Commission on Intellectual Property Rights, Innovation and Public Health

Background and Vaccines
Background

- Background Paper (WHA 56/17)
- WHA Resolution (WHA56.27)
- Executive Board Information Note (EB113/INF.DOC.1)
WHA Resolution

• “…to establish the terms of reference for an appropriate time-limited body
• to collect data and proposals from the different actors involved and
• produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries, and
• to submit a progress report to the Fifty-seventh World Health Assembly and a final report with concrete proposals to the Executive Board at its 115th session (January 2005).”
Executive Board Note

• Summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact

• Review the volume and distribution of existing research and development and innovation efforts directed at these diseases

• Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases

• Analyse proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them

• Produce concrete proposals for action by national and international stakeholders
The Terms of Reference

The terms of reference essentially ask for two main things:

“…an analysis of intellectual property rights, innovation, and public health,…”

“…including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries…”
Work Programme

- Timetable
- Studies
- Consultations
  - Website
  - Workshops
  - Conferences/Hearings
  - Country visits
- Commission Meetings
- Report Writing
The Commission web site

www.who.int/intellectualproperty

Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)

The Commission was established by the World Health Assembly in 2003:

"...to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries..."

Intellectual property rights are important for innovation relevant to public health and are one factor in determining access to medicines. But neither innovation nor access depend on just intellectual property rights. The work of the Commission focuses on the intersections between intellectual property rights, innovation and public health.

This web site

The purpose of this web site is to share information and knowledge regularly with all those interested in intellectual property rights, innovation and public health. We will be launching a new web site at the end of April with a new look that reflects the individual identity of the Commission.

The web site contains background information on the Commission members, a calendar of events, news items and a range of information from around the world related to the areas of work of the Commission. A list of useful links are also listed on the site. Finally, a series of documents, both produced by the Commission and by others, are posted on the web site.

The web site also provides updates on the work of the Commission and its findings.
CHARACTERISTICS OF VACCINES

Important to differentiate characteristics of drugs and vaccines in evaluating impact of IP on vaccine production and access. These include:

• Small market – total vaccine revenues are less than some single blockbuster drugs – tiny fraction in developing countries
• Public sector involvement in purchase (and pricing) is very much greater than for drugs (even in the USA)
• Biological rather than chemical products. Vaccine production to ensure potency and quality is often complex and costly. The delivery systems required for vaccines are more demanding than most drugs.
CHARACTERISTICS OF VACCINES

- Similarly, clinical trials and obtaining regulatory approval, particularly for new classes of vaccines, may be more costly and time consuming.
- Because of their nature and development and production characteristics, copying the product is likely to be more difficult/costly than in the case of medicines.
Implications for R&D

• The incentive for producing new vaccines is less than for medicines. The market is very much smaller and it undervalues vaccines more as compared to drugs. Social benefits, and the externalities particularly associated with vaccines, are not captured by market and IP incentives.

• Why are there 15 antiretrovirals for treatment of HIV/AIDS but no vaccines? Is that a function of the incentive structure or the intrinsic relative difficulty of the science?

• In 1967 there were 26 large pharma companies manufacturing vaccines – now there are four.
Implications for R&D

- If the IP and market incentive works less well for vaccines, it may also be that the disincentives associated with IP (patent thickets) are more prominent in some cases. For example, the malaria vaccine initiative referred to in the paper.

- In this context, rules on patenting research tools (e.g. Bayh-Dole type rules on university patenting) may require examination to mitigate these type of hold-up problems in innovation.
IMPLICATIONS FOR ACCESS

- Because of the different characteristics of the production and distribution of vaccines, it may be a mistake to pursue too closely the analogy with drugs.
- This is because of low unit value (even for expensive vaccines), the absence in most countries of a private market (where IP exclusive rights could be exercised), and the costs of delivery. And generic production may be more difficult (e.g. under compulsory licensing).
IMPLICATIONS FOR ACCESS

• Access is, of course, a critical issue but because governments, or their agents, in most countries are the predominant purchasers it is not clear that IP, as such, is a major factor hindering access. Price will be a matter for negotiation.

• Rather, the key access problem is the absence of vaccines that could save millions of lives, and dollars in the longer term through avoided treatment.