Access to medicines and Free Trade Agreements

BD - CIEL

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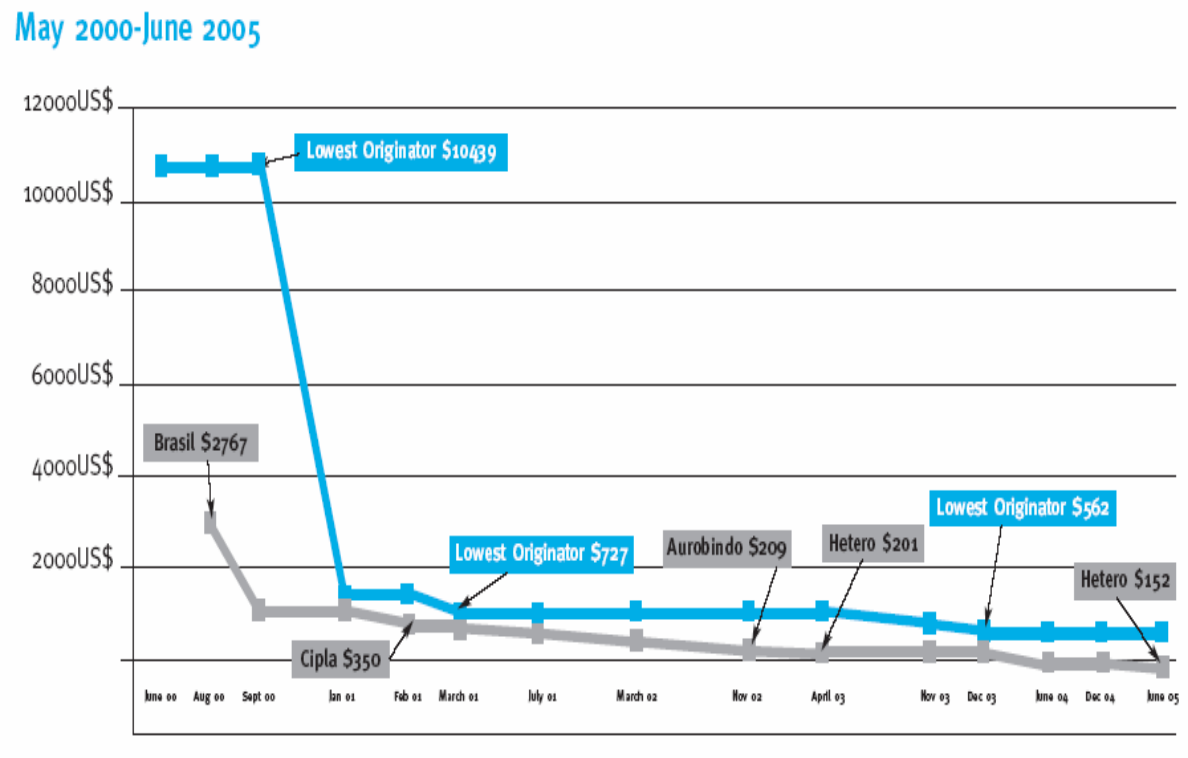
Ellen ‘t Hoen
Médecines Sans Frontières
Access to Essential Medicines Campaign
Ellen.t.Hoen@paris.msf.org
www.accessmed-msf.org


2 PILLS
A DAY
SAVES LIVES


GPO-VIR
Fixed-dose combination
antiretroviral drug


May 2000-June 2005
12000US$
10000US$
8000US$
6000US$
4000US$
2000US$
Lowest Originator $10439
Brasil $2767
Lowest Originator $727
Aurobindo $209
Hetero $201
Lowest Originator $562
Hetero $152
Cipla $350
June 00
Aug 00
Sept 00
Jan 01
Feb 01
March 01
July 01
March 02
Nov 02
April 03
Nov 03
Dec 03
June 04
Dec 04
June 05

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

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Globalisation of patent rules

- WTO Patent rules have been globally implemented (Trade related aspects of intellectual property rights agreement - TRIPS)
  - minimum' standards of protection of intellectual property rights
- 20 year patents on pharmaceutical products
  - Note! Patents are granted nationally
- No differentiation between lifesaving medicines and trivial goods
- 'One size fits all" - no differentiation between countries

Doha Declaration 2001

- “we affirm that the [TRIPS] 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***”.

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Clarified TRIPS Provisions

- The right to grant compulsory licences and the freedom to determine the grounds
- Definitive green light for parallel import
- LDCs may extend granting and enforcing drug product patents until at least 2016
- Left unresolved: production for export under CL
  - **August 30 2003 decision**
  - **December 2005 TRIPS amendment**

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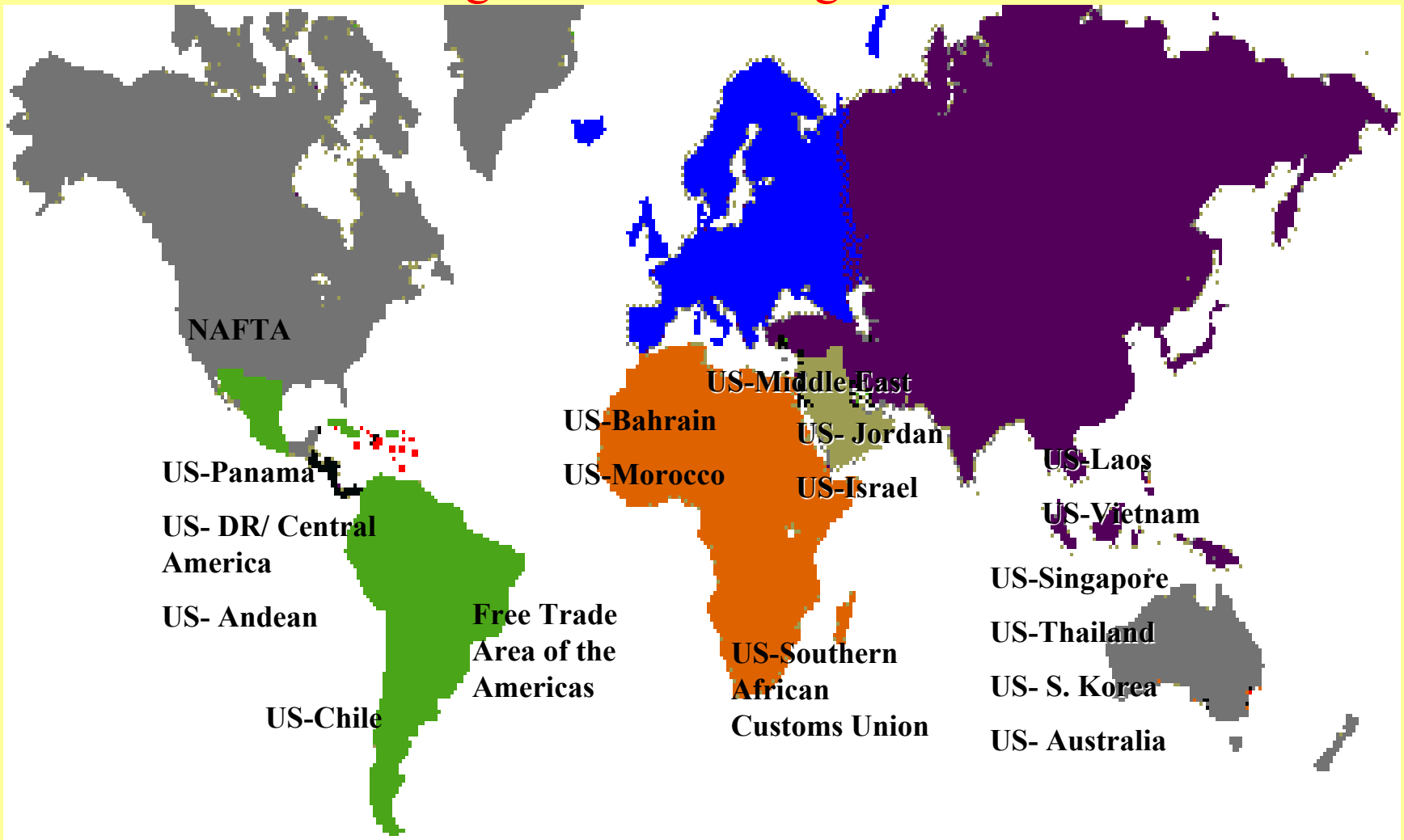
Current US Bilateral & Regional Agreements signed or under negotiation



US Free Trade Agreements

- US objectives: to strenghen the rights of IP holders beyond the minimum requirements of TRIPS
- Countries forced to accept restrictive IP provisions that limit generic competition and affordable drug prices
- No transparency - Draft agreements not made public before conclusion

Restrictive IP provisions

- New role of « patent police » for drug regulatory authorities (DRAs)
- 5-year data exclusivity protection
- Patent extention beyond 20-year
- Additional patents monopoly for new uses of known compounds
- Restrictions to countries'right to issue compulsory licenses

New role of patent police for DRAs

- No generic approval during the lifetime of the patent
- Use of compulsory licenses blocked
- Enforcement of « bad quality » patents without assessment of their quality
- Public health agencies requested to enforce private commercial rights
- Not required by TRIPS

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5-year data exclusivity

- DRAs prevented from approving generics on the basis of bioequivalence only
- Generic competition of non-patented drugs delayed for 5 years (new « patent-like » monopoly)
- Compulsory licenses blocked for 5 years
- No medicines available at all if originator company not interested in marketing
- Not required by TRIPS

Patent extension

- To compensate for « unreasonable » delays in drug marketing approval or in patent granting
- Extension of patent monopoly and high prices beyond 20 years
- What is « unreasonable »?
- Not required by TRIPS

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Additional patents for new uses

- Obligation to grant patent to protect any new therapeutic use of known medicine
- Additional 20-year monopoly for a known product (already patented)
- Impossible to prescribe generic versions of the medicine for the new indication
- Not required by TRIPS

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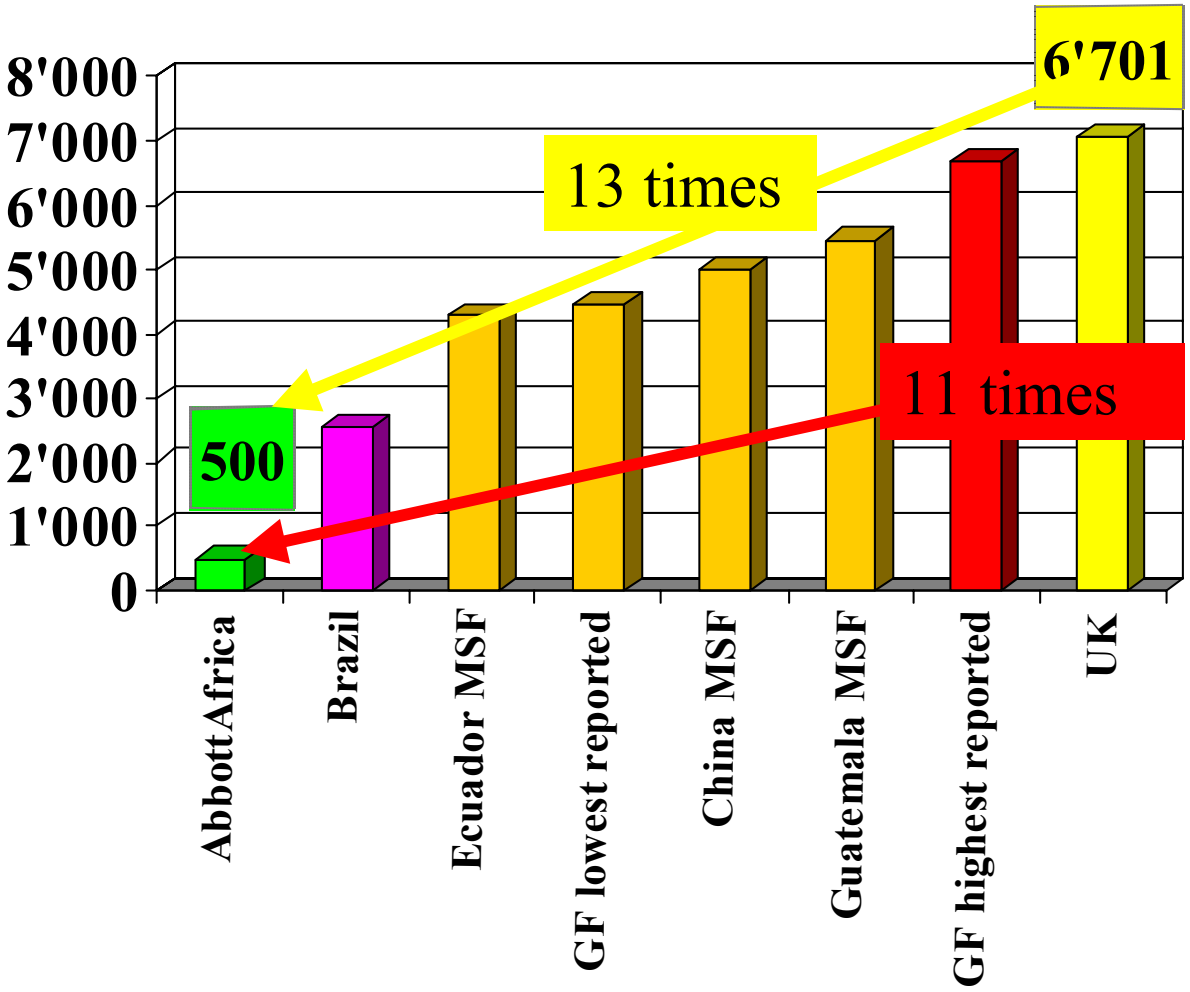
Compulsory licenses restricted

- Only in cases of emergencies, public non-commercial use or to remedy anti-competitive practices
- Cancel countries inherent right to grant compulsory licenses for whatever reason (expressly acknowledged by Doha Decl.)
- Limit recourse to generic competition to lower drug prices
- Not required by TRIPS

Price variability: Lopinavir/ritonavir (Kaletra®) in different countries (yearly price 2004-5 in USD)



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Conclusion: IP out of FTAs!

- Restrictive IP provisions in FTAs prevent countries to make use of TRIPS flexibilities « to promote access to medicines for all »
- TRIPS IP requirements high enough
- No need for expanding the rights of IP holders in free trade agreements

(Almost) Everyone Agrees …

- WHA resolution A59/24
  - 2.(4) *to encourage trade agreements to take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health;*

… Again

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But no one does …

How to turn this around? 1

- Moratorium on TRIPS plus provision in FTA's
  - "We ask that Members agree to a moratorium on any new bilateral and regional trade agreements that include provisions involving intellectual property rights and medicines, and that all WTO Members agree they will not enforce any provisions in such agreements that are contrary to the 2001 Doha Declaration on TRIPS and Public Health."

(Joint NGO Statement on Need for WTO Moratorium on Regional and Bilateral Trade Agreements and Policies Undermining Access to Health December 17, 2005)

How to turn this around? 2

- Make health innovation the focus E.g. health R&D investments instead of higher levels of IP protection

WHA resolution 59/24:

- *to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an intergovernmental working group open to all interested Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission. Such a strategy and plan of action aims at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;*