PUBLIC HEALTH, INTELLECTUAL PROPERTY, AND TRIPS AT 20:

Innovation and Access to Medicines; Learning from the Past, Illuminating the Future.

WHO-WIPO-WTO Joint Symposium
28 October 2015

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Medicines Law & Policy
20 Years TRIPS and (almost 15 years) Doha Declaration on TRIPS and Public Health

"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, 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.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
Learning from the Past
Use of TRIPS/Doha Flexibilities

Sources:

• Literature (legal, medical)
• Media
• Government publications
• Websites
• Procurement agencies
Use of TRIPS flexibilities

- Between 2001 – 2014

- 34 instances of compulsory licensing by 24 countries

- 48 instances of “government use” of patents by 34 countries

- 32 instances of use of the pharma waiver (par 7 mechanism) by 23 LDCs

  - Peak ‘04-’08
  - Context of procurement
  - Predominantly for HIV medication
  - Provided legal certainty to suppliers
The "almost" compulsory licenses

• 10 of the GU/CL not executed

  • 8 DCs, 2HICs

  • Reasons: no patent, discount, donation, VL for local production.

    • 1 pending (ARV in MIC)
    • 2 rejected
    • 5 concerned non-HIV products
Use of TRIPS flexibilities ‘01 – ’14 widespread

4/5 non HIV
Learning from the past ...

Absence of pharmaceutical product patents in India

Use of Doha
• Compulsory licensing/ Government use
• Paragraph 7 Doha (LDC extension)

... is mostly learning from HIV/AIDS
Illuminating the Future
New Essential Medicines and Patents

• Post TRIPS - medicines are subject to patenting more widely
• For ARVs → Medicines Patent Pool – no such mechanism exists for other medicines
• 2015 WHO EML update contains new, patented and high-priced essential medicines
  • Including biologics
• Huge challenges for access to these essential medicines
# New essential medicines and patents

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Company (originator)</th>
<th>Expiry date primary patent</th>
</tr>
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<tbody>
<tr>
<td><strong>Tuberculosis</strong></td>
<td></td>
<td></td>
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<tr>
<td>bedaquiline</td>
<td>Janssen</td>
<td>2023</td>
</tr>
<tr>
<td>delamanid</td>
<td>Otsuka</td>
<td>2023</td>
</tr>
<tr>
<td>terizidone</td>
<td></td>
<td>2024</td>
</tr>
<tr>
<td><strong>Hepatitis C</strong></td>
<td></td>
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<tr>
<td>sofosbuvir</td>
<td>Gilead</td>
<td>2024 (‘28 prodrug)</td>
</tr>
<tr>
<td>simeprevir</td>
<td>Janssen</td>
<td>2026</td>
</tr>
<tr>
<td>daclatasvir</td>
<td>Bristol-Myers Squibb</td>
<td>2027</td>
</tr>
<tr>
<td>ledipasvir</td>
<td>Gilead</td>
<td>2030</td>
</tr>
<tr>
<td>ombitasvir</td>
<td>Abbvie</td>
<td>2030</td>
</tr>
<tr>
<td><strong>Cancer</strong></td>
<td></td>
<td></td>
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<tr>
<td>bendamustine</td>
<td>Cephalon (US)</td>
<td>2026</td>
</tr>
<tr>
<td>imatinib</td>
<td>Novartis</td>
<td>2014 (2018 second.)</td>
</tr>
<tr>
<td>rituximab</td>
<td>Roche (others)</td>
<td>2008 (‘19-’20 –’30 form.)</td>
</tr>
<tr>
<td>trastuzumab</td>
<td>Roche</td>
<td>2009</td>
</tr>
</tbody>
</table>
# Price / cost of new essential medicines

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Originator price intro US</th>
<th>Cost of production¹</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tuberculosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bedaquiline</td>
<td>$30,000 (6 month)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Hepatitis C</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sofosbuvir (SOF)</td>
<td>$84,000 (12 week)</td>
<td>$68 - 136</td>
</tr>
<tr>
<td>SOF+ledipasvir</td>
<td>$95,000 (12 weeks)</td>
<td>$193</td>
</tr>
<tr>
<td>simeprevir</td>
<td>$66,360 (12 weeks)</td>
<td>$130 - 270</td>
</tr>
<tr>
<td>daclatasvir</td>
<td>$63,000 (12 weeks)</td>
<td>$10 - 30</td>
</tr>
<tr>
<td><strong>Cancer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>imatinib</td>
<td>$30,000 - &gt;$100,000 (1y)</td>
<td>$119 - 159</td>
</tr>
<tr>
<td>rituximab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>trastuzumab</td>
<td>$54,000 (1 year)</td>
<td>$242</td>
</tr>
</tbody>
</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)

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]
Imatinib – for treatment of Leukaemia (CML and ALL)

Annual prices of Imatinib (400mg) in selected countries

Imatinib (Gleevec)
Patent expired (USA)
US price: $106,322/year
Target generic price: $159

Thanks to A.Hill who Presented this at 18th ECCO - 40th ESMO European Cancer Congress, 27th September 2015, Vienna, Austria [abstract number: 1203]
Learning from the ancient past

• WHO Essential Medicines policy firmly rooted in generic policies
• Essential Medicines in some countries had special status with regards to patentability
Action for Essential Medicines: some recommendations

- The WHO designation “Essential Medicine” should have consequences
- Action is required to make new essential medicines affordable and available
- Today: Grant the LDC request for extension of Pharmaceutical waiver
- Licensing of patents in case of patent barriers to affordable pricing

  - Governments can do this through compulsory licensing /government use
  - Collaborative models ➔ Essential Medicines Patent Pool
  - New rules for financing of R&D for missing essential medicines ➔ innovation + access
Thank you!

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