Pharmaceutical patent system

Policy options

TRIPs & developing countries
Patent system and local production of pharmaceuticals

MEDECINS SANS FRONTIERES

- Field operations in about 70 countries. In 2010:
  - 7.3 million outpatient consultations
  - 362 thousand hospital admissions
  - 983 thousand (confirmed) malaria cases
  - 183 thousand on HIV anti-retroviral treatment
  - 301 thousand children with severe malnutrition treated
  - 4.5 million vaccinated against measles

“*Today, a growing injustice confronts us. More than 90% of all death and suffering from infectious diseases occurs in the developing world. Some of the reasons that people die from diseases like HIV/AIDS, tuberculosis, sleeping sickness and other tropical diseases is that life saving essential medicines are either too expensive, are not available because they are not seen as financially viable, or because there is virtually no new research and development for priority tropical diseases.*

This market failure is our next challenge.

The challenge however, is not ours alone. It is also for governments, international government institutions, the pharmaceutical industry and other NGOs to confront this injustice. What we as a civil society movement demand is change, not charity.

Nobel Lecture delivered by Dr. James Orbinski, Médecins Sans Frontières International President 1998-2001, after MSF was awarded the Nobel Peace Prize in 1999.

”

The Access Campaign's main issues:

- Access Campaign Founded in 1999 because MSF medical staff frustrated at not being able to diagnose and treat patients with appropriate and effective tools

- **Unaffordable:** Existing medicines, vaccines and diagnostics are priced out of reach -too expensive for individuals and government treatment programs.

- **Unavailable:** Certain diseases 'neglected' few or no drugs or diagnostics exist or are being developed. (NTD, TB) Production of essential medicines and diagnostics that are needed but do not make profits are abandoned

- **Unsuitable:** Not adapted for needs of developing countries e.g heat stable, child formulations, diagnostic tools

Brief history

Post independence high prices of medicines, because of patent law carried over from British rule

Monopoly: Product patents to MNCs meant that Indian domestic producers could not manufacture

Know How: No capacity to manufacture

Unaffordable: Highest prices in the world

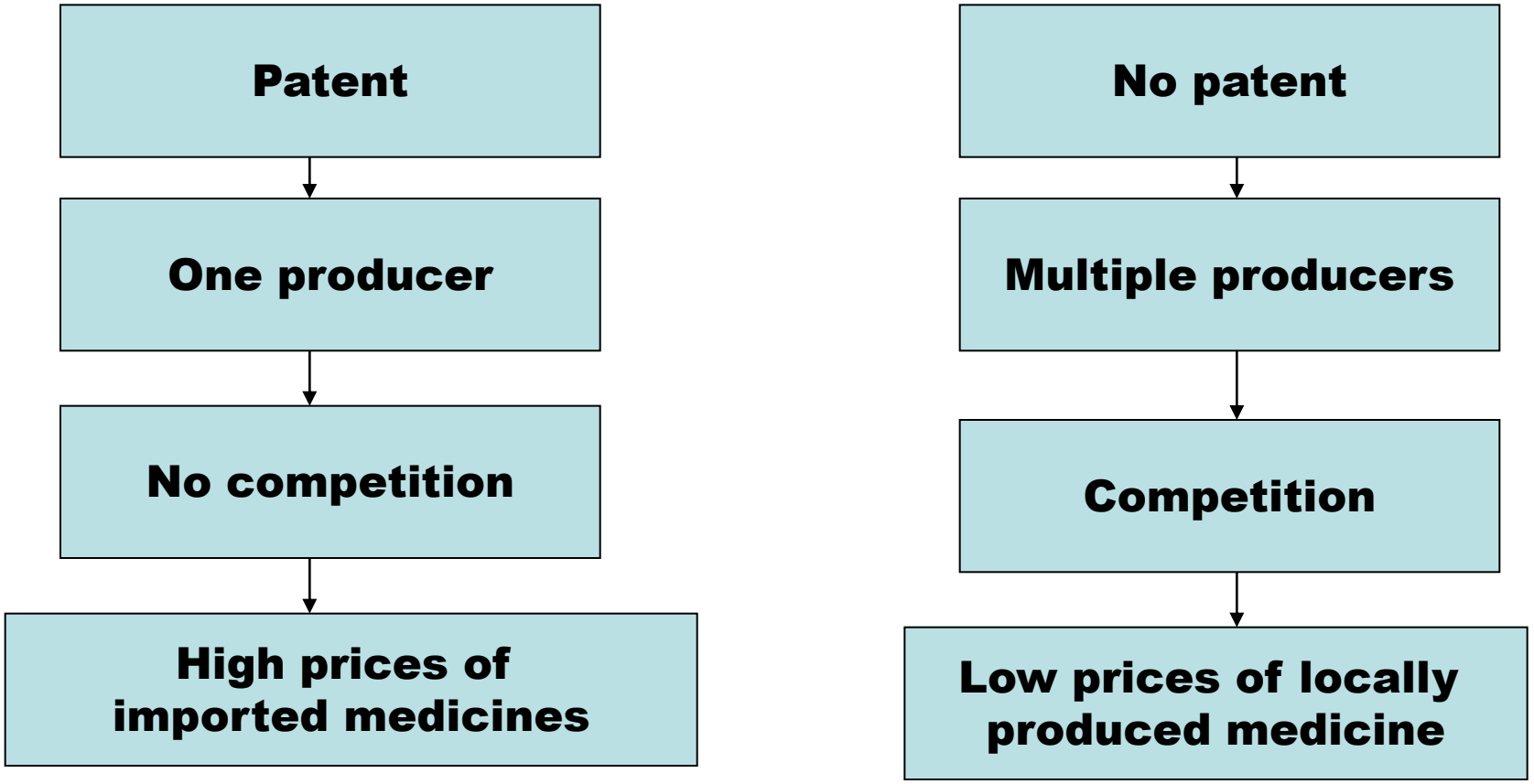
1970: Legal reform aimed at Local production

“no product patents” in 1970 Patents Act

Set up PSUs who developed know how to produce API (raw material) and formulations

1970 – 2005: Indian generic companies become the “pharmacy of the developing world”

Patents and local production



2000

South Africa: Historic "Defiance Campaign" Imports Generic Fluconazole

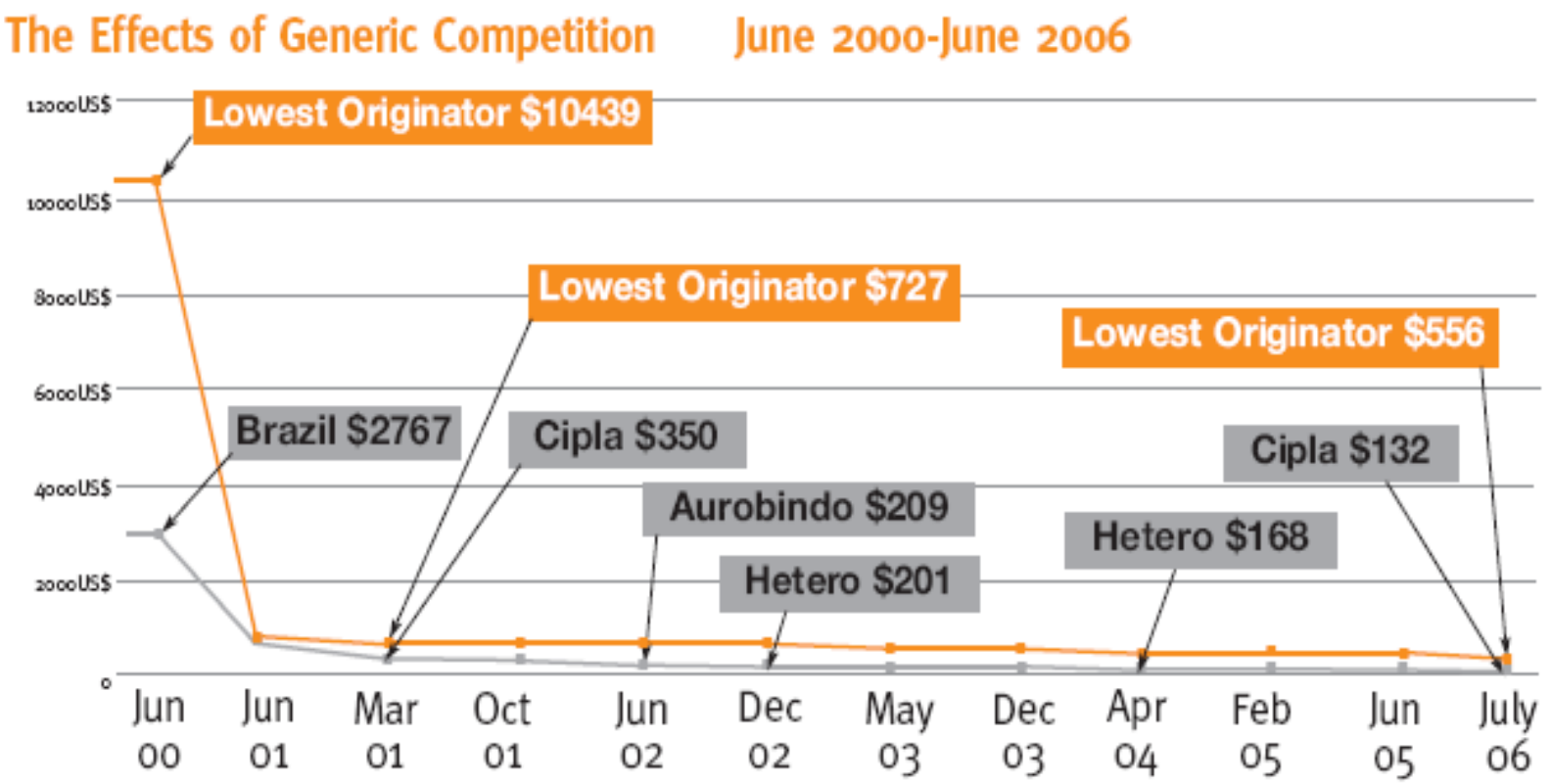
By John S James
From AIDS Treatment News

October 20, 2000

This week South Africa's Treatment Action Committee (TAC), the major HIV treatment activist group in the country, defied patent laws by importing generic fluconazole from Thailand, where TAC purchased it more than 50 times cheaper than the South African retail price, according to news reports in the country. Many people in Africa have died because they could not afford the

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.*



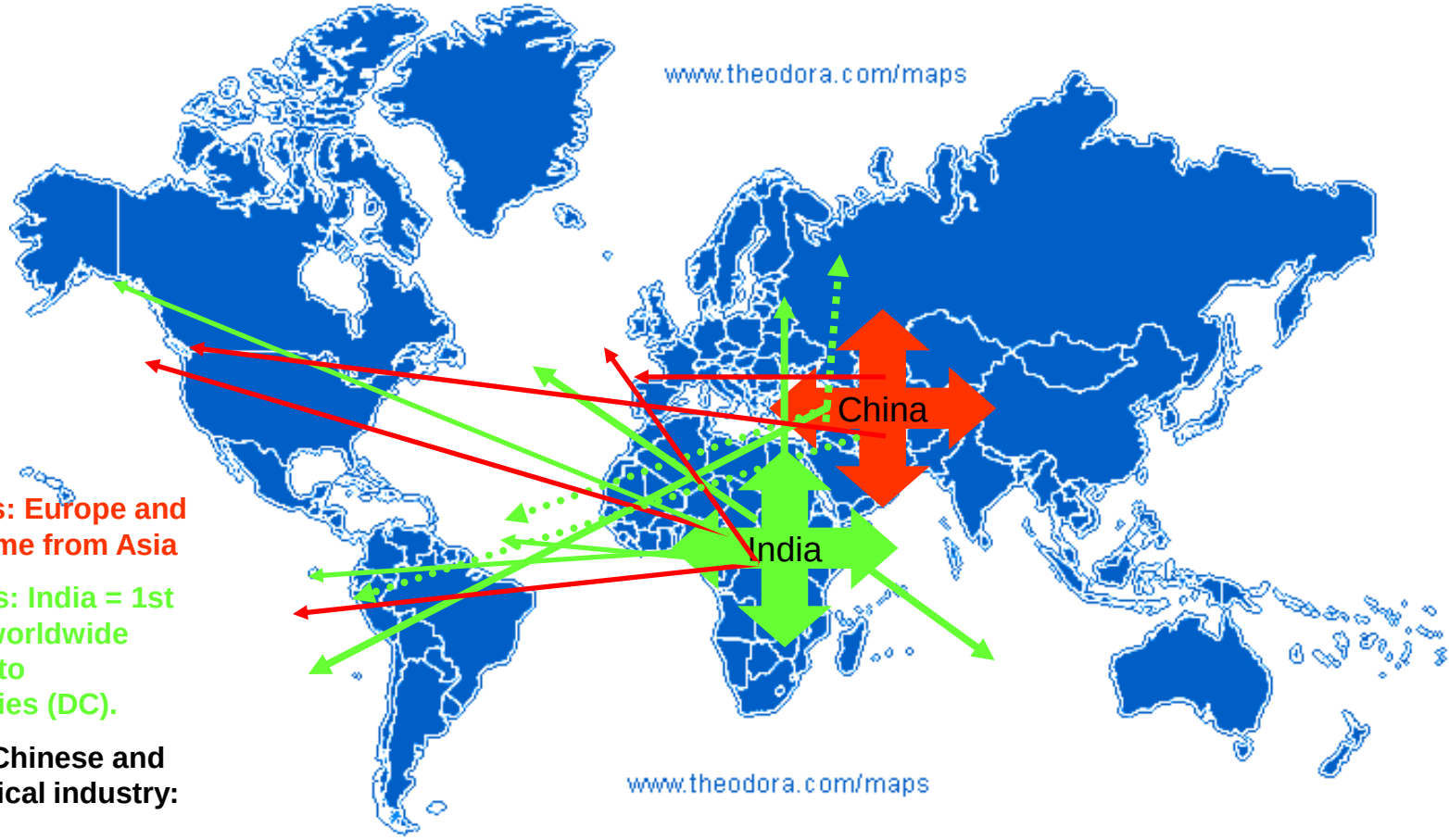
Generic competition has shown to be the most effective means of lowering drug prices.

The lack of patents allowed INDIAN generic Companies to innovate simpler treatment – fixed dose combinations

Production of drugs

TODAY

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES



- Active Ingredients: Europe and USA: 80 to 90% come from Asia

- Finished Products: India = 1st generic producer worldwide and main exporter to Developing Countries (DC).

- Yearly growth of Chinese and Indian pharmaceutical industry: about 15 to 20%

- 56% of indian exports are made in D.C.

- more than 50% of worldwide prescriptions are generics. Can be 80% - 90% in some DC

Active Ingredients

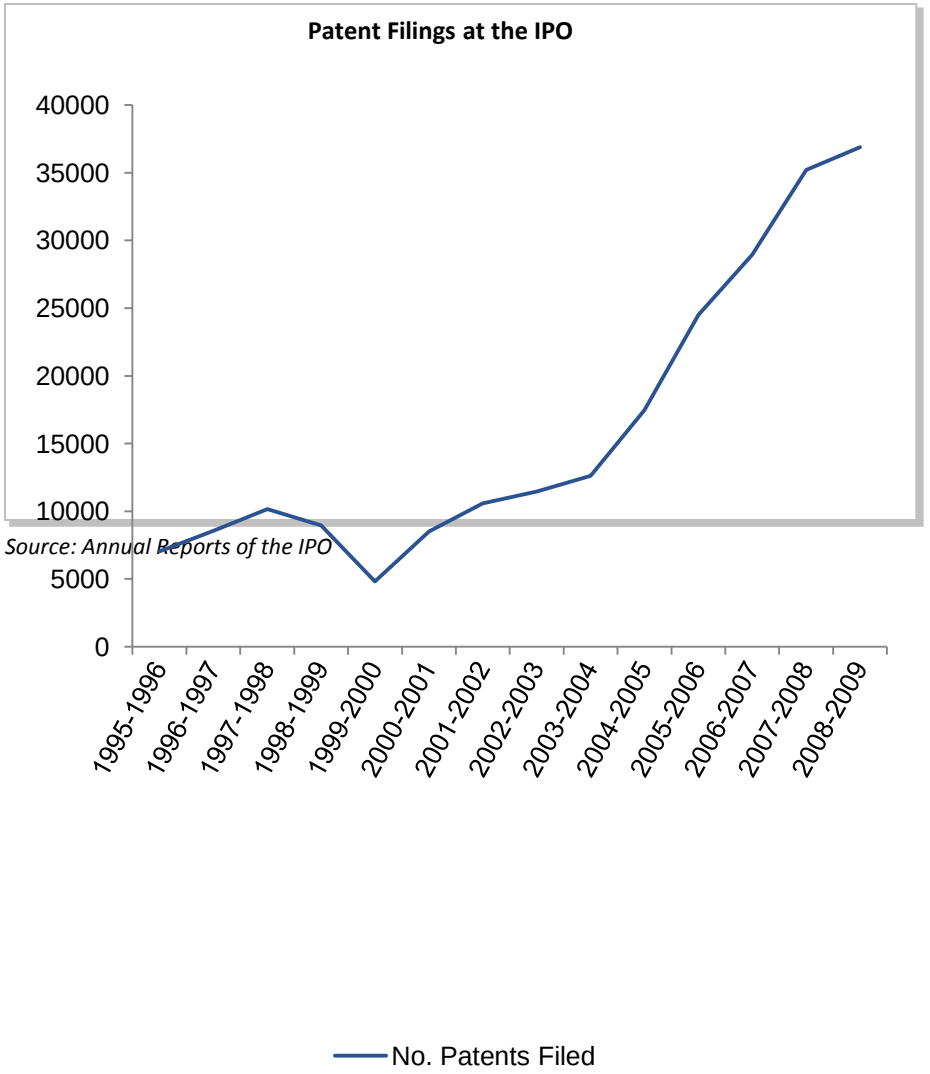
Finished Products

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 lifesaving medicines and trivial goods
- **2005 India has to amended patents act to be compliant with TRIPS and starts to grant product patents (transition period ends).**

Patent Filing Trends in India

- Major Increase in the number of patent applications filed at the Indian Patent Office (IPO)
- PCT is the favorite filing route
  - ~60% applications filed with the IPO were national phase filings under PCT
- Majority of filers are foreign residents (Bayer, Gilead)



Source: Annual Reports of the IPO

Source: Annual Reports of the IPO

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

The Glivec story

In 2001 Novartis introduced Glivec (Imatanib Mesylate) in India

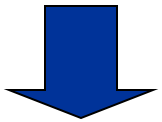
Comparative prices

	1 month	1 year
Glivec	**US$ 2,500**	**US$ 30,000**
Generic equivalent	**US$ 200**	**US$ 2,500**

The Glivec story

In 1995…

INDIA SIGNED AN AGREEMENT WITH WTO TO MOVE FROM PROCESS PATENT



2005: PROCESS & PRODUCT PATENTS FOR MEDICINES

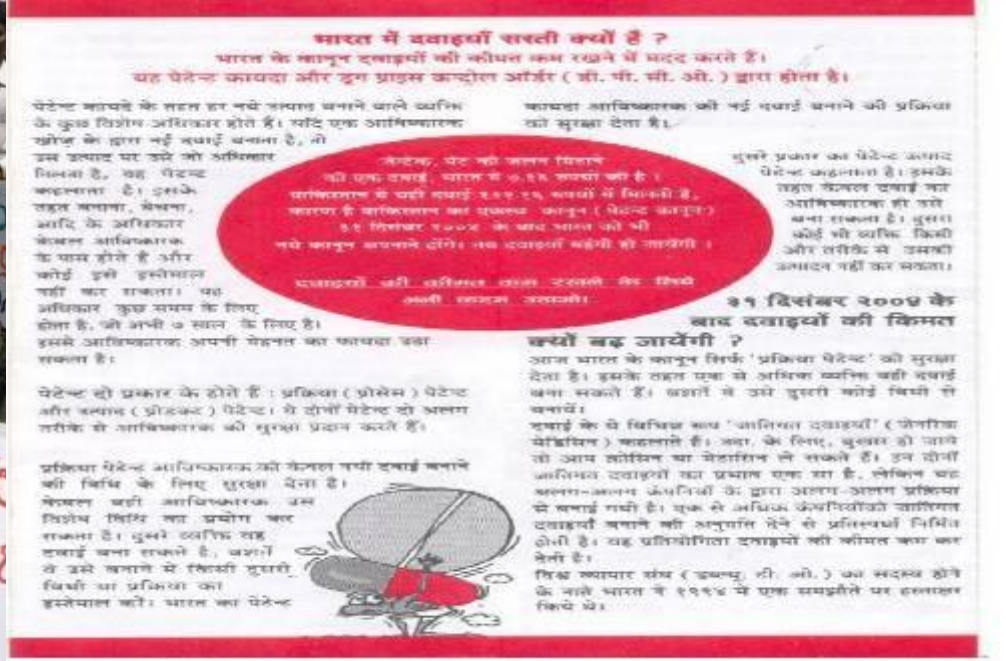
The Glivec story

1998	**Novartis applied for patent in India on** for a crystalline form or polymorphic form of its anticancer drug imatinib mesylate (Glivec)
Jan 2003	**Based on this application Novartis applied for 5 yr EMR in India (no examination required or opposition allowed)**
Nov 2003	Novartis granted EMR pharmaceutical companies told by court to stop marketing affordable generic versions of imatinib

2004: Result of Glivec's EMR

CANCER PATIENTS AID ASSOCIATION

CPAA could no longer supply the drug at subsidized rates.



भारत में दवाइयाँ महंगी क्यों हैं ?

भारत के कानून दवाइयों की कीमत कम रखने में मदद करते हैं।

यह पेटेन्ट कानून और ट्रेड रिलेटेड इन्टेलेक्चुअल प्रापर्टी राइट्स एग्रीमेन्ट (ट्रिप्स) द्वारा होता है।

पेटेन्ट कानून के तहत हर नये उत्पाद बनाने वाले व्यक्ति को कुछ विशेष अधिकार होते हैं। यदि एक आविष्कारक खोज के द्वारा नई दवाई बनाता है, तो उस उत्पाद पर उसे जो अधिकार मिलता है, वह पेटेन्ट कहलाता है। इसके तहत बनाना, बेचना, आदि के अधिकार केवल आविष्कारक के पास होते हैं और कोई इसे इस्तेमाल नहीं कर सकता। यह अधिकार कुछ समय के लिए होता है, जो अपने ७ साल के लिए है। इससे आविष्कारक अपनी मेहनत का फायदा उठा सकता है।

पेटेन्ट दो प्रकार के होते हैं : प्रक्रिया (प्रोसेस) पेटेन्ट और उत्पाद (प्रोडक्ट) पेटेन्ट। ये दोनों पेटेन्ट दो अलग तरीके से आविष्कारक की सुरक्षा प्रदान करते हैं।

प्रक्रिया पेटेन्ट आविष्कारक को केवल वही दवाई बनाने की विधि के लिए सुरक्षा देता है। केवल वही आविष्कारक उस विशेष विधि का प्रयोग कर सकता है। दूसरे व्यक्ति वह दवाई बना सकते हैं, जहाँ वे उसे बनाने में किसी दूसरी विधी या प्रक्रिया का इस्तेमाल करें। भारत का पेटेन्ट कानून आविष्कारक की नई दवाई बनाने की प्रक्रिया को सुरक्षा देता है।

दूसरे प्रकार का पेटेन्ट उत्पाद पेटेन्ट कहलाता है। इसके तहत केवल दवाई का आविष्कारक ही उसे बना सकता है। दूसरा कोई भी व्यक्ति किसी और तरीके से उसकी उत्पादन नहीं कर सकता।

११ दिसंबर २००४ के बाद दवाइयों की किम्मत क्यों बढ़ जायेंगी ?

आज भारत के कानून सिर्फ 'प्रक्रिया पेटेन्ट' को सुरक्षा देता है। इसके तहत एक से अधिक व्यक्ति वही दवाई बना सकते हैं। वहाँ से उसे दूसरी कोई किसी से खरीदें।

दवाई के दो विभिन्न नाम 'जानीमत दवाइयाँ' (जेनरिक मेडिसिन) कहलाते हैं। जहां, के लिए, चुनकर हो जाये तो आम क्रोसिन या पेरासिटेमोल ले सकते हैं। इन दोनों जानीमत दवाइयों का प्रभाव एक सा है, लेकिन भाव अलग-अलग कंपनियों के द्वारा अलग-अलग प्रक्रिया से बनाई गयी है। एक से अधिक कंपनियोंको जानीमत दवाइयाँ बनाने की अनुमति देने से प्रतिस्पर्धा निर्माण होती है। यह प्रतियोगिता दवाइयों की कीमत कम कर देती है।

विश्व व्यापार संघ (डब्ल्यू. टी. ओ.) का सदस्य होने के नाते भारत ने १९९४ में एक समझौते पर हस्ताक्षर किये थे।

ACROSS INDIA...

2005: India parliament inserts safeguards into Indian patent law against patent abuse

Local Examination of patent applications by patent office

Pre grant/post grant opposition of patent applications and invalid patents

Patentability criteria > What is not patentable: **new use** of an old drug, or simply **derivatives of old drugs** or **combinations** of old drugs

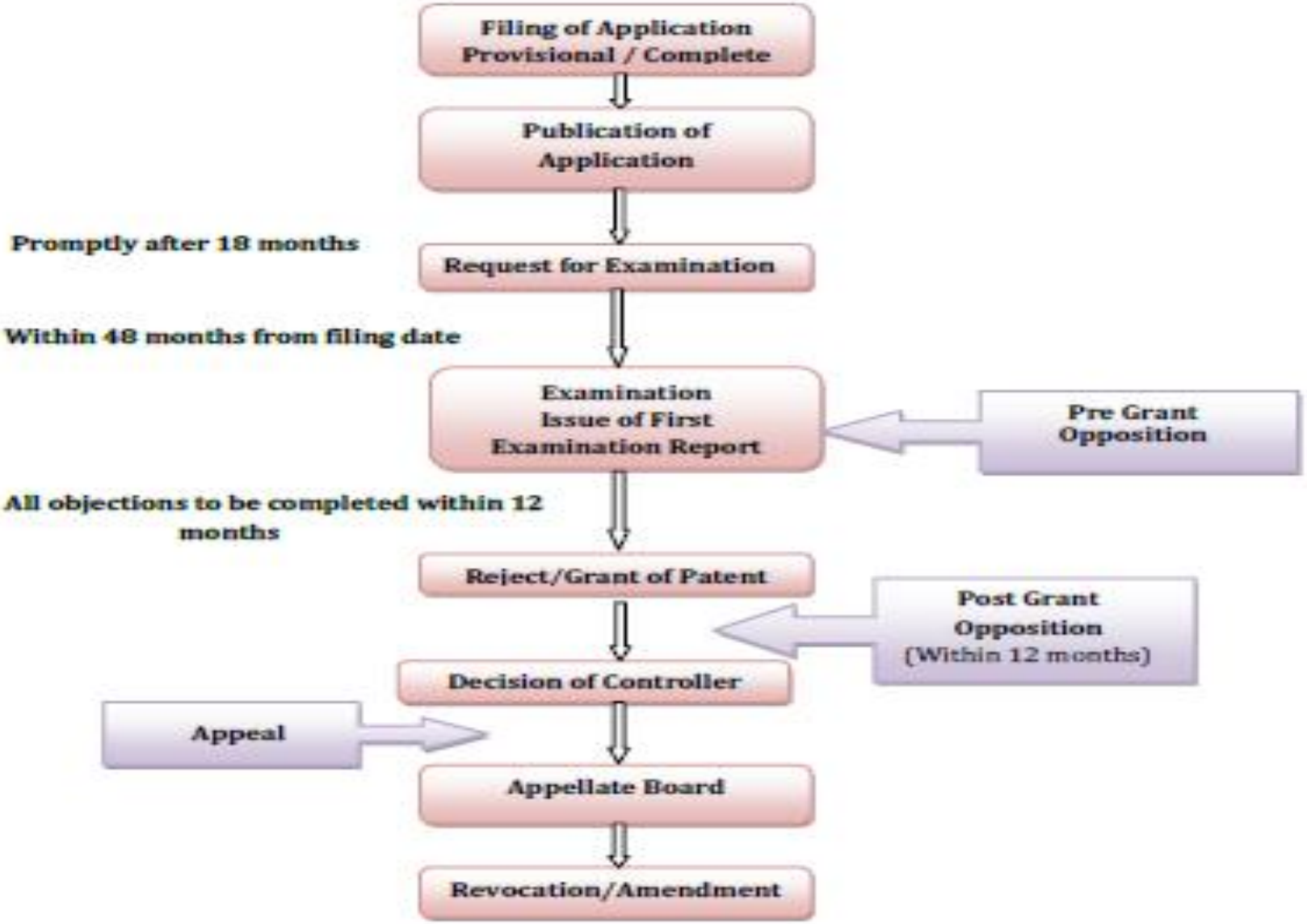
Compulsory license (license to generic companies to produce & market) and **automatic licensing** for drugs already in production

Government use (public non-commercial use)

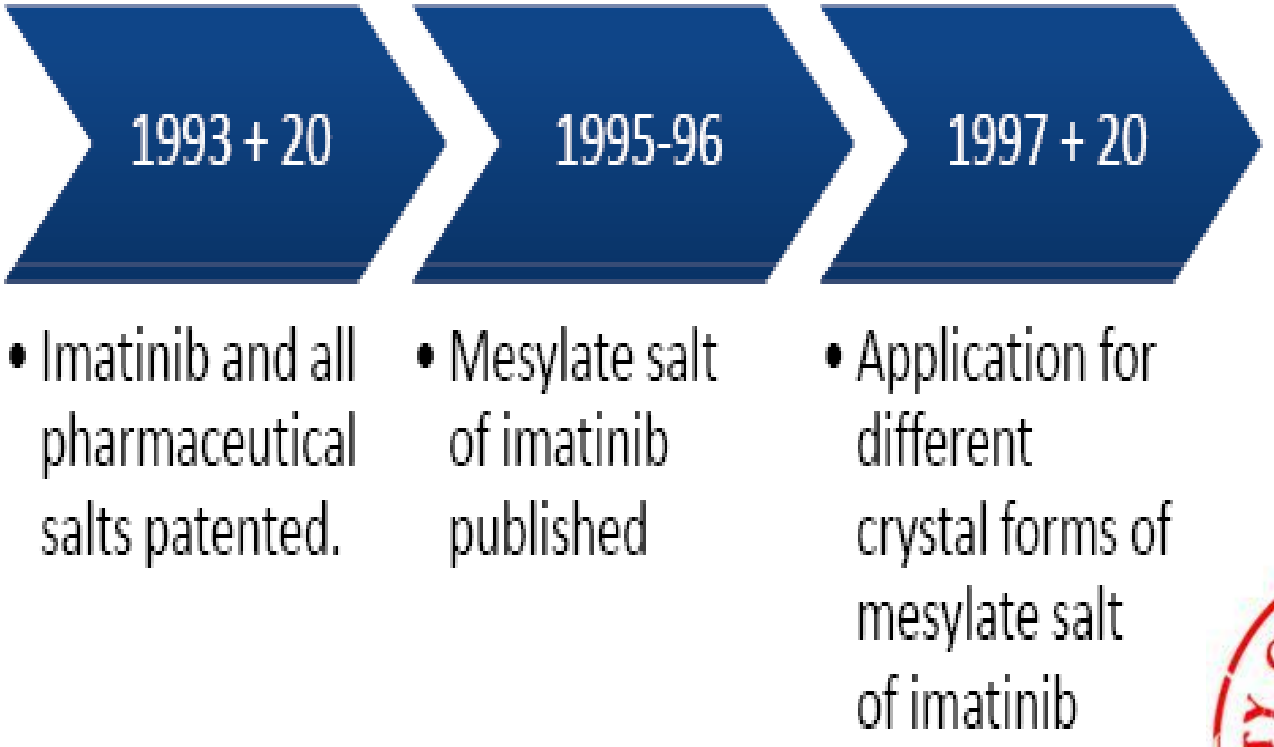
Bolar exception (preparation for generic launch i.e. production for marketing approval & marketing approval)

Parallel importation

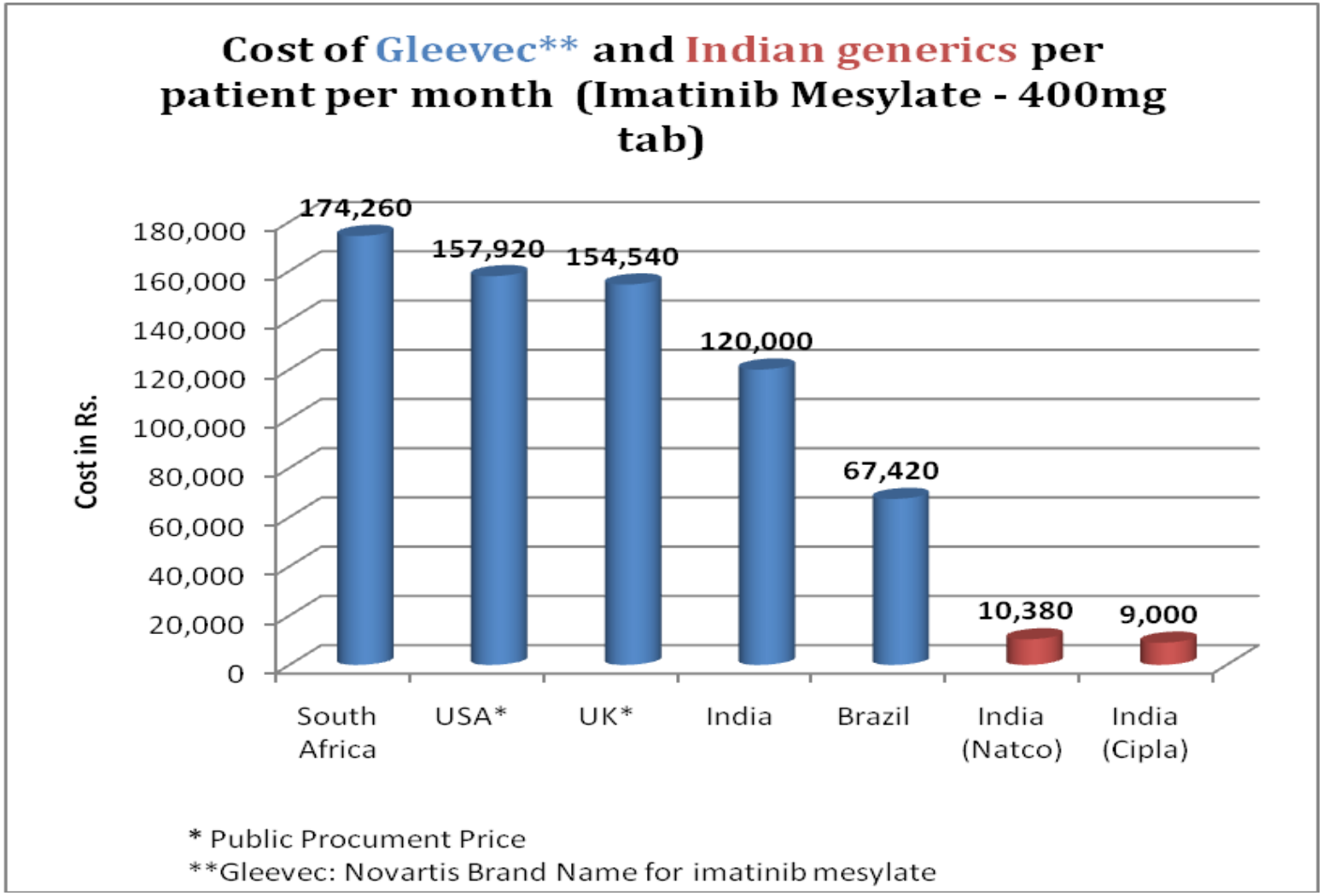
STAGES OF PATENT EXAMINATION IN INDIA



Novartis patent application on life saving cancer drug – CPAA files opposition in 2005



Glivec's patent 1993 application on the base compound was not eligible for an Indian filing because India joined the WTO only in 1995.


Cost of Gleevec** and Indian generics per patient per month (Imatinib Mesylate - 400mg tab)
Cost in Rs.
180,000
160,000
140,000
120,000
100,000
80,000
60,000
40,000
20,000
0
174,260
157,920
154,540
120,000
67,420
10,380
9,000
South Africa
USA*
UK*
India
Brazil
India (Natco)
India (Cipla)
* Public Procument Price
**Gleevec: Novartis Brand Name for imatinib mesylate

Efforts to stop evergreening

Not all patent applications are valid. Many patent applications are for a new use of an old drug, or simply for derivatives of old drugs or combinations of old drugs. (TRIPS requires patent protection for 'inventions')

E.g. AIDS drug patent applications:

1. a fixed dose combination of **lamivudine/zidovudine** used in the treatment of HIV/AIDS: not a new invention but simply the combination of two existing drugs. **Status of application - Withdrawn**

2. **tenofovir disoproxil fumarate (TDF)**, a key AIDS drug: forming a salt (fumaric acid) out of an existing compound (tenofovir disoproxil), is common practice within the pharmaceutical industry, and should not be considered a new invention.

II. **Any person can oppose the grant of a patent application**

Rejections due to local examination and patent opposition

	KNOWN SUBSTANCE	NEW FORM
Salt	Tenofovir disoproxil	Fumarate salt of tenofovir disoproxil
Ester	Ganciclovir	Mono-L-valine ester prodrug of ganciclovir (valganciclovir)
Polymorph	Imatinib mesylate (1993-1996)	Beta crystalline form of imatinib mesylate (1997)
Combinations	Zidovudine, Lamivudine, glidants	Combivir

Combivir patent opposition – Indian and Thai groups hold protests on the same day, issue joint press release…

7 August 2006: PLHIV protest outside GSK offices in Bangkok, Thailand.

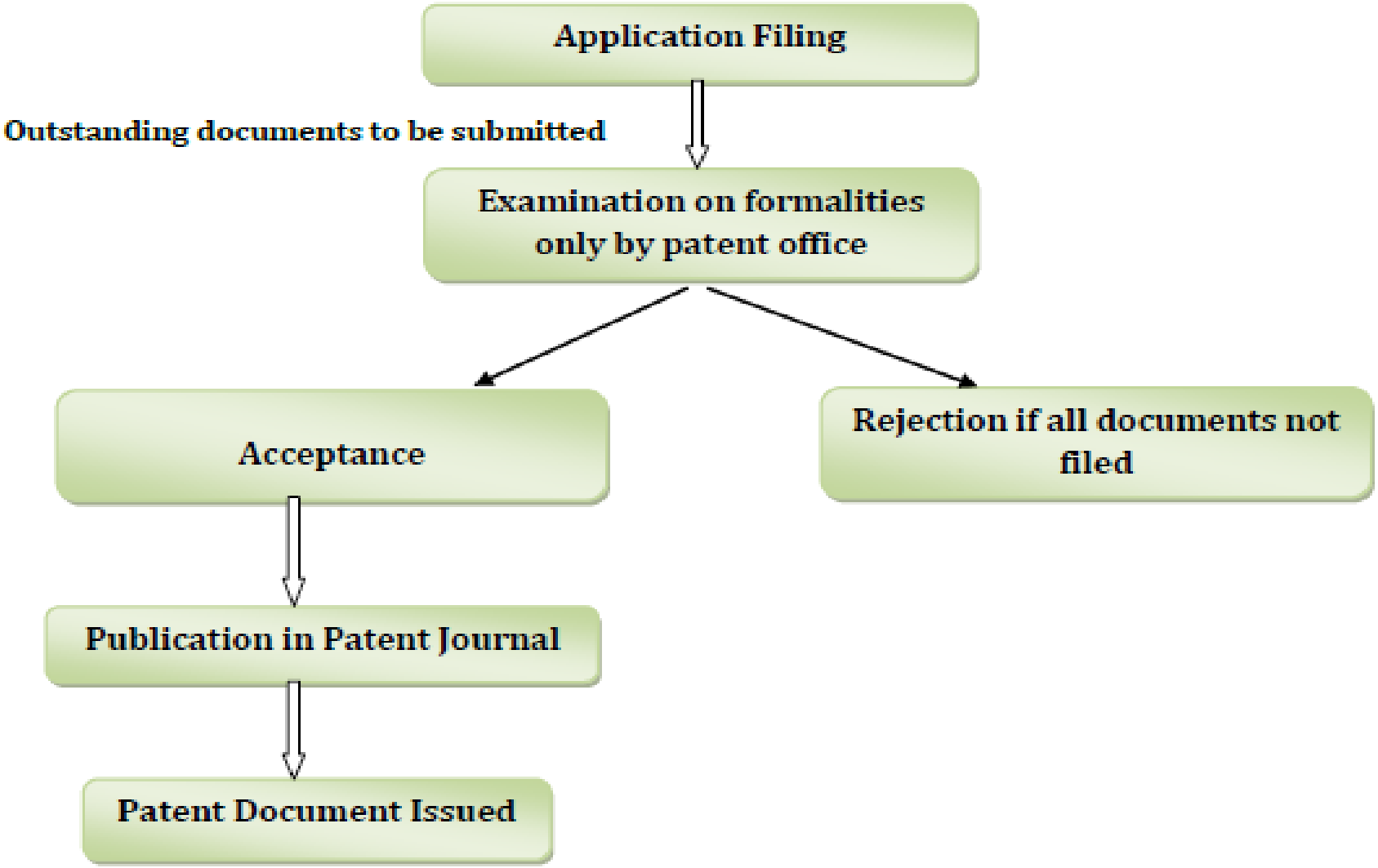
7 August 2006: Indian groups demonstrate outside GSK offices in Bangalore, India.

…GSK announces withdrawal of Combivir patent application

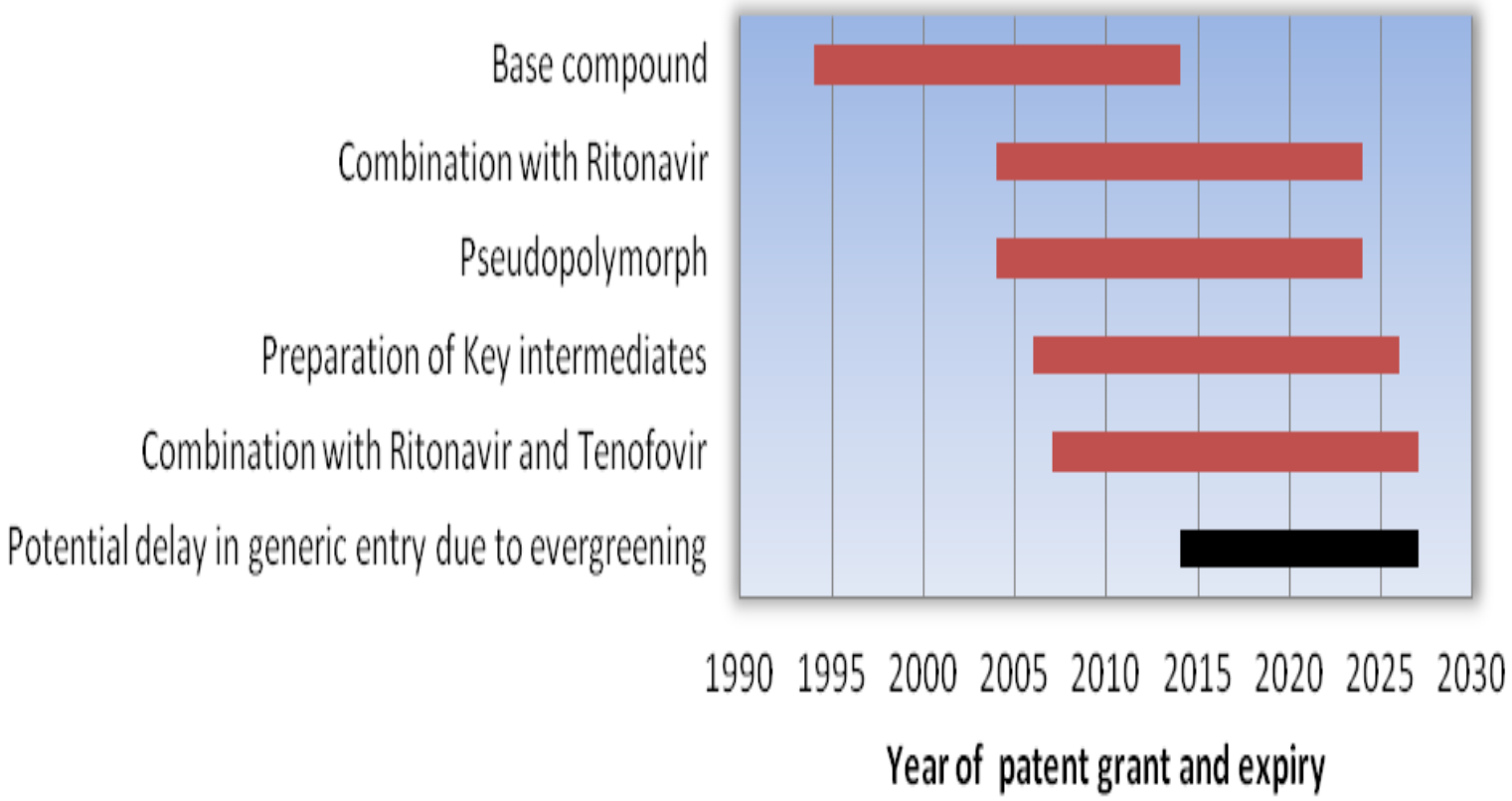
Loon Gangte, President of DNP+ being interviewed on the tenofovir opposition, 10 May 2006

"policy makers in the health area, as well as patent examiners, should be aware that decisions relating to the grant of a patent…can directly affect the health and lives of the people of the country where the patent is granted and enforced." –
WHO/UNCTAD 'Guidelines for the examination of pharmaceutical patents: Developing a public health perspective.'

PATENT REGISTRATION SYSTEM IN SOUTH AFRICA

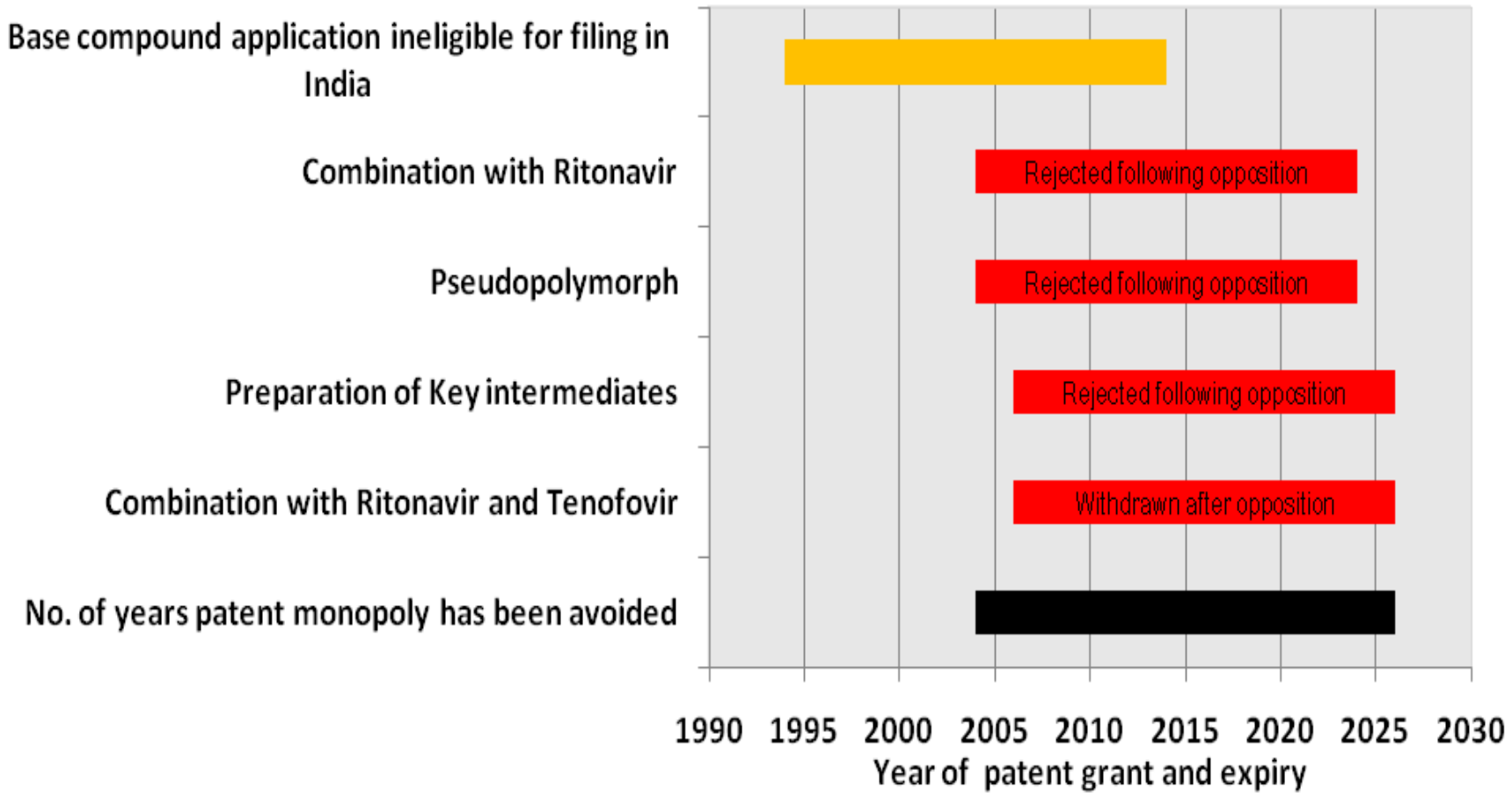


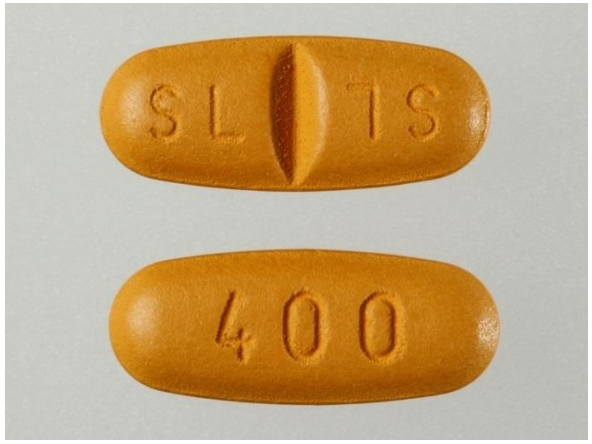
Darunavir Patent Status in South Africa



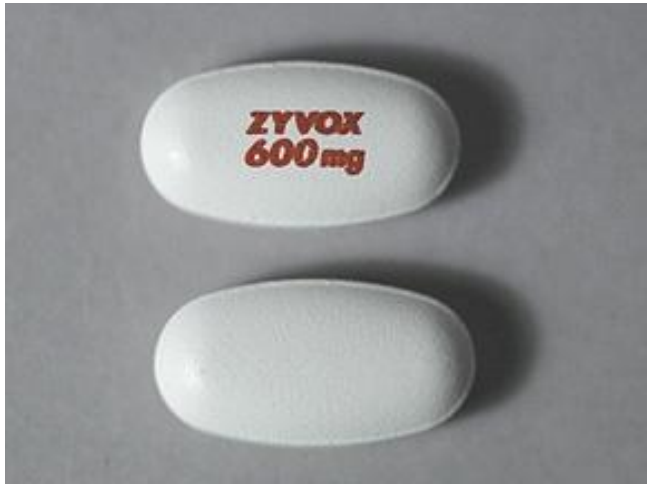
Examination system weeds out patent applications that should not be granted

Darunavir Patent Applications in India





Imatinib (cancer): R867 per tablet in SA vs R86 per tablet in India (400 mg).



Linezolid (TB): R264 per tablet or R8,460 per patient per month.

R676 per tablet for use in the private sector and by NGOs.

The product patent set to expire in 2014. An additional patent on the crystalline form of the medicine was granted in 2002. Will it block generic entry after 2014 - until 2021?)

Generic versions in India as low as R10 per tablet.

Examples of cancer medicine prices in the South African private and public sectors versus prices available in India			
Medicine	**South African private sector price**	**South African public sector price**	**Indian generic price**
Imanitib mesylate	R863 per 400 mg tablet	N/A	R46.20 per 400 mg tablet
Sorafenib	R381 per 200 mg table	N/A	R8.55 per 200 mg tablet
Bortezomib	R11,548.70 per 3.5 mg vial	N/A	R2,980 per 3.5 mg vial
Oxaliplatin	R2,331.79 per 50mg/10ml injection R4,663.53 per 100mg/20ml injection	R702 for 50 mg injection for infusion R1,405.34 for 100 mg injection for infusion	50 mg price not sourced R585 per 100 mg vial for injection
Rituximab	R2,789.50 per 10mg/ml infusion R13,947 per 500 mg injection	R1,589.99 for 100 mg injection R 7,950.01 for 500mg injection	R1,542 per 100 mg vial R6,173 per 500 mg vial
Temozolomide	R958.73 per 100 mg tablet	R903.44 per 100 mg tablet	R273.79 per 100 mg tablet (Note: Cipla has announced it will reduce the price to R74 per tablet)

N/A means the medicines is not procured in the public sector. More detailed information is available in the table below.

FIX THE PATENT LAWS!

Growing movement – SA, Thailand, Argentina, Philippines - Examination system weeds out patent applications that should not be granted. Direct benefit with earlier expiry of patents on ARVs.

COMPULSORY LICENCE

Patents on essential drugs: Need for Compulsory Licensing

Thailand:

Thai 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

compulsory licensing in the interest of public health
Indian Patent Act

Specific Provisions:

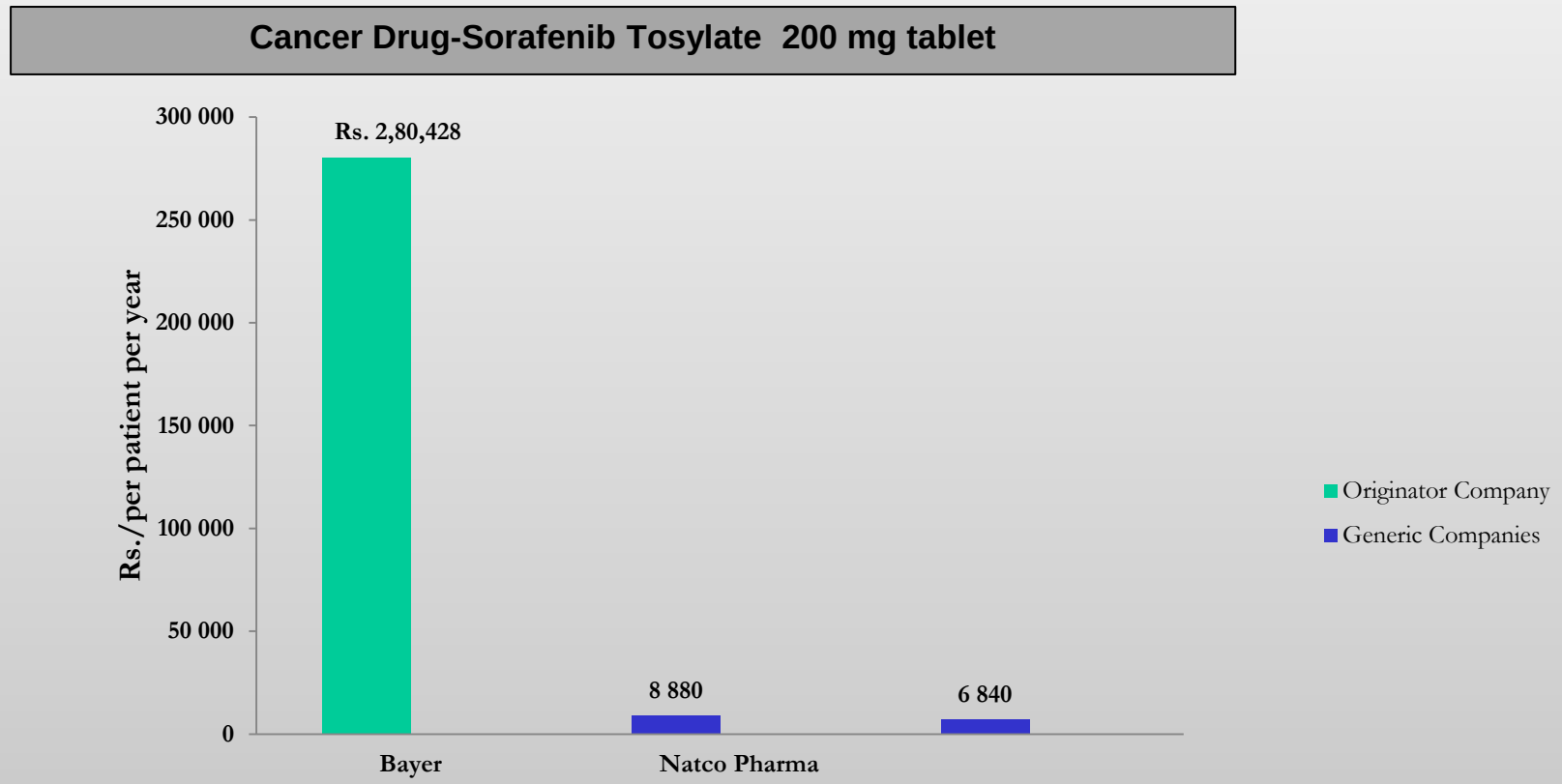
Sec. 84 – On application by generic companies

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 issued when generic company applies



*** The graph highlights the generic price of the cancer drug sorafenib tosylate. The drug is patented in India and Bayer's price is unaffordable. Natco has applied for a compulsory license to the Indian patent office in July 2011 and has committed to substantially reduce the prices by 97%(31 times) for cancer patients in India who need the drug if the compulsory license to produce the generic version is granted to the company by the Indian patent office.**

South Africa: R381.00 per 200 mg tablet (Bayer) as compared to R11 in India

First CL in India

- Natco Pharma requested for a CL for the anti-cancer drug Nexavar (*Sorafenib Tosylate)*, patented by Bayer
- Not for drug supplied to the public sector but actually sold in the private sector

- Granted in March 2012:
  - Bayer's import was grossly inadequate to the needs (hardly 2%)
  - No import in certain years
  - Price not reasonably affordable to the public. Bayer price 5210 USD for 120 tabs for a month; Natco 164 USD


EU FTA
KILLS
PATIENTS
F.T.A


한미FTA
저지!


FTAs KILL
DOMESTIC
PRODUCTION OF
MEDICINES !


FTA
농가
부채


WHAT DOES THE EU-INDIA FREE TRADE AGREEMENT MEAN ?
MORE COSTLY DRUGS
MORE SUFFERING
FOR MORE THAN 6.5 CRORE INDIANS LIVING WITH MAJOR MENTAL ILLNESSES
TORCHBEARERS


DON'T
TRADE AWAY
OUR LIVES
USFTA
STOP the US Free Trade Agreement
Release
the
TEXT


OPPOSE
EU-INDIA
FTA


LIFE IS NOT FOR SALE
© picture alliance/ANN/The Statesman


HIV
POSITIVE

Trade deals with India on the horizon

So called 'free trade' deals include IP rules, although they contradict free trade thinking

European Union (EU) - India-EU free trade and investment agreement
12th round of negotiations completed

European Free Trade Association (EFTA) – Norway, Switzerland, Iceland & Liechtenstein
7th round of negotiations completed

US – India FTA – Follow up to Obama's visit; reports of MoUs signed

What to Watch out for: **NO TRANSPARENCY**

"These bilateral agreements are attracting little public attention, are often highly technical in nature, and are being negotiated in secret, despite repeated requests from civil society to open them to public debate."

Developed countries consistently refuse to release the draft text of their FTA proposals and simultaneously extract promises of secrecy from their negotiating partners.

No access to draft text - no disclosure to the public or the Indian Parliament. Consultation only through FICCI &CII

This shroud of secrecy limits democratic review and civil society participation in the negotiation process.

Inadequate information for the people and Parliament to study/understand its impact.

Getting the Negotiating Text

- Allegations, “fears” on provisions in the text are easily dismissed; vague re-assurances from EC and Indian government
- **Leaked Texts**: First leak (**2009 –** shows Indian government total rejection of EU demands), Second leak (**2010 –** EU comes back with more detailed demands), Third leak (**2010 –** Demands from EC on Enforcement), Fourth leak (**2011 –** Investment provisions)
- **RTIs**: Some portions of text received from Ministry of Environment and Forests, Ministry of Agriculture
  - More recent RTI rejected by Ministry of Commerce; Appeal to Chief Information Commissioner (CIC) unsuccessful
    - **CIC says**: The disclosure of a premature draft of a Free Trade Agreement, which certainly involves deliberations at international plane and policy making at the highest level, can lead to jeopardizing and prejudicially affecting the strategic and economic interest of the State.

Police beat People living with HIV with lathis during 2nd Udyog Bhavan protest Oct 2010

Comment posted "I have never seen so many police people with batons and guns."
http://www.bbc.co.uk/news/health-11488711

European Commission demands Patents may last for longer

Indian patent law 2005: patents only have to be for 20 years

TRIPS+: may have to give Patent for longer than 20 years (patent term extension)

EC's demand
Block the marketing approval of generic medicines

Data Exclusivity: DCGI in India cannot register generic medicines

Impact: If a medicine is not registered with the DCGI, it cannot be legally used in the country.

COLCHICINE: HOW A TRADITIONAL MEDICINE IN THE US WAS MONOPOLISED THROUGH DATA EXCLUSIVITY.

- **Extracted from** plants of the genus *Colchicum* (autumn crocus, *Colchicum autumnale*, also known as "meadow saffron")
- Use particularly as a therapeutic agent in the treatment of gout has a history of 3000 years; cannot be patented
- Tablet formulation was widely available as a generic prescription drug in the United States since the 19th century.
- It costs almost nothing to produce but was granted marketing exclusivity after US FDA accepted a **1 week trial** of the drug done by a company & was then bound to grant DE.
- The company enforced its exclusivity rights forcing other manufacturers off the market & **the drug price rose 50 times from $0.09 to $4.85**.

Impact of DE

- **Jordan**
  - **Up to 800% increase in medicine prices**
  - **1 hospital alone has increased its medicine spending 6-fold,**
  - **over 25% of the Ministry of Health's budget is now spent on buying medicines,**
  - **data exclusivity has delayed the introduction of cheaper generic versions of 79% of medicines even though there is NO PATENT on them**

- **Colombia:**
  - **Colombia would require an extra US$1.5billion to be spent on medicines every year by 2030**
  - **If this is not spent, Colombians will have to reduce their medicine consumption by 44% by 2030**

- **Guatemala:**
  - **Price differences of up to 845000% in the same therapeutic class**

Chilling effect IP enforcement measures

Court orders to stop generic production

Customs to stop medicines on their way to other countries

Police to collect evidence, freeze bank accounts

Involves third parties (suppliers, transporters, chemists) in patent disputes

Intellectual Property as Investment

- **This is a threat to the right of governments to regulate health, environment etc**
- **Normally a treaty is between two countries – so if there is a dispute one country sues the other**
- **Under "investment chapters" the companies get to sue the government directly – unlike WTO (for expropriation)**
- **Includes intellectual property as investment**
- **Secret arbitration – bypassing constitution and domestic courts**
- **Tobacco case: Phillip Morris v. Uruguay**
- **Phillip Morris v. Australia**
- **Uses trademark infringement as an excuse**

Uruguay Warns Citizens of Tobacco Risks, Philip Morris Sues for millions of US$

FCTC and Australian law under attack

Int tobacco trade mag admits "#plainpack can kill your business" - ummm.. that's the whole idea, actually.#smoking

152 248 days ago

Press Conference

TB

- Old Drugs - Old diagnostics

Fundamental diagnostic: 1882

Fundamental diagnostic: 2006

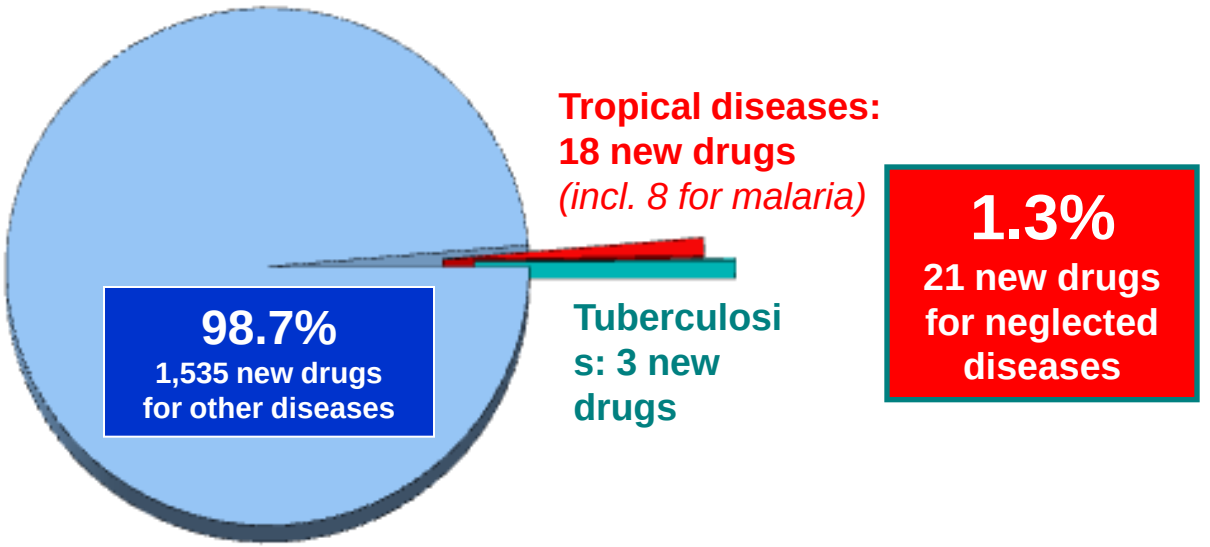
leave half of all patients undiagnosed!

A Fatal Imbalance

Tropical diseases (including malaria) and tuberculosis account for:

- 12% of the global disease burden
- Only 1.3% of new drugs developed

(1975-2004)



Source: Chirac P, Torreele E. *Lancet*. 2006 May 12; 1560-1561.

Innovation in decline?

patent protection has increased over the la
years, but the mean innovation rate h

ugs approved by the FDA
om 1989-2000
icines that contained
rovide
dation, 2002)

were fo
signif

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)

68% of 3,096 ne
between 1981 and 200
over previously available pr
(Prescrire International, 2005)

Main Rec: Binding Health R&D Instrument

- Need for a coherent **global framework** that combines the different elements and recommendations in a concerted mechanism.

- Conventions as a means by which countries enter into agreements with legal force to achieve common goals (i.e. WHO Framework Convention on Tobacco Control).

- Conventions can have funding provisions attached to them (i.e. Global Environment Facility (GEF) is the financing mechanism for four international treaties, including the UNFCCC; examples of funds include Multilateral Fund and Green Climate Fund).

- **Rec: to begin negotiations on a binding agreement on Health R&D under** Article 19 of WHO Constitution: "The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. (…).

Recommendations

- Generic production and procurement key for increase acess (NCDs too). TRIPS and FTAs should be seen as undermining access to affordable generic medicines in developing countries.
- Developing countries must locally examine patents. Patient groups should have the right to oppose secondary patents
- FTA text should be made public at the time of negotiations (right to information)
- Investor-state dispute mechanism much be reviewed by developing countries for their impact on govt's ability to regulate
- R&D treaty – long term sustainable solution to the access & innovation crisis in pharmaceuticals (drugs, diagnostics, vaccines)


LEGAL ACTIONS
DIRECT ACTION
COMMUNITY ACTIONS IN INDIA USE MULTIPLE STRATEGIES
MEDIA ADVOCACY
INTERNATIONAL ACTION
LEGISLATIVE ADVOCACY

Any Questions?