25 Years of the TRIPS Agreement – Past, Present and Future
24 November 2020

Evolution of the TRIPS Agreement: Doha, the Public Health Dimension & Subsequent Cooperation

Roger Kampf, WTO Secretariat
I.
Setting the Scene:
TRIPS & Health –
Working in a Complex Environment
Pulling the relevant policy dimensions together: Intersections between health, IP and trade
Ensuring policy coherence

Different Levels & Actors

Multilateral Framework:
• WHO
• WIPO
• WTO

Bilateral & Regional Trade & Investment Agreements

Regional Framework:
• ARIPO
• OAPI
• EUIPO
• others

Key actors:
• IGOs
• Regional Organizations
• Governments
• Private Sector
• Civil Society

Domestically:
• IP policy & strategy
• Legislation
• Courts
Link Between Public Health, IPRs and Trade: Key Questions Framing the Debate

• IPR as an important factor for development of new medicines, but: concerns expressed about effect on prices

How best to reconcile the need for incentives to invest in R&D and access to medicines?

• Importance of flexibilities recognized, but: need to preserve balance of rights and obligations

How best to achieve an optimal balance between IPRs and public health?

• TRIPS as part of wider national and international action to address health problems, but: cannot solve issues on its own

How best to ensure capacity to deal with innovation-access cycle in a holistic manner?
II. Doha Declaration & Subsequent Instruments: Affirming Capacity to Respond to Pressing Needs & Making TRIPS Part of the Broader Picture
Why to Adopt the Doha Declaration?

• **Context:**
  • HIV/AIDS crisis in Africa in late 1990s
  • Coincides with TRIPS implementation by developing countries in 2000

• **Purpose:**
  • Respond to concerns about impact of strengthened IPR protection on access to medicines

• **Significance:**
  • Different views about the nature and scope of TRIPS flexibilities
  • Interpretation of TRIPS flexibilities in a broad pro-public health manner
  • Concerns about pressure from trading partners not to use existing flexibilities
Doha Declaration: A Blueprint for Policy Coherence

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
Doha Declaration: A Milestone for the WTO

Main Achievements

- Basis for multilateral cooperation
- Clarification
- Support for use of existing flexibilities
- Addition of new flexibilities
- Guidance in DS cases

**CLs:**
- Right to grant
- And to determine grounds

- Right to determine what constitutes situation of extreme urgency
- Freedom to choose exhaustion regime
- Special Compulsory Licensing System
- LDC Transition Period in pharma sector
Clarifying Policy Options: The Example of Standard Compulsory Licences

- Implementation (WIPO document SCP/30/3, 2019):
  - 156 jurisdictions provide for CL/government use licences
  - Plus several regional instruments
- Use:
  - Initially limited in most jurisdictions
  - But: increased use in relation to pharmaceutical patents since 2010
  - Trilateral Study analyzes 34 selected cases in which CL/government use licences have been considered or granted
  - Other sources report 108 cases since 2001 with CL granted in 74 cases

### Table 4.1: Selected country experiences with compulsory licences and government-use licences

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Medicine</th>
<th>Type of licence</th>
<th>Outcome</th>
<th>Indication (non-exhaustive)</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2005</td>
<td>LPV/r</td>
<td>CL</td>
<td>Not issued</td>
<td>HIV/AIDS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2007</td>
<td>Efavirenz (EFV)</td>
<td>CL</td>
<td>Issued</td>
<td>HIV/AIDS</td>
<td>By 2012, the estimated savings for the Brazilian Government reached US$ 236.8 million.</td>
</tr>
<tr>
<td>Colombia (see Box 4.2)</td>
<td>2014</td>
<td>Imatinib mesylate</td>
<td>CL</td>
<td>Not issued</td>
<td>Leukaemia</td>
<td>Price control applied.</td>
</tr>
<tr>
<td>Ecuador</td>
<td>2010</td>
<td>Ritonavir (RTV)</td>
<td>CL</td>
<td>Issued</td>
<td>HIV/AIDS</td>
<td>Maximum price for 30 x 100 mg RTV tablets set at US$ 29.40 from US$ 289.99, 4 per cent royalty rate based on tiered royalty method (TRM) or 0.42 per cent of the US price.</td>
</tr>
<tr>
<td></td>
<td>2013</td>
<td>Abacavir/lamivudine (ABC/3TC)</td>
<td>CL</td>
<td>Issued</td>
<td>HIV/AIDS</td>
<td>Maximum price for ABC set at US$ 6.11 from US$ 24.83, 5 per cent royalty rate based on TRM. A 30–70 per cent saving on the cost of purchase has been reported by the Ecuadorian Ministry of Public Health.</td>
</tr>
</tbody>
</table>

Creating Additional Flexibilities (1): Trade-Related Compulsory Licences for Export

• Para.6 Doha Declaration
  • Identified difficulties for Members with insufficient/no manufacturing capacities in the pharmaceutical sector to make effective use of CL

• Concern: availability of supply from generic producers in third countries
  • Art. 31(f): production under CL "predominantly for the supply of the domestic market"
  • Countries with important generic industry obliged to provide full patent protection for pharma products since 2005

• The solution: derogations from restrictive conditions in Art. 31(f) and (h) TRIPS
• A System that addresses...

...a health problem
In the importing Member

...a legal problem
In the exporting Member
Steps Towards Putting the System in Place

Members’ Voices (30 Jan. 2017):

• “Marks a significant step forward for the Members of the WTO” (LDC Group)

• “Truly a historic measure that has been taken, the first ever amendment to the WTO Agreements” (Bangladesh)

• “Important because it demonstrates that the WTO is capable of responding in an adequate way to essential needs beyond trade policy” (EU)

• “Provides legal certainty to our quest for affordable medicines” (African Group)

• “An important signal to everyone that this Organization is not only about trade liberalization” and “the System is part of a broader picture which includes other important aspects” (South Africa)

• 30 August 2003
  • Adoption of waiver decision

• 6 December 2005
  • Adoption of Protocol Amending TRIPS

• 23 January 2017
  • Entry into force of permanent TRIPS Amendment
Creating Additional Flexibilities (2): LDC Transition Periods and Waivers

1. Initial Transition Period
   - 14.11.2001

2. Extension
   - 1.1.2006

3. Extension: TRIPS Obligations / All Sectors
   - 1.7.2015

4. Article 70.9 Waiver
   - (General Council Decision)
   - 1.1.2006

5. Extension
   - (General Council Decision)
   - 1.7.2013

   - 1.1.2016

7. Art. 70.8 Waiver
   - (General Council Decision)
   - 1.1.2016

   - 1.7.2021

9. Initial Transition Period
   - 1.1.2033
III.

Cooperation: Evolving from Silos to Inclusiveness
Intensifying Cooperation with External Partners

- More than 10 years of trilateral cooperation: WHO, WIPO, WTO
  - Pulls expertise in different areas together
- Reach-out to other IGOs and key stakeholders
- For this to be effective: need to mirror close cooperation at domestic level
WTO Secretariat: Not Working in Silos Anymore!

From Working in “silos”

To health contact group in 2013

To COVID-19 Trade Monitoring Group

2001: Adoption of Doha Declaration on TRIPS&Health
2007: Adoption of WIPO Development Agenda
2008: Adoption of WHO GSPA-PHI
2010: Since 2010: Enhanced trilateral cooperation
2013: Series of Trilateral Symposia
2020: Trilateral Study, 2nd edition
Exemplifying Joint Secretariat Efforts to Ensure Transparency and to Build Capacity

COVID-19 Related Work:

➢ Regularly updated list of measures regarding trade-related aspects of IPRs, goods and services

➢ Information notes, e.g.:
   • The TRIPS Agreement and COVID-19 (Oct. 2020)
   • How WTO Members have used trade measures to expedite access to COVID-19 critical medical goods and services (July 2020)

➢ Vaccines Checklist of Issues with Trade Impact and Infographic (November 2020)

➢ Other resources:
   • List of Members’ proposals
   • List of Members’ notifications
   • Enquiry points

https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm
IV. Capacity Building: Evolving Towards an Integrated and More Tailored Approach
Annual Trade and Public Health Workshop

- Organized by WTO Secretariat since 2005
- Initial focus on IP
- Integrated approach since 2014
- Based on close collaboration with WHO and WIPO Secretariats
- Organisation of similar activities at regional and national level
News item and presentations available at:


WTO Technical Workshop
Organized by the WTO Secretariat
with the cooperation of
the WHO and WIPO Secretariats

An Integrated Health, Trade and Intellectual Property Approach to Address the COVID-19 Pandemic

21 October 2020

12:00 to 15:00 (Geneva time)
WHO-WIPO-WTO Study (2nd edition, 2020)

Full publication: https://www.wto.org/trilateralstudy2020

## Trilateral Symposia: Gathering Empirical Data

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
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<tbody>
<tr>
<td>2019</td>
<td>Technical Symposium to address opportunities and challenges of cutting-edge health technologies</td>
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<tr>
<td>2018</td>
<td>Trilateral Symposium to examine how innovative technologies can promote health-related SDGs</td>
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<tr>
<td>2016</td>
<td>WHO, WIPO, WTO Symposium to examine how to foster appropriate use of antibiotics, access and innovation</td>
</tr>
<tr>
<td>2014</td>
<td>Symposium on Innovation and Access to Medical Technologies: Challenges for Middle-Income Countries</td>
</tr>
<tr>
<td>2013</td>
<td>Technical Symposium on Medical Innovation — Changing Business Models</td>
</tr>
<tr>
<td>2010</td>
<td>Symposium on Access to Medicines: Pricing and Procurement Policies</td>
</tr>
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V.

Personal Thoughts: Looking at the Way Forward
Taking Stock

• Experience from TRIPS implementation shows positive developments:
  • Responding to pressing public health needs
  • Placing TRIPS into broader context, developing from an IP-focused to an integrated approach
  • Enhancing and exemplifying cooperation both in house and key stakeholders
  • Demonstrating
    • Possible positive sum impact of working within the existing framework
      • Example: COVID-19 vaccines development within record time
    • Need for non-static legislation, subject to constant review to adapt to specific circumstances
      • Example: streamlining and facilitating domestic compulsory licensing provisions in the context of COVID-19 pandemic

• How to build on this experience?
Future Developments: What Is Needed?

• Empirical data and evidence to support informed decision-making
• More tailored capacity building responding to specific needs of Members
• Transparency, including easy access to patent information and patent landscape reports

• Further development of integrated approach:
  • Government strategy for R&D and access, including financing and IP management
  • Efficient and expeditious marketing approval mechanisms
  • Transparent and efficient rules governing public procurement
  • Legal and institutional framework for the effective application of competition law
  • Alignment of industrial policy objectives with public health goals
  • Consideration of broader trade issues, in particular as regards export/import opportunities

• Doha Declaration 2.0?