DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH AND THE PARAGRAPH 6 SYSTEM OF SPEICAL EXPORT LICNENSE FOR MEDICNES UNDER TRIPS

WTO-ESCAP-IIUM Regional Workshop on IP and Public Health and Environment Policy for Asian and Pacific Region

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Outline of Presentation

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- Doha Declaration on the TRIPS Agreement and Public Health
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- Implementation of the Doha Declaration on the TRIPS Agreement and Public Health

Background on Doha Declaration on TRIPS and Public Health

- Ministerial Conference
  - Highest decision-making body of the WTO
  - Meets once every 2 years
    - 6 ministerial meetings so far, 4th at Doha (11/2001)
  - In intervals between ministerial meetings, General Council takes on these functions
- Results of the Doha ministerial meeting:
  - Declaration on the TRIPS Agreement and Public Health
  - Ministerial Declaration
  - Decision on Implementation-Related Issues and Concerns

Why the Doha Declaration ?

- Widespread concerns that strengthened IPR protection would lead to reduced access to essential medicines
  - The purpose of the Declaration was to respond to the concerns that had been expressed about the possible implications of the TRIPS Agreement for access to drugs.
- Concerns raised:
  - different views about the nature and scope of the flexibility in the TRIPS Agreement, for example in regard to compulsory licensing and parallel imports;
  - whether this flexibility would be interpreted by the WTO and its Members in a broad, pro-public health way;
  - The extent to which governments would feel free to use to the full this flexibility without the fear of coming under pressure from trading partners or industry.

The Declaration: General Statements

Ministers:

- Recognize the gravity of the public health problems...,especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics
- Recognize that intellectual property protection is important for the development of new medicines and recognize concerns about its effects on prices
- Agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.
- Reaffirm commitments made in the TRIPS Agreement and affirm that TRIPS can and should be interpreted and implemented in a manner supportive of Members' right to protect public health and, in particular, to promote access to medicines for all

- *Note: these important declarations signal an acceptance by all WTO Members that they will not seek to prevent other Members from using these provisions.*

The Declaration: Guidance for Disputes

Ministers:

- Reaffirm Members' right to use, to the full, the TRIPS provisions which provide flexibility for this purpose and in this context:
  - Recognize that each provision shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles

- *Note: provides important guidance to both individual Members and, in the event of disputes, to WTO dispute settlement bodies.*

The Declaration: Clarification on Compulsory Licences

Ministers:

- Recognize that Members have the right to grant compulsory licences and freedom to determine the grounds for compulsory licences.

- *Note: a useful corrective to the views often expressed in some quarters implying that some form of emergency is a pre-condition for compulsory licensing.*

The Declaration: Clarification on Emergency

Ministers:

- Recognize that Members have the right to determine what constitutes a national emergency or other circumstances of extreme urgency (public health crises including those relating to HIV/AIDS, TB, malaria and other epidemics can be an example).

- *Note: useful clarification as such use cannot be easily challenged on grounds that it is not a national emergency etc*.

The Declaration: Clarification on Exhaustion

Ministers

- Recognize that the effect of the TRIPS provisions relevant to exhaustion of rights is to leave Members free to establish their own regimes for exhaustion, subject to MFN and national treatment

- *Note: much debate about what exactly TRIPS Article 6 says in regard to a Member's freedom to choose its own regime for exhaustion and parallel imports. This provision makes it clear that Members are free to choose and need not fear challenge of their regime.*

The Declaration: Instructions for Further Work

Ministers:

- Instruct the TRIPS Council to find, before the end of 2002, an expeditious solution to the problem of WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing under TRIPS.

- Agree to extend the transition period for LDCs from 2006 to 2016 with respect to pharmaceutical products as far as TRIPS obligations relating to the protection and enforcement of patent and undisclosed information and instruct the TRIPS Council to give effect to this pursuant to Article 66.1.

The Declaration: Transfer of Technology

Ministers:

- Reaffirm the commitment of developed country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to LDCs pursuant to Article 66.2

- *Note: remains a contentious issue for WTO LDC Members.*

Implementation of the Doha Declaration(1)

- Implementation of paragraph 7: to extend LDCs transition period as regards protection and enforcement of patent rights/undisclosed information in the field of pharmaceutical products
  - Decision of the TRIPS Council on the Extension of the Transition Period under Article 66.1 for LDCs for Certain Obligations with Respect to Pharmaceutical Products (IP/C/25, June 2002)
  - General Council's Decision on LDC Members – Obligations under Article 70.9 with Respect to Pharmaceutical Products (WT/L/478 – July 2002)
    - Mailbox required, but exclusive marketing rights waived

Implementation of the Doha Declaration (2)

- Implementation of paragraph 6: to find an expeditious solution to the problem of WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing under TRIPS.
  - General Council's Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health (WT/L/540, August 2003)
  - General Council Chairman's statement (WT/GC/M/82 – para. 29)

Paragraph 6 Decision

- Para. 6 of the Declaration: recognizes that Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS
- Instructs the TRIPS Council to find an expeditious solution and report to the General Council before the end of 2002
- ☐ reference to "Paragraph 6 System"

Compulsory licences under TRIPS

- Members can issue compulsory licences for importation / domestic production
- Availability of supply from generic producers in third countries ?
- Art. 31(f) requires production under compulsory licenses "predominantly for the supply of the domestic market of the Member" ☐ need to address legal problem resulting from Art.31(f) conditions in exporting Member
- Solution: three derogations, adopted in light of Chair' statements

First Derogation: Compulsory Licence to Produce for Export

- Basic rule under Article 31(f): production under compulsory licence predominantly for supply of domestic market
- Paragraph 6 System waives requirement for exporting Members in cases of production/export of a pharmaceutical product to eligible importing Members
- Subject to conditions on transparency and safeguards

Second Derogation:No Double Remuneration

- Basic rule under Article 31(h): remuneration to be paid where compulsory licence is granted
- Under Paragraph 6 System:
  - Exporting Member: adequate remuneration is to be paid taking into account the economic value of the authorization in the importing Member
  - Importing Member: Article 31 h) is waived; no remuneration payable if paid in exporting Member for the same products

Third Derogation: Regional Trade Agreements

- Objective: economies of scale, enhance purchasing power, help local production
- Derogation from Art. 31(f) if:
  - RTA falls within WTO rules
  - At least half of the RTA members are LDCs
  - Members concerned share the health problem in question

  ⇒ *Note: derogation does not affect any patent status in importing countries - principle of territoriality*
- Promotion of regional patent systems
- Developed countries, in conjunction with IGOs, to provide technical cooperation

Selected Key Elements

- Scope and coverage:
  - diseases and products
- Eligible participants:
  - importing Members: the "special" case of LDCs, opt-out countries, non-WTO Members
  - exporting Members: optional participation
- Conditions / notification requirements:
  - importing Members
  - exporting Members
- Safeguards against diversion to ensure use of system for intended purposes

Chairman's Statement 2003/2005

- Represents key shared understandings of Members:
  - Good faith use of the system:
    - Health vs. commercial/industrial policy objectives
  - All reasonable measures to prevent diversion
  - Information on manufacturing capacities ("*how*")
  - Expeditious review in TRIPS Council and good offices of DG or Chair of TRIPS Council
  - List of voluntary partial/full opt-out countries

Implementing Legislation

- 12 Members have formally notified legislation to TRIPS Council
- Can be divided in three categories:
  - exclusively for export:
    - Norway; Canada; India; EU; Switzerland; Albania; Croatia
  - for import purposes only:
    - Singapore (in situations of extreme urgency)
  - both as importers and exporters:
    - Hong Kong, China; Philippines; China; Korea

Use of Paragraph 6 System

- Example of Rwanda / Canada
- Functioning of the System: is it delivering effective and expeditious results ?
  - TRIPS Council looks into narrow and broader aspects (see annual review 2010)
  - Concerns expressed:
    - Too complex and bureaucratic
    - Limited number of acceptances of the Protocol
  - Others argue that:
    - Rwanda/Canada example shows that System can work
    - Less need to use System due to other measures enhancing access to medicines

Legal Instruments

- General Council Decision of 30 August 2003:
  - contains three waivers
  - in effect since 30 August 2003, terminates when amendment replaces it for each Member
  - called for the TRIPS Council to prepare permanent amendment (para.11)
- GC Decision of 6 December 2005 / Protocol Amending TRIPS proposes insertion of:
  - new Article 31*bis* consisting of 3 waiver provisions of August 2003 Decision
  - Annex setting out terms for using Paragraph 6 system
  - Appendix to Annex dealing with assessment of manufacturing capacities (former annex to August 2003 Decision)

  ⇒ *"technical exercise", no changes in substance to Paragraph 6 System*

Acceptance of the Protocol

- Submitted to Members for acceptance
  - how to accept the Protocol depends on domestic constitutional requirements
  - notifications to WTO:
    - need to refer to Protocol and clearly state that it is accepted
    - signature by Minister of Foreign Affairs / External Relations or by ambassador with powers to sign
- Period for acceptance runs until end 2013 (can be further extended if necessary)
- Takes effect upon acceptance by two thirds of membership:
  - status of acceptances

⇒ *Para.6 System under August 2003 Decision continues to apply until entry into force of amendment in a Member*

⇒ *Distinct from implementation of Paragraph 6 System*

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