Intellectual Property Rights and Vaccines in Developing Countries

Introduction

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Outline

- Why are we organizing this meeting?
- Context and questions
- Objectives
- Agenda
Why are we organizing this meeting?

- In 1997, Strategic Advisory Group of Experts (SAGE) discussed WTO/TRIPS and access to vaccines
- WHO and others engaged in R&D and technology transfer need a clearer understanding of related IP issues
- WHA adopted in 2003 a resolution on IPRs, Innovation and Public Health
- International debate on IP has developed in the field of pharmaceuticals with very few references to vaccines
IPRs have not been so far a major obstacle in the worldwide supply of vaccines.

IP may however become one of the factors affecting access to new vaccines in developing countries.

IP is likely to become one of the factors affecting the production of new vaccines and other related technologies in developing countries.
A Changing context (1)

- The world of vaccines has radically changed during the last 20 years in terms of research, production, supply, legal requirements, costs, prices, actors..

- World Vaccine Market: geographical segmentation and diverging markets in terms of products and presentations

- Developing country manufacturers are an increasingly critical source of vaccines (almost 70% for UNICEF in terms of volume)
A Changing context (2)

- Different types of technical and production arrangements are being made between R&D-based industry, biotechs and emerging producers

- Most vaccine research activities that are promising for developing countries are undertaken by Public-Private Partnerships

- Regulatory and quality requirements as well as liability concerns are raising substantially the production costs
A Changing context (3)

- Patent portfolio is increasingly a critical component of companies’ assets

- Extension of IP rights: Scope and territories

- Tendency of "evergreening" of patents where protection is extended by allowing patents on minor amendments to the basic product

- Developing a new product may require gaining access to multiple patents owned by different actors with conflicting interests and strategies: possible deadlock
Questions

- Is IP protection likely to contribute to the research and development of vaccines that are of particular relevance to the developing countries?

- How may the TRIPS agreement affect the global production of vaccines that are of particular importance to developing countries?

- How does IP protection impact on the strengthening of viable vaccine production in developing countries?

- What are the IP issues faced by the Public-Private Partnerships?
Objectives

1. To review how intellectual property protection affects access to vaccines in developing countries: an update on IP issues and future access to vaccines.

2. To discuss directions and options for ensuring an appropriate balance between stimulating RD and enhancing access to most needed vaccines in developing countries.

3. To provide an informal input on the above issues to the WHO commission on IPRs, Innovation and Public Health.
Agenda

Day 1: 3 sessions:

- Setting the stage: general presentations
- Addressing technology transfer dimensions
- Raising research and development concerns

Day 2:

- Synthesis of day 1
- Presentation and discussion on options and directions
- Working groups for in-depth discussions on existing and future vaccines
- Plenary session and general discussion on common efforts and directions to consider
FORUM

- To update our knowledge, data, assumptions,..

- To share our concerns and questions

- To identify common challenges and goals

- To discuss how to move towards a new paradigm assuring protection of innovation and access to most needed vaccines.