IP and Dengue Vaccines: A case study

Joint Technical Symposium by WHO, WIPO and WTO on Access to Medicines, Patent Information and Freedom to Operate

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The world’s only legally constituted International Research Organization dedicated exclusively to research on new vaccines for the world’s poorest people
- Established by treaty (40 countries and WHO) in 1997 as a result of an international competition overseen by UNDP
- Priority to enteric diseases, respiratory infections, and Flaviviruses (Dengue and Japanese encephalitis)
- Over 120 staff and an annual budget over $20 million
The DVI Program Areas

- Data for Decision Making
- Policy & Access

DVI does not directly support R&D but rather undertakes parallel and supportive programs to development.
# Vaccines in Advanced Development

<table>
<thead>
<tr>
<th>Developer</th>
<th>Approach</th>
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<tbody>
<tr>
<td>sanofi pasteur</td>
<td>Yellow fever – Dengue chimera</td>
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<tr>
<td>GSK</td>
<td>- Cell culture passage</td>
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<td></td>
<td>- Inactivated (with Fiocruz, Brazil)</td>
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<td>Biological E (India)</td>
<td>US NIH, Dengue 4 - dengue chimeras and</td>
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<tr>
<td>Butantan (Brazil)</td>
<td>gene deletion</td>
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<td>Panacea (India)</td>
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<td>Vabiotech (Vietnam)</td>
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<td>Inviragen</td>
<td>Dengue 2- dengue chimeras</td>
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<td>Merck (Hawaii Biotech)</td>
<td>Subunit vaccine</td>
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DVI and IP

- We do not have enough resources to directly control IP

- Want to understand IP environment and then take appropriate actions to influence access by the poor.

- Want to encourage competitive environment to obtain affordable prices.
  - Do multiple developers have Freedom to Operate
    - To conduct R&D?
    - To market in developing countries?
Result: Do the sponsors have Freedom to Operate in development?

- Each sponsor seems to have all the IP needed to bring its vaccine candidate to regulatory agency approval and to market widely.

- This is quite different from some other PDPs, e.g. malaria vaccines, where there is a patent thicket.
Activities of U.S. NIH

- Scientists developed vaccine candidate through Phase 1
- NIH has obtained many patents but not filed in developing countries
- Access to materials. NIH will supply clones only to licensees and only in accordance with terms of license, i.e. geographic limitations.
- DVI strongly endorses this IP management policy because it allows participation of developing country manufacturers – a proven source of high quality, low cost vaccines.
Dengue is caused by four viruses (DEN1-4) and a vaccine must be tetravalent.

However, the vaccine viruses interfere with each other in the vial (and in the person).

Vialing separately (e.g. 2 X 2) could reduce the problem.

Patent applications protect such procedures for all vaccines.
Dengue Vaccine – only a LMIC market

- Companies can market to the private sector which appears very attractive

- Companies must market to public sector, but what determines price?

- Because we cannot control IP directly, DVI will publish detailed cost of goods studies
Summary

- No significant IP limitations to development
- No significant IP limitations to market
- DVI strategy for access
  - Promote developing country producers
  - Rely on “market realities”
  - Publish cost of production studies
  - Monitor IP landscape
Overall Conclusion

- IP is only one factor influencing access in developing countries.
- Others are
  - Multiple manufacturers, esp. in developing countries
  - Market realities – requirement to meet public health needs
  - Regulatory pathways
  - Knowledge about cost of goods
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