‘Paragraph 6 System’ and Compulsory License for Access to Medicines

HU Yuanqiong
Senior Legal and Policy Advisor
Access Campaign, Médecins Sans Frontières
yuanqiong.hu@geneva.msf.org

South Centre, TRIPS Council side event, Geneva, November 08, 2016
MSF and Access to Medicines

Médecins Sans Frontières (MSF), founded in 1971
-international, independent, medical humanitarian organization
-delivers emergency aid to people affected by armed conflict, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries.

“Today, a growing injustice confronts us. ……

Life saving essential medicines are either
- too expensive,
- are not available because they are not seen as financially viable,
- or because there is virtually no new research and development for priority tropical diseases.

This market failure is our next challenge.

The challenge however, is not ours alone. It is also for governments, international government institutions, the pharmaceutical industry and other NGOs to confront this injustice.

What we as a civil society movement demand is change, not charity.”
Challenges to Access to Medicines

Affordability as a continued battle --
https://www.youtube.com/watch?v=3Ug3LbVRuhw

Main TRIPS flexibilities

- Strict patentability criteria
- Compulsory license
- Parallel import
- Anti-competition

Affordability
Availability
Suitability
Generic Competition as a Catalyst for Price Reduction

**GRAPH 3: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.**
The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.

Today: Still Unaffordable

- HIV: the price of a third-line regimen is more than 17 times higher than the recommended first-line.

- post-TRIPS + FTA era sees slower pace of forming generic competition at global level.

Dilemmas with Subsidies, Procurement and Price Discrepancies

- Manufacture cost of HPV is only $0.45-0.59 per dose (Chaevia Clendinen et. al., Manufacture Cost of HPV Vaccines for Developing Countries, Vaccine, October 2016)

- Duopoly continues as lacking of competition

- Subsidized price benefit will be lost when country gets categorised otherwise

- Role of patents in retain monopoly?
  – e.g. GSK patents on 2-dose regimen, age groups application, compositing new serotypes with existing technologies…
Use of August 30 Decision System: MSF’s Experience

• Paragraph 6 of the Doha declaration, November 14, 2001

  “We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem…….”

• WTO General Council Decision, August 30, 2003

  – Notification based mechanism to implement Para 6
  – Both countries issue compulsory license (if patented in both)
  – Anti-diversion requirement

  – So far only one test case between Canada and Rwanda in 13 years
Testing Canada’s Bill C9 - The Jean Chrétien pledge to Africa

- Canada being the first country enacted national law to implement August 30 decision (2004)

- MSF in need of Fix-dose-combination of ARV for HIV/AIDS treatment --- AZT/3TC/NVP

- MSF joined legislative consultation and approached generic producers in Canada to use the new law for exportation
Timeline of the story

• Oct 2003 – Jan 2004, legislative consultations on Bill C9
  – Issues of right of first refusal by patent holders, list of eligible countries removed; open for non-government procurement
  – List of eligible medicines remained
• May 2004, Bill C9 passed

• August 2004, MSF proposed 5 ARVs to be considered in using the law

• February 2005, Apotex agreed to produce AZT/3TC/NVP
• April 2005, Apotext trial batch out for testing

• May 2005, Bill C9 entered into force

• June 2005, MSF proposed to amend the Bill and eligible medicines list

• September 2005, AZT/3TC/NVP added to the list and Apotext applied for regulatory approval in Canada
November 2005, Apotex started negotiation with respective patent holders of AZT/3TC/NVP (GSK, BI); MSF started convincing potential importing countries

Same period, India produced generic AZT/3TC/NVP applied for WHO Pre-qualification

June 2006, Hetero got WHO PQ approval; MSF started procurement for its projects; shortly, Aurobindo got WHO PQ on the same product

July-October 2007, Canada and Rwanda notified WTO using August 30 decision

Canada/Rwanda remains the only case when August 30 decision is used
Has August 30 decision fulfilled the mandates set forth by Doha declaration?
Is this an effective and expeditious mechanism?
Intersection with Trade Agreements and IP Rules

1995 Agreement on Trade Related Intellectual Property Rights (TRIPS), WTO

Pre-TRIPS

- Non binding
- Diversified

Post-TRIPS

- Binding
- Unified/flexible

Patent on pharmaceutical products
Minimum 20 years protection
General criteria for patenting
Compulsory license incl. gov. use
Exceptions and limitations
Data protection
Parallel Import/ Voluntary License

TRIPS-plus provisions in free trade agreements (FTA)

Data exclusivity
Broad patentability
Patent term extension
Narrow exceptions and limitations
Limits compulsory license

Investor protection/ ISDS
Patent linkage
Border enforcement- goods in transit
Judicial enforcement- expanding scope of liabilities
What has changed in the past decade?

• Use of compulsory license for importation and production remains on medicines

• Excessive political pressures remain by industrial and governments, for instance:
  • Abbott announced withdrew of new drug registration in Thailand after a CL issued, 2007
  • Pharma association campaign in weakening patent law reform in South Africa which is intending to strengthen the CL mechanism, 2014
  • Use of CL conceived as ‘bad’ for trade, in lieu India on US Special 301 priority watch list after CL issued on medicines
• Practices of countries continue in light of Doha declaration since 2001
  ➢ 34 instances of compulsory licence
  ➢ 51 instances of government use
  ➢ 32 instances of LDC exception use

Recommendations [2.6.1 (a)-(e)] on TRIPS flexibilities and TRIPS-plus provisions

- Commitment and respect Doha declaration
- Curtail evergreening by adapting and applying rigorous definitions of invention and patentability
- Effectuate quick, fair, predictable and implementable compulsory licenses on medicines
- Revise Para 6 decision to enable swift and expedient export of medicines under compulsory license and consider a waiver and permanent revision of TRIPS to enable above
- Report pressures undermine the use of TRIPS flexibilities during Trade Policy Review
- Exclude public health harmful provisions in bilateral and regional trade and investment treaties with a public health impact assessment

• Thank you!

http://www.msfaccess.org