

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

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**MEDICINES
SHOULDN'T BE
A LUXURY**

www.msfacecess.org



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.



Nobel Peace Prize Lecture 1999

Dr. James Orbinski

Médecins Sans Frontières International
President

“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. ”

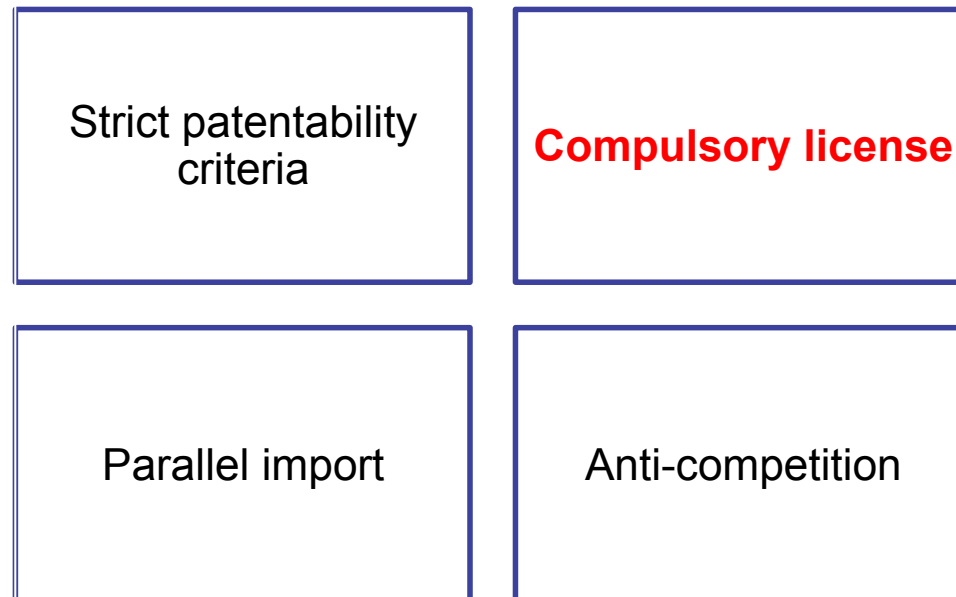


Challenges to Access to Medicines

Affordability as a continued battle --

<https://www.youtube.com/watch?v=3Ug3LbVRuhw>

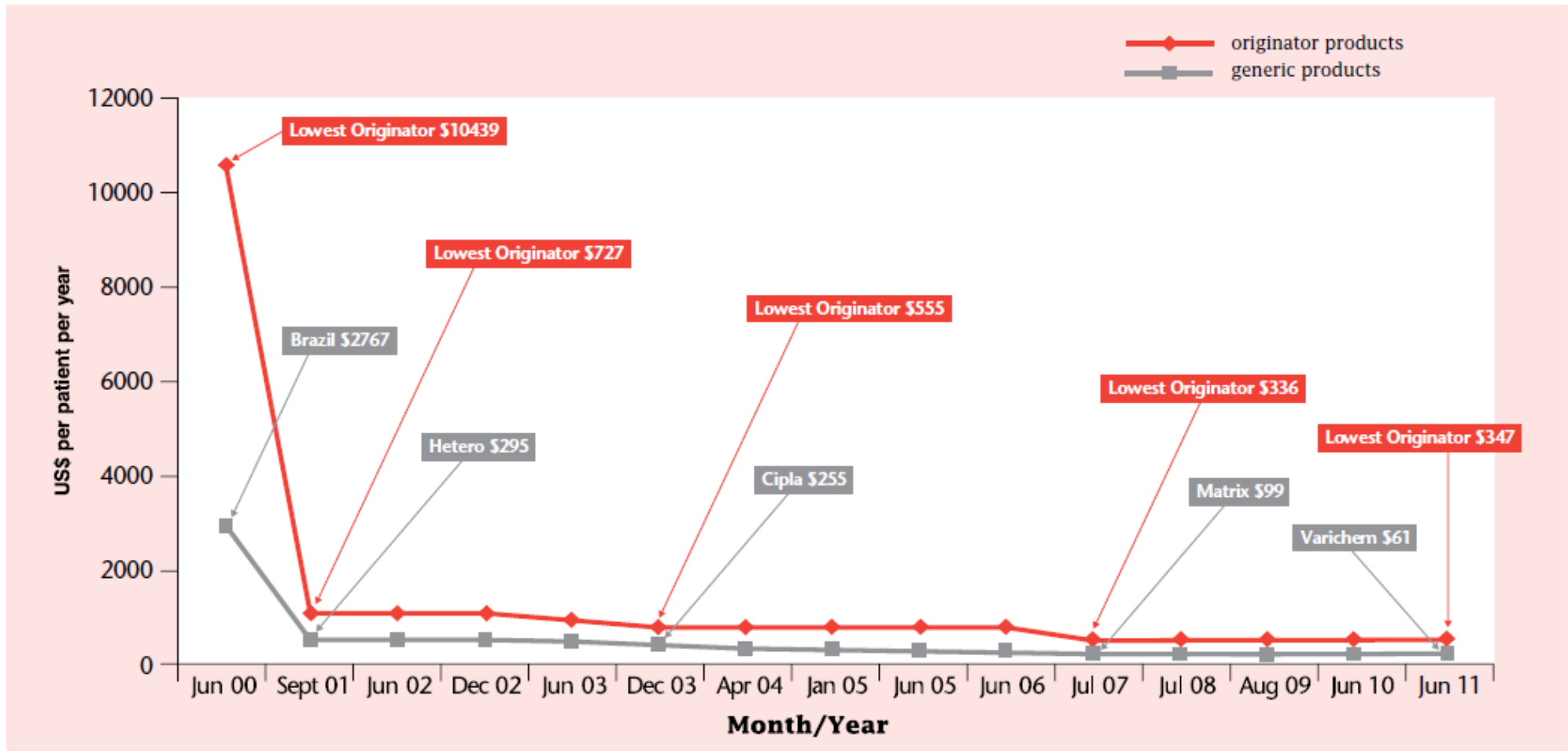
Main TRIPS flexibilities



Generic Competition as a Catalyst for Price Reduction

GRAPH 3: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.

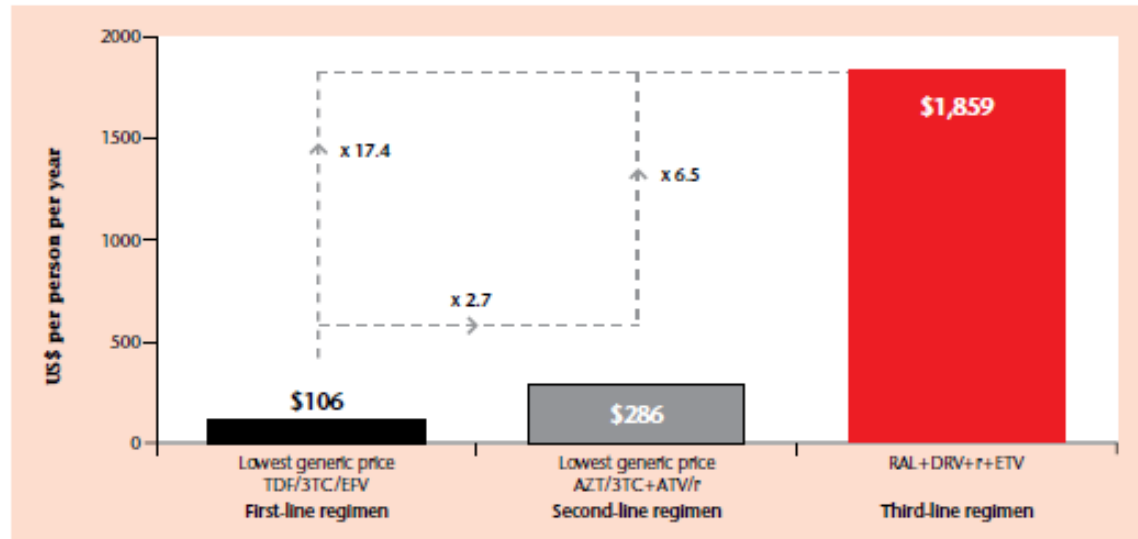
The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.



Source: MSF Untangling the Web of Antiretroviral Price Reductions, 15th Edition, July 2012

Today: Still Unaffordable

GRAPH 5: PRICE COMPARISONS OF FIRST-LINE, SECOND-LINE AND POSSIBLE THIRD-LINE TREATMENT REGIMENS

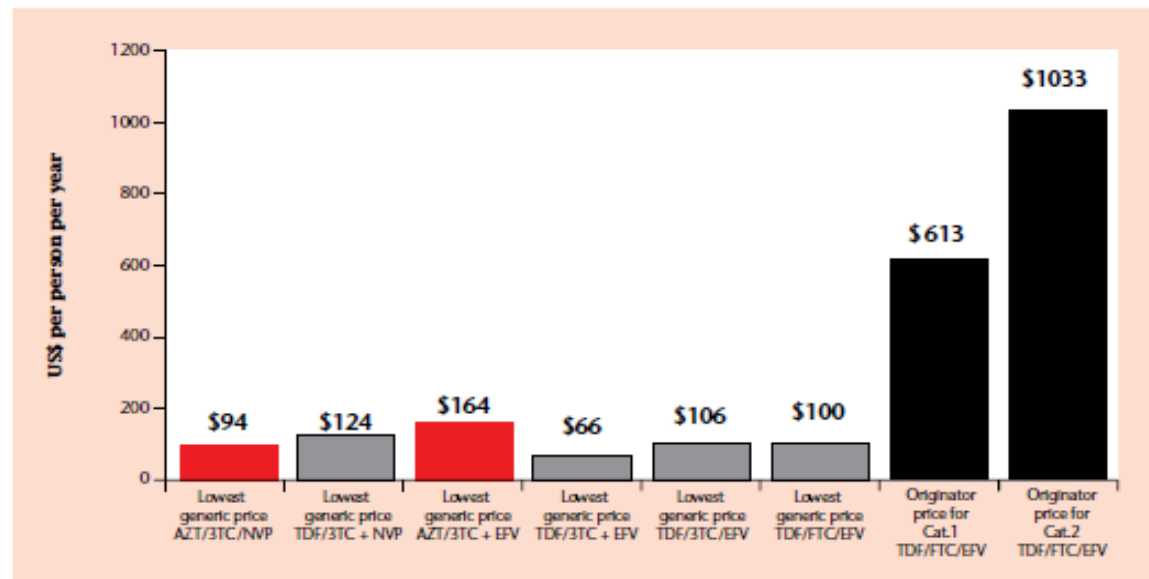


- HIV: the price of a third-line regimen is **more than 17 times higher** than the recommended first-line

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

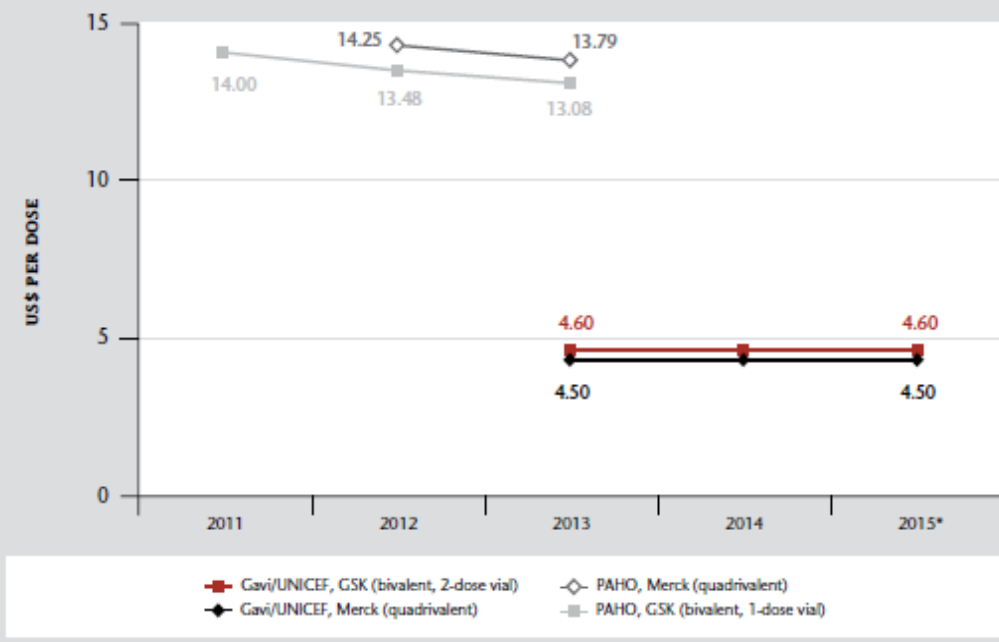
Source: MSF *Untangling the Web of antiretroviral Price Reductions*, 18th Edition, July 2016

GRAPH 2: THE PRICES OF DIFFERENT FIRST-LINE REGIMENS TODAY



Dilemmas with Subsidies, Procurement and Price Discrepancies

Graph 6: Price evolution of Human Papillomavirus Vaccines (HPV) for PAHO and Gavi/UNICEF



Sources:
PAHO Revolving Fund, UNICEF Supply Division

Source: *The Right Shot – Bringing Down Barriers to Affordable and Adaptive Vaccines*, MSF, January 2015,
http://www.msfaaccess.org/sites/default/files/MSF_assets/Vaccines/Docs/VAC_report_ProductCardHPV_ENG_2014.pdf

- 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, Apotex 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 Apotex applied for regulatory approval in Canada

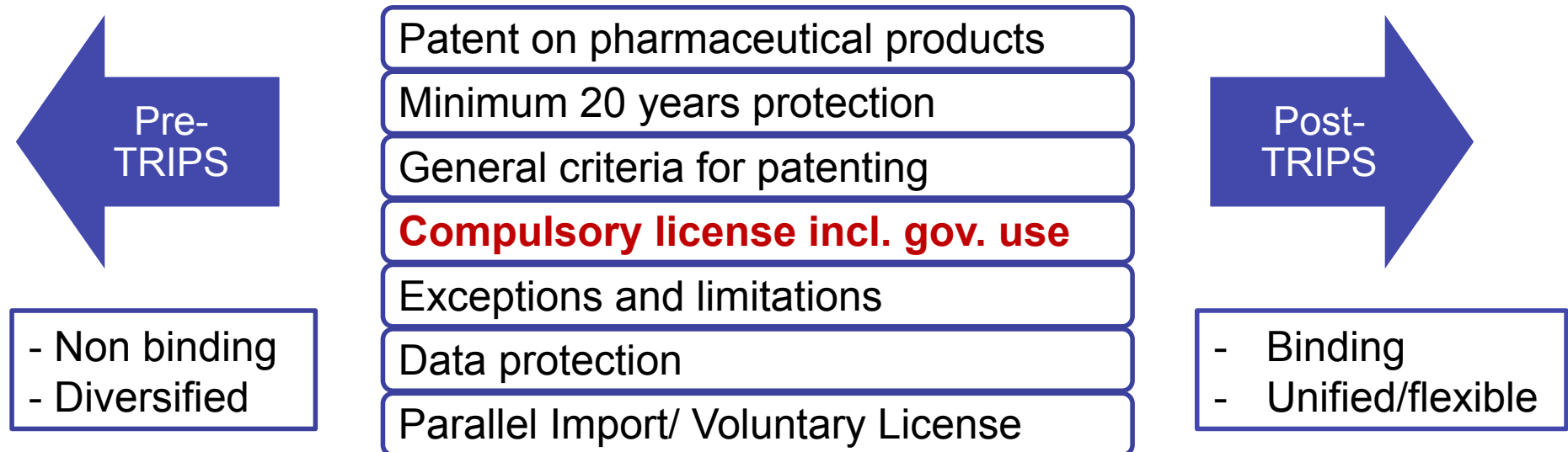


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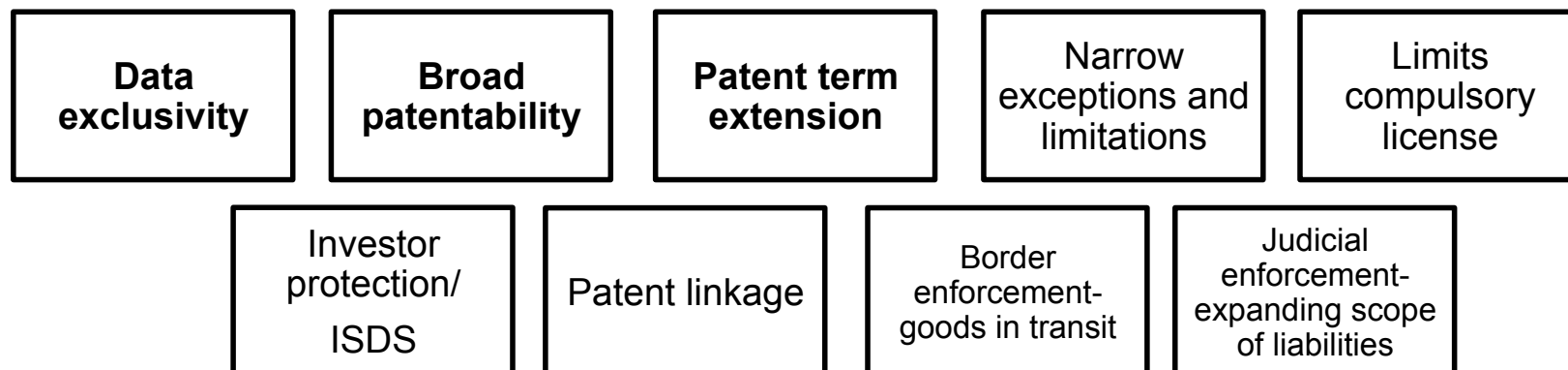
- November 2005, Apotex started negotiation with respective patent holders of AZT/3TC/NVP (GSK, BI); MSF started convincing potential importing countries
- Same period, India produced generic AZT/3TC/NVP applied for WHO Pre-qualification
- June 2006, Hetero got WHO PQ approval; MSF started procurement 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



TRIPS-plus provisions in free trade agreements (FTA)





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

FIGURE 4 INSTANCES OF COMPULSORY AND GOVERNMENT USE LICENCES (PER DISEASE AREA)

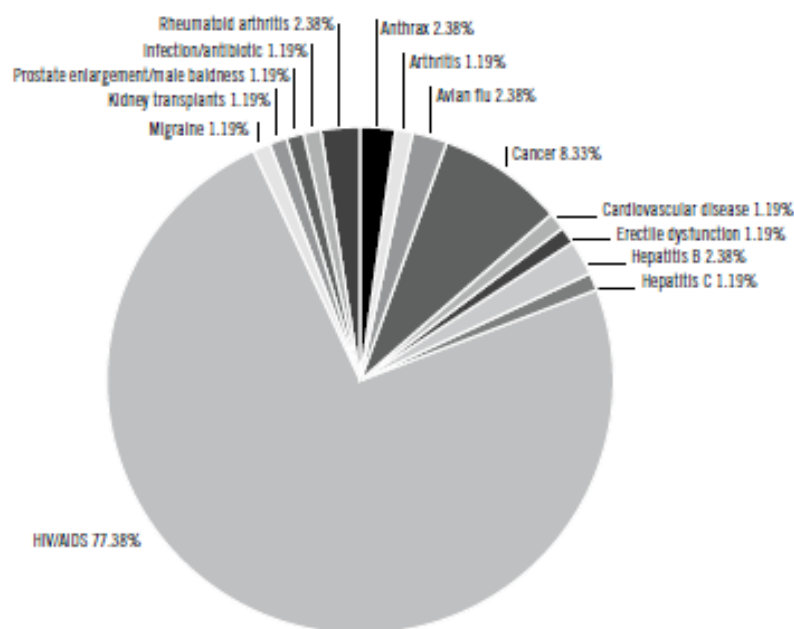


TABLE 1 COMPULSORY LICENSING INSTANCES BETWEEN 2001 AND 2014

CLASSIFICATIONS:

HIC = High-income country
DC = Developing country
LDC = Least-developed country

ORIGINATORS:

BI = Boehringer Ingelheim
BMS = Bristol-Myers Squibb
GSK = GlaxoSmithKline
MSD = Merck, Sharp and Dohme

COUNTRY	DATE	CLASSIFICATION	COMPOUND	ORIGINATOR	DISEASE
Argentina*	2005	DC	oseltamivir	Roche	Avian flu
Brazil*	2001	DC	neftravir	Roche	HIV/AIDS
Brazil	2007	DC	efavirenz	Merck	HIV/AIDS
Cameroon*	2005	DC	NVP,3TC, 3TC+AZT	BI,GSK	HIV/AIDS
Canada*	2001	HIC	ciprofloxacin	Bayer	Anthrax
Canada	2007	HIC	3TC+NVP+AZT	GSK,BI	HIV/AIDS
China	2005	DC	3TC/d4T/NVP	GSK,BMS,BI,	HIV/AIDS
China	2007	DC	3TC/d4T/NVP and LPV/r	GSK, BMS, BI, Abbott	HIV/AIDS
Ecuador	2010	DC	ritonavir	Abbott	HIV/AIDS
Ecuador	2012	DC	abacavir/3TC	GSK	HIV/AIDS
Ecuador	2014	DC	etoricoxib	Merck	Arthritis
Ecuador	2014	DC	mycophenolate sodium	Novartis	Kidney transplant
Ecuador	2014	DC	sunitinib	Pfizer	Cancer
Ecuador	2014	DC	certolizumab	UCB	Rheumatoid arthritis
Egypt	2002	DC	sildenafil	Pfizer	Erectile dysfunction
India	2012	DC	sorafenib tosylate (Nexavar)	Bayer	Cancer of the liver
Italy**	2005	HIC	imipenem/cilastatin	MSD	Infection/antibiotic
Italy**	2006	HIC	sumatriptan	GSK	Migraine
Italy**	2007	HIC	finasteride	MSD	Prostate enlargement/male baldness
Ivory Coast	2007	DC	ARVs (specified)	Various	HIV/AIDS
Kenya*	2004	DC	ARVs	GSK, BI	HIV/AIDS
Korea*	2002	DC	imatinib	Novartis	Cancer
Mongolia	2007	DC	specified medicines	Various	Various
Mozambique	2004	LDC	NVP, D4T, 3TC	BI, BMS, GSK	HIV/AIDS
Pakistan	2006	DC	ARVs (specified)	Various	HIV/AIDS

United Nations' Secretary General High Level Panel Report on Access to Medicines

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**

UN HLP on access to medicines report:
<http://www.unsgaccessmeds.org/final-report/>
 (September 2016)



- Thank you!

<http://www.msfaccess.org>