
Developing public health perspective for the examination of pharmaceutical patents



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People are dying because of lack of access to essential drugs

- 10.3 million children under 5 years of age die in developing countries each year. About 8 million of these deaths could be prevented if those at risk had access to essential drugs.
- 6 million people need antiretroviral (ARV) treatment - only 1.2 million have access to ARVs
- 19 000 children under 15 years of age infected by HIV every day...

Concerns expressed by several countries on the impact of TRIPS



- High prices for new patented drugs
- Weakening of local pharmaceutical industry
- Generic competition delayed
- IPR restrictions of the FTA's

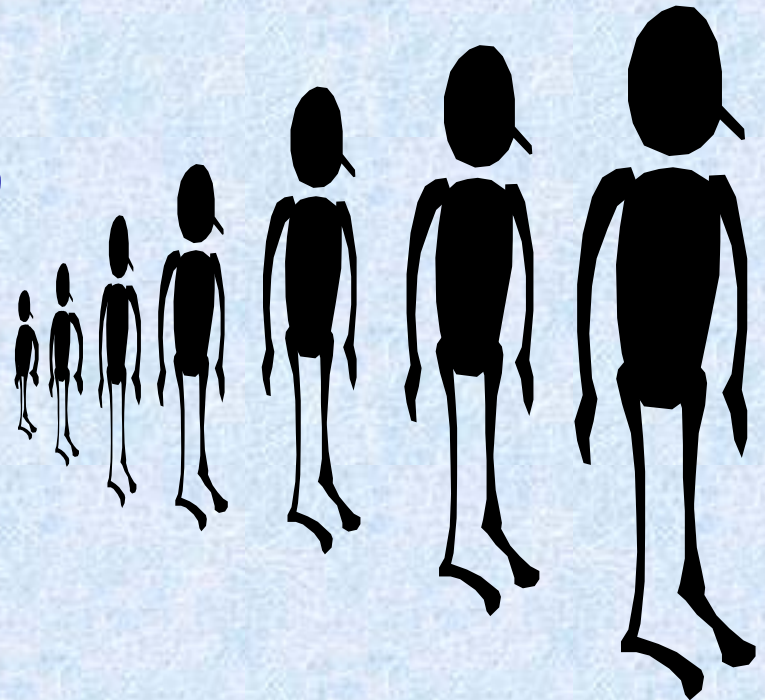
New actors...



1977: MOH and WHO

2007:

- WHO/MOH, other Ministries
- UNICEF, UNAIDS, UNDP, UNCTAD, WTO
- WHO Collaborating Centres (+20)
- WB and regional deveop. Banks
- Global Fund,
- Gates and Clinton Foundations
- UNITAID, GDF, Pefpar,
- Academic sector
- South Centre in Geneva
- Profit and not-for-profit NGOs
- PPPs (+80),
- Industry donations



New actors...



"More money is being spent on global health than ever before, but because the efforts are narrow, uncoordinated and heedless (...) the current age of generosity might actually make things worse instead of better" Laurie Garrett in *Foreign Affairs*, February 2007.



Access to medicines, globalization and IPR: a priority in the global health agenda

- 1996 (WHA 49.14) requesting WHO to study and inform on the impact of WTO on medicines
- 1998 publication of the "Red/Blue book"
- 1999 (WHA52.19): Revised Drug Strategy
- 2001 (WHA54.11): Revised Drug Strategy
- 2002 (WHA55.14): Ensuring accessibility of essential medicines
- 2003 (WHA56.27): Intellectual property rights, innovation and public health
- 2006 (WHA59.24): Public health, innovation, essential health research and IPR: towards a global strategy and plan of action
- 2007 (WHA60.30): Public health, innovation and intellectual property
- IGWG Process... Creation of PHI

WHO Mandate...

Two parallel ways:

1. Use of the flexibilities (short-
mid-term)
2. IGWG process (mid- long term)

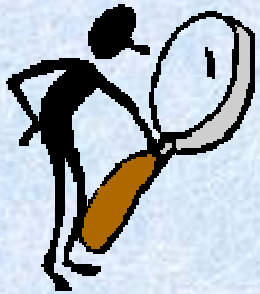
TRIPS Flexibilities to protect public health

- Article 7 and 8 (OBJECTIVES, PRINCIPLES)
- Flexibility to interpret the 3 criteria of patentability: **Novelty**, inventive step, and industrial application
- Compulsory licences, government use
- Parallel imports
- Exceptions to patent rights (early working or "Bolar" provision).
- No patents for medical treatments
- Use of the transitional periods

Patents and new medicines

A common belief is that patents are normally granted to protect new medicines... but the number of patents annually to protect real new pharmaceutical products is small and declining.

Only 15% of new drug approvals were medicines providing significant clinical improvement (1989-2000) according to the NIH of USA



Guidelines for the examination of pharmaceutical patents

- A working paper that suggest elements for the development of public health sensitive guidelines for the evaluation and review of pharmaceutical patents

A working paper...

- This working paper is the result of an ongoing series of technical consultations and seminars organized by ICTSD, UNCTAD and WHO
- Geneva, Bangkok, Buenos Aires, Beijing, New Delhi...

Challenges and next steps...

1. Incorporation and use of TRIPS flexibilities, including the introduction of public health criteria for the examination of pharmaceutical patents.
2. The current WHO-IGWG has the mandate to explore new alternatives to promote R&D for new, needed medicines... (IGWG)