

# **Brazilian Experience – HIV/Aids.**

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# Brazilian Context

- Health system: universal access;
- Constitutional concept of "health" as global welfare - citizen's right and duty of State - Structured Programs (HIV / AIDS, hepatitis ,...)
- HIV/Aids Universal access law - 1996 – centralized procurement – MoH (only buyer)
  - budget 2008 = US\$ 640 million
- Until 2010 - 200.000 people on ART

# Brazilian Context

- Fundamental human right
- Incorporation into domestic law: the obligation to grant patents for medicines – TRIPS
- Obligation of countries to accept the granting of patents for pharmaceutical products and its processes.

# Health Sector Participation

- National level:
  - involvement of the health sector in the analysis of the applications of pharmaceutical products and processes - the prior consent of ANVISA;
  - Active participation in the Interministerial Group of Intellectual Property - GIPI
  - Health sector at international meetings (Brazil and India – WHO and IBSA - WIPO).

# International context

- Global Strategy and plan of action on public health, innovation and intellectual property.
  - WHO's mandate.
  - Priorities that we can work together.
- Counterfeit
  - We want to talk about the sanitary aspects in WHO.
- Both: important to be discussed with a public health perspective, impact and objectives.
- The importance of a health perspective not only in WHO – WIPO (flexibilities, MDGs, etc), WTO (30<sup>th</sup> August Decl).

# Nationally: Pre-grant and post grant measures

- Which measures we are talking about?
- What is their impact for the health sector?

# Brazilian Law (9.279/96) – Previous Consent

Art. 229-C. The granting of patents for pharmaceutical products and processes depend on the prior consent of the National Agency for Sanitary Surveillance - ANVISA.

- Maximum 120 days to analyze. 4% not granted
- It's not a linkage.
- Pre-grant measure.
- Some cases:
  - Valcyte: no novelty; Ritonavir: no novelty;
  - Taxotere: process to product

## Possible consequences for public health of a frivolous patent

- Restriction of access to medicines.
- Improper payment of royalties.
- Abuse of the exclusive exploration of the subject of the patent.
- Undue protection for inventions that do not have the patentability criteria.
- Suggestion: IBSA using the guidelines for the examination of pharmaceutical patents or/and an opposition database.

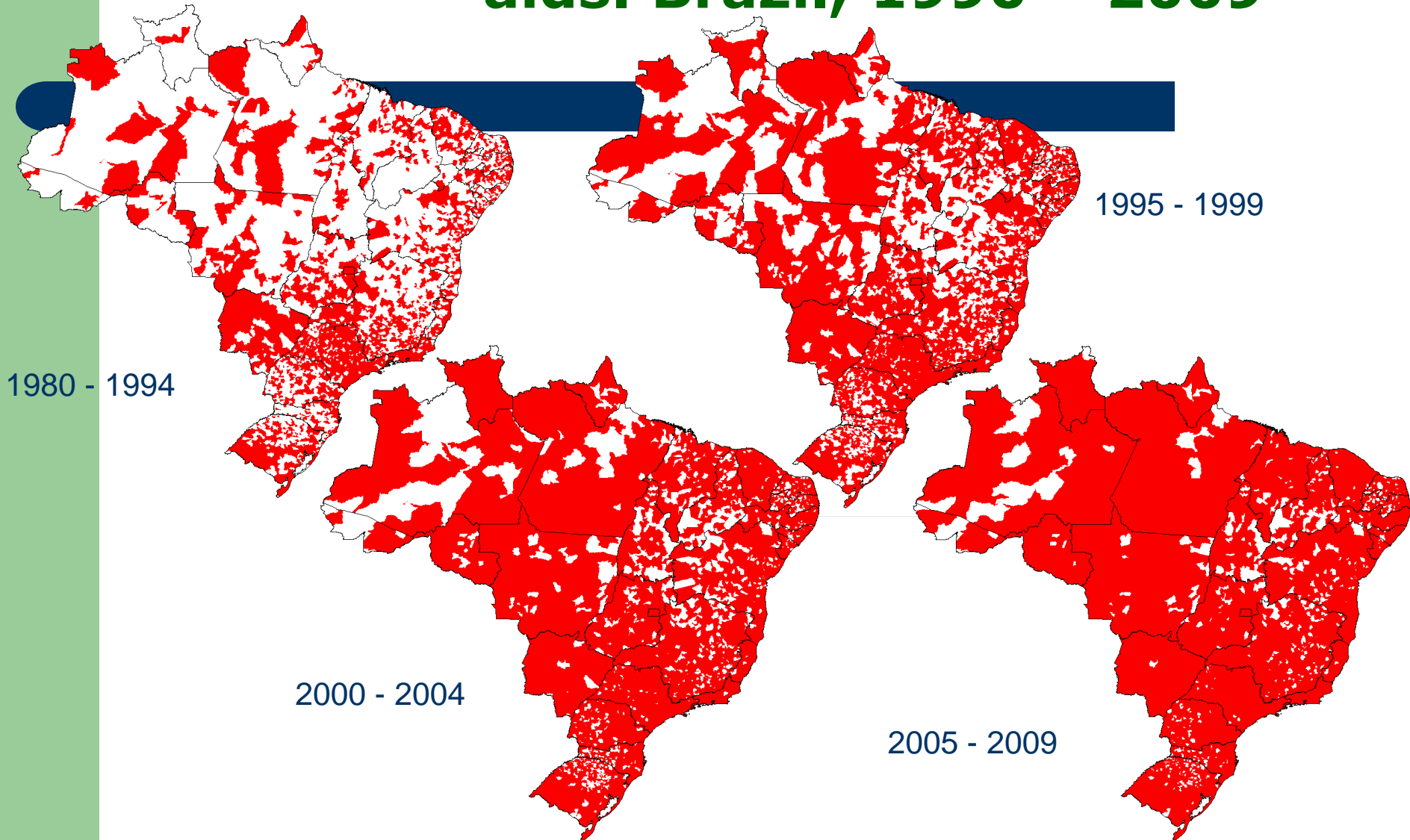
<http://ictsd.org/i/publications/11393/>



# IP and health

- Why people from health is so interested in IP aspects?
- 33.000 – 35.000 new cases of Aids/year.
- **Study**: Technical, legal and economical aspects. UNDP and STD, HIV, Hepatites Programme.

# Cities with at least 1 case of aids. Brazil, 1990 – 2009

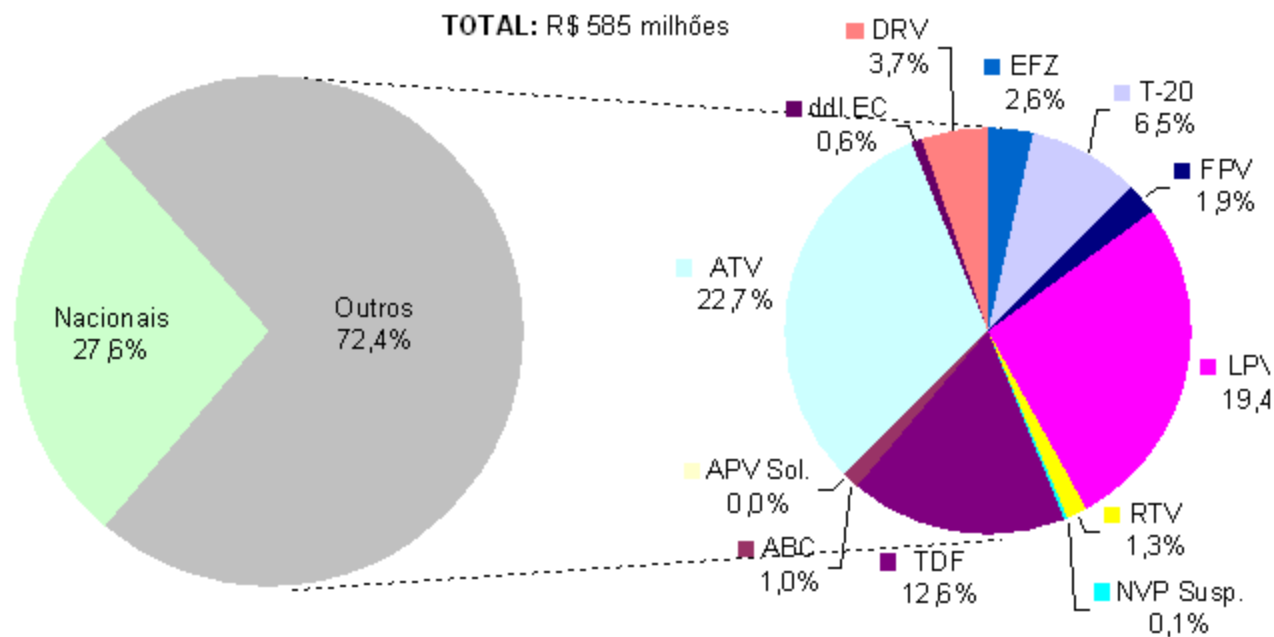


# Access and prices.

- Many prices in other countries are still lower than Brazil negotiates.
- IP as an element of price definition.
- Necessary use of the flexibilities.
- The important role of Judiciary .
- Competition law.
- Opposition: as in the Tenofovir case (the role of civil society in Brazil and in India for example. ).

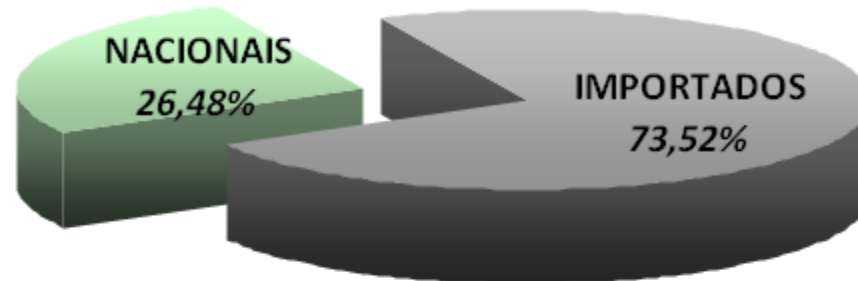
# Proportion - Expenditure with ARV, 2008

**GASTO (EM MILHÕES DE R\$) COM AQUISIÇÃO DE ARV, SEGUNDO FORNECEDOR  
BRASIL, 2008**



Total	R\$ 585.270.960,11	100,0%
<b>Nacionais</b>	<b>R\$ 161.555.223,60</b>	<b>27,6%</b>
<b>Importados</b>	<b>R\$ 423.715.736,51</b>	<b>72,4%</b>
ABC	R\$ 5.736.116,50	1,0%
APV Sol.	R\$ 175.095,65	0,0%
ATV	R\$ 133.048.560,00	22,7%
ddi EC	R\$ 3.375.540,00	0,6%
DRV	R\$ 21.913.650,00	3,7%
EFZ	R\$ 15.356.145,52	2,6%
T-20	R\$ 38.165.601,60	6,5%
FPV	R\$ 10.862.190,00	1,9%
LPV/r	R\$ 113.762.860,32	19,4%
RTV	R\$ 7.335.226,92	1,3%
NVP Susp.	R\$ 469.750,00	0,1%
TDF	R\$ 73.515.000,00	12,6%

## GASTO ESTIMADO COM A PROGRAMAÇÃO PARA AQUISIÇÃO DE MEDICAMENTOS/AIDS - 2009\*



Total	R\$ 656.822.982,41	100,00%
<b>NACIONAIS</b>	<b>R\$ 173.903.800,00</b>	<b>26,48%</b>
<b>IMPORTADOS</b>	<b>R\$ 482.919.182,41</b>	<b>73,52%</b>
Abacavir (ABC)	R\$ 4.833.990,50	0,74%
Atazanavir (ATV)	R\$ 92.602.112,40	14,10%
Darunavir (DRV)	R\$ 30.601.268,16	4,66%
Didanosina EC (ddI EC)	R\$ 5.094.684,00	0,78%
Efavirenz (EFZ)	R\$ 1.321.537,80	0,20%
Enfuvirtida (T-20)	R\$ 68.215.328,55	10,39%
Lopinavir/ritonavir (LPV/r)	R\$ 119.559.335,00	18,20%
Nevirapina (NVP) Suspensão Oral	R\$ 88.320,00	0,01%
Raltegravir (RAL)	R\$ 44.537.706,00	6,78%
Ritonavir (RTV)	R\$ 10.908.900,00	1,66%
Tenofovir (TDF)	R\$ 105.156.000,00	16,01%

Fonte: Coordenação-Geral de Assistência Farmacêutica de Medicamentos Estratégicos - CGAFE/DAF/SCTIE/MS e DST/AIDS

\* Gasto estimado com base nas últimas aquisições (Sujeito a alteração).

# Efavirenz

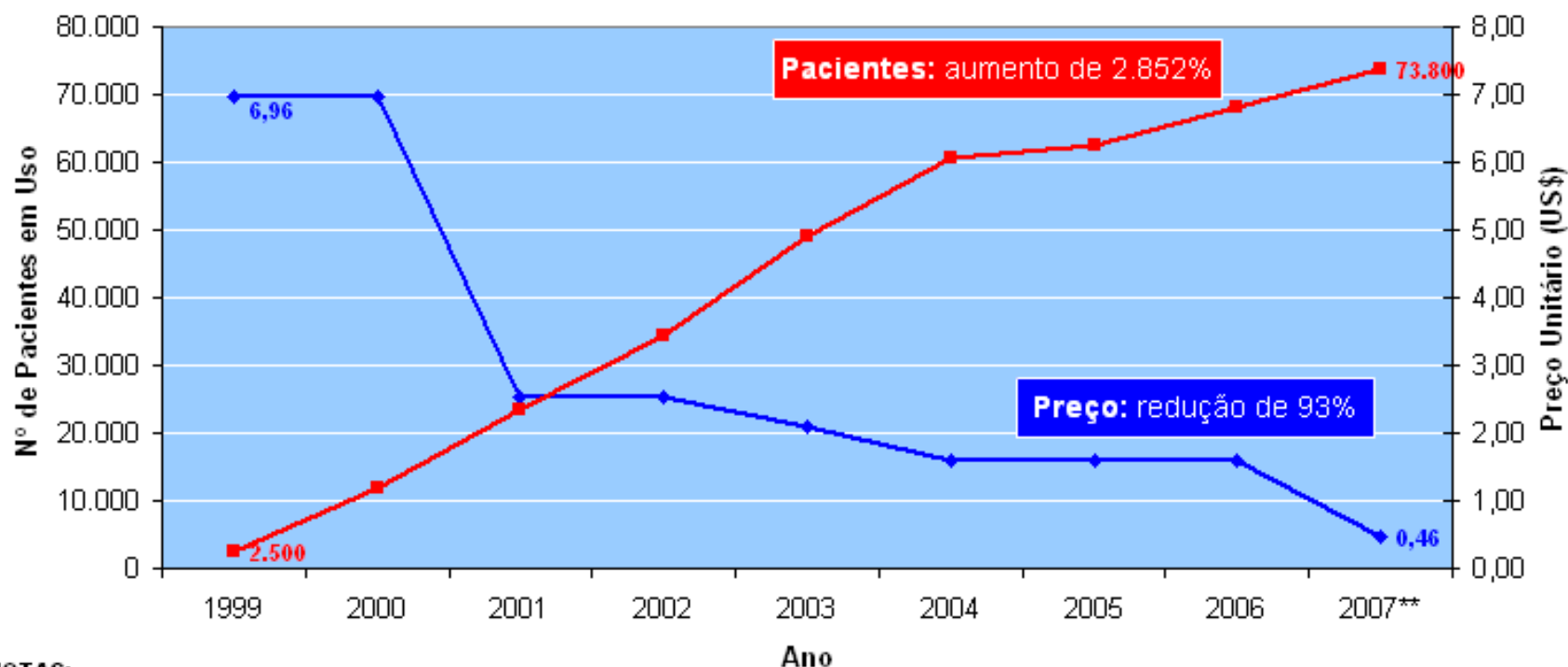
- 75,000 patients (2007) to 90,000 patients (2009)
- Long negotiation process – price stable since 2003 - US\$ 1,59/tb
  - Thailand – 1,2% prevalence
    - 17,000 patients – **US\$ 0,67/tb**
- Annual cost - from US\$ 580.00 to US\$166.36
- Estimated “savings” until 2012 - US\$ 237 millions  
Saving \$ 30 million / year.
- A clear example of the relationship between Patent - Price - Access.
- National production in 2009

# Efavirenz Case

- Portaria 886, April 24th 2007 - Public Interest
- Decree No. 6108 of 4 May 2007 - granted compulsory license for public interest, patents relating to Efavirenz, for public non-commercial use;
- Duration (5 years) and the possibility of extension (5 years) ;
- Patent holder – remuneration (1,5%);
- Patent holder must provide the necessary and **sufficient information** for the reproduction of the object;

## EFAVIRENZ (EFZ) PREÇO E PACIENTES EM USO BRASIL, 1999 a 2007\*

◆ Preço Unitário (US\$)    ■ N° de Pacientes em Uso



### NOTAS:

\* Dados referentes a julho/2007.

\*\* Média entre o preço unitário AUROBINDO/UNICEF (US\$ 0,4662) e RANBAXY/OPAS (US\$ 0,4460).

- De 1999 a 2002, aquisição da apresentação cápsula de 200mg.

- A partir de maio/2003, aquisição da apresentação comprimido de 600mg.

- Para efeito de comparação, de 1999 a 2002, os preços unitários do EFZ 200mg foram obtidos a partir da multiplicação do preço do EFZ 600mg por 3.



# Tenofovir

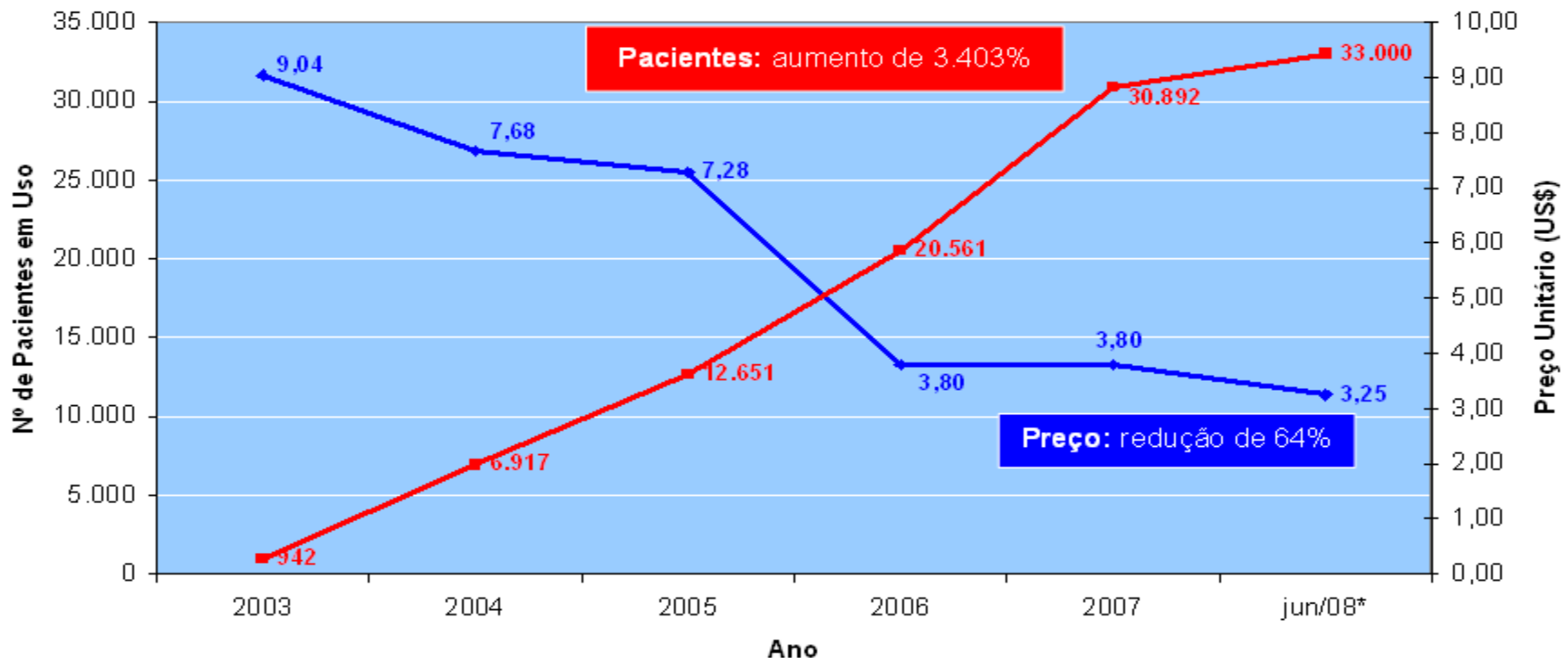
- 1<sup>st</sup> line ARV – increase fastly - 47,000 patients (2009)
- Patent deposited in Brazil in 1995
- Opposition
- MoH declared it of public interest in April 2008
- Brazilian Patent Office does not grant the patent (2009)
- HIV/Aids and hepatitis B.
  - Brazil – US\$ 3.25/tb = US\$ 1,186/yr
  - Thailand – US\$ 1,24/tb = US\$ 454/yr
- CIPLA- prequalified
- Not granted in India to.

# Challenges for price negotiation 2009

TDF = US\$ 42 millions = 14,7% budget imported ARV

## TENOFOVIR (TDF) 300mg PREÇO UNITÁRIO (US\$) E PACIENTES EM USO BRASIL, 2003 a JUN/08\*

◆ Preço Unitário (US\$) - Brasil    ■ N° de Pacientes em Uso



Fonte dos preços: CGAFE/DAF/SCTIE/MS.

\* Sujeito a alteração.

# Technological Network on HIV/AIDS:

<http://www.aidstechnet.org/>

- Argentina, Brazil, China, Cuba, Nigeria, Russia, Thailand, Ukraine.
- Production of anti-retroviral medicines and other medicines for treatment and prevention of opportunistic infections, aiming at the universal access, price reduction and the effective and rational use of generic medicines.
- IP elements.
- India participate in the first meeting.

# R&D Transfer of Technology

- Cuba.
  - Pegylated Interferon
  
- Mozambique
  - Capacity building and manufacturing.
  - Fiocruz and MoH
  
- H1N1 vaccine
- Atazanavir, darunavir etc.

# Challenges for all of us

- Expand access to fair prices
- Use of the flexibilities provided by the declaration of the Doha on TRIPS and Public Health.
- WHA 2010 - Global Strategy on Innovation, Public Health and Intellectual Property - implementation...
- The need for cooperation and exchange of information among the developing countries.
- Transfer of technology.



*Mind the Gap!*



JARRAS

# Thank you!

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