WHO workshop on IP and Vaccines
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Suggested directions and options to consider?
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Vaccine patents

• What is the range of vaccine related inventions that may now be patented?

• In terms of the vaccines of most interest, what is the patent situation in the relevant countries (e.g. where produced, where used)?

• How will geographical vaccine patent ‘coverage’ likely change as the full effects of TRIPS are felt (years, decade(s))? 

• For a vaccine producer, which countries would be most desirable to obtain patent protection in (e.g. location of competitors)?
Know-How & Art 39 TRIPS

• What is the extent of the know-how (inc trade secret) gap between developed and developing country vaccine manufacturers? Is it increasing or decreasing?

• What progress is being made on the issue of “well characterised products” that may permit greater equivalency or “comparability” of vaccine products to be established? What impact will the protection of ‘undisclosed test or other data’ have on vaccines in the future?
A vaccine IP access methodology?

- Consider systematic methodology for analysing issues of access to existing vaccines in terms of the various types of monopoly e.g. a patent monopoly, a know-how (including trade secret) monopoly, an ‘undisclosed test or other data’ monopoly and/or any other pertinent factors, as well as in terms of the scope of those monopolies.
A vaccine IP access methodology?

- Patent mapping (MVI) or patent licence mapping?
- Know-how mapping (MVP)?
- Characterise gaps between IP owner and any other relevant entities (e.g. potential competitors?)
- Such an analysis will be dynamic, rather than static – is it perhaps likely that for a large know-how gap, patents less important, for a small know-how gap, patents more important?
- The analysis could be supported by case studies?
Simple Example?

• Imagine that the analysis reveals that an OECD vaccine manufacturer (selling a vaccine at a comparatively high price in both the developed and developing world) and emerging manufacturers are ‘separated’ by:
  – know-how (e.g. relating to one specific technical problem); and
  – a product patent (in the relevant country(ies)).
Access options?

• What could be the options to improve the access situation?

• Understanding the options could be helpful if only to better negotiate with the OECD vaccine manufacturer?

• What role(s) could the UN agencies, and/or more broadly the international community play? Involved actor, catalyst, observer?
Tiered pricing

- The OECD vaccine manufacturer could adopt a tiered pricing scheme?
- Time scale?
- How will tiered pricing be affected by ‘schedule divergence’ and market segmentation?
Bulk purchasing

• Procurement agency could negotiate a bulk purchase agreement with the OECD vaccine manufacturer, with lowered price for increased volume?

• Time scale?

• In the longer term, if geographical patent ‘coverage’ included the home countries of all potential competitors, presumably only the OECD vaccine manufacturer could supply? How effective will competitive tender processes for IP protected vaccines be?
Voluntary patent & know-how licensing

- The OECD vaccine manufacturer could grant a patent licence to one or more of the emerging manufacturers (depending on e.g. quality) along with a transfer of the necessary know-how?
- Licensure, production time scale?
- MVP indicates price will likely be significantly lowered, IFPMA indicates that price unlikely to be significantly lowered?
- What can be expected from the private sector business model approach to technology transfer (‘packing and filling’ vs bulk production)? How desirable is technology transfer for local production?
Compulsory patent licensing & contract know-how agreement?

• One or more of the emerging manufacturers could apply for a compulsory licence(s), along with entering into an agreement with an (OECD) contract research company to develop and transfer the missing know-how?

• Licensure, production time scale?

• In terms of the know-how portion, how replicable is the MVP model?
IP and private sector R&D

• What role does IP in developing countries play for OECD vaccine manufacturers in terms of R&D?
• How will a developing country IP system contribute to stimulating R&D for a health need shared with rich countries?
• How will a developing country IP system contribute to stimulating R&D for a health need exclusive to poor countries?
• Incentives in addition to IP?
IP and private sector R&D

• *What role does IP in developing countries play for developing country vaccine manufacturers in terms of R&D?*

• *If and when they develop OECD-like technical capabilities, can they be expected to behave differently from OECD vaccine manufacturers in terms of predominantly aiming R&D at rich markets?*
IP and public sector R(&D?)

• Public Sector as a source of:
  – Research: after Bayh Dole is the public sector taking on private sector characteristics (e.g. more aggressive IP management)? What impact is this having on vaccine R&D?
  – Funding: what are the types of terms in funding agreements that best secure public health goals?
  – Development and production: what is the impact on the ‘IP model’ of the discussions and proposals for public sector vaccine development and production (e.g. IOM)?
PPP IP and R&D

- What progress are the various vaccine related PPPs making?
- What have been found to be the most successful strategies for managing IP?
- What are the best tactics to draw in e.g. the desired industry partners? What impact does this have on the PPP?
- How often is/will IP able to link e.g. a viable market to a non-viable market?
- What expectations are there now for future PPP success?
IP blocking R&D?

• What is the effect of ‘upstream’ patenting and/or patent ‘thickets’ on vaccine R&D for the needs of the developing world.

• Is negotiation with and between different IP holders being successful or are vaccine R&D efforts being blocked?

• How can this phenomenon best be managed? Is patent pooling a possibility? Who best should take the initiative to create such a pool?
UN agencies, IP and R&D?

• *What role(s) could the UN agencies play in terms of IP and vaccine R&D? Involved actor, catalyst, observer?*

• *How best to help ‘square the circle’ between the profit-based R&D (private sector) and R&D based on the needs that e.g. WHO experiences in the developing world?*
Next steps

• Working groups
• Aiming towards an effective vaccine innovation system, stimulating the vaccine R&D necessary for the developing world and providing timely and effective access to the new vaccines produced for all those in need?