WHO workshop on IP and Vaccines
Geneva 19th-20th April 2004

Introduction to the IP issues
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Vaccine access, R&D and technology transfer issues are intimately linked.
WHO Workshop on IP and Vaccines

• Workshop Questions:
  – Which forms of IP are relevant to vaccines?
  – How does IP impact access to vaccines?
  – How does IP impact vaccine R&D?
  – How does IP impact vaccine technology transfer?

• Context: previous documents, new developments?

• Purpose of this presentation – asking questions, stimulating debate, gathering evidence, examples.
Previous WHO/CVI/WTO documents (I)

- “The World Trade Organisation: What is it and why is it relevant to vaccines?”, prepared by the Global Programme for Vaccines and Immunization of the WHO and the Children’s Vaccine Initiative (CVI), submitted to the SAGE meeting of 11-13 June 1997 in Geneva, reference GPV/SAGE.97/WP.14
- “Intellectual property protection: Its role and benefits” prepared by the CVI, CVI/99.04
- “WTO Agreements & Public Health, A joint study by the WHO and the WTO Secretariat”, 2002
Previous WHO/CVI/WTO documents (II)

• General hypothesis:
  – IP can be expected to stimulate R&D, can be expected to encourage technology transfer, and does not seem to present a barrier to accessing vaccines, for example, by raising prices
  – Some caveats, for example, business case considerations for technology transfer

• To what extent does this represent current thinking? What has changed since then?
Developments

• “Access to Medicines” debate, including e.g. inadequate R&D spend on neglected diseases
• WTO Doha Declaration on TRIPS and Public Health (14th November 2001)
• UK Commission on Intellectual Property Rights Report (September 2002)
• WTO August 30th (2004) Decision to address compulsory licensing problems of countries without adequate manufacturing capacity.
• TRIPS-plus bilateral Free Trade Agreements (2004)
IP and vaccines (I)

• Vaccines are different from medicines (including their biological nature, market structure, liability issues etc)

• Patents (Arts 27-34 TRIPS)
  – Wide range of patentable vaccine related inventions from ‘upstream’ research related inventions to ‘downstream’ product and delivery related inventions.

• ‘Patent portfolios’
IP and vaccines (II)

• Know-How (IP?)
  – Know-how perhaps more important for vaccines than medicines? e.g. complexity of manufacturing process?

• ‘Undisclosed Information’ (Art 39 TRIPS)
  – ‘Trade secrets’ protected against disclosure, acquisition or use if contrary to ‘honest commercial practices’
IP and vaccines (III)

• ‘Undisclosed test or other data’ (Art 39.3 TRIPS)
  – Clinical trial or other regulatory approval related data, protected against ‘unfair commercial use’ and ‘disclosure’
  – For medicines ‘bioequivalence’ or e.g. 5 years of ‘data exclusivity’
  – Vaccines more complex? Each manufacturer conducts own clinical trials for licensure?
  – ‘Well characterised products’ in the future?
  – Other issues?
IP and access to vaccines (I) – The access problem

• There is very clearly a lack of access to much needed vaccines in many parts of the developing world.
• A number of contributory factors, of which IP is only one.
• Ventures such as the Global Alliance for Vaccines and Immunization (GAVI) and other Public-Private-Partnerships (PPPs) set up to address the issue.
• What is the underlying situation though – what role does IP play? What role can it be expected to play in the future?
IP and access to vaccines (II)

- Key patent issue is ‘MONOPOLY VS COMPETITION’
- Patent monopolies are inherently limited so that competition may still be possible during the lifetime of the monopoly and will be afterwards.
- If competition is not possible during the lifetime of the patent monopoly, then the owner of the monopoly is perhaps substantially free to price at whatever level will maximise their profit.
- Maximising return on investment and ensuring access for all are different – patents are therefore an obvious access concern.
- Access to R&D inputs may be impacted by IP as well as access to end-products – also an access concern (R&D).
IP and access (III) – Competition to a patented product?

• **Scope** (same or similar result using different technique c.f. plasma and rDNA vaccines)

• **Geographical extent**
  – patents are granted on a country by country basis: no patent, no protection in that country
  – Countries used to be free to choose whether or not to provide patents for pharmaceutical products
  – TRIPS Agreement represents a **radical** change – 1st Jan 2005 all WTO Members (except LDCs) required to provide patents for pharmaceutical products

• **Time** (20 years (10 years) not acceptable to wait? Patent extensions, evergreening?)

• Patent **licensing** (exclusive, non-exclusive, effect on vaccine price compared to lack of competition)?
IP and access to vaccines (IV)

• The case of (rDNA) Hepatitis B is used as an example (CVI, WHO/WTO) to show patents in general are not a major barrier to vaccine access.

• Competition or monopoly?
  – “A major factor that drove down the price of the recombinant DNA vaccine was competition with the plasma-derived vaccine”, p45, Asian Development Bank report
IP and access to vaccines (V)

- Mechanisms to facilitate access to IP protected vaccines include:
  - Tiered pricing (no parallel importation? but what about ‘schedule divergence’?)
  - Bulk purchasing (but what about IP and procurement, especially post 1\textsuperscript{st} Jan 2005?)
  - Voluntary licensing (What can be expected? What are the business case considerations)
  - Compulsory licensing (could introduce competition but what will the impact of a know-how gap be? Example of Hep B in Israel? WTO August 30\textsuperscript{th} Decision?)
IP and access to vaccines (VI)

- What impact has the IP protection of patents, know-how (trade secrets) and undisclosed test or other data, had on access to vaccines?
- What impact are they likely to have in the future? TRIPS post-2005, know-how gap: global monopolies more likely?
- Which mechanisms will facilitate access to vaccines in the future?
IP and vaccine R&D (I)

- Vaccine R&D for the developing world *is* insufficient
- Private sector R&D:
  - To stimulate private sector investment, IP monopoly rights have to be valuable: rich market = R&D, poor or no market = little or no R&D (CMH; CIPR)
  - There is some private sector R&D (IFPMA report) but a profit based R&D agenda simply cannot match the needs of the developing world
  - What can be expected from IP and developing country private sector R&D (post-TRIPS), where will they focus?
    - *IP, TRIPS cannot alone deliver R&D for the poor?*
    - Extra incentives?
IP and vaccine R&D (II)

• Public sector R (&D) possibilities?
  – Source of research: Bayh-Dole Act effects?
  – Source of funding: IP or other access requirements in publicly funded research?
  – Public sector development and production?

• Public-Private-Partnerships (PPPs)
  – IP as the heart of the PPP arrangement, e.g. linking a non-viable market to a viable market
  – Still in an investigatory phase?
  – IAVI, MVI, MVP etc
IP and vaccine R&D (III)

• IP acting as a dis-incentive to R&D?
• “Can Patents Deter Innovation? The Anticommons in Biomedical Research”, Heller and Eisenberg, SCIENCE, Vol. 280, 1 May 1998:
  – “the recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an “anticommons” in which people underuse scarce resources because too many owners can block each other. Privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development”
• H5N1 – Avian flu patents
• Solutions? Patent pooling?
IP and vaccine technology transfer (I)

- TRIPS Agreement has provisions to encourage technology transfer (incentives).
- Private sector models including business considerations other than IP: OECD supplier and emerging supplier tension between strategic cooperation and competition?
- Public sector technology transfer?
- PPP – Meningitis Vaccine Project model (contract research, development and technology transfer to an emerging supplier)?
IP and vaccine technology transfer (II)

- Technology transfer for local production (linked to impact on access and R&D base)?
- There is a debate: Is local vaccine production:
  - Essential, e.g. to enable developing countries to master the necessary technologies and provide a sustainable supply?; or
  - Undesirable, e.g. in terms of economies of scale and quality issues?
Vaccines and IP: past, present and future?

• What impact has the IP protection of patents, know-how (trade secrets) and undisclosed test or other data, had on access to vaccines, on R&D for vaccines and on vaccine technology transfer?

• What impact is this IP protection likely to have in the future, especially post-2005? How will this be best managed?

• Does this scenario promise 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?