

WTO NEGOTIATIONS ON TRIPS AND PUBLIC HEALTH: AN OVERVIEW

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Outline

- Background to discussions in the TRIPS Council, including
 - WHO-WTO Workshop on Differential Pricing and Financing of Essential Drugs in April 2001
- TRIPS Council Special discussion on IP and access to medicines
- Doha Declaration on the TRIPS Agreement and Public Health
- Waivers on Article 31(f), 31(h): Decision on the Implementation of Paragraph 6 of the Doha Declaration, 30 August 2003
- Protocol amending the TRIPS Agreement of 6 December 2005
- Summing up...

Background to discussions in the TRIPS Council

- Civil society outcry on inadequate access to patented medicines, esp. HIV/AIDS medicines gained momentum in 1999-2000
- WHA resolutions since 1996 as a part of the response to HIV/AIDS as well as the WHO medicines strategy
- UNGA special session on HIV/AIDS, June, 2001
- Various legal commentaries on the TRIPS Agreement agree that there are flexibilities (for e.g. no restriction on grounds for CL)
- WTO website explains pharmaceutical patents and compulsory licences, early 2001

WHO-WTO WORKSHOP, APRIL 2001

- Unusual initiative by the WTO Secretariat
 - co-organized with the WHO Secretariat a multi-stakeholder workshop to discuss **Differential Pricing and Financing of Essential Drugs** in Høsbjør, Norway, 8-11 April 2001
- http://www.wto.org/english/tratop_e/trips_e/tn_hosbjor_e.htm#finalreports

TRIPS COUNCIL SPECIAL DISCUSSION ON IP AND ACCESS TO MEDICINES

- **IP/C/M/31**: Reproduces statements made by Members on 20 June 2001
 - Statement of the African Group: pages 3-6
 - Statement of the EC: pages 6-9
 - Statement of the United States: pages 33-41
- **IP/C/W/280** - Submission by the EC
- **IP/C/W/296** - Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, the Philippines, Peru, Sri Lanka, Thailand and Venezuela.

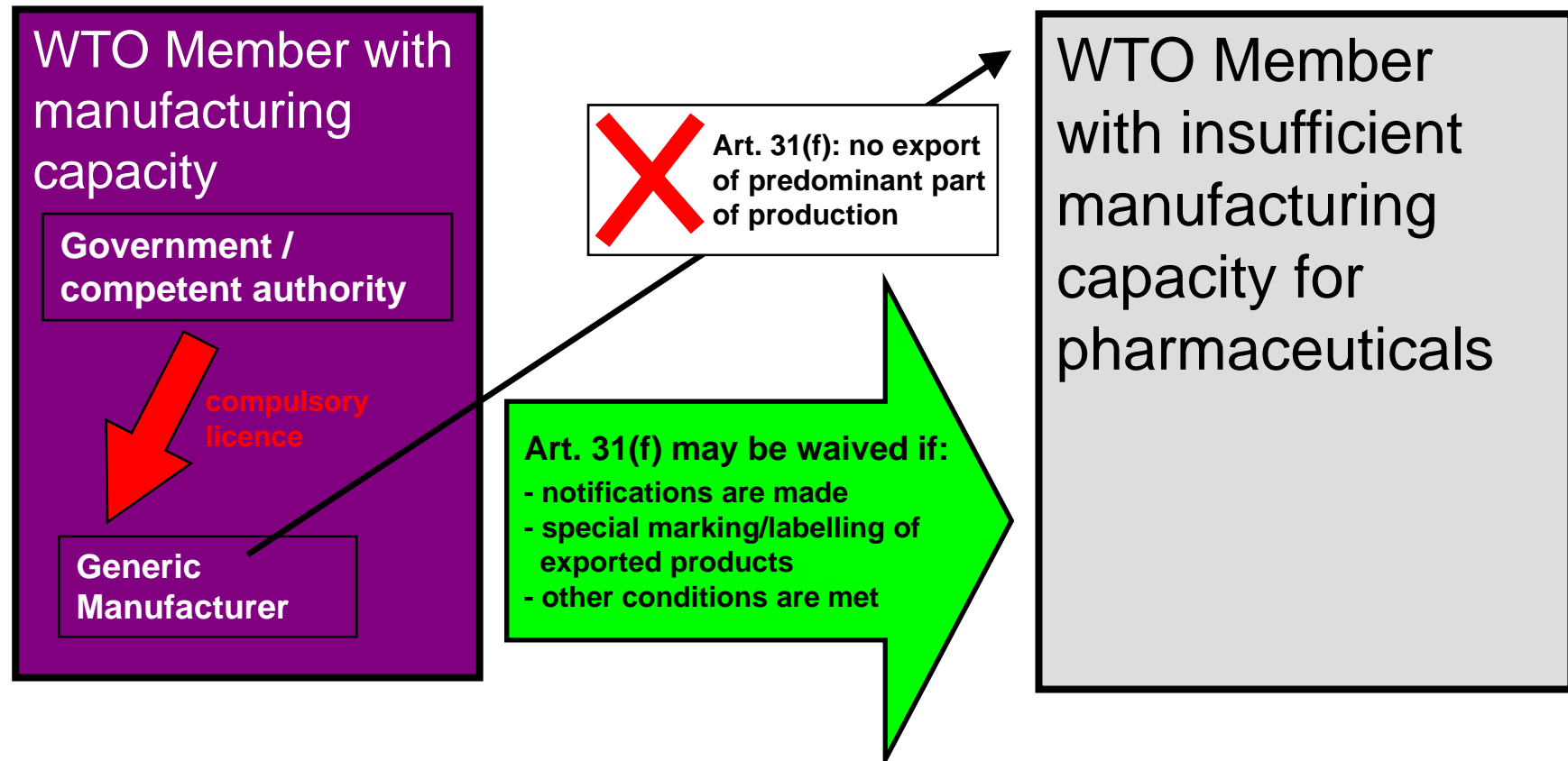
Doha Declaration on the TRIPS Agreement and Public Health

- Did not amend TRIPS nor provided agreed interpretation, yet clarified TRIPS flexibilities
 - Can choose own exhaustion regime without challenge
 - Right to grant CL and the freedom to choose grounds for such grant
- Instructed TRIPS Council to extend LDC transition period in respect of medicines to January 2016.
- Instructed TRIPS Council to find expeditious solution by the end of 2002 for those who cannot make their needed medicines

MAKING COMPULSORY LICENCES EFFECTIVE FOR THOSE WHO CANNOT MAKE THEIR OWN MEDICINES: ISSUES DISCUSSED

- **PRODUCT AND DISEASE COVERAGE**
 - To address public health problems such as HIV/AIDS, TB, malaria or wider?
- **BENEFICIARY IMPORTING COUNTRIES**
 - Assessment of insufficient manufacturing capacity - self assessment based on objective criteria, which are...?
- **ELIGIBLE SUPPLYING COUNTRIES**
 - Only developing countries with sufficient manufacturing capacity or any country?
- **SAFEGUARDS AND CONDITIONS**
 - Safeguard measures to prevent diversion - existing or additional?
 - Adequate remuneration in both countries, if there are two CLs?
- **LEGAL MECHANISMS**
 - Waiver, amendment, interpretation, moratorium?
- **TRANSFER OF TECHNOLOGY AND "DOMESTIC MARKET"**
 - Long term solution is building up local capacity?

Solution of 30.08.2003: Decision on waivers and GC Chairman's statement



- Art. 31(h) may be waived to avoid double remuneration
- other Art.31 conditions continue to apply
- Special provisions for Regional Trade Agreements with 50% LDCs

Protocol Amending the TRIPS Agreement

GC Decision WT/L/641, 6.12.2005

- Basis: para.11 of August 2003 Decision which instructed TRIPS Council to initiate work on amendment by end 2003 with a view to its adoption within 6 months
- GC adopted a Protocol amending the TRIPS Agreement on 06.12.2005 and submitted it to Members for acceptance
- Takes effect upon acceptance by two thirds of membership
- Note that Paragraph 6 System as established under August 2003 Decision continues to apply until entry into force of amendment in a Member

To sum up...

African initiative in
April 2001

- TRIPS Council discussions
- Doha Declaration on the TRIPS Agreement and Public Health, Nov 2001

Paragraph 6 of the
Doha Declaration
Paragraph 11 of the
August 2003 Decision

- Waivers decision, August 2003
- Protocol amending TRIPS, December 2005