Compulsory licensing: the Brazilian implementation experience in the framework of WTO

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Background to the TRIPS and Public Health Controversy

- Intellectual property rights
  - Developed countries
  - Push for patent protection

- TRIPS

- Public health
  - Developing countries
  - Push for greater access to drugs
• Production of patented product without the consent of the patent owner
• Royalty fee to compensate the patent owner
• Right of the WTO member to decide when to use
• TRIPS does not and should not prevent WTO members from taking public health actions (¶4)
• TRIPS can and should be interpreted to support WTO members’ right to protect public health and promote access to medicines for all (¶4)
• Each WTO member has the right to grant compulsory licenses (¶5.b)
• Each WTO member has the right to determine what constitutes a national public health emergency (¶5.c)
EFAVIRENZ CASE
Brazilian Universal Health System

• 1988’s Constitution - ‘Health is an universal right and a duty of the State’

• Universal access to ARVs guaranteed by law in Brazil in 1996

• Centralized procurement – MoH, only buyer
Efavirenz Case

- Brazilian Law of Industrial Property: 1996 (Incorporation into domestic law: the obligation to grant patents for medicines – TRIPS)

- 75,000 patients on EFV in 2007

- The patent owner initially offered a price of US$1.59 per pill (end of negotiation: US$1.11)

- EFV in Thailand: US$ 0.65 per pill
• Ordinance #886 (April 24th 2007): Public Interest

• Presidential Decree #6.108 (May 4th 2007): granted compulsory license (CL) of Efavirenz, for public non-commercial use:
  – Duration: 5 years, allowing extension for equal period
  – Royalty fee for the patent owner: 1.5%
  – Patent holder must provide the necessary and sufficient information for the reproduction of the object
  – Renewal of CL by the Decree # 7.723 (May, 2012)

• National production in 2009
Efavirenz Case

• Estimated ‘savings’ until 2012: US$ 237MM (US$ 30MM/year)

• Average annual cost per patient after CL: from US$580 to US$166
Lessons learned and Challenges

• Access to health is a public matter
• Search for more efficient mechanisms to pay less, including flexibilities provided by the declaration of the Doha on TRIPS and Public Health
• Need for cooperation and exchange of information among developing countries
• Discuss effective transfer of technology
30 years of the Brazilian HIV response

- State Policy, not a Government Policy
- Brazil exercises its leadership and takes risks
- History of strong partnership with civil society
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Obrigada! Thank you!

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