The Brazilian experience:
the campaign for access to lopinavir/ritonavir
and efavirenz compulsory license

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Introduction

• Strong civil society participation at recent democratization process demanding for right to health
• 1988: Constitution: universal public health system
• 1996: Law of universal access to HIV/AIDS treatment (today 200.000 people are on antiretroviral therapy in Brazil)
• 1996: changed IP law to become WTO TRIPS Agreement compliant
Introduction

• Long period of treatment, need to switch to newer drugs
• No local production - great impact in public health policies – higher prices of medicines
• Intellectual Property Rights identified as a barrier to access to medicine
• 2005: MoH report – sustainability of HIV/AIDS program is at risk
• 2005: National Health Counsel – recommended CL for lopinavir, efavirenz and tenofovir
GTPI/Rebrip

- 2003: GTPI/Rebrip (NGOs, unions, social movements, researchers)
- Many actions related to the use of TRIPS flexibilities and resistance against TRIPS-plus measures
- I’ll focus my presentation on:
  - Campaign for access to lopinavir/ritonavir
  - Efavirenz compulsory license
CL and price reduction

- Until 2005: threats to issue CL - backed by local production capacity
- Pharmaceutical companies preferred to reduce prices than to have their patents licensed
- Threats were not enough and price reductions stopped
- 7 medicines produced in Brazil – 20% of budgeted for ARV
- 9 branded medicines – 80% of budgeted for ARV
- 19% of the budget for ARV spend on lopinavir/r
- 21% of the budget for ARV spend on efavirenz
Campaing for access to lopinavir/r

- 2005 – Lopinavir/ritonavir (Kaletra®) – Abbott
- Main patent expires in December 2015
- Government took a first step to issue CL
- But made a deal with the company and did not issue a CL (TRIPS-plus measures)
  - no use of flexibilities in any of lopinavir/r patents
  - no price reductions until 31 December 2011
  - no technology transfer
Campaing for access to lopinavir/r

- 2005: GTPI LAWSUIT DEMANDING CL
- Brazilian IP law: CL in case of national emergency or public interest
- Judiciary:
  - CL is stealing – clear lack of knowledge about TRIPS flexibilities
  - Fear of retaliation - US Special 301 report
  - Fear of shortage – no generic available; lack of local production capacity
- Appeal – final decision pending
Global Kaletra Campaign

- 12 countries (Brazil, China, Colombia, Peru, Ecuador, USA, Malaysia, India, Indonesia, Thailand, Vietnam, Sint Maarten)
- Brazil: GTPI LC case
- Brazil: GTPI 2 patent oppositions (against evergreening — patent protection from 2017 to 2024);
- Brazil: GTPI challenged the constitutionality of the patent — case still pending in Constitutional Court (granted through a mechanism known as “pipeline” — revalidated patents granted in other countries and that were already in the public domain in Brazil - 1182 patent applications – 745 for medicines - ARVs, cancer, cardiovascular, high cholesterol, esquizofrenia, etc)
- 2012: Lower Judiciary decision annulled the patent
Compulsory License - Efavirenz

- 2007: CL ISSUED FOR EFAVIRENZ (ARV) – Merck
- 1996: Patent granted through pipeline mechanism (expires on August 2012)
- 2007: 75,000 thousand patients on EFV
- 2007: Merck offered a price reduction of 30% (US$1.11 per pill - US$ 0.65 per pill in Thailand)
- Brazil considered this unacceptable
Compulsory License - Efavirenz

- May 2007: CL issued on the ground of public interest, for public non-commercial use
- Royalty fee for the patent owner (1.5% on the cost of the finished product)
- Patent owner obligated to transfer knowledge and information necessary to reproduce the patented medicine
Compulsory License - Efavirenz

• Merck (original price): US$ 580 ppy
• India (importation of generics): US$158 ppy – 1/3
• Brazil (2009 – local production): US$ 279 ppy – ½

• Total savings from 2007-2011 with the Compulsory License was around US$ 103,600,000
• With the compulsory license Brazil has saved 58,47% buying from generic suppliers
Compulsory License - Efavirenz

• Problem: local prices are higher than best available price at international market
• price to pay for local production?
Compulsory License - Today

• 2011: UN High Level Meeting Non Communicable Diseases - Dilma’s speech – use of compulsory license beyond AIDS
• What we see: moving towards voluntary licenses
• Lack of transparency – new access to information law – “classified information”
“NO PATENTS, NO PROBLEM”
THANK YOU

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