



Trade, TRIPS+ & Access to Medicines

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Health Action International

- A not-for-profit global network
- Established in 1981
- Made up by consumers, public interest NGOs, health care professionals, academics and individuals
- HAI Europe: European office, based in Amsterdam
- Working on access to medicines and rational use of medicines policy

Trade, TRIPS+ and Access to Medicines



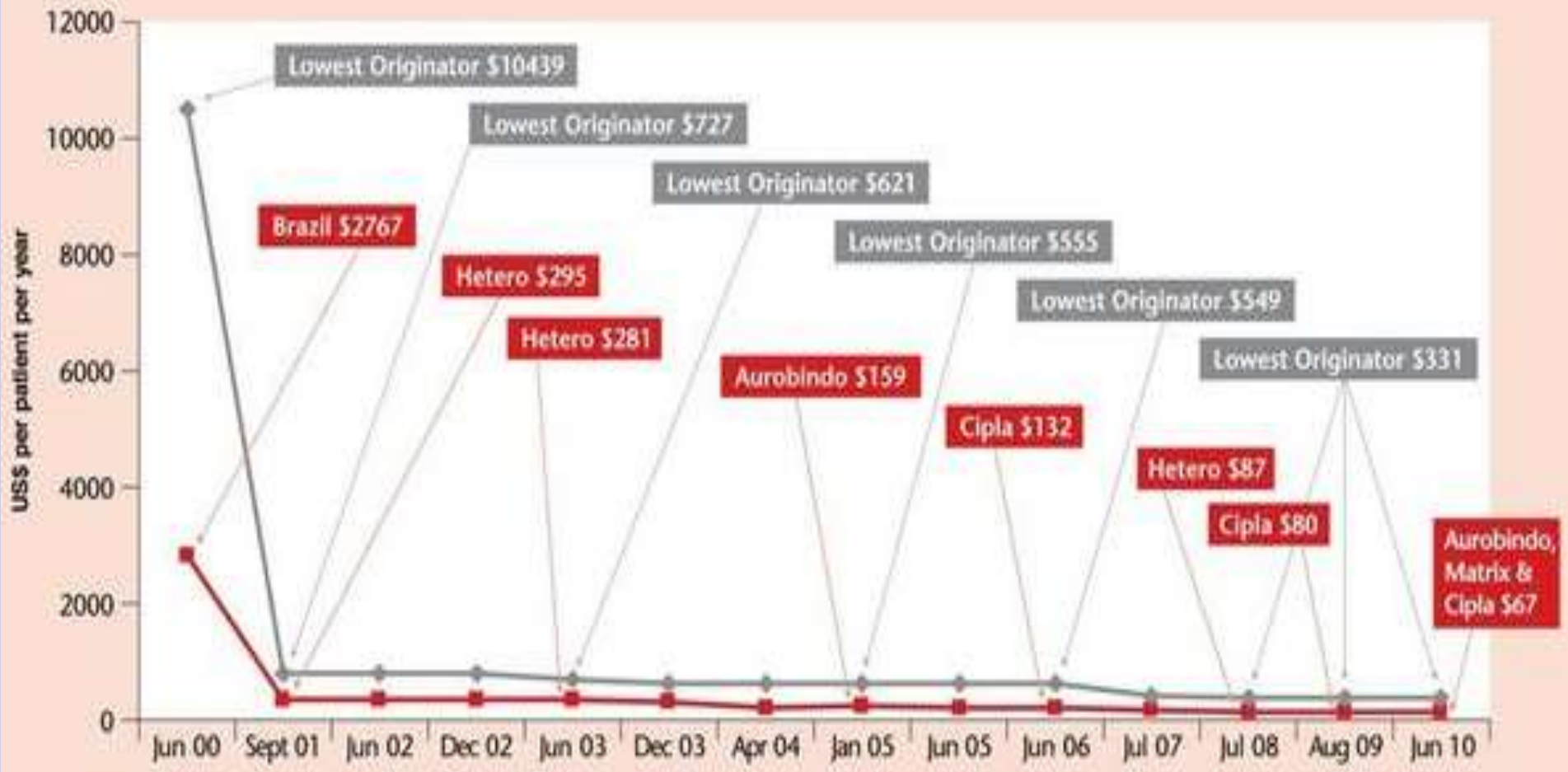
Outline presentation

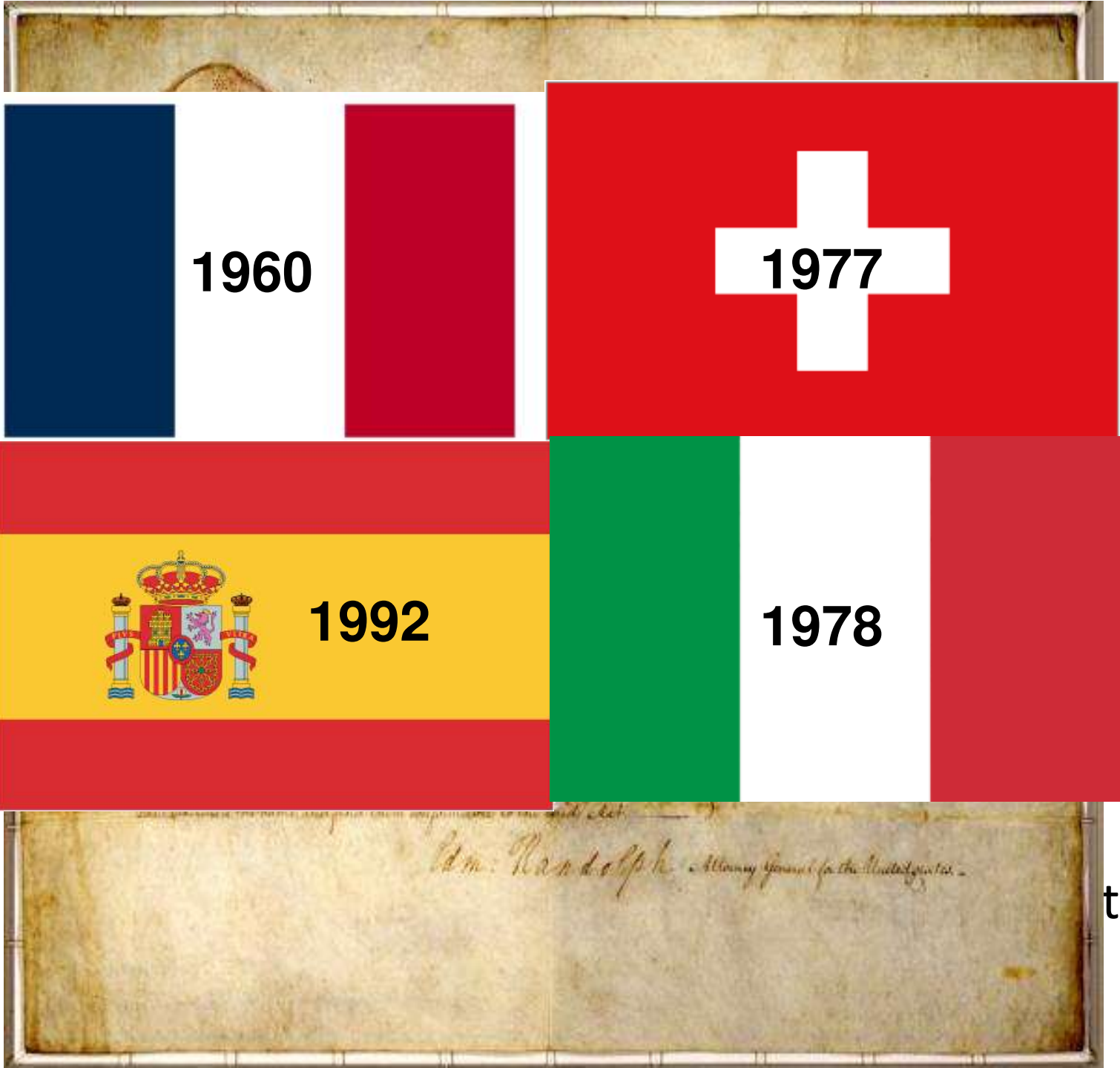
- Link access to medicines and trade: IP and medicines
- TRIPS Agreement (1994)
- 1990s HIV/AIDS crisis South Africa
- Doha declaration on TRIPS and Public health 2001
- TRIPS flexibilities & examples
- Opposition against use TRIPS flexibilities
- Push for TRIPS+ IP protection US and EU outside WTO: Free Trade Agreements
- Key TRIPS+ demands FTAs
- Case studies (Andean, India, recent developments)

Why important?

- Right to health widely acknowledged
- Yet, 2 billion people lack regular access to essential medicines in developing countries
- Price is a major barrier for access in developing countries
 - 20-60% health care spending
 - no universal health insurance
 - high out of pocket expenditure

IP and Medicines (I)





1960

1977

1992

1978

Edm. Randolph - Attorney General for the United States.

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How access to medicines became trade-related

- Since early 20th century: move to harmonize and internationalize IP protection, but no enforcement mechanisms
- In 1980s: intensified push for stronger international protection&enforcement IP
- Business community framed IP protection as a trade-related issue that belonged in WTO (General Agreement on Tariffs and Trade GATT)

Agreement on the Trade Related Aspects of Intellectual Property rights → (TRIPS)

TRIPS (1994)

how it came to pass

- **Proponents (developed):**
IP needed for investment,
development and technology transfer
- **Opponents (developing):**
 - IP will limit development and have immediate effect of increase prices
 - Implementation costs



Pressure + promised trade benefits: led to signature TRIPS Agreement in 1994

TRIPS: revolutionary

- 159 WTO members: minimum standards IP protection
- IP enforced through WTO dispute settlement system
- Pharmaceuticals:
 - Globalised 20 year patent monopolies
 - Requires product patents on medicines
- Recognises certain flexibilities+ transitions period - BUT: obliges countries to give up much of the diversity and flexibility in IP protection
- http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

After TRIPS: HIV/AIDS Crisis



After TRIPS: HIV/AIDS Crisis

- 6 February 2001: Generic Manufacturer CIPLA offers triple-therapy HIV/AIDS for 350 USD per patient/year (US: 15,000/year)
- Dramatic price difference: hammered message home that drug companies abused monopolies in fact humanitarian crisis
- <http://fireintheblood.com/>



Police guard WHO official after assaults and threats

Special report: Aids

John Vidal

The Guardian, Friday 31 August 2001 02:15 BST

A senior international civil servant has been attacked and threatened with death on three continents in the past three months in what appears to be a crude attempt to subvert his investigations into the pricing policies of the pharmaceutical industry.

German Velasquez, head of the drug action programme at the World Health Organisation in Geneva and a leading critic of the industry's policy of denying affordable drugs to poor countries, is being guarded by the police and told not to talk about what has happened.

Dr Velasquez, who is coordinating a WHO investigation into the industry's pricing of life-saving drugs in developing countries, was in Rio de Janeiro, Brazil, at the end of May for a meeting when he was attacked by two unidentified individuals and had his arm slashed by a knife.

Believing that this was little more than a mugging, he travelled to Miami for another WHO meeting on economic restructuring.

On the eve of the conference he was pursued down a road and attacked by two men. They waved a pistol, threatened him with death and kicked him to the ground.

As they left, one shouted: "We hope you learned the lesson of Rio. Stop criticising the pharmaceutical industry."

Dr Velasquez, a Sorbonne-trained Colombian economist, reported the incident to the Miami police, the UN in New York and the WHO's offices in Geneva before travelling back to Switzerland

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ohnvidal

Changed landscape? Doha Declaration (2001)

- 2001: TRIPS Council: session on access to medicines
- Doha Declaration on TRIPS and Public Health
- Consensus: TRIPS (IP) should not interfere with public health
- Why did it pass this time?



Doha: key achievements

*“We agree that the TRIPS Agreement does not and **should not prevent Members from taking measures to protect public health.***

*Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, **to promote access to medicines for all.**”*

Doha: key achievements

- TRIPS should not interfere with public health
- Emphasized that MS have the right to use TRIPS flexibilities to promote public health
- LDCs can postpone protection & enforcement of pharmaceutical product patents + test data until 2016
- Consensus on impact patents on high prices medicines

http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html

Key TRIPS flexibilities

- Countries can set their own patentability criteria:
 - Indian Patent Act, Philippines,South Africa?
- Compulsory licensing:
Doha: *“Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”*
- Flexibilities not limited!

Compulsory licensing

- Governments can authorise generic competition for products while they remain on patent: payment royalty patent owner
- This reduces prices and promotes access to medicines by creating competition in the market for a particular drug
- Not limited to emergency or urgency! Countries are free to use CL for whatever ground they choose
- Problem: These products should in principle be

**→ WTO decision par. 6 Doha Declaration 2003:
production for export under a compulsory
license**

Compulsory licensing: examples (I)

- 2001, 2003, 2005: Brazil negotiated lower prices for HIV/AIDS treatments using threat CL
- 2007: Brazil issues CL
- 2007: Thailand 4 CLs HIV/AIDS. Save 8,000 lives/year, USD 3,2 bio./20 years
- Indonesia, Mozambique, Zambia, Eritrea, Ghana, India and Ecuador also issued CLs for HIV/AIDS

Compulsory licensing: examples (II)

- Recent examples: expansion CLs to cancer and hepatitis B:
 - 2008 Thailand: CLs for several cancer medicines
 - 2012: Indonesia 7 CLs, including for hepatitis B
 - Jan. 2013: India CL to generic producer Natco on liver and kidney cancer drug from Bayer upheld in court
- The U.S. regularly uses CLs in a wide variety of circumstances

¶6. (SBU) In an October 7 meeting, the president of Ecuador's Intellectual Property Rights Institute, Andres Ycaza, sought to reassure SCO and ECONOFF that the GoE was not planning to annul all pharmaceutical patents. Ycaza said he had been surprised by Correa's statements as well, having received notice of them while attending a World Intellectual Property Organization meeting in Geneva. However, Ycaza said the GoE was conducting a review of all pharmaceutical patents and does plan to issue compulsory licenses to address problems of access to medicine, specifically referring to cancer and HIV/AIDS treatments. In response to points raised by SCO and Econoff that compulsory licensing typically is used for emergency situations, permitted for only a specific time period and pursued only after negotiations with patent holders, Ycaza emphasized the GoE's intent to conduct the process in a manner consistent with Ecuador's legal obligations under the WTO TRIPS Agreement and Ecuador's Intellectual Property Law. He also mentioned that Ecuador would be justified in issuing compulsory licenses due to reasons of "public interest." Ycaza noted the need to provide access to medicines that are prohibitively expensive, mentioning a cancer drug that costs \$6,000 per injection as an example.

¶7. (SBU) While departing IEPI's offices, Embassy staff met Peter Maybarduk, a representative of U.S. NGO Essential Action, who is providing legal counsel to IEPI on compulsory licensing as part of the NGO's Access to Medicines program. For its part, U.S. industry is trying, through well placed contacts, to get a better idea of President Correa's core objectives. Once it is clearer whether the President's interests principally relate to access to medicine or promotion of domestic industry, the companies intend to try to develop a positive agenda they can present to the President as a way of opening the door to a more collaborative relationship. Embassy plans to consult with the Missions of other international pharmaceutical companies (French, British, Swiss, German, Swedish) and to continue seeking better definition of GoE intentions through meetings at the Coordination Ministry for Production and the Ministry of Health. At this point, Embassy interaction with the GoE on the issue remains one of seeking information.

¶8. (SBU) Comment. Ycaza's focus on IPR is relatively narrow. Although he may believe the GoE's plans are motivated purely by an interest in providing better access to medicine, compulsory licensing coupled with the government's new discriminatory public tender process, President Correa's close personal relationship to certain local pharmaceutical producers and his rhetoric suggest that Correa's more fundamental agenda is promotion of the domestic pharmaceutical industry. This would be consistent with the emphasis Correa has been placing on national production across industry lines (petroleum sector as an example) in the name of Ecuadorian sovereignty.

HODGES

... to sum up (I)

- Price is a key barrier for access to medicines
- IP protection (patents) a major factor in price
- Patents medicines not a given: history
- 1994: TRIPS: global standard 20 year patent protection pharmaceuticals
- HIV/AIDS crisis South Africa/Asia

... to sum up (II)

- 2001: Doha declaration: TRIPS should not interfere with public health & LDC extension pharmaceuticals until 2016
- Key TRIPS Flexibilities: patentability criteria & compulsory licensing
- Compulsory Licensing: Governments can authorise generic competition for products while they remain on patent.
Examples Thailand, Indonesia, India, Ecuador
- Opposition use TRIPS Flexibilities

After Doha: US and EU push for more

Higher standard protection to protect industry

No longer possible through WTO: deadlock

New venue: bilateral trade agreements (FTAs)

Ask for more than TRIPs: TRIPs-plus

Overview key US and EU FTAs since 2001

FTAs: TRIPS+

(I)

Data exclusivity: enhance protection of safety and efficacy data of medicines patent owner by providing up to 11 years if exclusive use of such data to obtain marketing approval

Extension patent terms: extending patent term protection through supplementary protection certificates. The extension will be equal to the time elapsed between the filing of the patent and the date of the first market authorisation (keeping protection at a minimum of 15 years)

data excl and a2m

Data exclusivity & Extension patent terms

- Data excl will apply to all medicines, whether patented or not (for example: see MSF slide)
- De facto: data excl creates additional level monopoly protection:

Impact:

- Impact studies (Jordan, Peru/Colombia) explain a bit about studies: show increase meds expenditure

FTAs: TRIPS+

(II)

Enforcement IP:

significantly strengthening position of IP right holder (pharma) to the detriment of generic competitors: effectively leading to extended monopolies in developing countries

Potentially obstruct import, transit and export of generic medicines

Example measures :

- Speed up proceedings, alleged infringer not heard: sentences can pass, goods destroyed based on mere presumption of infringement
- Border measures goods in transit: outside jurisdiction

Impact enf measures

- Comp report EU: misuse enforcement rights
- Border measures: example seizures: Netherlands, Germany and Paris
- Costs implementation significant (see welfare paper overview) / public resources dev countries used to protect rights western multinational rights holders

TRIPS plus: concerns international community

- As seen by WHO (briefing note a2m March 2006):
from perspective health: preferably not to grant this:
countries should not trade away their access to
medicines in FTAs

- EP resolution

- International organisations:
 - Committee HIV AIDS and the Law
 - UNDP
 - Rapporteur (Grover)

- Many more.... check

Latest move: include ISDS

- IP protected as investment
- Investor to state arbitration
- Impact:
 - Regulate for health challenge for using flexibilities
 - Examples: Philip Morris. Australia, recently Eli Lilly and Canada

Recap: FTAs, TRIPS+ & Impact

In practice: Case studies FTA negotiations

- Andean
- India

Recent developments:

TPP

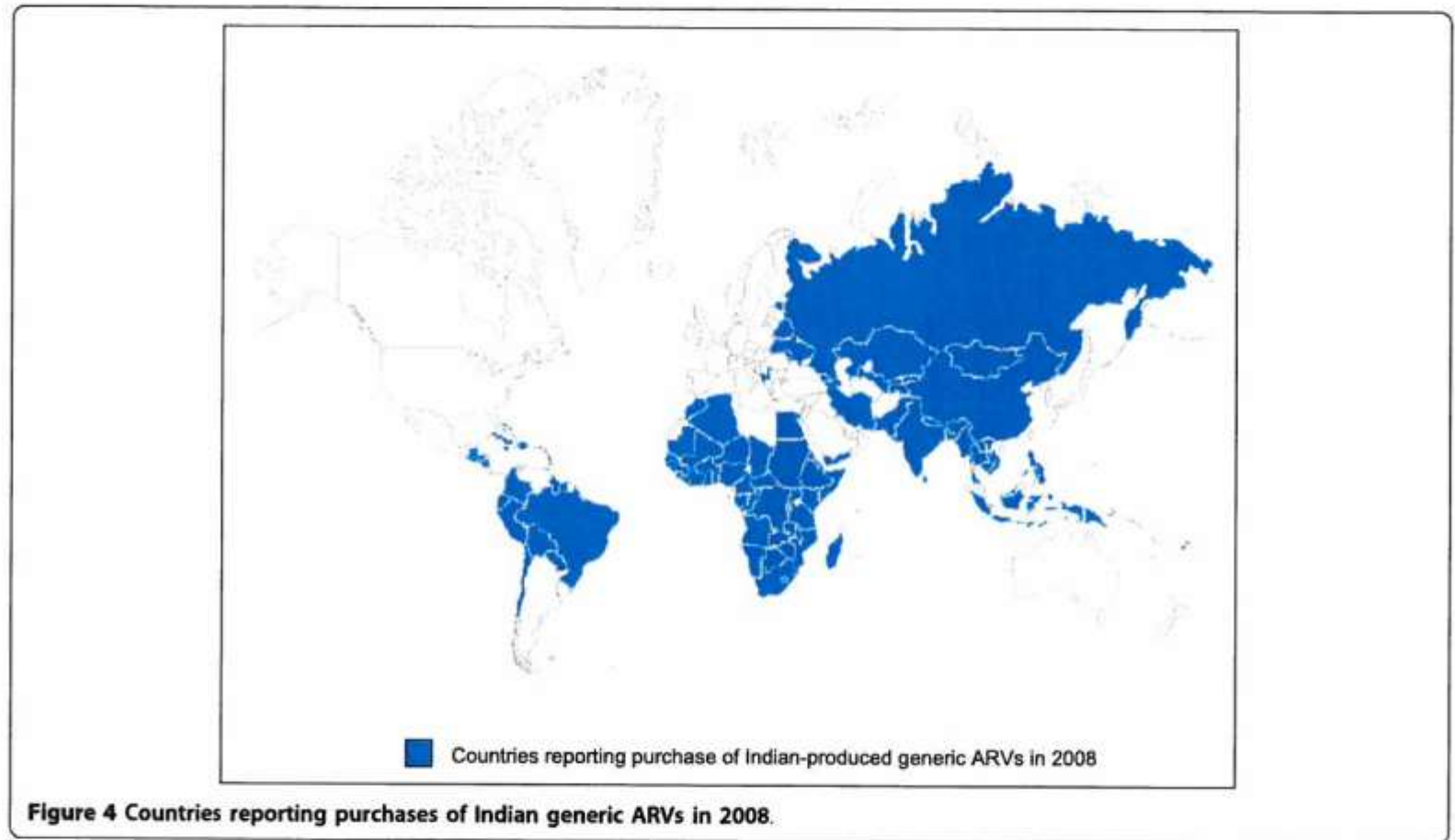
EU-Thailand

EU- ANDEAN FTA

EU- India FTA

- Negotiations launched in 2007
- Since 2007 11 negotiating rounds in India and Brussels, last round in April 2013 Brussels
- Data exclusivity, enforcement, investment chapter
- First negotiations that includes investment chapter

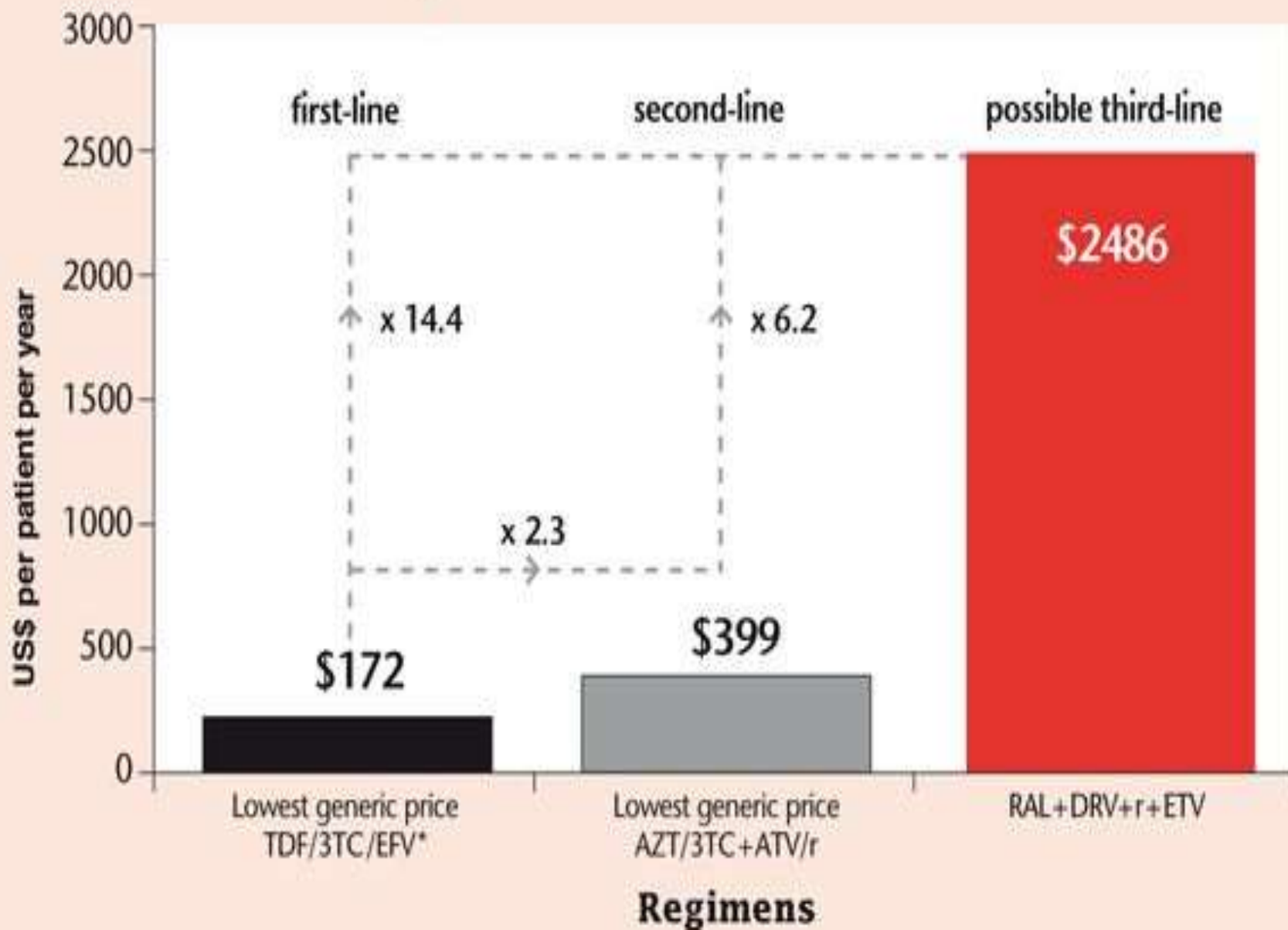
<http://ec.europa.eu/trade/policy/countries-and-regions/countries/india/>



numbers of people in need of treatment. At the same time, countries are trying to adopt the new ARV regimens recently recommended by WHO [19,25]. These

Tuberculosis, and Malaria have been cut [26], while pledges and contributions appear flat, raising concerns that funds will not be available in-country to adopt the

Price comparisons of first-line, second-line and possible third-line



The FTA negotiations

- Negotiations: behind closed doors
- European Parliament critical from the start:
March 2009: FTA should ***“not preclude access to essential medicines”***

25 MEPs: December 2010:

TRIPS+ provisions ***“would severely affect India’s ability to provide affordable medicines for the treatment of AIDS, malaria and cancer, not only for India but worldwide”***

Leaked draft July 2010

- Leaked draft confirmed TRIPS plus demands
- Patent term extensions, data exclusivity and enforcement measures
- No impact assessment on access to medicines in India done

<http://www.bilaterals.org/spip.php?article17290>

Data exclusivity (I)

- EU asked for data exclusivity in draft text
- Questions European Parliament
- DG Development concerns data exclusivity in letter to Trade Commissioner De Gucht
- Commission on the defense: “protection of test data can be reconciled with ensuring access to medicines”
- Worldwide mass protests civil society

Protests

<http://vimeo.com/20870296>

Data exclusivity (II)

- India also critical about data exclusivity:

2011: ***“grant of data exclusivity would have considerable impact in delaying entry into the market of cheaper generic drugs”***

“India shall not take any obligation beyond TRIPS and domestic law”

Commission: ***“protection test data can co-exist with instruments as compulsory licensing and exceptions public health needs”***

→ June 2011: India rejects data exclusivity (at UN high level meeting HIV/AIDS)



Current status

- Negotiations in small working groups
- Silence
- Elections India 2014.....



TPP

- Of TPP uitgebreid bespreken, of een kort idee geven van wat nu mees actueel is”:
- TPP
- Thailand (diezelfde week onderhandelingen)



To conclude

- Discourse IP, Trade and a2m has changed
- but still EU and US push Trips-plus: even exploring new terrains, IP and investment
- Urgency remains: 2nd and 3rd line ARVs & 90% preventable NCDs deaths occur in developing countries
- No longer only a developing country issue: Austerity and access to medicines in Europe

.....want to take action?

- <http://haieurope.org/work-areas/access-to-essential-medicines-2/eu-ftas-access-to-medicines/>
- <http://www.oxfam.org/en/campaigns/trade>
- <http://www.msfaccess.org/>
- <http://www.citizen.org/Page.aspx?pid=4955>
- <http://www.aidsactioneurope.org/partners/action-against-aids-germany>
- <http://www.stopaidscampaign.org.uk/>
- <http://www.tac.org.za/>
- <http://www.actupparis.org/>
- <http://www.bukopharma.de/index.php?page=pharma-brief>

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Broader context: Innovation and Access to Medicines

- Rationale stronger IP protection:
 - protect innovation/knowledge economy,
 - need to attract FDI (good for development)
- Tension: knowledge producing/knowledge consuming countries
- Are premises rationale valid (because if not... then maybe alternative system needed)?
 - Did stronger IP in dev countries lead to more FDI (check articles Brook Baker on LDCs)
 - Does stronger IP lead to innovation we need?