Doha Declaration on TRIPS and Public Health

"the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health".

...

“we affirm that the 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.”

TRIPS Flexibilities
(non exhaustive)

• Compulsory licensing/Government Use
• Parallel import
• LDCs transition – delays obligation to grant/enforce medicines product patents and data protection
• Special CL for export (2017 TRIPS amended: 31bis)

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

www.medicineslawandpolicy.org
THE USE OF TRIPS FLEXIBILITIES
TRIPS Flexibilities 2001-2016

- 176 instances (89 countries) 2001-2016
- 100 (56.8%) CL/GU
- 40 (22.7%) LDC non-enforcement of patents
- 1 PI
- 3 research exception
- 32 non-patent related
- 137 (78%) HIV
### TRIPS Flexibilities Database

The TRIPS Flexibilities Database was developed by Medicines Law & Policy. For more information, visit their website [here](http://tripsflexibilities.medicineslawandpolicy.org/).

Type something to search the database...

[Medicines Legend] [FAQ] [Other resources]

**Show or hide column(s)**
- Country
- Date
- WTO Classification
- Type of Flexibility
- Products
- Patent filed/granted
- Originators
- Licensees
- Diseases
- Royalty rate
- Executed
- Reason if not executed

Showing 155 result(s)

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<tr>
<th>Country</th>
<th>Date</th>
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<th>Product</th>
<th>Patent filed/granted</th>
<th>Disease</th>
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<td>Sunitinib, Erlotinib</td>
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<td>Art 31</td>
<td>rusinesen</td>
<td>Yes</td>
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<td>Yes</td>
<td>HIV/AIDS</td>
<td>No</td>
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<td>Ciprofloxacin</td>
<td>Yes</td>
<td>Anthrax</td>
<td>No</td>
<td>Price discount</td>
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<td>May 2018</td>
<td>Art 31</td>
<td>HCV medicines</td>
<td>Yes</td>
<td>HCV</td>
<td>No</td>
<td>Subscription model for lowering price</td>
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• For use in procurement of medicines
• Model licenses
• Non enforcement declaration for LDCs
• Helpful decision making charts to select most appropriate tool
There are several model uses of TRIPS flexibilities available from Medicines Law & Policy, depending on your particular circumstances and needs. To find the right tool for your purposes, follow the flow chart below. The yellow hexagons link to model uses of the appropriate tool on the Medicines Law & Policy site.

Is the product you wish to purchase protected under patent in your country? You can search for the patent status of medicines for HIV, TB and Hepatitis C at MedsPal.org. Your national patent office will have information on all patents.

- **YES**
  - Has the patent holder granted a voluntary licence (VL) on the product, i.e. through the Medicines Patent Pool?
    - **YES**
      - **NO**
    - **NO**
      - **YES**

- **NO**
  - **NO**
    - **YES**
      - **NO**
    - **YES**

You are free to purchase generics from sub-licences.

Click here for a case study on how countries can benefit from a VL whether or not they are in the licence territory.

You are a Least Developed Country (LDC) member of the World Trade Organization?

- **YES**
  - **NO**
  - **NO**
    - **YES**

Your country can issue a compulsory licence for public non-commercial use, or "government use" in order to purchase generics.

Click here for a model public non-commercial use licence that can be adapted to your country's needs.

Your country can use the "LDC Waiver" to not implement patent protection and/or not enforce existing patents.

Click here for a model certificate of use of the LDC Waiver, which can facilitate purchase from generic companies.

Is your country a member of a Regional Economic Community (REC) comprised of more than 50% LDC member states?

- **YES**
  - **NO**

Your country can make use of TRIPS "Article 31bis," which addresses the specific needs of countries that lack manufacturing capacity to make needed medicines.*

Click here for special options available to REC's with a majority of LDC members.

Click here for more information and guides on how to invoke TRIPS Article 31bis.

What if generic products are not readily available?

- **OK, BUT...**

You are free to purchase generic product, including by import from other countries.

Click here for information and guidelines on how to purchase generics.

* Some high income countries have opted out of the use of this provision.

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Least Developed Country?

- Yes
  - LDC pharma waiver
  - Buy generic from quality source

- No
  - Medicine patented?
    - No
      - Buy generic from quality source
    - Yes
      - Patent license agreement and your country is part of the territory?
        - Yes
          - License agreement allows generic supply to a country with TRIPS flexibility?
            - Yes
              - Gov. non-commercial use
              - Are there other sources of generic product?
                - Yes
                  - TRIPS 31bis special CL for export
                - No
                  - Government non-commercial use
            - No
              - Buy generic from licensee

- No
  - No
    - No
      - No
Compulsory Licensing Developments in Europe

- France 2018 - Cancer researchers request GU for cancer drugs
- Germany 2016 - Court ordered in patent dispute re HIV med
- Greece 2016 - High cost of new meds/withdrawal of cancer med
- Ireland 2017 - Resolution by the Irish Medical Association
- Italy ‘05, ‘07 - Competition authority issued CLs
- Romania 2015 - Hepatitis C – request by civil society
- Russia 2018 - Lenalidomide
- Scotland 2018 - Request by cancer patients (Perjeta – pertuzumab)
- Spain 2015 - Hepatitis C patients demand
- The Netherlands 2019 - MoH/EZ established commission on CL
- UK 2019 - requests by cancer patients/CF patients (Orkambi)
- Switzerland 2019 - request by cancer patients (Perjeta - pertuzumab)
TODAY, ARE PATENTS THE LEAST OF OUR WORRIES?
Patent and non-patent exclusive marketing rights

- Patents (minimum 20 years)
- Patent extensions e.g. Supplementary Protection Certificate (EU)
- Orphan medicine market exclusivity (USA 7/EU10-12 yr)
- Pediatric medicine market exclusivity
- Regulatory test data and market exclusivity (EU 8+2+1)
Patent and Regulatory Market Exclusivity

Figure 52: Relation between the different patent/SPC and regulatory protections for pharmaceutical products.

DEVELOPING NEW MEDICINES IS COSTLY
“We cannot achieve any real progress without acknowledging that the current patent-based business model and the way we apply international patent rules need to change. The system is broken.... Patent and intellectual property exclusivities are the only cornerstone of the current model. Companies can ask the price they like. This will no longer do. We need to develop alternative business models. And if public money is used for the development of new medicines, agreement upfront is needed about what this public investment will mean for the final price. We believe that companies must provide full transparency regarding the costs of research and development (R&D). “

NL Ministers E. Schippers (Health) and L. Ploumen (Foreign Trade and Development Cooperation)
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31905-5/fulltext
Conclusion

• High medicines pricing have their roots in the financing model of pharmaceutical R&D.
• Based on granting of market exclusivities without a “sufficiency check”.
• This is not a situation we can “compulsory license” out of.
• Time to review of current pharmaceutical incentives.
• New models of R&D financing are needed that delink price from cost.
• Greater transparency on cost and pricing.
Thank you!

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For background sources please visit:
www.medicineslawandpolicy.org
http://tripsflexibilities.medicineslawandpolicy.org/
REST SLIDES
Transparency in Cost of R&D

R&D cost estimates (mill)
Lancet Commission, UNHLP (and others) recommend “Delinkage”

The concept of delinking costs from prices is based on the premise that costs and risks associated with R&D should be rewarded, and incentives for R&D provided by means other than through the price of the product. If the R&D cost of new medicines did not have to be recouped through high prices, those medicines would be free of market exclusivity and could be made more widely available and more affordably priced through better competition.
Gaming the Orphan Drug Act: CDCA in the Netherlands

- CDCA – Rx for gallstones since 1976
- Off label used for CTX ->€ 308,- pppy
- Leadiant obtained marketing rights and withdrew it
- 2004 obtained orphan drug designation based on presentation of 2 small trials
- Became sole supplier
- Increased price to € 158.000 pppy
- Hospital pharmacists make it in house