Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

*Topic 8: Compulsory Licenses*
Enhancing Access to Medicines through Licenses

Regional Seminar on Patent-Related Flexibilities

Dr. Peter Beyer
Some underlying health facts

- Between 20% and 60% of the health budget in LIC goes to medicines expenditures.

- In some countries, up to 80 to 90% of medicines are purchased out-of-pocket as opposed to being paid for by health insurance schemes.

- In 2009, in 36 out of 89 countries for which data are available out-of-pocket expenditures for health accounted for more than 50 per cent of total health spending.

- Average availability of selected generic medicines in LMICs:
  - public sector less than 42%
  - private sector almost 72%
What is a license?

Contract between two parties = outcome of a negotiation process

- Patent holder allows the contracting party to use the patent (to exercise the patented invention)
- Against a payment of royalties or free-of-charge
- For a defined period of time
- Worldwide or in specific countries (defined territory)
- Subject to additional conditions
# Recent compulsory licenses & government use

<table>
<thead>
<tr>
<th>Country</th>
<th>Medicine</th>
<th>Indication</th>
<th>Measure</th>
<th>Period</th>
<th>Royalties</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>trastuzumab; ixabelone; dasatinib</td>
<td>Breast cancer; leukemia</td>
<td>CL</td>
<td>2013</td>
<td>To be decided</td>
<td>Decision pending</td>
</tr>
<tr>
<td>Ecuador</td>
<td>abacavir/lamivudine</td>
<td>HIV/AIDS</td>
<td>CL</td>
<td>2012</td>
<td>5%</td>
<td>Local prod.</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Seven products</td>
<td>HIV/AIDS; hepatitis B</td>
<td>Gov use</td>
<td>2012</td>
<td>0.5%</td>
<td>Local prod.</td>
</tr>
<tr>
<td>India</td>
<td>sorafenib</td>
<td>Cancer</td>
<td>CL</td>
<td>2012</td>
<td>6%</td>
<td>Local prod.</td>
</tr>
<tr>
<td>Ecuador</td>
<td>ritonavir</td>
<td>HIV/AIDS</td>
<td>CL</td>
<td>2010</td>
<td>5%</td>
<td>Import; local prod.</td>
</tr>
<tr>
<td>Thailand</td>
<td>erlotinib; letrozole; docetaxel; clopidogrel; Lopinavir/ritonavir</td>
<td>Cancer, heart disease HIV/AIDS</td>
<td>Gov use</td>
<td>2006-2008</td>
<td>3-5%</td>
<td>Import</td>
</tr>
<tr>
<td>Brazil</td>
<td>efavirenz</td>
<td>HIV/AIDS</td>
<td>CL</td>
<td>2007</td>
<td>1.5%</td>
<td>Import &amp; local prod.</td>
</tr>
</tbody>
</table>
Example: India/sorafenib

Anti-cancer medicine: sorafenib (Nexavar - Bayer)

Compulsory license issued on request of local generic company in 2012 for local production.

**Reason:** unaffordable price

- Generic price: USD 175/120 tablets
- Originator price: USD 5500/120 tablets

= 97% reduction
Example: Brazil/efavirenz

HIV/AIDS treatment: efavirenz (Merck Sharp&Dome)

Government issues a CL after protracted negotiations with the patent owner.

Reason: high price
- Generic price: USD 0.43 per dose
- Originator price: USD 1.59 per dose
= 73% reduction

But it took two years to set up local production…
Example: South Africa/stavudine

- University of Yale owns the patent on stavudine
- Bristol-Myers-Squibb holds exclusive license
- Aspen - immunity-from-suit-agreement to produce generics for African countries
Example: oseltamivir

Pandemic pressure leads to licenses:

**Problem:**
- Threat of H5N1 (avian flu) pandemic: patent holder faced explosive demand
- Countries threaten to use compulsory licenses
- Some countries later discover that there is no patent
- One compulsory license issued, but finally not used

**Solution:**
- Patent holder issues a worldwide call to apply for sub-licenses
- Royalty-bearing licenses granted to four generic companies
- Limited to pandemic preparedness (emergency situation) allowing for governmental stockpiling
Objective:

- To ensure that licenses are negotiated in a way that facilitates access to the licensed product in countries in need of affordable prices for patients

Adds **a dimension of social responsibility** to the economic dimension of licensing without necessarily compromising the business (in developed countries)

- When is a license socially responsible?
<table>
<thead>
<tr>
<th>Company</th>
<th>Medicine</th>
<th>Indication</th>
<th>Geographic scope</th>
<th>Number of Licensees</th>
<th>No of countries</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMS</td>
<td>ATV ddi; d4T</td>
<td>HIV/AIDS</td>
<td>SSA, India</td>
<td>7 &gt;3</td>
<td>48 50</td>
<td>immunity-from-suit</td>
</tr>
<tr>
<td>Boehringer</td>
<td>NVP/TPV</td>
<td>HIV/AIDS</td>
<td>All Africa, LDC, LIC;</td>
<td>Several</td>
<td>75</td>
<td>immunity-from-suit agreements</td>
</tr>
<tr>
<td>Gilead / MPP</td>
<td>TDF (FDC) EVG/Quad COBI</td>
<td>HIV/AIDS</td>
<td>unlimited</td>
<td>Country list</td>
<td>112 100 103</td>
<td></td>
</tr>
<tr>
<td>MSD (Merck)</td>
<td>EFV RAL</td>
<td>HIV/AIDS</td>
<td>SA SSA, LIC</td>
<td>6 2</td>
<td>1 60</td>
<td>EFV: No patents in SSA outside SA</td>
</tr>
<tr>
<td>Roche</td>
<td>SQV oseltamivir</td>
<td>HIV/AIDS; influenza</td>
<td>SSA; LDC Africa; China; India</td>
<td>13</td>
<td>65</td>
<td>oseltamivir for pandemic prepared.</td>
</tr>
<tr>
<td>Tibotec (J&amp;J)</td>
<td>DRV ETR RIL</td>
<td>HIV/AIDS</td>
<td>SSA; LDC; India</td>
<td>2 2 5</td>
<td>65 65 112</td>
<td></td>
</tr>
<tr>
<td>ViiV (GSK&amp; Pfizer)</td>
<td>AZT; 3TC; ABC</td>
<td>HIV/AIDS</td>
<td>SSA; LDC; LDC; LIC</td>
<td>11</td>
<td>68</td>
<td></td>
</tr>
</tbody>
</table>
Initiated by UNITAID in 2010 with the objective to

- negotiate license agreements with companies regarding HIV/AIDS products, with the aim of sub-licensing these products to generic companies to increase access to treatment in low- and middle-income countries.

- assemble the necessary intellectual property rights regarding key HIV/AIDS products in order to develop new fixed-dose combination products that unite different products in one pill or formulation

- develop missing paediatric formulations of existing treatments.
## Medicines Patent Pool

<table>
<thead>
<tr>
<th>Achievements</th>
<th>Criticism</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Expansion of territory for licenses</td>
<td>- But still limited territory excluding most middle-income countries</td>
</tr>
<tr>
<td>- License to Gilead’s TDF (tenovofir) combination with other products.</td>
<td>- Relation between royalties and actual patent coverage</td>
</tr>
<tr>
<td>- In collaboration with WIPO establishment of patent database for antiretrovirals</td>
<td>- Transparency of the process</td>
</tr>
<tr>
<td></td>
<td>- Involvement of patient groups</td>
</tr>
</tbody>
</table>
Trends & Challenges: Compulsory license

- established flexibility under TRIPS Agreement
- has been used by a number of countries to lower prices and make medicines more affordable with a recent increase in 2012
- initially focus on HIV/AIDS, now also medicines for non-communicable diseases
Trends & Challenges: Voluntary licenses

- Competition policy, Medicines Patent Pool and industry’s attention to performance ratings on Access to Medicines Index led to expansion: 7 out of 8 originator ARV companies grant licenses.

- More recent agreements cover new and pipeline products, but limited to HIV/AIDS.

- Average territory expanded from SSA, LDCs and LICs to up to 112 countries. (Upper)-middle-income countries still mostly excluded.

- Trend towards lower royalties; except for agreements covering new products and more extensive territory.

- Agreements have to ensure robust competition and include tech transfer where necessary.
Dr Peter Beyer
Senior Advisor, WHO
beyerp@who.int