Price control and patented drugs

Médecins Sans Frontières(MSF)

Campaign for Access to Essential Medicines

Since 1999 working internationally to improve access to essential medicines

12 April , 2008

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

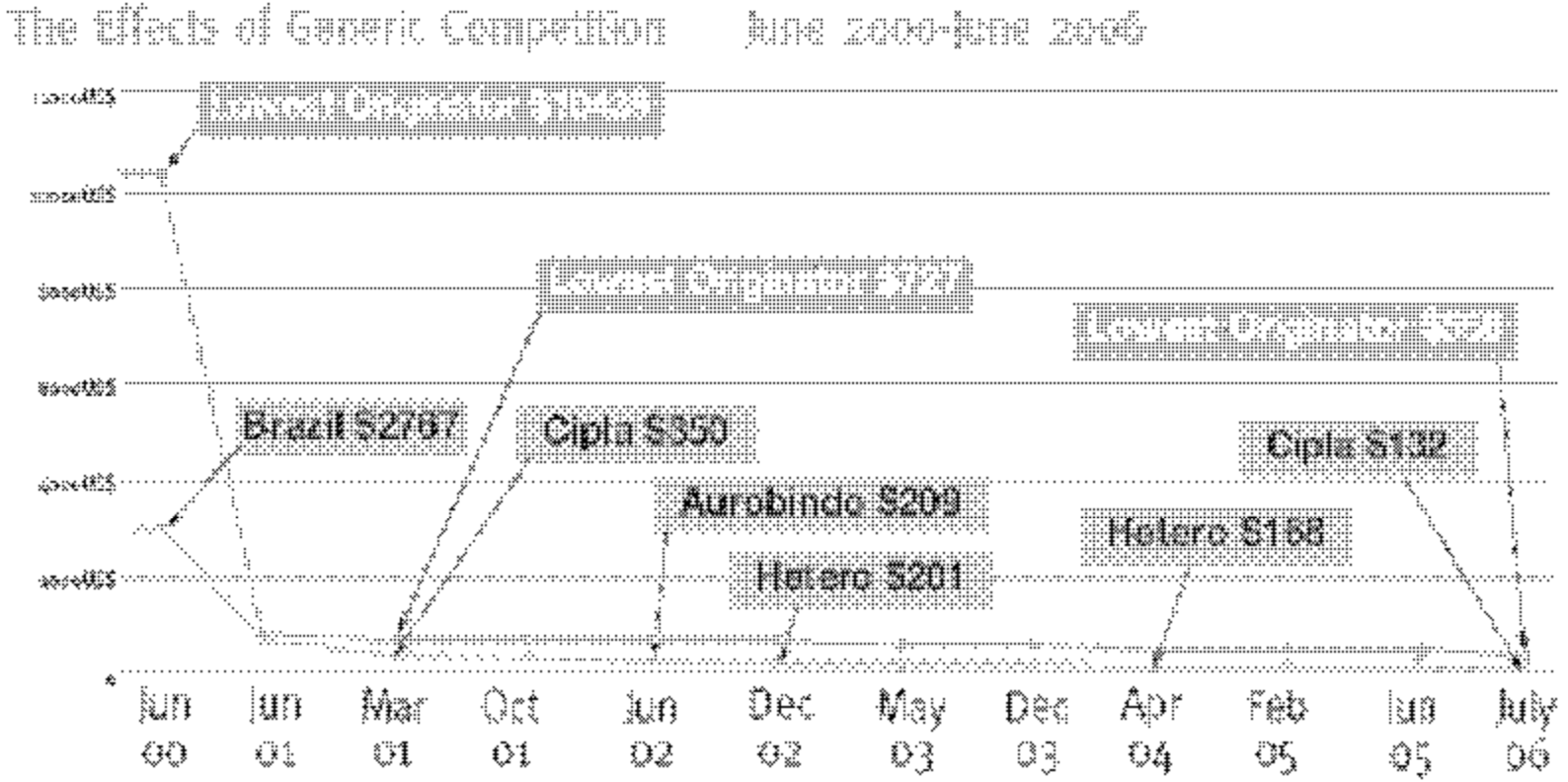
Why are we concerned about patents?

- 100% of AIDS drugs used by GoI for HIV/AIDS treatment are affordable generic drugs
- 84% of the drugs used by MSF for treating more than 100,000 people living with HIV/AIDS in 30 different countries are affordable generic antiretrovirals

Production of /access to quality affordable generic medicines is therefore key in making life-extending treatment available to more people who need it.

Generic competition needed to drive prices down: the example of AIDS medicines

Graph 1: *Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.*



Generic competition has shown to be the most effective means of lowering drug prices.

Absence of patents leads to "three in one AIDS pill"

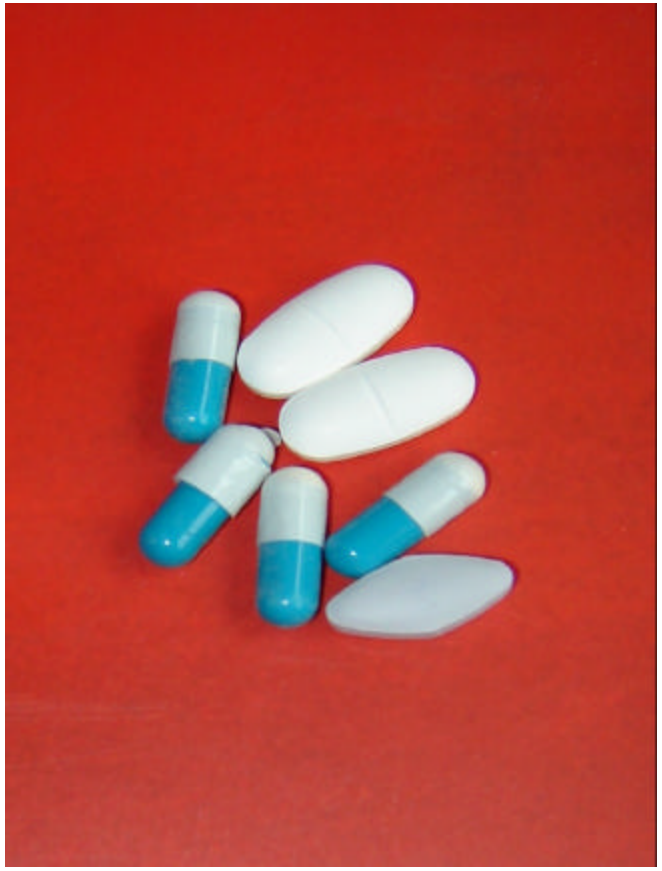
d4T/3TC/NVP (fixed dose combination - FDC)

Individual compounds were not patented in India

Made treatment possible in resource poor countries

Presence of patents in China means no "three in one AIDS pill"

As 3TC is patented in China, no FDC possible



India a Key Supplier of life saving drugs

- ***MSF's patients depend on Indian generic AIDS medicines***

- 50% of PLWA in the developing world depend on Indian generics
- 67 % of medicines exports from India go to developing countries.
- Approx. 50% of the essential medicines that UNICEF distributes in developing countries come from India
- 75-80% of all medicines distributed by the International Dispensary Association (IDA) are manufactured in India.
- In Zimbabwe, 75% of tenders for medicines for all public sector health facilities from India
- Lesotho, buys nearly 95% of all ARVs from India

The situation pre- TRIPS

- Brazil, No Pharmaceutical Patents

- 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

- Pharmaceutical products became patentable in West Germany, 1967; France 1967; Italy 1979; Spain 1992

- India Patents Act, 1970 no patents on pharmaceutical products (Based on German model)

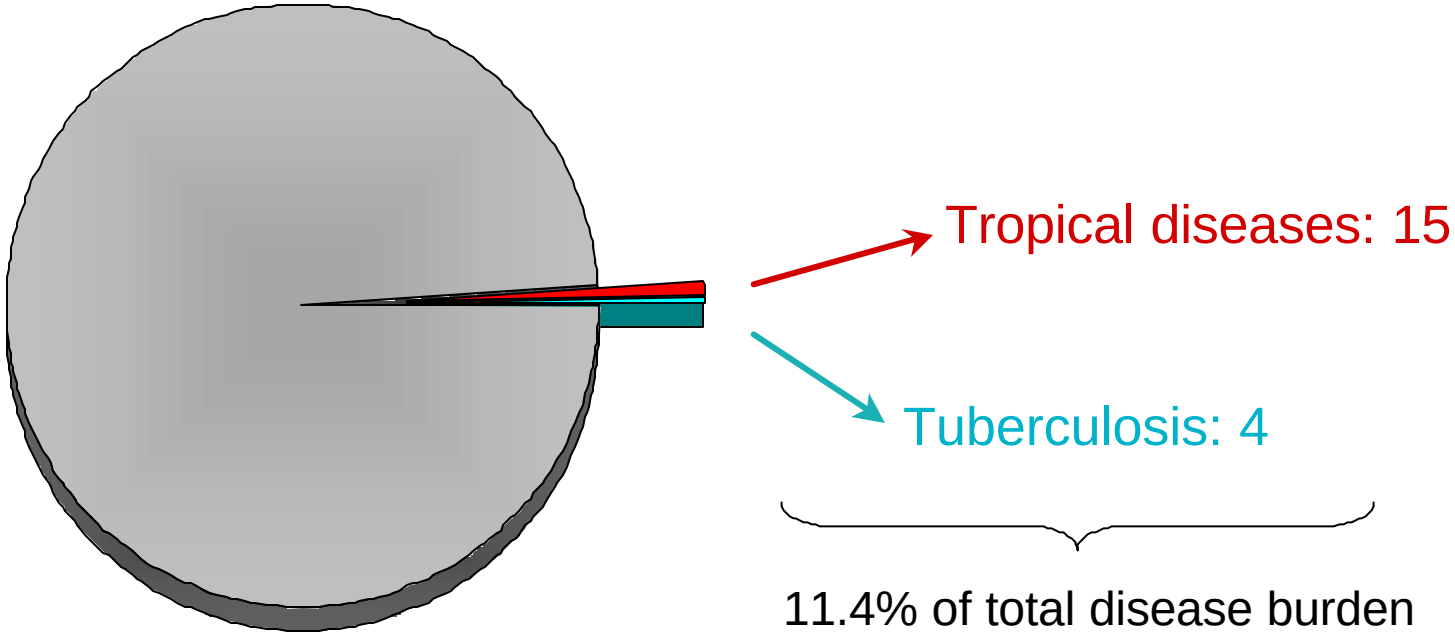
The argument for more & more patents: The justification of the TRIPS agreement

Patent system is a social policy tool. Primary justification for granting patents is the benefit to society as a whole by promoting innovation in exchange for a limited monopoly.

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**

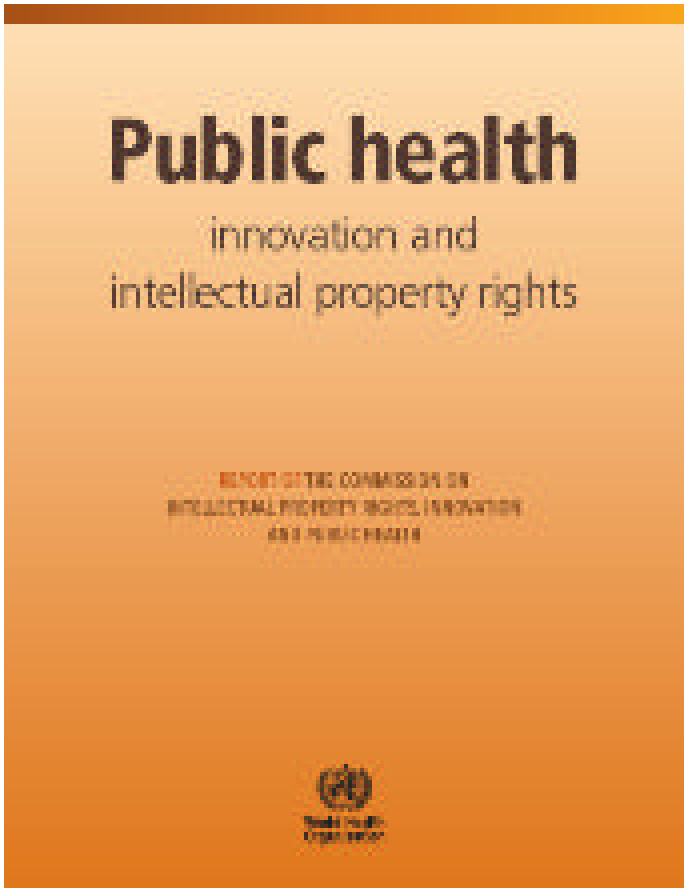


*Trouiller et al., Lancet 2002, **359**:2188-94; updated figures: Torreele, Chirac 2005*

Patent sys fails to stimulate R&D for neglected diseases

- **Sleeping sickness**, treatment ineffective or toxic
- **Kala' azar -** most common treatment was developed in the 1930s.
- **TB -** increasingly ineffective drugs dating from the 1950-1960s. Commonly available test, developed in 1882 detects only in 45-60% of cases
- **AIDS treatment** often not adapted to resource poor countries

Bad Bargain?



- "There is no evidence that the implementation of 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

Globalisation of Patent Rules

- 1995 WTO Trade related aspects of intellectual property rights agreement (TRIPS)
- “minimum” standards of protection of intellectual property rights
- **20 year patents on pharmaceutical products**
- No differentiation between essential medicines and trivial goods
- **2005 Indian amended its patents act to be compliant with TRIPS and starts to grant product patents (transition period ends).**

Prognôsis

A granted patent in India for an essential drug (including Antiretrovirals) will block generic production by Indian companies and make drugs either unavailable or unaffordable (or both) across the developing world

Therefore India must be careful in granting patents and should implement public health safeguards to limit the no of patents granted and mitigate the impact of TRIPS

...impacts on generic production

- **Indian co(s) can no longer produce a low cost essential drug if a patent is granted**

E.g. of drugs patented in India

- **HIV / AIDS –** valganciclovir, etravirine
- **Cancer –** erlotinib, sunitinib maleate
- **Hepatitis C -** pegylated interferon alfa-2a

Do patented drugs need price monitoring/regulation and control?

Price>Patented drugs:

Price of Valganciclovir – Rs. 1040/tablet

(AIDS related opportunistic infection which causes blindness)

Price of erlotinib – Rs. 3200/tablet

Used in lung cancer

Availability>patented drugs:

(Most patented drugs imported into India, No local API production

The drug has to be ordered from a particular dealer)

If yes, NPPA needs information on drug patents from the Indian Patent Office

- *Affordable Pricing*

How?

Reference pricing??

Difficulties:

- Price of patented drug in other countries even after price negotiation is not affordable!

E.g. Lopinavir/Ritonavir heat stable:

- *In 2006 no Indian generic on the market*
- Prices obtained in **Brazil** after price negotiation $1518/ppy
- **In Thailand in two years of negotiations:**
- Before 2006 – 2967/ppy
- In 2006 – 2000/ppy
- Thais issue CL. Abbott offers $1000/ppy
- First generic comes on the market in 2007 >$676/ppy >$500
- Thais buy the generics
- **Brazil is still paying $1518/ppy to Abbott**
- Middle income countries are unable to pay high prices of MNCs

Price negotiations?

Efavirenz 600 mg
Used in the treatment of HIV/AIDS, first line & second line therapy, prescribed by WHO

Merck is the originator company

- **Not patented in India**
- (under opposition on grounds of new form of old drug)
- More than four producers. Lowest price **$ 165/ppy**

Patented -

- Thailand $468/ppy
- Brazil - $580/ppy
- China - **$ 900/ppy** (Merck)

Price negotiations

- Price negotiations to succeed >generic reference pricing crucial!

EFV price negotiation in Brazil

- In 2003 for EFV - Merck offers Thailand $760/ppy
- Since 2004 Merck prices EFV in Thailand $468 /ppy
- In 2006 Thailand issues CL > $216>$170 /ppy
- Merck after CL offers Thailand $288 /ppy

EFV price negotiation in Brazil

- In 2006 Brazil pays $580 /ppy (price after price negotiations
- After price negotiation Merck offers Brazil 2%discount on $580 >$568 /ppy
- Brazil issues CL > $170 /ppy

Recent MSF experience of price negotiation
Oral Valganciclovir (four month therapy)

Treatment for:

cytomegalovirus retinitis (CMV) in people with AIDS can lead to blindness

alternative treatment:
using **intravenous** ganciclovir requires infusions twice a day for 2 or 3 weeks, and then daily infusions for another 2 or 3 months.
with intraocular injections of ganciclovir **- doctors have to repeatedly jab patients in one or both eyes**

In most countries Roche price
US$ 10,000

No generic available as patented in India (patent is being challenged as it is a old drug in a new form)

After negotiations price from Roche of € 1,281 (US$ 1,899). This price is unaffordable for patients, govts and MSF. Without generic production from India price is not likely to fall

Indian Patent Act 2005

Light at the end of the tunnel?

2005 Indian Patents Act

- *Public health safeguards:*
  - Automatic licensing for drugs already in production
  - Pre-grant opposition
  - Section 3d – Narrows the scope of patentability & limits patenting to real innovations
  - **Compulsory licensing** for drugs patented in India but not yet produced by generic manufacturers

- *Indian law sets international precedent for TRIPS implementation for developing countries*

Bitter /Strong Medicine?

generic competition for patented drugs…

Need for Compulsory Licensing to reduce prices

Need:

- If patented drugs are unaffordable and/or unavailable. A compulsory license for local production is often the only solution to solve procurement problems, increase local availability of drugs and save on costs for patients and the national health budget.

Why:

- Increase the power of the Ministry of Health to purchase drugs and medicines from sources independent of the patentee
- Increase access to affordable medicines of patients in India and other developing countries

How:

- Compulsory Licensing allows generic competition. License to produce /sell to competitor to reduce prices

Compulsory licensing

Thailand:

Provision – « …any govt ministry, bureau or dept can issue a CL to carry out any service for public consumption, to prevent or relieve a severe shortage of drugs or for any other public service »

Health authorities issues compulsory licenses in 2006/2007 on AIDS drugs (efavirenz & kaletra) & heart disease drug (Clopidogrel) for universal health scheme

>Reduced the price of Clopidogrel from 70 baht/day to 7 baht/day

> Threat of CL: Novartis agrees to supply the Thai govt imatinib (gleevec) free of cost

Requires political will!

compulsory licensing in the interest of public health
Indian Patent Act

Specific Provisions:

Sec. 84 – On application by generic companies

Sec. 92 – notification by central govt for public non-commercial use / national emergency / extreme urgency

Sec. 92A – for export

Sec. 100 – govt use

Compulsory license: India

India « is still to make use of CL provisions

India « some legal reform needed for CLs to be issued

- Three year waiting period if Indian generic companies file for CL
- Sec 90 (2): forbids the grant of CL for purposes of importation, which may raise problems in cases importation of raw materials needed for the manufacture of essential medicines in India

India >> Rules to be notified to the Act

- No renumeration/royalty guidelines. To minimize the incidence of expensive and delaying litigation on CL

Preparing for a compulsory license

- Requires legal amendments
- Requires Ministry of health involvement in identifying drugs for which CLs need to be issued
- Requires an interministerial process between Ministry of Commerce, Health, Fertilizers & Petrochemicals

A paradigm shift is needed:

Changing patent rules to prioritize people's health needs over profit