Para. 6 of the Doha Declaration on TRIPS and Public Health
A South Centre Side Event

Geneva, 8 November 2016

Special Compulsory Licences for Export of Medicines

Roger Kampf, WTO Secretariat
I. Putting the System Into Context
Para.6: Part of a Holistic Approach
II.
Where the System Finds its Roots:
The Doha Declaration on the TRIPS Agreement and Public Health
A Blueprint for Policy Coherence on Public Health

WORLD TRADE ORGANIZATION

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking
What Doha Achieved

- Shapes framework for multilateral cooperation on IP and public health (in particular: **trilateral study**)
- Clarifies flexibilities (**exhaustion** and **compulsory licensing**)
- Helps governments to make full use of TRIPS flexibilities
- Reinforces understanding that TRIPS supports balanced and flexible IP framework responsive to broader policy agenda
- Extended LDC transition period
- Led to adoption of **Paragraph 6 System**
Selected WTO Members’ Role and Views

• Process initially led by EU
  – 2002 concept paper and subsequent communications (IP/C/W/339, 352, 416)

• African Group and individual members
  – Presented several proposals as of 2002 (IP/C/W/351, 437, 440)
  – Welcomed adoption of 2003 waiver decision as “historic moment” (WT/GC/M/82)
  – Subsequently called for “legally permanent and multilateral solution” (IP/C/M/39, 47)
    • Supported by LDC Group and ACP Group

• Flexibilities offered by the System:
  – “great assistance for developing countries in having access to affordable medicines” (IGDC, WTO General Council, 20 Feb. 2015)
What Multilateral Institutions Have Been Saying

• **WHO:**
  - Global Strategy and Plan of Action, Element 5.2
  - Called for stable international legal framework, (IP/C/M/37)
  - Noted full commitment to the Decision and its implementation (IP/C/M/45)

• Widespread calls within multilateral system for acceptance and implementation, e.g.:
  - UN Political Declaration on HIV/AIDS (7 June 2016) called “for early acceptance of the amendment to article 31 of the TRIPS Agreement…”
III. What the System Does and How it Works
The Para.6 System Has Been Conceived to Address...

...a *health* problem in the importing Member

...and a *legal* problem in the exporting Member
How the Para.6 Waivers Work

Article 31(f): CL to predominantly supply domestic market
Waiver
Possibility to authorize production under CL exclusively for export

Article 31(h): Remuneration to be paid to right holder
Waiver
Remuneration, based on economic value in importing country
No remuneration in importing country

Article 31(f): CL to predominantly supply domestic market
Waiver
Export of imported/locally produced medicines to other RTA members w/o further notification
IV. Why and How to Accept the Protocol Amending TRIPS
Why to Accept the Protocol

- Formal consent to be bound by amendment
- Transforms political commitment by all Members into permanent part of TRIPS
- Signalling function: first ever amendment to WTO agreements, reflecting importance attached to public health
- Supported by the international community, including UN organizations
How to Accept the Protocol

• Submitted to Members for acceptance
  – How to accept the Protocol depends on domestic constitutional requirements
  – WTO notification to meet formal requirements
  – See hand-out on « how to accept TRIPS amendment »

• Period for acceptance runs until end 2017 (can be further extended if necessary)

• Takes effect upon acceptance by two thirds of membership
Two Third Threshold: A Moving Target

- Members yet to Accept
- 2005-2015 NM Deposited Instruments
- 2005-2015 New Members Accumulated
- Instruments Deposited Accumulated
- Threshold

Yearly breakdown from 2005 to 2016 Q3:
- 2005: 100
- 2006: 100
- 2007: 101
- 2008: 102
- 2009: 102
- 2010: 102
- 2011: 102
- 2012: 105
- 2013: 106
- 2014: 107
- 2015: 108
- 2016 Q1: 108
- 2016 Q2: 108
- 2016 Q3: 110

Threshold is indicated with a black circle on the right side.
V.
By Whom and How Has the System Been Implemented?
WTO Members / Observer with specific legislation to act as exporters

WTO Members with specific legislation to act as exporters and importers

WTO Members with specific legislation to act as importers

Who Has Implemented the System?

Only applies to Zanzibar
Pharmaceutical Exports in 2013 for 149 Countries (in US$MN)

- **Total:** 490,984.96
- **WTO Members with Implementing Legislation:** 390,373.34
- **Other Countries w/o Implementing Legislation:** 100,611.62

Covers 80% of World’s Exporters

(http://www.ifpma.org/fileadmin/content/Publication/2014/IFPMA_-_Facts_And_Figures_2014.pdf)
# Comparing Regular and Special CL

<table>
<thead>
<tr>
<th>Selected Conditions</th>
<th>Reg. CL</th>
<th>Spec. CL</th>
<th>+ Para.6 Implementing Measures (IM)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-grant Conditions</strong></td>
<td></td>
<td></td>
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<tr>
<td>Prior efforts to obtain VL, except extreme urgency/public non-commercial use</td>
<td>✓</td>
<td>✓</td>
<td>Some IM: limit negotiating period (28 days to 6 months)</td>
</tr>
<tr>
<td>Within reasonable period of time</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Quantity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limited to purpose of authorization</td>
<td>✓</td>
<td>✓</td>
<td>One IM: accelerated procedure to adjust quantities</td>
</tr>
<tr>
<td>Limited to needs of importing country (IC)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limited to purpose of authorization</td>
<td>✓</td>
<td>✓</td>
<td>One IM: simplified procedure to review</td>
</tr>
<tr>
<td>Can be terminated earlier</td>
<td>✓</td>
<td>✓</td>
<td>One IM: limited to two years, once renewable</td>
</tr>
<tr>
<td><strong>Remuneration</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Based on economic value of authorization</td>
<td>✓</td>
<td>✓</td>
<td>Some IM: specific guidance how to calculate remuneration</td>
</tr>
<tr>
<td>Based on economic value in IC</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Not to be paid by IC</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Regulatory Approval</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ø</td>
<td>Ø</td>
<td>Some IM: set regulatory requirements</td>
</tr>
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VI.

Use of the System and Its Operation
Use of Paragraph 6 System: Example of Rwanda-Canada

- **June 06**: Health Canada approves Apo-Triavir
- **To July 07**: No request for Apo-Triavir
- **July 07**: Apotex seeks VL from right holders to use patents
- **July 07**: Rwanda notifies its intention to import under Para.6
- **Sept. 07**: Apotex files CL application to produce/export to Rwanda
- **Sept. 07**: CL granted by Patent Commissioner in Canada
- **Oct. 07**: Grant of CL notified to WTO by Canada
- **May 08**: Apotex announces it has won public tender in Rwanda
- **Sept. 08-09**: Shipment of medicines to Rwanda
Use of Paragraph 6 System: Is It Functioning Well?

- TRIPS Council looks into narrow (e.g. annual review 2015) and broader aspects (e.g. annual review 2010)

- Concerns expressed:
  - Too complex and bureaucratic, including as regards certain implementing legislation
  - Limited number of acceptances of the Protocol
  - Political and trade ramifications

- Others argue that:
  - Rwanda/Canada example shows that System can work
  - Less need to use System due to other measures enhancing access to medicines
  - No member has demonstrated obstacles to use of the System
To Facilitate Use: Model Notifications

- See illustrative guide on dedicated WTO webpage:
  http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm
VII.
Way Forward
Selected Issues for Consideration

• How to:
  – use the System as a practical procurement tool
  – integrate Ministries of Health and procurement agencies more actively in process
  – ensure that national implementing measures put in place an easy to use system
  – make best use of information resources
  – make participation economically viable and sustainable for potential suppliers
  – clarify that the use of the System is widely supported

• What kind of additional guidance is needed in order to facilitate implementation and use

• What concrete lessons can be drawn from past experiences
REPORT ON THE WORKSHOP ON THE WTO DECISION ON ACCESS TO MEDICINES AT AFFORDABLE PRICES FOR COUNTRIES WITH NO OR INSUFFICIENT MANUFACTURING CAPACITIES, ORGANIZED BY THE COMMONWEALTH SECRETARIAT IN CO-OPERATION WITH THE ACP GENEVA OFFICE AND THE AGENCY FOR INTERNATIONAL TRADE INFORMATION AND COOPERATION (AITIC) (GENEVA 12-14 OCTOBER 2004)

The following communication, dated 9 February 2005, is being circulated at the request of the Delegation of Barbados on behalf of the Group of Commonwealth Developing Countries and the Commonwealth Secretariat.
To Be Considered in Practice

• Early notification of anticipated needs to share information about procurement:
  – No obligation to use System in the end

• Notification to increase bargaining power:
  – Example of Rwanda

• Measures to make System commercially viable:
  – Regional approaches and joint notifications to enhance economies of scale

• Potentially increasing need for the System:
  – New generations of patented medicines
  – In the event of a global pandemic

• For RTA waiver:
  – Possibility to support local production