

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 International Vaccine Institute

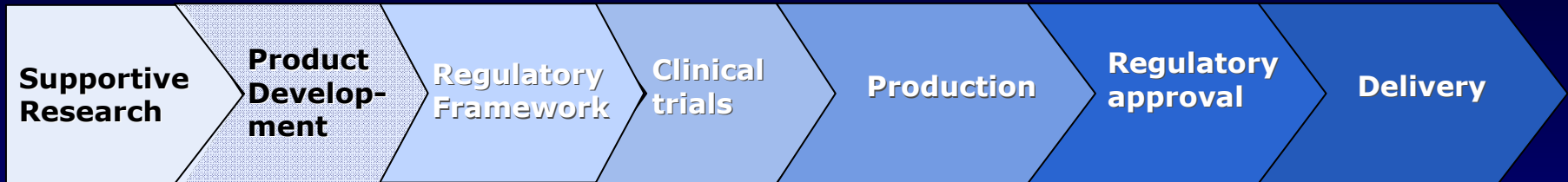


The International Vaccine Institute

- 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



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

Developer

Approach

sanofi pasteur

Yellow fever – Dengue chimera

GSK

- Cell culture passage
- Inactivated (with Fiocruz, Brazil)

Biological E (India)

Butantan (Brazil)

Panacea (India)

Vabiotech (Vietnam)

US NIH, Dengue 4 - dengue chimeras and gene deletion

Inviragen

Dengue 2- dengue chimeras

Merck (Hawaii Biotech)

Subunit vaccine

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.



Delivery patents

- 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 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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