

Balancing Health and Trade: Doha Declaration on TRIPS & Public Health

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- **The Doha Declaration**
 - Context and background
 - Trade, TRIPS and access to medicines
- **TRIPS flexibilities**
 - What are they?
 - How to use them
- **Using the TRIPS flexibilities**
 - Institutional and resource issues
 - Emerging issues

Context & Background

- Pre-TRIPS: A diversity in IP systems
- TRIPS and min. standards of IP protection
- **Implementation deadlines**
 - Application of principle of *special and differential treatment* to developing countries
- **Pharmaceutical patents**
 - 20 year patent term
 - *all* fields of technology
 - patents for products *and* processes
- **Patentability criteria:** definition and application of criteria

Trade, TRIPS & access to medicines

- **Patents affect access to medicines because patent monopoly allows patent holders to control production, supply and pricing of medicines**
- **Market competition and generic introduction are key factors in driving, and keeping, drug prices down**
- **All WTO Members required by the TRIPS Agreement to provide patent protection for pharmaceutical products for a minimum 20-year period**
- **What are the implications for pharmaceutical production and prices?**

**MILLIONS HAVE
A DRUG PROBLEM.**

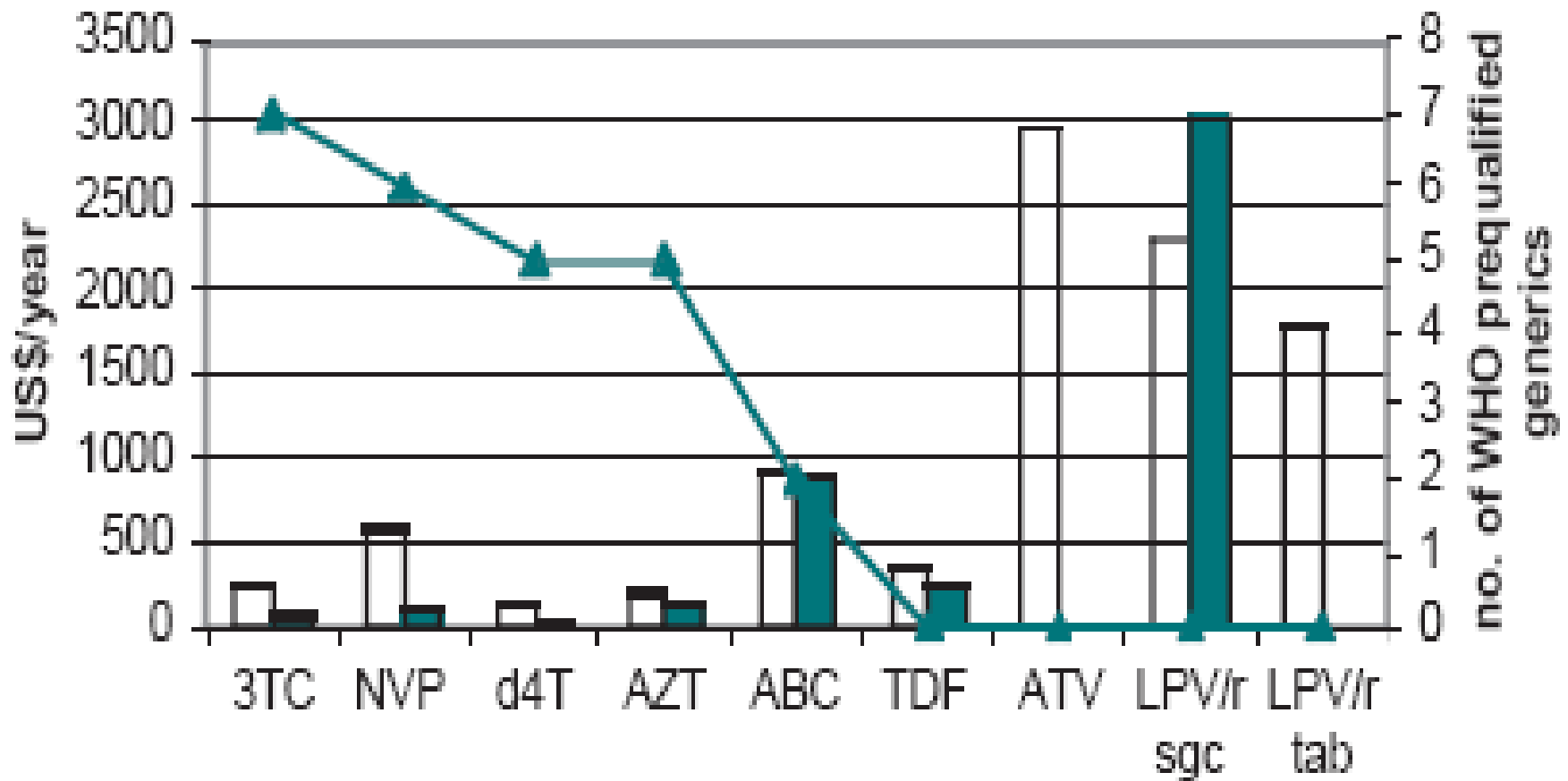
THEY CAN'T GET ANY.

Context & Background

- **Backdrop of HIV/AIDS epidemic**
- **Legal challenges to developing countries legislation**
 - **South Africa (1997):** Pharmaceutical company challenge of amendment to Medicines and Related Substances Act
 - **Brazil (2000):** US complaint to WTO Dispute Settlement on local working provision
 - **Debate at WTO TRIPS Council 2001**
 - **Developing country position**
 - **Common understanding among WTO Members**
 - **Clarification of TRIPS provisions**

The competition effect:

Prices drop with generic introduction



average ori average gen no. of WHO prequalified generics

Doha Declaration on TRIPS Agreement and Public Health

- **Arose from from developing countries' proposal to examine impact of TRIPS on access to medicines**
- **Adopted at the WTO 4th Ministerial Conference in Doha, 14 November 2001**
- **Clarification that TRIPS Agreement does not prevent WTO Members from taking measures to protect public health**
 - **Interpretative guide to TRIPS provisions**
 - **Affirmation of right to use flexibilities in TRIPS**
 - **Expeditious solution for countries with insufficient or no manufacturing capacities**
 - **Extension of LDC transition period to 2016**

Interpretative guide

Paragraph 4:

- *The TRIPS 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*

Paragraph 5(b):

- *... each provision of the TRIPS Agreement shall be read **in the light of the object and purpose of the Agreement** ..., in particular, in its objectives and principles*

Objectives of TRIPS

Article 7:

- Protection and enforcement of IPRs should contribute to promotion of technological innovation and to 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

Principles of TRIPS

Article 8

- Members may ... adopt measures necessary to **protect public health and nutrition**, and to promote the **public interest** in sectors of vital importance to their socio-economic and technological development
- Appropriate measures ... may be needed to **prevent abuses of IPRs** by rights holders or resort to practices that **unreasonably restrain trade or adversely affect the international transfer of technology**

Affirmation of right to use flexibilities

Paragraph 4:

- *We affirm the right of WTO Members to use, **to the full**, the provisions in the TRIPS Agreement, which provide **flexibility** for this purpose*

Paragraph 5: ... we recognize that these **flexibilities** include:

- *Each member has the **right to grant compulsory licenses** and the **freedom to determine the grounds upon which such licenses are granted***
- *Each member has the **right to determine what constitutes a national emergency or other circumstances of extreme urgency ...***
- *... leave each member free to establish its own regime for such exhaustion without challenge*

Expeditious solution

Paragraph 6

- *... WTO members with **insufficient or no manufacturing capacities** in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.*
- *We instruct the Council for TRIPS to find an **expeditious solution** to this problem and to report to the General Council before the end of 2002*

LDC transition deadline

Paragraph 7:

- *... the least-developed country members will **not be obliged**, with respect to **pharmaceutical products**, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement, or to enforce rights provided for under these Sections until **1 January 2016***
- *... without prejudice to the right of least-developed country members **to seek other extensions of the transition periods** as provided for in Article 66.1 of the TRIPS Agreement*

Types of flexibilities in TRIPS

Time-based provisions

- Transition periods for developing countries and LDCs
- Deadlines: ~~2000~~, ~~2005~~, ~~2006~~, 2013, 2016

Substantive provisions

- Flexibilities specifically recognised in Doha Declaration
- E.g., compulsory licences, exhaustion of rights
- Public health interpretation of other TRIPS provisions
- E.g., exceptions, patentability criteria, test data protection

Transition periods for LDCs

TRIPS implementation deadline

- 2006 deadline, extended until 2013
- Request by Zambia, on behalf of LDC Group
- TRIPS Council Decision (November 2005)
“Extension of the transition period under Article 66.1 for Least-developed Country Members”
- Recognizing “special needs and requirements of LDC, the economic, financial and administrative constraints that they continue to face, and their need for flexibility to create a viable technological base

Transition periods for LDCs

Implementation re pharmaceutical products

- Doha Declaration Paragraph 7
- TRIPS Council Decision (June 2002), "Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products"
- Without prejudice to right of LDCs to seek other extensions of transition periods

What are the implications for LDCs?

- Extension applicable to patents, marketing rights and data protection for pharmaceutical products
- Medicines procurement and manufacturing capacity in LDCs

TRIPS-consistent policy options to promote access to medicines

- **Compulsory licences and government use**
 - Import and/or production of generic versions of patented drugs
- **Parallel importation**
 - Import of medicines sold cheaper in another market
- **Bolar or early-working exception**
 - Preparations for marketing approval prior to expiry of patent, to enable prompt marketing of generic drug

Designing public-health-sensitive patent laws in developing countries:

- **Scope** – what should be the scope of patentable subject-matter?
- **Standards** – strict requirements for patentability, commensurate with inventive contribution and disclosure made
- **Safeguards** – ensure patent rights may not be exploited inappropriately
- **Competition** – restrict ability of patentees to prohibit others from building on or designing around patented inventions

Post-2005 and access to medicines

- **Post-2005 environment:** When all but LDCs have to implement full patent protection, how will production and supply of raw materials and generic medicines be affected?
- What are available means to promote **market competition** in patented pharmaceuticals? Generic competition drove down 1st-generation ARV prices, but this strategy may not be possible in post-2005
- **Effective use** of all TRIPS flexibilities will be crucial to enable generic competition

**What about new drugs and
vaccines?**

New drugs for diseases that disproportionately affect developing countries	New drugs to replace ineffective or toxic treatments	New drugs for emerging diseases
<p>The “10/90 gap”: 5% of global resources being applied to low and middle-income countries, where 93% of preventable deaths occur</p>	<p>More effective HIV drugs and combinations still needed</p> <p>Drug resistance to existing TB, malaria treatments</p>	<p>Over 20 diseases have emerged in past decade; including new strains of cholera, SARS, avian flu, H1N1</p>
<p>Only 1% drugs in last 25 years for tropical diseases and TB (which make up 11% of the GDB)</p>	<p>New drugs are needed to replace current toxic treatments for diseases, such as trypanosomiasis and leishmaniasis</p>	<p>Urgent need for new treatments and vaccines</p>

Emerging Issues

Re-examining IP, innovation & public health

- IP protection alone does not guarantee innovation
- UK CIPR, WHO CIPIH, WHO GSPOA, WIPO Devt Agenda
- Public vs. private investments in health R&D
- But worrying trend in TRIPS-plus provisions

Increasing R&D and innovation

- Meeting public health and developing country needs
- Alternative models of innovation?
- Medicines Patent Pool for HIV drugs, GSK “patent pool”, WIPO Re:Search
- WHO R&D Treaty?