

# Workshop on Flexibilities in Intellectual Property Rules and Local Production of Pharmaceuticals

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**World Health  
Organization**

# The Context

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During the past decade, a growing international debate concerning the wider aspects of the relationship between intellectual property rights, innovation and public health, has been taking place against a backdrop of discussions on poverty reduction and improving access to health care.



# WTO Trade-Related Aspects of IPRs

- Came into force in 1995
- Most comprehensive multilateral agreement on intellectual property rights
- Applies to copyright, trademarks, geographical indications, industrial designs, patents, layout designs, and trade secrets
- Patent available to any inventions, both products and processes, in all fields of technology



# WTO Agreement on TRIPS

## Article 7- Objectives

*The protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations*



# Doha Declaration on TRIPS and Public Health (2001)

*We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.*



# WHO and the right to health

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## WHO Constitution (1946)

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.



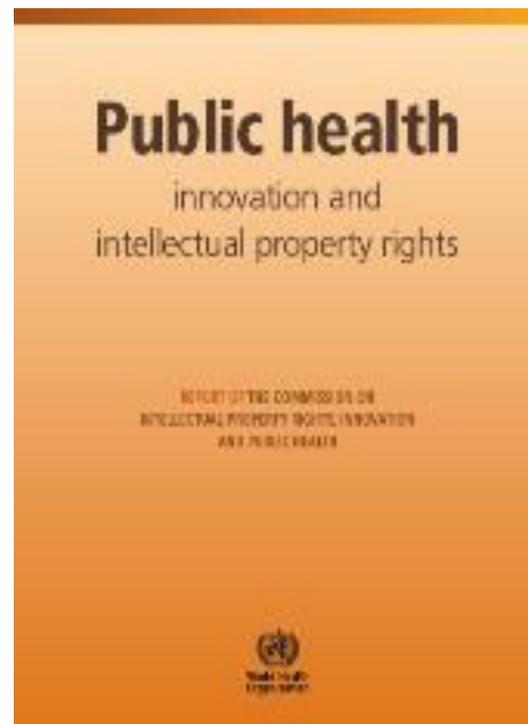
# WHO Resolutions relevant to public health, innovation and intellectual property

- 1996 (WHA 49.14) requesting WHO to study and inform on the impact of WTO on medicines
- 1999 (WHA52.19): Revised drug strategy
- 2000 (WHA53.14): HIV/AIDS: confronting the epidemic
- 2001 (WHA54.11): WHO medicines strategy
- 2002 (WHA55.14): Ensuring accessibility of essential medicines
- 2003 (WHA56.27): Intellectual property rights, innovation and public health
- 2004 (WHA57.14): Scaling up treatment for HIV/AIDS
- 2006 (WHA59.24): Public health, innovation, essential health research and IPR: towards a global strategy and plan of action
- 2006 (WHA59.26): International trade and health
- 2007 (WHA60.30): Public health, innovation and intellectual property
- 2008 (WHA61.21): WHO Global strategy and agreed parts of the plan of action on public health, innovation and intellectual property
- 2009 (WHA62.16) : WHO Global strategy and agreed parts of the plan of action on public health, innovation and intellectual property



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

- In 2004, WHO tasked an independent commission with analysing the relationship between intellectual property rights, innovation and public health
- The report was published in April 2006 and contained around 60 recommendations aimed at fostering innovation and improving access



# Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

- The World Health Assembly in May 2006 adopted resolution WHA59.24 requesting the DG to establish an Intergovernmental Working Group (IGWG).
- IGWG to draw up a global strategy and plan of action that aims at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries.
- Negotiations took place over 18 months, beginning in December 2006
- Supported by public hearings, regional consultations and other meetings



# The Global Strategy on Public Health, Innovation and Intellectual Property

## Global Strategy and Plan of Action on Public Health, Innovation and IP

The global strategy is designed to promote innovation, build capacity, improve access and mobilize resources.

Eight elements of the plan of action:

- *prioritizing research and development needs;*
- *promoting research and development;*
- *building and improving innovative capacity;*
- *transfer of technology;*
- *application and management of intellectual property;*
- *improving delivery and access;*
- *ensuring sustainable financing mechanisms;*
- *establishing monitoring and reporting systems.*



# The Global strategy on Public Health, Innovation and Intellectual Property

- Landmark resolution
- First forum to address both innovation and access
- Involves many stakeholders: Member States, WHO, other international intergovernmental organizations, other relevant stakeholders
- Taking this strategy forward requires a collective effort and new ways of working



# Public Health and Intellectual Property

- *Intellectual property rights are an important incentive for the development of new health-care products. This incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain (Op 7)*
- *Encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for R&D (Op. 14(e))*



# Local Production and IP Interface

- Also relates to both innovation and access
- Local pharmaceutical production may promote sustainable supply
- Pharmaceutical substances needed for local production in DCs are often patented by foreign companies
- Member States may implement flexibilities



# Project on improving access to medicines in developing countries through local production and related technology transfer

- WHO, in partnerships with UNCTAD and ICTSD, and with the support of the EU, is exploring questions regarding local production and related technology transfer
- Relates to elements 3 and 4 of the GSPOA, with a particular focus on technology transfer
- 4 Parallel Research Activities- Stakeholder survey, Trends analysis, Case studies, Stakeholder workshops

# TRIPS Flexibilities

- LDC transition periods
- Patent exceptions
- Parallel imports
- Compulsory licensing
- Limited scope of future patents
- Non-exclusive rights in test data



# Transition Periods for least developed countries

- Until 1 July 2013 for all TRIPS obligations
- Until 1 January 2016 protection of pharmaceuticals



# Exceptions to Patent Rights

The patented substance may be used

- for marketing approval of generic products
  - Approved by WTO jurisprudence
- for research & new drugs development
  - Main purpose must be research/promotion of technological progress



# Parallel imports

- Permitted under TRIPS
- Many local producers need to import substances (active pharmaceutical ingredients/APIs) that are under domestic patent
- May be available at lower cost abroad



# Compulsory licensing

- Authorization by the government of a third party to use an invention without the consent of the right holder
- Powerful negotiating tool for government



# The scope of patents

- To promote access to pharmaceutical substances, governments determine the scope of patentability
  - Exclusions from patentability
    - Methods of medical treatment
    - Natural substances
  - Patentability requirements
    - May define what is industrially applicable, new and exhibiting inventive step

# Protection of Pharmaceutical Test Data

- Data submitted to drug regulatory authorities (DRAs) for marketing approval purposes
- More than one approach under TRIPS :
  - Data exclusivity
  - Unfair competition approach

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# Thank You

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