Access to medicines and human rights

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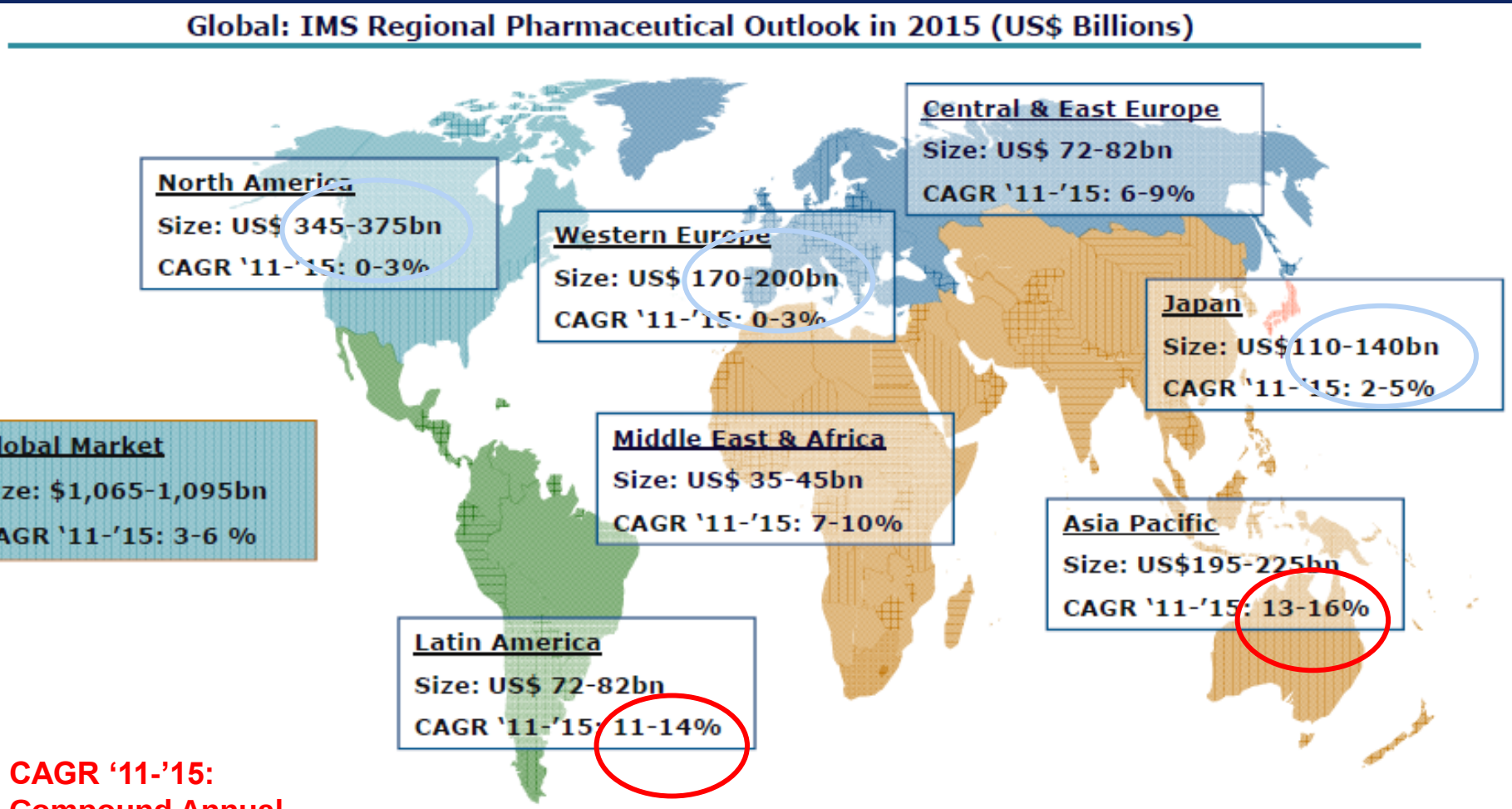
Consumption: has been greatest in HICs but now moving to LMICs



CAGR '11-'15: Compound Annual Growth Rate 2011-2015

"Pharmerging" markets

IMS Health, Market Prognosis, Apr 2011. www.bvgh.org/LinkClick.aspx?fileticket=kMaOKGUbqgI%3D&tabid=168

Technologies for global health
Example 1: pharmaceuticals

The geography of medicines

- Drugs needed for diseases that are exclusively or predominantly found in LMICs may not be developed, because the market will not provide for cost recovery and profit.

- Drugs developed for diseases commonly found in LMICs may be too expensive for use in LMICs during the patent period: so there may be a time lag of many years before they become available in LMICs as cheap generics (by which time, they may have been superseded by much better new, patented drugs).

Three main issues

- Existing medicines, diagnostics and vaccines are priced out of reach (ARVs)
- Production of essential medicines, diagnostics and vaccines that are needed but do not make profits are abandoned
- Medicines, diagnostics and vaccines that are needed do not exist

Is assess to medicines a human right?

Access to medicines As a human right

- ICCPR, Art 6
  - *Right to life*
- ICESCR, Art 12
  - *Health is a fundamental human right indispensable for the exercise of other human rights*
  - Access to health care
- UDHR, Art 3
  - *Access to health care*
- International Covenant on Economic, Social and Cultural Rights: Article 12
  - *The prevention, treatment and control of epidemic, endemic, occupational and other diseases*
- ICESCR, GC 12
  - *To provide essential drugs, as defined under WHO Action Programme on Essential Drugs*

Do pharmaceutical companies have an obligation to ensure access to medicines?

Case study: tetracycline in the UK

Mid-1950s: tetracycline marketed by pfizer for 90 pounds per 1000 tabs

1960s: price fell to 60 pounds/1000 tabs due to increased sales

1961: a new British company DDSA, introduced tetracycline for 6 pounds/1000 tabs

(This price included a 25% import tax)

Case study: tetracycline in the UK

DDSA purchasing from Italy, which did not provide patents on pharmaceutics

Clause 46 of the 1946 patent act allowed the UK government to override patents if considered in the public interest

Pfizer mounted legal challenge: House of Lords ruled in favour of the government

Inglis B. Drugs, doctors and disease. 1964

Globalization of drug patents

Up to 1990s around 50 developing countries either

- excluded medicines from patentability
- provided shorter periods of protection, or
- otherwise moderated patent rights for pharmaceuticals

India: Patents Act of 1970: no pharmaceutical product patents

Brazil: no pharmaceutical patents

Globalization of drug patents

- 1995: TRIPS Agreement
- 1996: Intellectual property concerns raised for the first time at the World Health Assembly (resolution WHA49.14)
- 1999: WTO Seattle - Access to Medicines on WTO agenda

Ed Pratt, CEO, Pfizer (1972-1991); Chair Advisory Commission on Trade Negotiations

"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."

Sell S. *Power and Ideas*. Suny Press, New York, p 193.

Access to fluconazole

Manufacturer	Country	Price ($US)
Biolab	Thailand	0.29
Cipla	India	0.64
Pfizer	Thailand	6.20
Pfizer	South Africa	8.25
Pfizer	Kenya	10.50
Pfizer	USA	12.20
Pfizer	Guatemala	27.60

Perez et al, *Lancet* 2000

Thailand and Guatemala

Guatemala
HIV prevalence <1.1%
GDP $4,167 per capita
HDI: 131

Thailand
- HIV prevalence <1.5%
- GDP per capita $7,694
- HDI: 103


ESSENTIAL DRUGS: PUBLIC PROPERTY, NOT


2 PILLS
A DAY
SAVES LIVES
PUT
MORE
MONEY
ON


MAKE
HIV
DRUGS
हमे भैजीने
का अधिकार है
H.I.V.
POSITIVE
H.I.V.
POSITIVE


GSK's greed
We suffer!
แกล็กโซ
หน้าด้าน
GSK's Shame
แกล็กโซ
เห็นแก่เงิน
ไม่สนใจชีวิตผู้ป่วย
NOW!

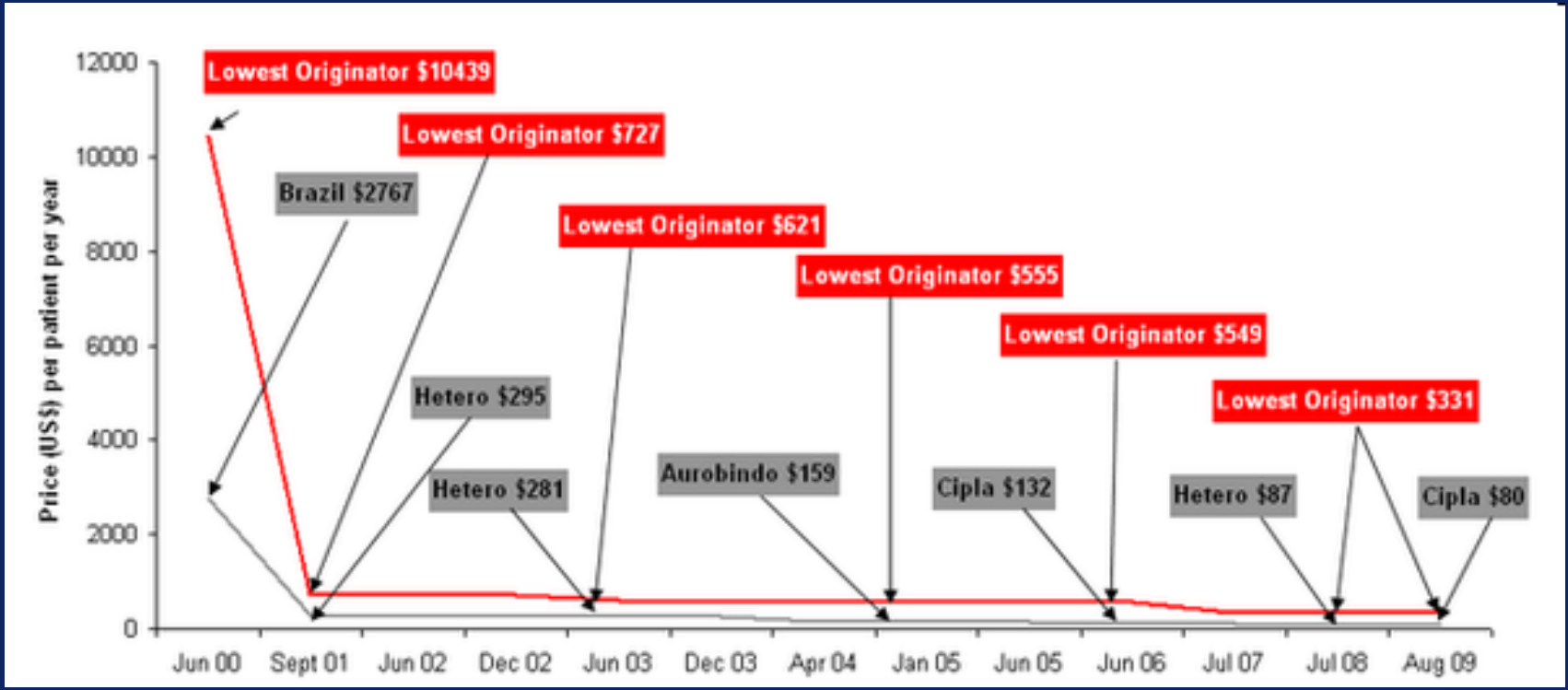
Doha Declaration TRIPS and Public Health 2001

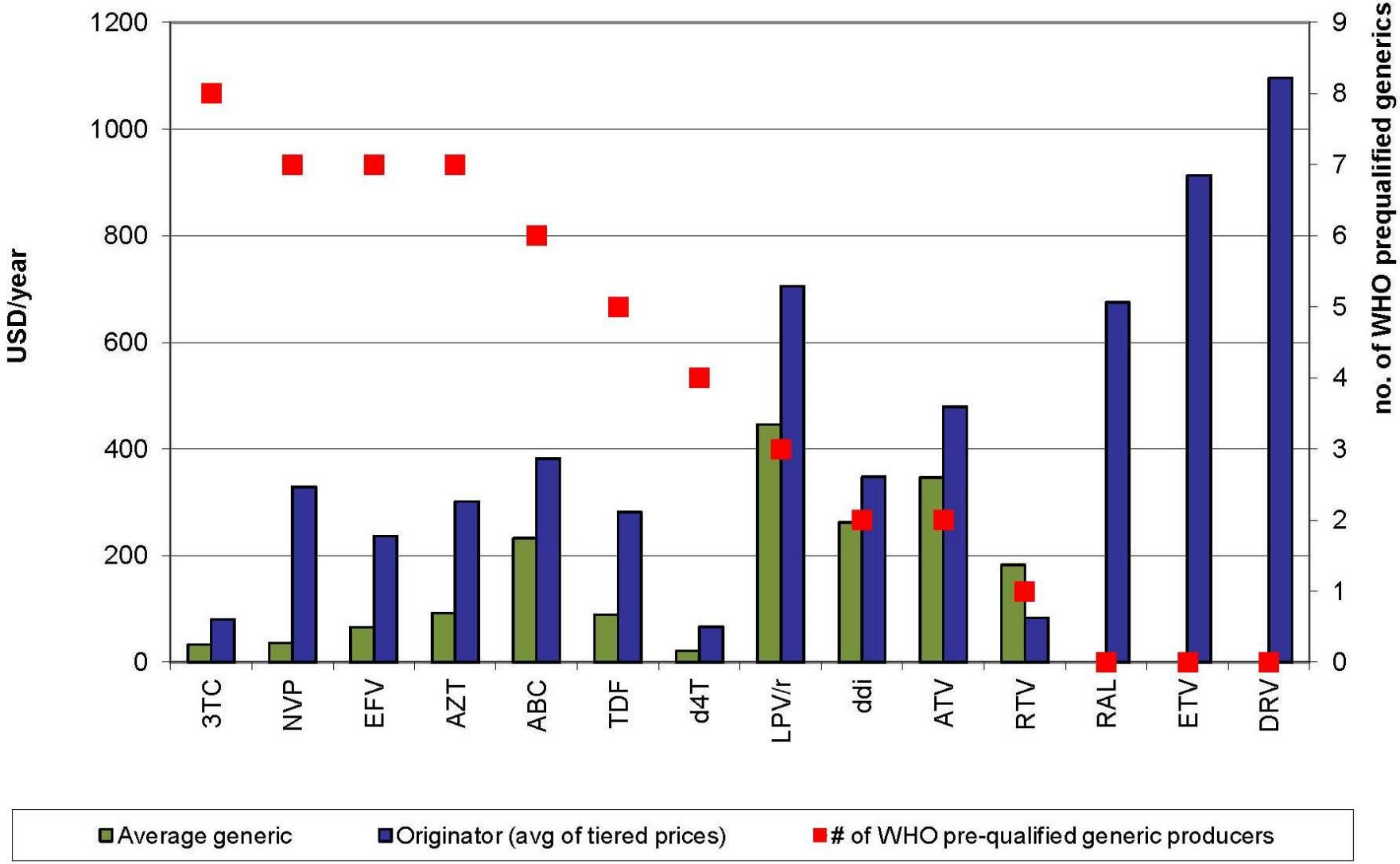
"We affirm that the (TRIPS) Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

WTO Ministerial Declaration on the TRIPS Agreement and Public Health

November 14, 2001

Access to Medicines: the Effect of Generic Competition

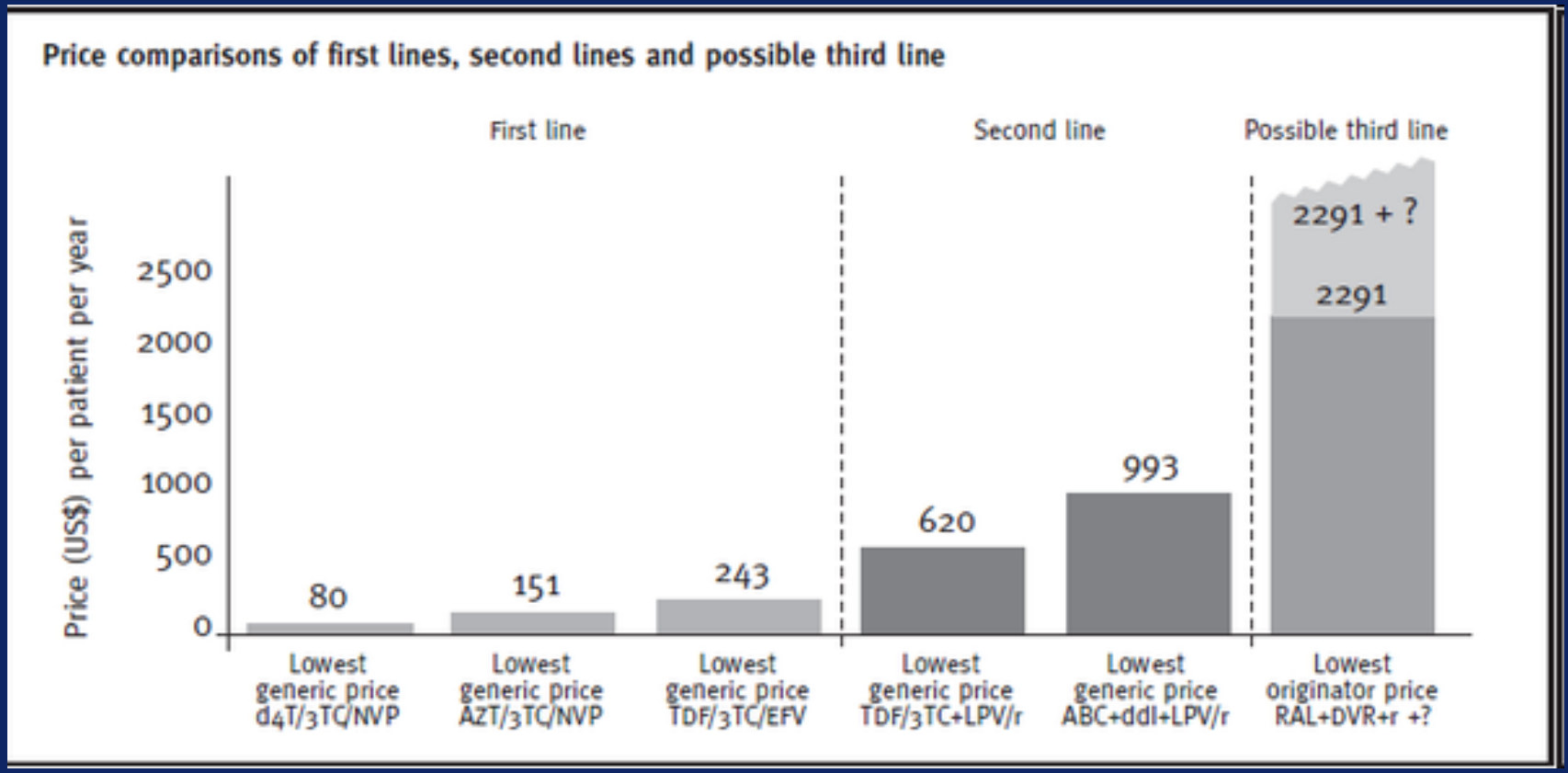



USD/year
1200
1000
800
600
400
200
0
9
8
7
6
5
4
3
2
1
0
no. of WHO prequalified generics
3TC
NVP
EFV
AZT
ABC
TDF
d4T
LPV/r
ddi
ATV
RTV
RAL
ETV
DRV
Average generic
Originator (avg of tiered prices)
# of WHO pre-qualified generic producers

Access to medicines post 2005

- 2005: WTO TRIPS agreement now fully implemented
  - globalisation of patent rules
  - 20 year patents on pharmaceutical products
- As a result all new drugs will be patented in all key generic producing countries (e.g. India, Brazil, Thailand)
- … while at the same need for affordable newer drugs increases (and price discounts insufficient)

Access to newer antiretrovirals



Limits of industry strategies

- Tiered pricing
  - Discounts not steep enough and not as effective as generic competition
  - No solution to patent barriers for innovation (i.e., FDCs, paediatric formulations)
- “Voluntary” licenses
  - Restrictions limit full effect of generic competition e.g., trade in API, export
  - Rare and often response to threats of legal action

Moon S et al. Global Health. 2011 Oct 12;7(1):39.

Efforts by national governments to overcome patents

- India's patent law – balancing IP and public health:
  - Patents not granted for new uses or new forms of existing medicines unless demonstrating significant increase in efficacy
  - Possibility for pre- and post-grant opposition by public interest groups (e.g. patients)
    - Pre-grant: venofovir patent rejected
    - Post-grant: valganciclovir patent rejected

Why have pharmaceutical patents?

Why have pharmaceutical patents?

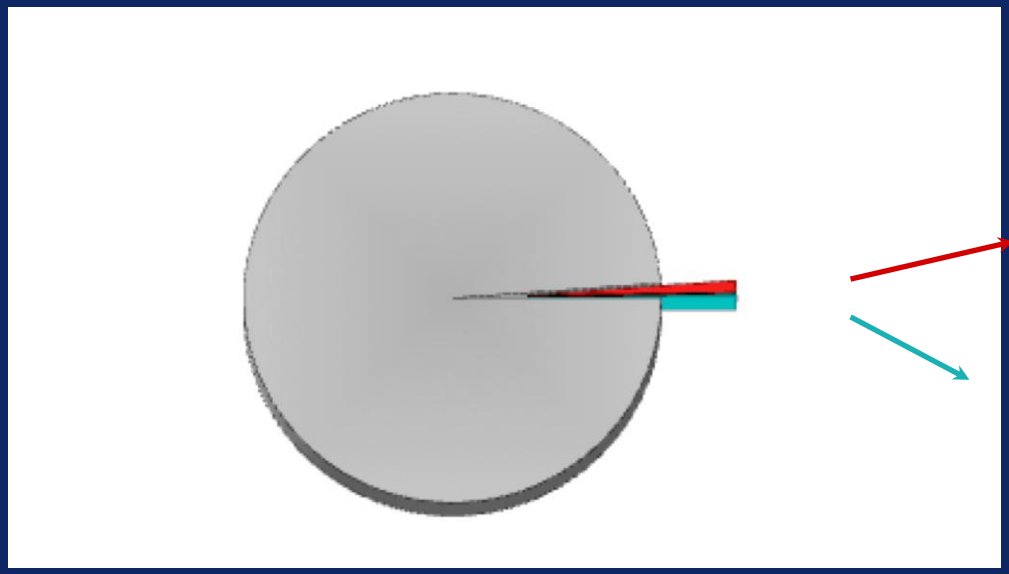
'*Patents constitute a temporary monopoly, but in the end society benefits'*

Fred Hassan,
CEO of Schering-Plough & president of IFPMA
October 2006

Which society benefits?

Trends in innovation over the last 3 decades

- 1,556 new chemical entities marketed globally between 1975 and 2004.
- Only 20 of these (1.3%) were for tropical diseases and tuberculosis, which account for 12 % of the total disease burden



Tropical diseases: 15

Tuberculosis: 4

Trouiller et al, Lancet 2002

Torreele, Chirac Lancet, 2005

Trends in innovation: country perspectives

Only 68 (5.9%) out of 1,147 newly patented drugs appraised by the Canadian Patented Medicine Prices Review Board between 1990 and 2003, met the regulatory criterion of being a breakthrough drug – the first drug to treat effectively a particular illness or which provides a substantial improvement over existing drug products. (Morgan et al, *BMJ* 2005)

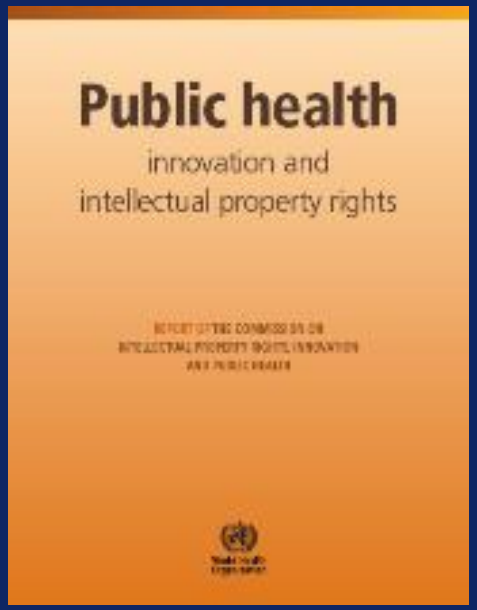
2,105 (68%) of 3,096 new products approved in France between 1981 and 2004 brought 'nothing new' over previously available preparations. (*Prescrire International*, 2005)

Access and innovation

2002 UK CIPR report

"All the evidence we have examined suggests that [IP] hardly plays any role at all, except for those diseases where there is a large market in the developed world, for example diabetes or heart disease."

Commission for Intellectual Property, Innovation and Public Health (CIPIH)



- "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, April 2006

http://www.who.int/intellectualproperty/en/

- **Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)The Commission was established by the World Health Assembly in 2003:*"…to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries…"***

WHA 2009:
Global Strategy and Plan of Action on Public health, innovation and intellectual property

- Ensure intellectual property barriers do not prevent access
- Examine feasibility of voluntary patent pools (element 4.3a)
- Exploratory discussions on biomedical R&D treaty (element 2.3c)
- Addressing de-linkage of the costs of R&D and the price of health products (element 5.3a)
- Explore award of prizes (element 5.3a)

Patent Pool for Innovation and Access

- Access:
  - Decrease price of newer ARVs by increasing the number of generic producers
- Innovation:
  - Encourage the development of fixed-dose combinations by overcoming patent barriers
  - Encourage the development of pediatric first- and second-line formulations
  - Encourage the development of formulations adapted to developing country needs (eg heat stable)

Summary points

- Access to medicines is a human right
  - Protected by numerous legal obligations
- These rights conflict with trade laws and pressures that limit government action
- Scale up of ART in the developing world has depended on access to generics
  - These options are becoming increasingly limited
- Patents are a temporary, government-granted incentive for innovation
  - If the system fails in certain areas, need to consider other measures