



The WTO TRIPS Agreement, Innovation and Access to Medicines Does the emperor have any clothes at all?

HAI Europe 25th Anniversary Conference, Oct 26 - 27
'06

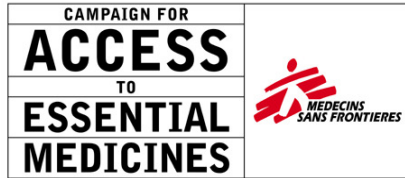
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MSF

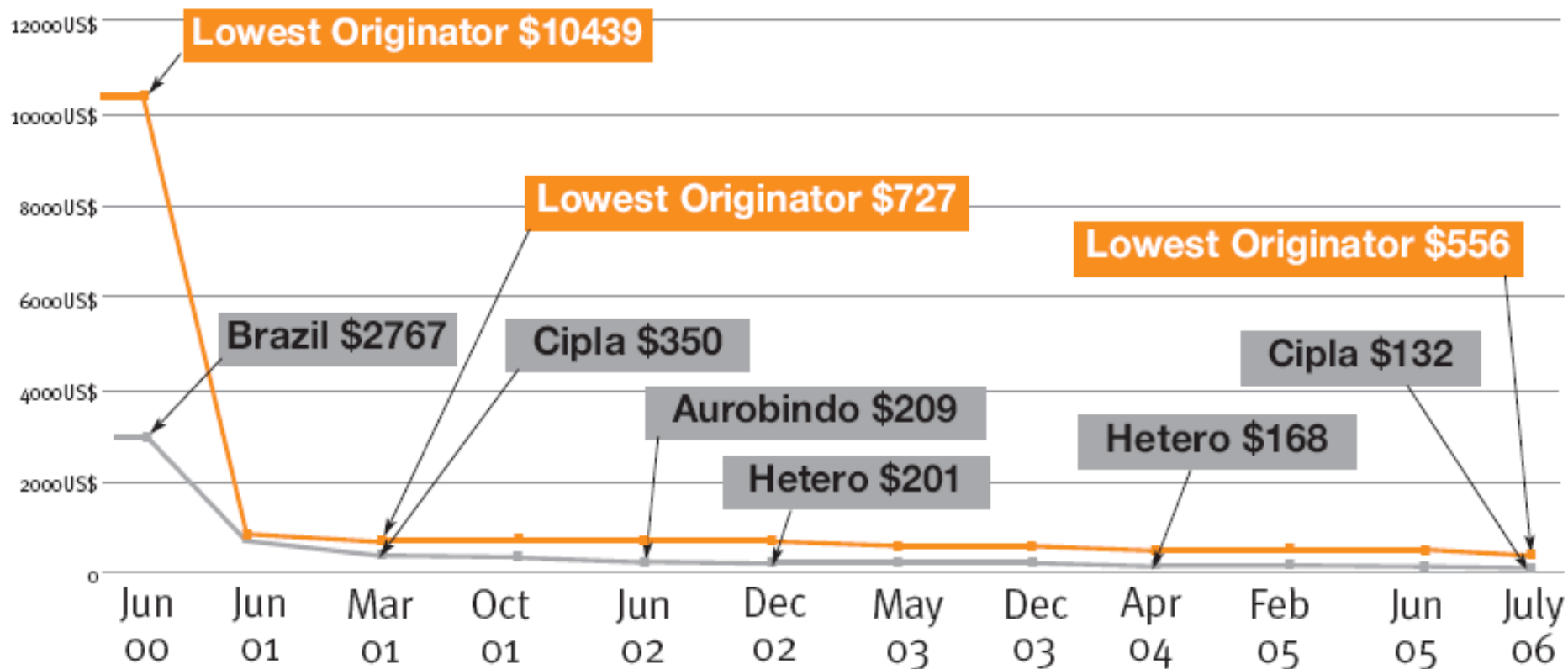
- Medical humanitarian organisation working in 80 countries
- Started the Access to Essential Medicines Campaign in 1999
- MSF started treatment with ARV in 2000
- Presently treating 69.000 people living with AIDS in 29 countries



AIDS Treatment

- 42 million people HIV positive
- 6 million in immediate need of treatment
- 1.3 million receive ARVs
- **50 % depend on generic ARVs mostly from India**
- **87 % of all new patients treated by MSF receive generic FDCs**

The Effects of Generic Competition June 2000-June 2006







Globalisation of patent rules

- 2005 WTO Global implementation of patent rules (Trade related aspects of intellectual property rights agreement – TRIPS ‘95)
- “minimum” standards of protection of intellectual property rights
- 20 year patents on pharmaceutical products
- No differentiation between lifesaving medicines and trivial goods
- ‘One size fits all’



The situation pre- TRIPS

- India Patents Act, 1970 no patents on Pharmaceutical products (Based on German model)
- Brazil, No Pharmaceutical Patents
- Pharmaceutical products became patentable in West Germany, 1967; France 1967; Italy 1979; Spain 1992
- Until early 1990s, approx. 50 developing countries either excluded medicines from patentability or provided shorter periods of protection or operated conditions which restricted patent holders' rights

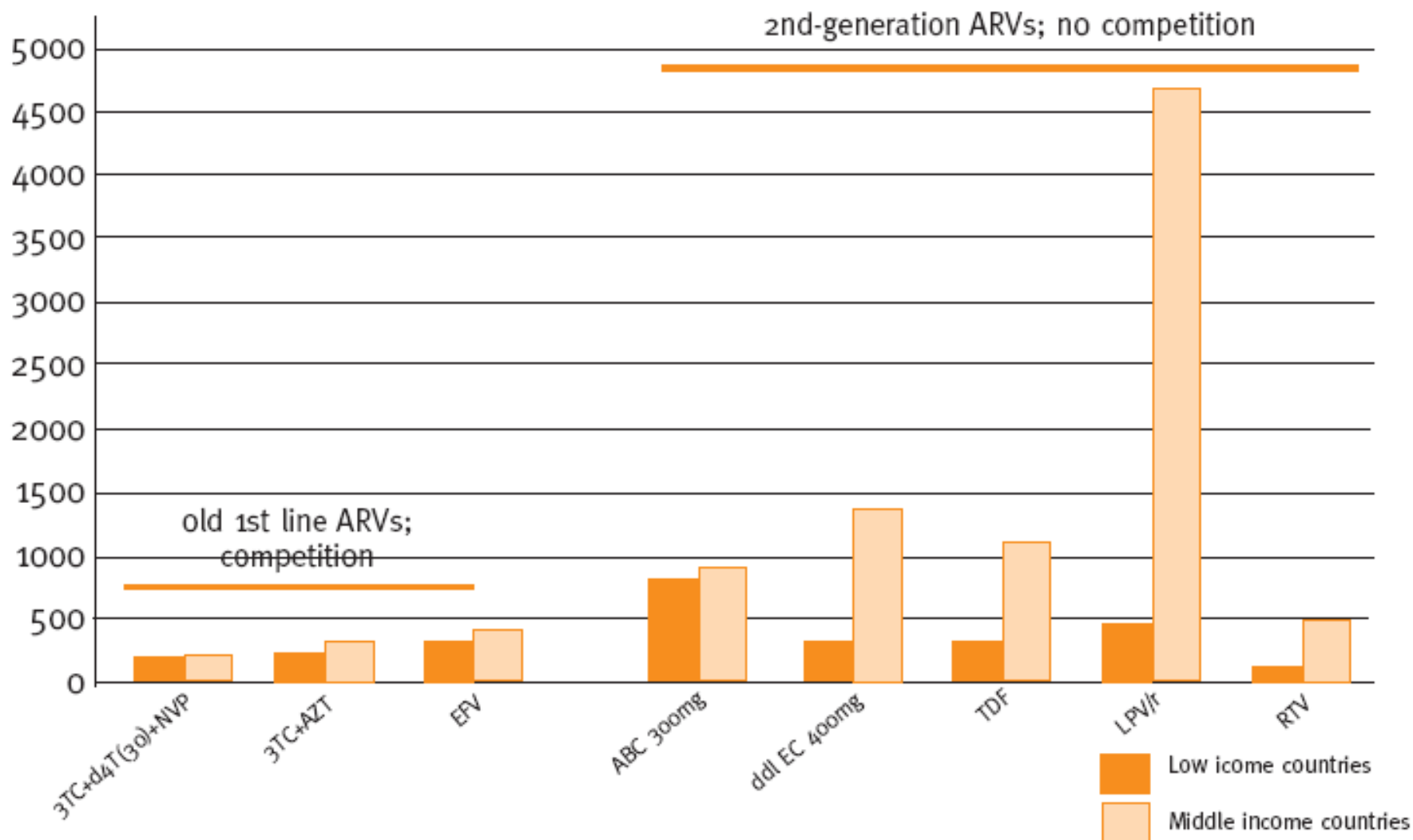


Ed Pratt in 1995

‘The current GATT victory, which established provisions for intellectual property, resulted in part from the hard-fought efforts of the US government and US businesses, including Pfizer, over the *past three decades*. We’ve been in it from the beginning, taking a leadership role’.

Ed Pratt Jr, CEO Pfizer (1972-91):

WHO GPRM Average prices paid in 2005



**Start ARTs:
 d4T/3TC/NVP**

**Substitute for
 toxicity:
 TDF/FTC+EFV**

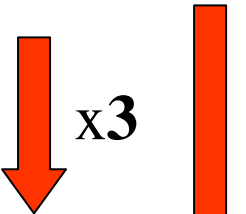
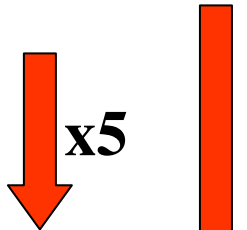
**Switch after failure:
 ABC+ddI+LPV/r**

LDCs

Middle-income

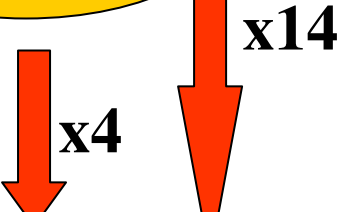
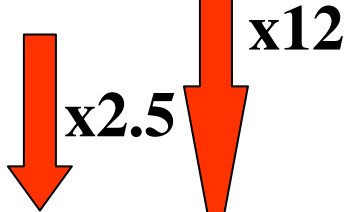
US\$140/y

US\$365/y



US\$689/y

US\$
 1,175/y

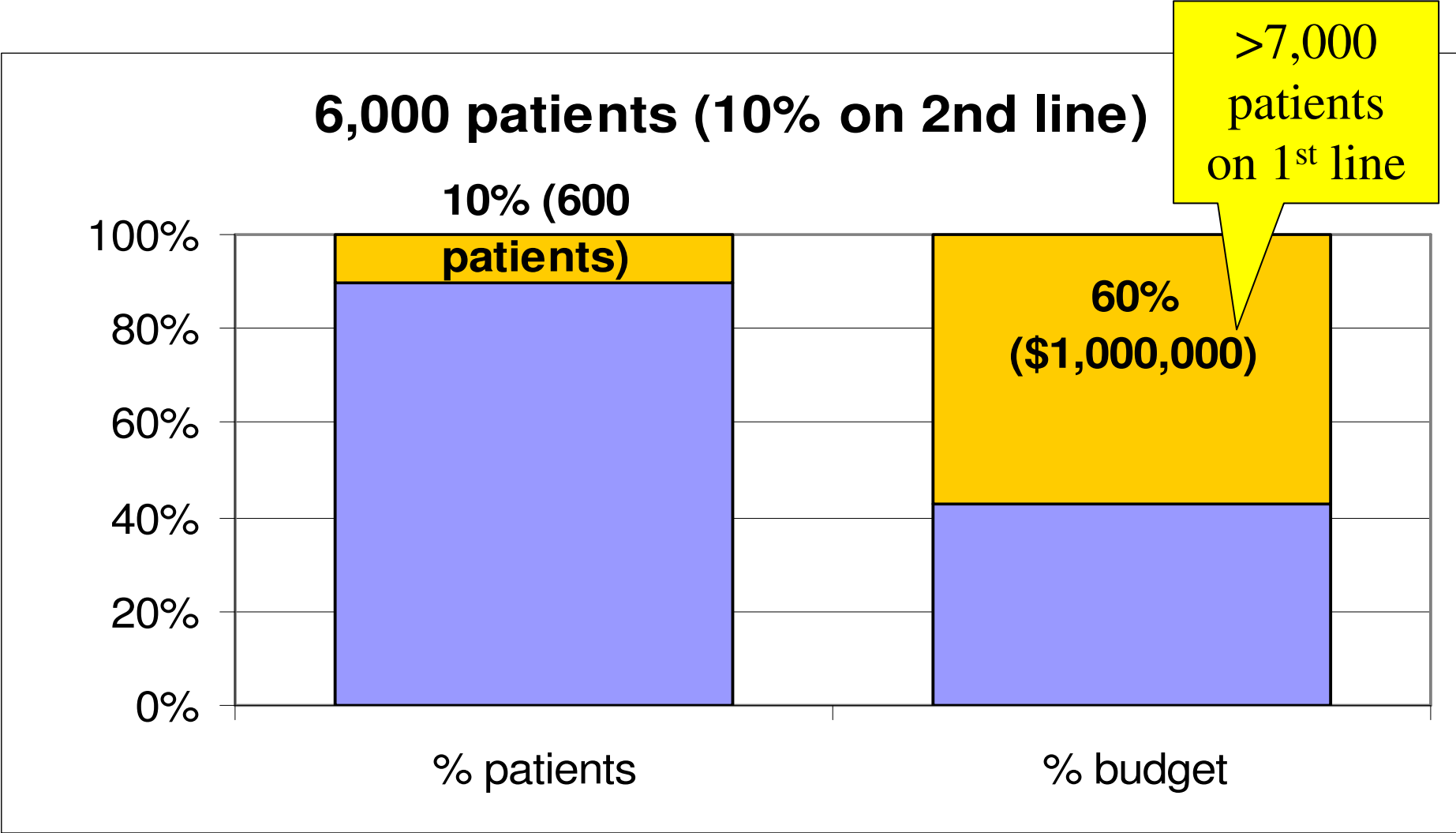


US\$
 1,700/y

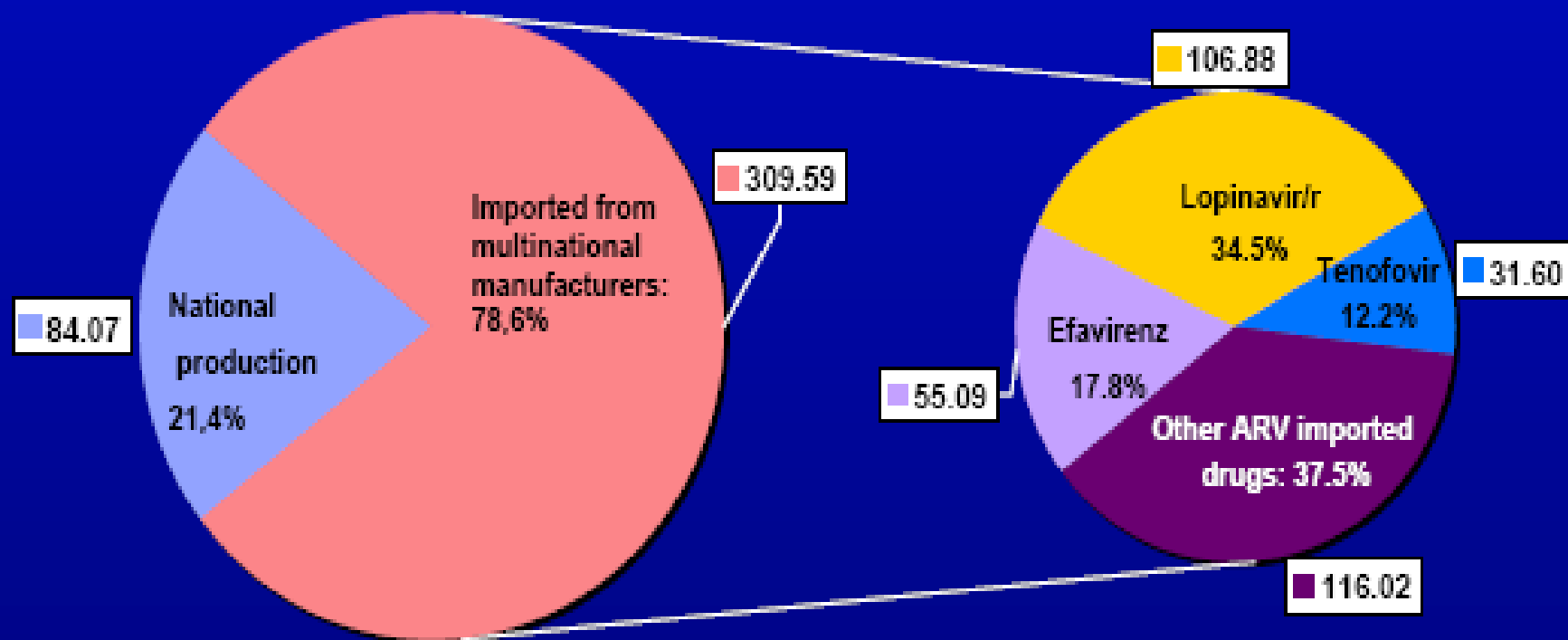
US\$
 5,200/y

Impact of 2nd line :

Treatment of 10% of patients accounts for 60% of budget



Breakdown of expenditure* on ARV procurement (2005), by source of drug. **Brazil, 2005**



*US\$ million for 180,000 patients



Hand to hand combat

- Thailand:
 - PLWA groups revoked the Ddi patent
 - Opposition to patenting of AZT/3TC (combivir)
- South Africa: TAC used competition law to force licenses on key AIDS drugs produced by GSK and BI
- India: pre grant opposition by patient groups e.g. Gleevec, ARVs.
(Brazil, China)



Why do we have patents?
Seems all pain .. where is the
gain?



Bargain...

- *‘Patents constitute a temporary monopoly, but in the end society benefits’*

Fred Hassan,
CEO of Schering-Plough president of
IFPMA on 10 Oct ‘06



- Drug companies: reason for not conducting research on tropical diseases is the lack of patent protection in developing countries.
- ‘The moment the enforcement of patent protection becomes effective (in developing countries, no later than 2006) tropical disease research should logically start again, funded by Western companies or by manufacturers in developing countries’

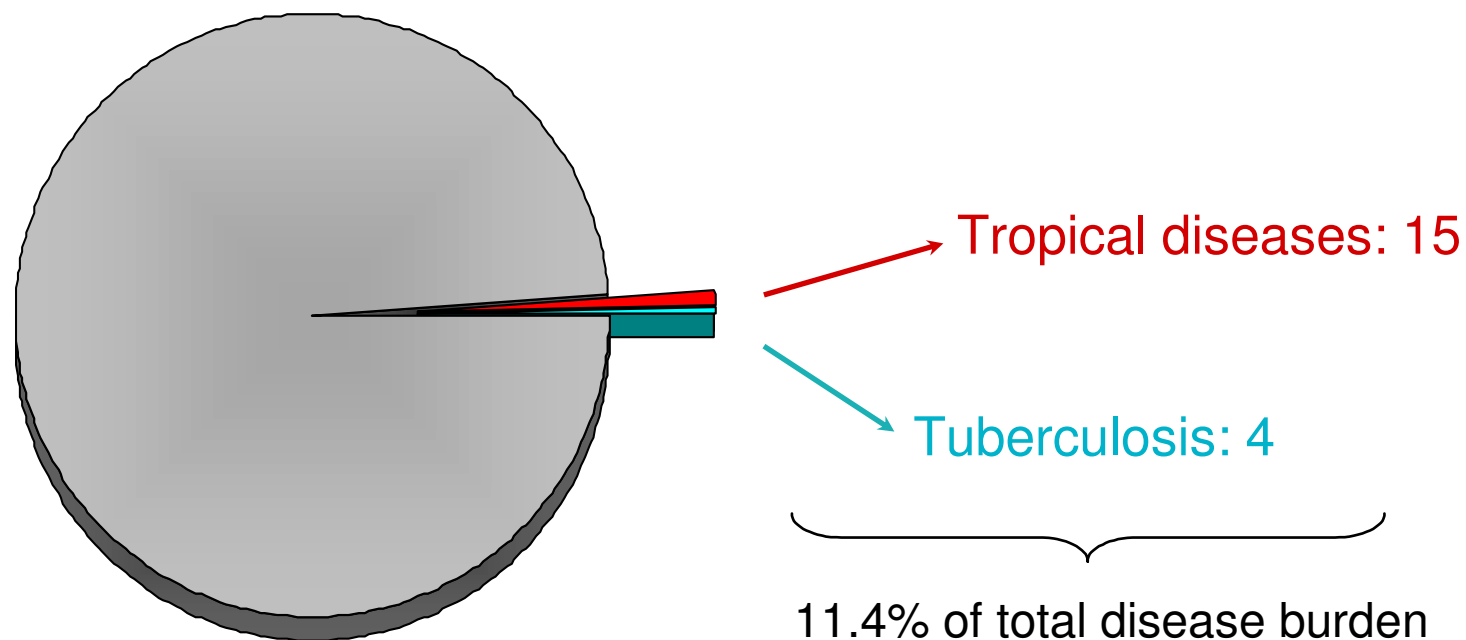
Pecoul et al. Access to Essential Drugs in Poor Countries. A lost battle? (1999) *Jama*



But Does It?

Fatal Imbalance

- 1975-1999: **1,393** new chemical entities marketed
- Only 1% of new drugs developed are for neglected diseases
- 1999-2004: + 163 NCEs, + 3 new drugs for neglected diseases





MILLIONS OF BABIES WON'T LIVE TO SEE THIS DAY.



Without treatment, half of all children with HIV/AIDS in developing countries will die before their second birthday. **We desperately need diagnostic tests that work for babies, and pills that kids can swallow.** HIV/AIDS is treatable, but millions of children are still waiting.

www.accessmed-msf.org





Innovation in decline?

- 68 % of the 3,096 new products approved in France between 1981 and 2004, brought 'nothing new' over previously available preparations. (2005 by *La Revue Prescrire*,)
- Barely 5 % of all newly-patented drugs in Canada as 'breakthrough.' (2005 *British Medical Journal*)
- 1000 new drugs approved by the US FDA between 1989 and 2000 over three quarters have no therapeutic benefit over existing products. (2002 NICHM)



US spending on R&D 50% increase (39 bill US\$)

QuickTime™ and a
TIFF (LZW) decompressor
are needed to see this picture.



Profitability of Pharma compared to other industries (CBO 2006)

QuickTime™ and a
TIFF (LZW) decompressor
are needed to see this picture.



TRIPS: A Bad Bargain

“All the evidence we have examined suggests IP hardly plays any role at all in stimulating R&D on diseases prevalent in developing countries, except for those diseases where there is a large market in the developed world (for example diabetes or heart disease) ...

Higher levels of intellectual property protection have not resulted in increased drug R&D for global health needs.”

UK Commission on Intellectual Property Rights
(CIPR) 2002



- *“ There is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on TYPE II and particularly Type III diseases. Insufficient market incentives are the decisive factor.”*

WHO Commission on Intellectual Property Innovation and Public Health (CIPIH). April '06



“We have no model which would meet the need for new drugs in a sustainable way” ... ”You can’t expect for-profit organisations to do this in a large scale. If you want to establish a system where companies systematically invest in this kind of area you need a different system”

Daniel Vasella, CEO Novartis in Financial Times
30/09/‘06



Doha Declaration

“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.”

**WTO Ministerial Declaration on the TRIPS
Agreement and Public Health
November 14, 2001**



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;



So what next?

- International mobilisation to support national campaigns e.g. Gleevec in India
- Governments back in the drivers seat
- Renew the international debate to replace the TRIPS model for a real innovation model (CIPIH report)
 - Essential health R&D that meet real health needs (beyond the big 3!)
 - Reject rationing as a basis for innovation
 - Divorce pricing from R&D financing (Love/Hubbard)

