Current issues in IPRs and Public Health

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Patents vs. Patients?

- Is Intellectual Property a zero-sum game?
  - If not, is it possible to get a fair and mutually beneficial deal?
  - How to correctly distribute benefits and responsibilities amongst the different players in order to make it possible the “enjoyment of the highest attainable standard of health” by everyone?
Is IP a barrier to public health?

- 95% of the Essential Medicines List are off patent worldwide and up to 99% in sub-Saharan Africa.
- The differential pricing scheme allows research-based companies to sell at cost or even at loss most of the patented drugs in the LDCs. For instance, some second-line drugs from originators are actually cheaper than the generic versions.
- When they feel that their technology will be protected, many companies do grant voluntary licensing for the production of some drugs.
- The TRIPS has given the LDCs a large period to enforce the IPRs.

- In case a country has truly public health needs and the manufacturer is unable to supply the drugs, it can use the *ad hoc* TRIPS flexibilities to import or produce locally generic versions patented drugs.

- Is it always economically advantageous to produce locally? Is public health the main concern behind the recent IP & health debate?
Is it really either profit or access?

Even Giving Away All Profits Would Not Change the Picture

USD Billion

If the whole Pharmaceutical Industry were “Not-for-Profit”, global health care costs would decrease by ~3% at best

90

Total annual profits of the worldwide pharmaceutical industry

130

Annual costs of running a health care system for a single mid-sized country (e.g., Canada)

1 500

Annual costs of the US health care system

1 Best Estimate
Source: Gvt websites; estimates
What can IPRs offer?

- Incentive to the R&D of new drugs

- Inspire confidence for Industry to engage in technology transfer initiatives, as well as in partnerships for the R&D of drugs without a viable market.

- Incentives for investments (both foreign and domestic) in more technology intensive industries
## IPR-based R&D System Addressing Global Burden of Disease

<table>
<thead>
<tr>
<th>Disease</th>
<th>Health Burden (% of global deaths/DALYs)</th>
<th>Existing treatments developed by R&amp;D pharmaceutical industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td>4.9/5.7</td>
<td><strong>All</strong> 21 drugs in 4 different classes</td>
</tr>
<tr>
<td>Respiratory Infections</td>
<td>6.9/6.3</td>
<td>All recent and effective antibiotics</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>29.3/9.9</td>
<td>All drugs in 8 different classes</td>
</tr>
<tr>
<td>Cancer</td>
<td>12.5 / 5.1</td>
<td>All most effective drugs in 8 classes</td>
</tr>
<tr>
<td>Depression</td>
<td>0 / 4.5</td>
<td>All recent drugs in 4 different classes</td>
</tr>
</tbody>
</table>
Market-based company and PPPs R&D for developing country health needs

- AIDS: 35 new ARVs, at least 6 additional pediatric formulations for ARVs and 19 vaccines
- Tuberculosis: 17 medicine projects, 2 vaccine projects
- Malaria: 18 medicine projects, 2 vaccine projects
- Other Tropical Diseases: 8 medicine projects, 2 vaccine projects
Some access activities

- Mectizan Donation Program: over 1.8 billion tablets worldwide (with an estimated value of USD 2.7 billion) and more than 530mi cumulative treatment since 1987.

- International Trachoma Initiative: 252 thousand or surgeries performed, 44mi treatments donated. Some countries are moving towards eradication.

- GAELF: 6 billion preventive albendazole treatments donated. WHO estimates that 100 million people have begun to be protected from LF.
Are IPRs enough? Are good drugs enough?

The Cycle of Health and Wealth of a Nation

- Culture
- Natural resources
- Education
- Trade
- Geographic location
- Political system
- Regulations
- Infrastructure
- Drugs/medical products
- Health professionals
- Health
- Hygiene

*IFPMA Brief on WHO IGWG, Sep 2007 © IFPMA 2007*
Shared benefits, shared responsibilities

- All countries benefit from a new drug. It is only fair that they contribute to the financing of this process, according to their resources.

- Developing countries should not be seen as passive recipients of foreign aid, but as key partners, responsible for the health of their people.

- Developed countries should help developing countries to establish performing and sustainable healthcare systems with their expertise and some start-up finance.
**Are we all doing our part?**

**Governments Need to Rise to the Challenge**

<table>
<thead>
<tr>
<th>Development aid as % of GDP 2004</th>
<th>Medicine access programs as % of 2004 sales company A</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.37</td>
<td>2.00</td>
</tr>
<tr>
<td>0.87</td>
<td>UN objectives for developed nations (0.7)</td>
</tr>
</tbody>
</table>

Source: OECD
**Price Components**

Table 14: Example of Price components in the Private sector

<table>
<thead>
<tr>
<th>Example 1: Medicine Name</th>
<th>Medicine Strength</th>
<th>Dosage Form</th>
<th>Target Pack Size</th>
<th>Dispensed Quantity</th>
<th>Type of Charge</th>
<th>Charge Basis</th>
<th>Amount of Charge</th>
<th>Price of Dispensed Quantity</th>
<th>Cumulative % Mark-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-trimoxazole suspension</td>
<td>8×40 mg/ml</td>
<td>millilitre</td>
<td>70</td>
<td>50</td>
<td>Cost, insurance, freight (CIF) price</td>
<td>NA</td>
<td>NA</td>
<td>51.71</td>
<td>0.00%</td>
</tr>
<tr>
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<td></td>
<td>Port charges, clearance, inspection</td>
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<td></td>
<td></td>
<td></td>
<td>Importer’s margin</td>
<td>percent</td>
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<td></td>
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<td>Distributor’s margin</td>
<td>percent</td>
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<td></td>
<td></td>
<td></td>
<td>Retailers’ margin</td>
<td>percent</td>
</tr>
</tbody>
</table>

Ghana

Table 12: Summary of calculated mark-ups for selected medicines

<table>
<thead>
<tr>
<th>Item</th>
<th>Public procurement</th>
<th>Public patient charge</th>
<th>Private patient charge</th>
<th>Mission patient charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciprofloxacin 500mg tab</td>
<td>25.00%</td>
<td>233.33%</td>
<td>387.59%</td>
<td>122.22%</td>
</tr>
<tr>
<td>Nifedipine retard 20mg tab</td>
<td>4.11%</td>
<td>177.78%</td>
<td>216.53%</td>
<td>185.71%</td>
</tr>
<tr>
<td>Cotrimoxazole suspension</td>
<td>53.88%</td>
<td>246.26%</td>
<td>27.35%</td>
<td>66.67%</td>
</tr>
<tr>
<td>Glibenclamide 5mg tablet</td>
<td>16.67%</td>
<td>233.33%</td>
<td>150.00%</td>
<td>106.25%</td>
</tr>
</tbody>
</table>
An “inclusive” debate

- Must ensure that policies for improving “public health” or “development” do not stifle innovation.
- Thus, dialog among IP experts and those creating intellectual property is vital, especially with creators of IP in developing and least-developed countries.
- Look at realities, not ideology.
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