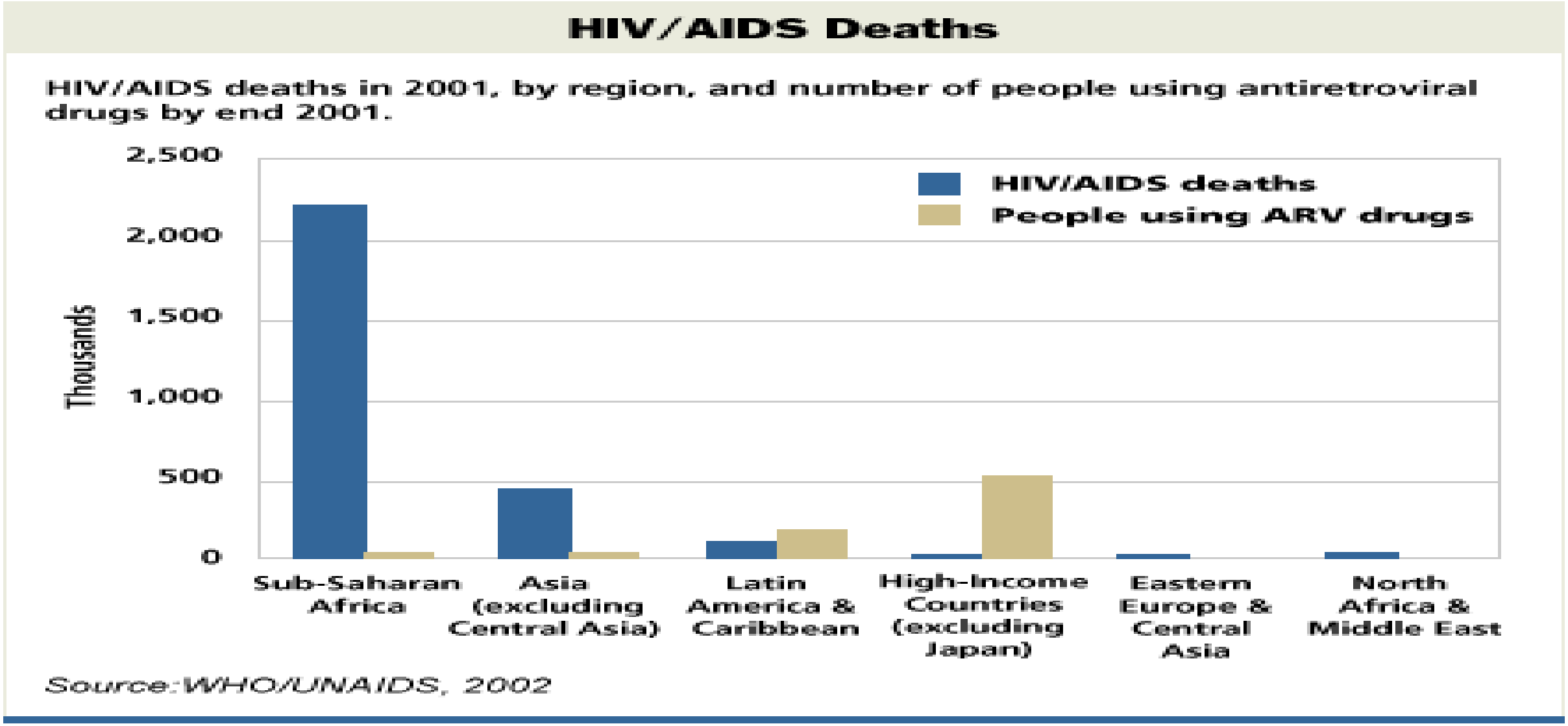
TRIPS and Access to Medicines

The Story so far…

TRIPS and Access to Medicines : A brief history

- 1981: HIV first clinically observed
- 1982-83: Named AIDS
- 1984: Discovery that it is caused by a virus
- 1986: Virus named HIV
- 1987: First ARV approved
- 1996-97: Triple combination therapy
- 2000: UN Secretary General: AIDS deaths estimated at 16 million.
- **UN: "…annual cost of ARV treatment for a person living with HIV still exceeds the annual per capita gross domestic product of many least developed countries."**

2001: The TRIPS Agreement and HIV



What happened in 2001

- UN efforts to get price discounts and donations were not working
- In 2000, Brazil had started local production of ARVs and decreased prices for itself by 72%

- **Feb 2001: Generic company's offer**
  - $600 per person per year for developing countries
  - $350 per person per year for international humanitarian agencies
  - No patents in India

AIDS triple therapy for less than $1 per day ?

February 7, 2001 - Geneva - Press Release

AIDS triple therapy for less than $1 per day: MSF challenges pharmaceutical industry to match generic prices

February 7, 2001, Geneva - Médecins Sans Frontières (MSF) welcomes the announcement made by generic drug manufacturer Cipla, that it will sell its triple-combination therapy for AIDS to MSF for $350 per year per patient and to governments for $600/year. The details of the offer request that government purchases have the "backing of MSF," which is not practical or necessary, therefore MSF requests that Cipla offer this price directly to governments and UN agencies.

This offer demonstrates that the target price of $200/year, set out in an MSF report at the international AIDS conference in Durban last July, is almost within reach. The $350 price is a discount of 96.6% off the price of the same combination in the US, which would cost about $10,400.

For the short term, MSF calls on the five pharmaceutical companies involved in the UNAIDS Accelerating Access Initiative to match the current offer, make their prices public, and streamline the implementation process, so that drugs can be delivered as quickly as possible to patients. The offer by Indian generic manufacturer Cipla demonstrates that proprietary companies can immediately reduce their prices further. On World AIDS Day, MSF called on the five companies to lower their US prices by 95%. No company has responded positively. Under the UNAIDS initiative, Senegal is currently paying $1008 to $1821 per year - almost three times the generic price -- while companies have refused to disclose prices for Uganda and Rwanda.

What happened in 2001

- **June: UN General Assembly Special Session**
- Access to medicines fundamental to right to health
- Impact of international trade agreements on access to or local manufacturing of essential drugs and on development of new drugs needs to be evaluated further
- Strengthen pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and the development of domestic industries

What happened in 2001

- 1997: South African law introduces provisions to improve access to generic medicines
- SA sued by 39 MNC pharma companies
- 2001: Public outrage and pressure results in case being dropped

- CASE NO: 4183/98

THE PHARMACEUTICAL MANUFACTURERS' ASSOCIATION OF SOUTH AFRICA First Applicant

v.

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA, THE HONOURABLE MR N.R. MANDELA N.O. First Respondent

What happened in 2001

- With the implementation of TRIPS increasingly leading to a crisis in access to medicines, WTO member countries met in Doha in 2001.
- Outrage over South African case results in WTO discussion on TRIPS and health
- **November 2001: All WTO members signed the Doha Declaration on TRIPS and public health.**

Quick Group Exercise

SO WHAT DOES THE DOHA DECLARATION SAY?

Doha Declaration: Interpretative guide

Paragraph 4:

- ***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***

Paragraph 5(b):

- ***... each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement ..., in particular, in its objectives and principles***

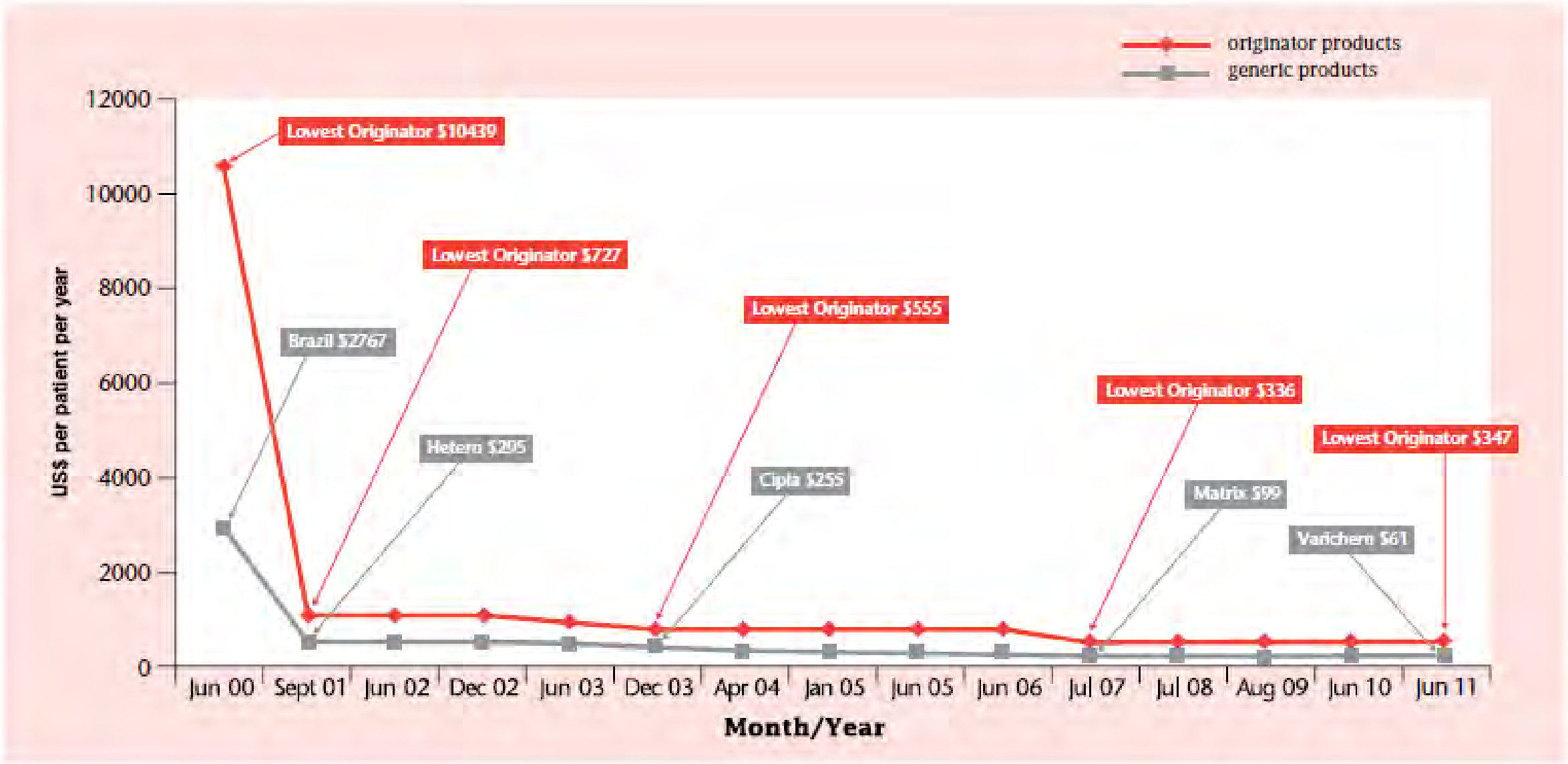
TRIPS: Article 7

- ***Article 7***
  Objectives
- The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

TRIPS: Article 8

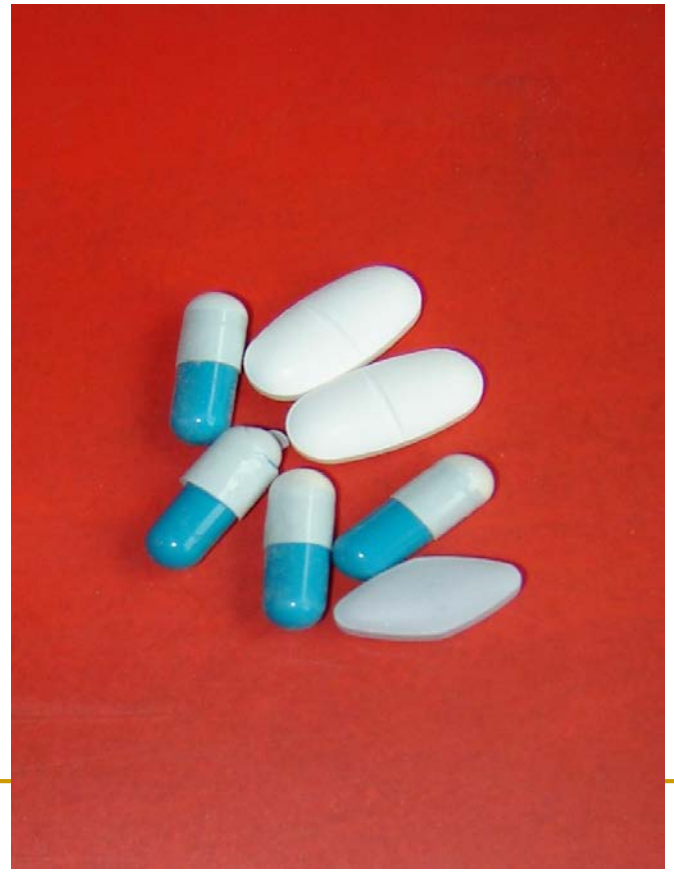
- ***Article 8:*** *Principles*
- 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
- 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

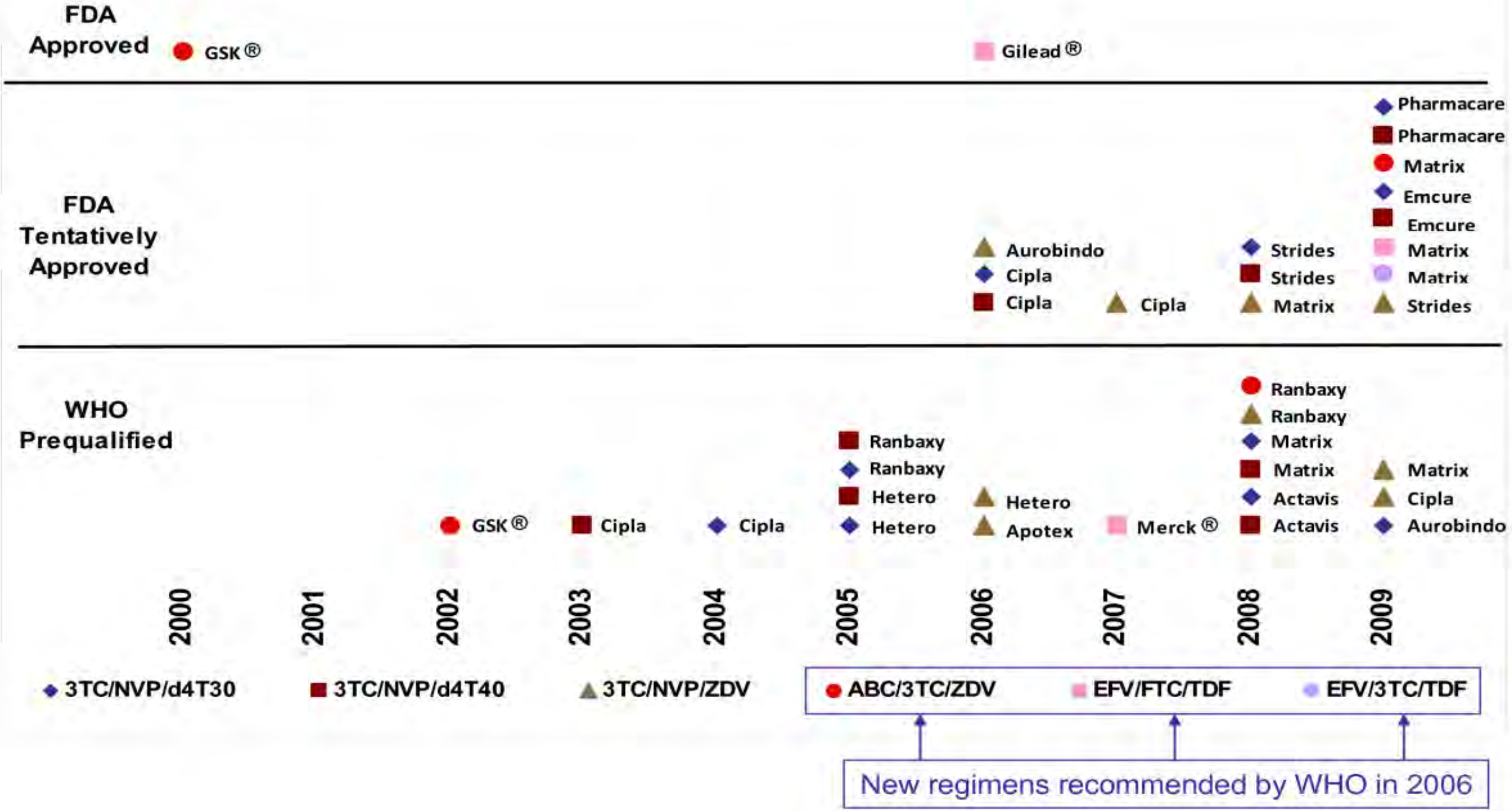
2001 – 2011: A decade of HIV treatment



Absence of patents leads to "three in one AIDS pill"
Eg. *d4T/3TC/NVP* (fixed dose combination – FDC)

- Individual compounds were not patented in India
- Simplified treatment in resource poor countries




FDA Approved
GSK®
Gilead®
FDA Tentatively Approved
Aurobindo
Cipla
Cipla
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Strides
Strides
Matrix
Pharmacare
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Emcure
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3TC/NVP/d4T30
3TC/NVP/d4T40
3TC/NVP/ZDV
ABC/3TC/ZDV
EFV/FTC/TDF
EFV/3TC/TDF
New regimens recommended by WHO in 2006

Competition key to lower prices, better formulations

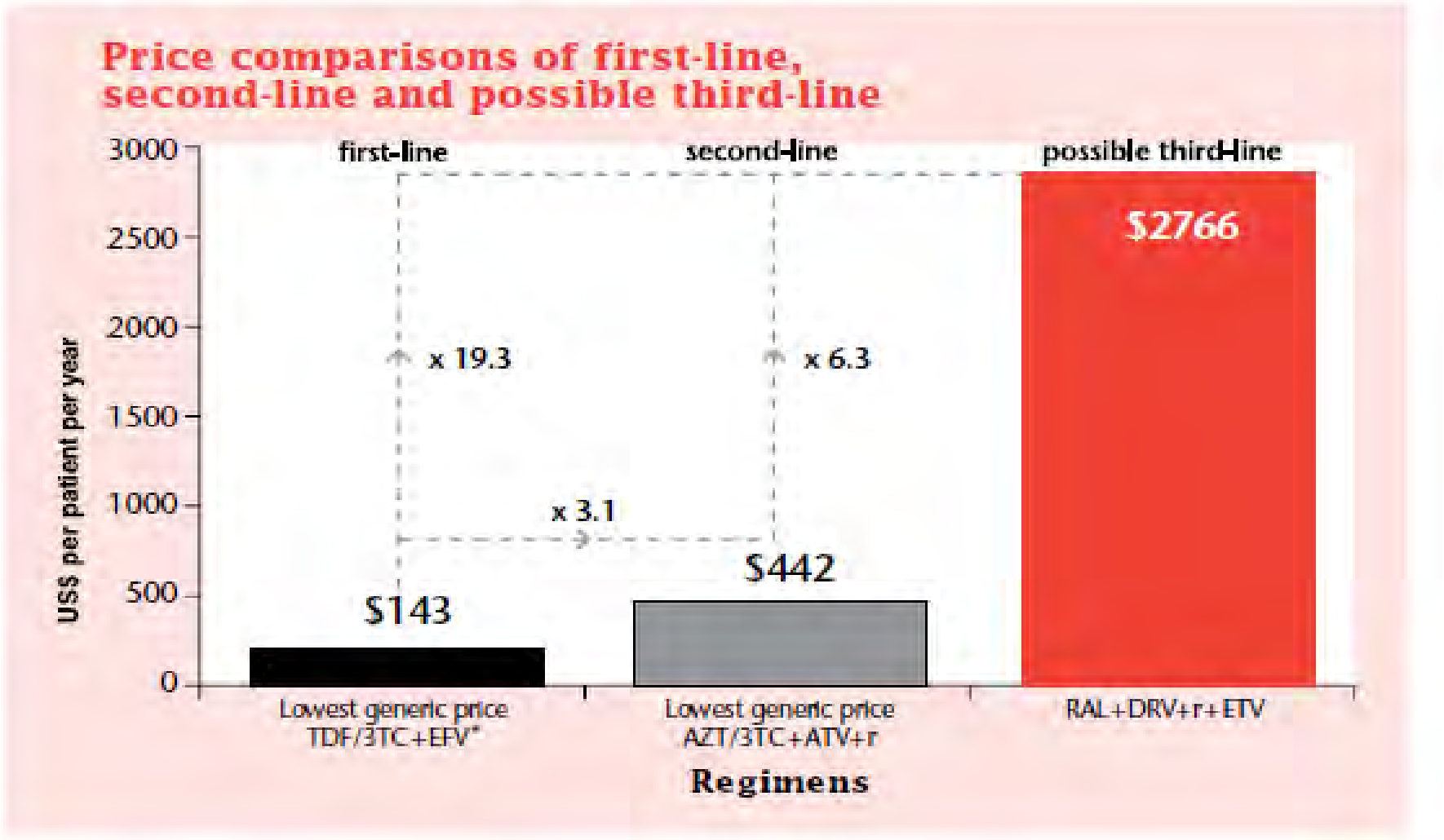
- While ARVs were under monopoly in the early 2000 s, prices remained high
- Generic competition lowered prices among generic producers and even of originator products.
- Fixed dose combinations and paediatric versions
- **Whether or not generic competition can take place depends on whether national laws and polices INCORPORATE TRIPS FLEXIBILITIES.**

Post – 2005?

- Post 2005, all developing countries who are WTO members have fully implemented the TRIPS Agreement

- This means they are granting and enforcing 20 year patents on pharmaceutical products

AIDS treatment: second and third line



HEP C TREATMENT COSTS

- Sofosbuvir: $1000 a pill; $84000 for a 12 week course of treatment
  - Gilead: May consider $900-2500 for some developing countries
  - Estimated **cost** of treatment in combination with other DAAs, diagnostic and genotyping: **$174-$354 without genotyping and $264-444 with genotyping**

- Pegylated Interferon: between $2500 - $30,000 (not including doctor's fees, medicines for side effects, loss of employment etc.)

CANCER TREATMENT COSTS

- Imatinib mesylate: Chronic Myloid Luekemia; Rs. 1,20,000 per person per month

- Sorefanib: Liver and kidney cancer; Rs. 2,50,000 per person per month

- Trastuzumab (Herceptin): Breast cancer medicine: Rs. 90,000, 54,000, 23,000 per injection

INCREASING USE OF TRIPS “FLEXIBILITIES”

“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

Incorporation of TRIPS flexibilities

- Cambodia (2002): Specific provision recognising LDC transition period
- Sri Lanka (2003): Through court intervention
- India (2005): Amendment to 1970s patent regime
- Philippines (2008): 10 years after originally complying with TRIPS
  - Amendments through Cheaper Medicines Act
- Indonesia (2016): Amendments to patent law

RELATED KEYWORDS: BMS Rejected | AIDS Patients

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Health | Fri Aug 16, 2013 5:00am EDT

Relate

Roche gives up on India patent for breast cancer drug

ZURICH

A phial and pack of herceptin are seen in London June 9, 2006.

PHOTOS OF THE DAY

Our top photos from the last 24 hours. Slide

TRENDING ON REUTERS

THE THAI COMPULSORY LICENSES

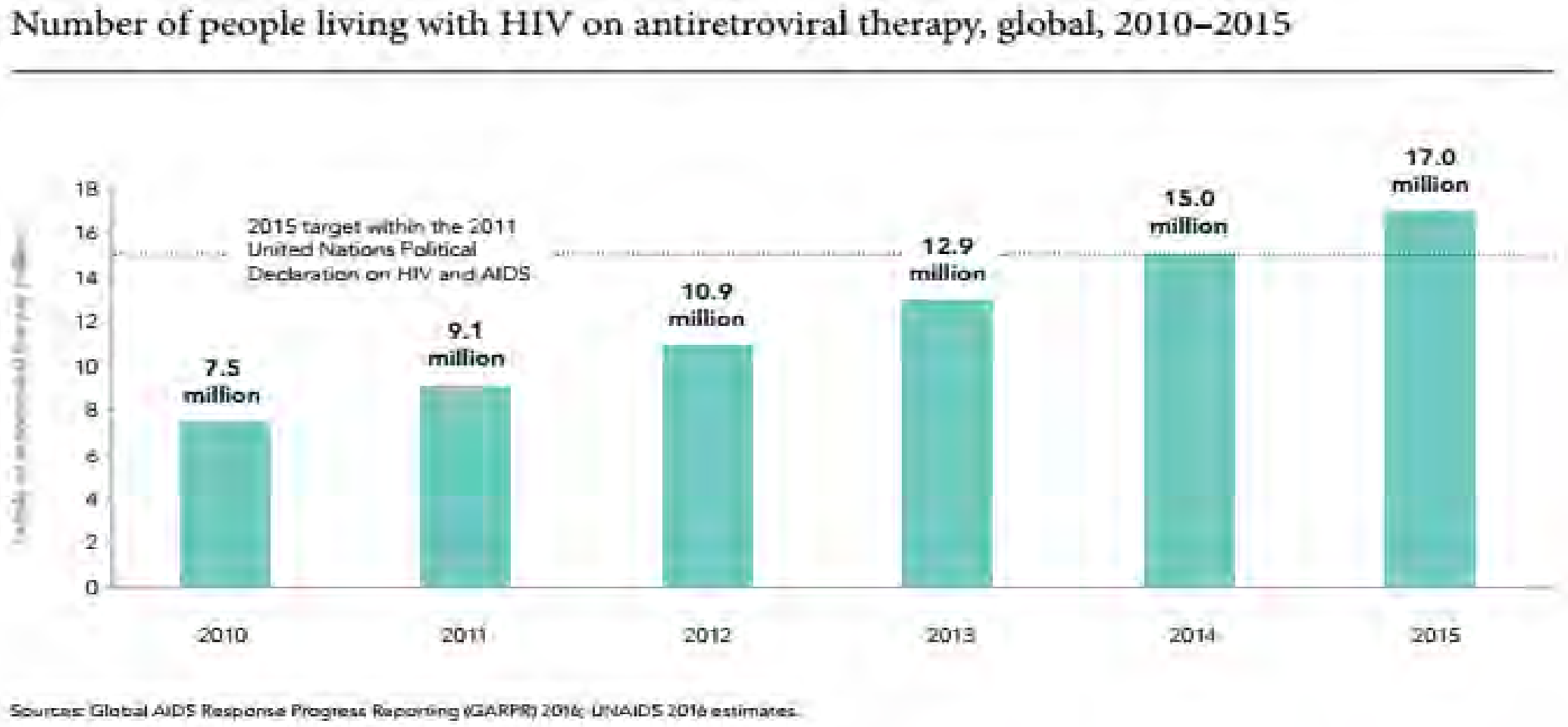
2006-2007:

CLOPIDOGREL (HEART DISEASE)
EFAVIRENZ (HIV)
LOPINAVIR/RITONAVIR (HIV)

2008:

LETROZOLE (CANCER)
DOCETAXIL (CANCER)
ERLOTINIB (CANCER)

2016: 17 million PLHIV on ARVs



TRIPS flexibilities before the grant of a patent

- Patentable Subject Matter
- Patent exclusions
- Patentability Criteria (including prohibition of evergreening)
- High Disclosure Standards
- Pre-grant Patent Oppositions

Working of the patent system

- Pro-health patent examination and trainings
- Proper disclosure in patent Applications (information and fees)
- Penalties for fraud on the system
- Limit and control divisionals
- Regulate Voluntary Licenses
- Working of the Patent

TRIPS flexibilities after the grant of a patent

- Research, Bolar and other exceptions
- Parallel Imports
- Personal Use/small quantity exceptions
- Post-grant Oppositions and Revocation
- Compulsory Licenses
- Use of Competition Law

TRIPS flexibilities in Enforcement of patents

- No Border measures for patents
- Court proceedings to take public interest into account
- Limits on Injunctions and other orders
- Limits on Damages, “judicial” CLs
- Ensure Civil, not criminal remedies

TRIPS FLEXIBILITIES: LDCs Transition Periods

- Two Transition Periods:
  - 2021: General TRIPS Transition Period
  - 2033: Pharmaceuticals TRIPS Transition Period

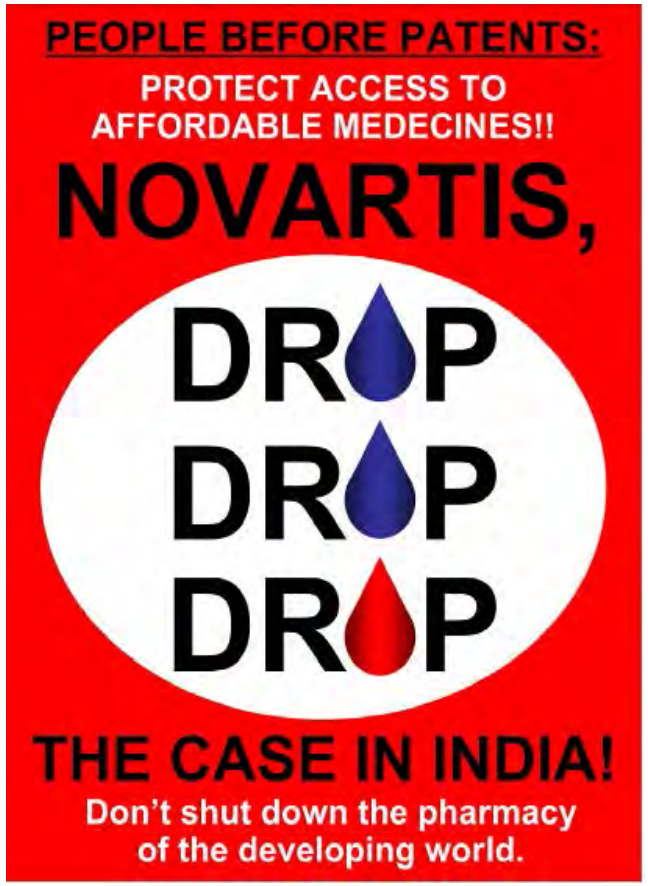
SDG 3b: Imperative for reviews and incorporation of all TRIPS flexibilities

- “[s]upport the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.”

So everything’s fine?

A reality check

Implementing TRIPS flexibilities – a reality check: litigation



Pharma v. South Africa

Novartis v. India

Bayer v. India

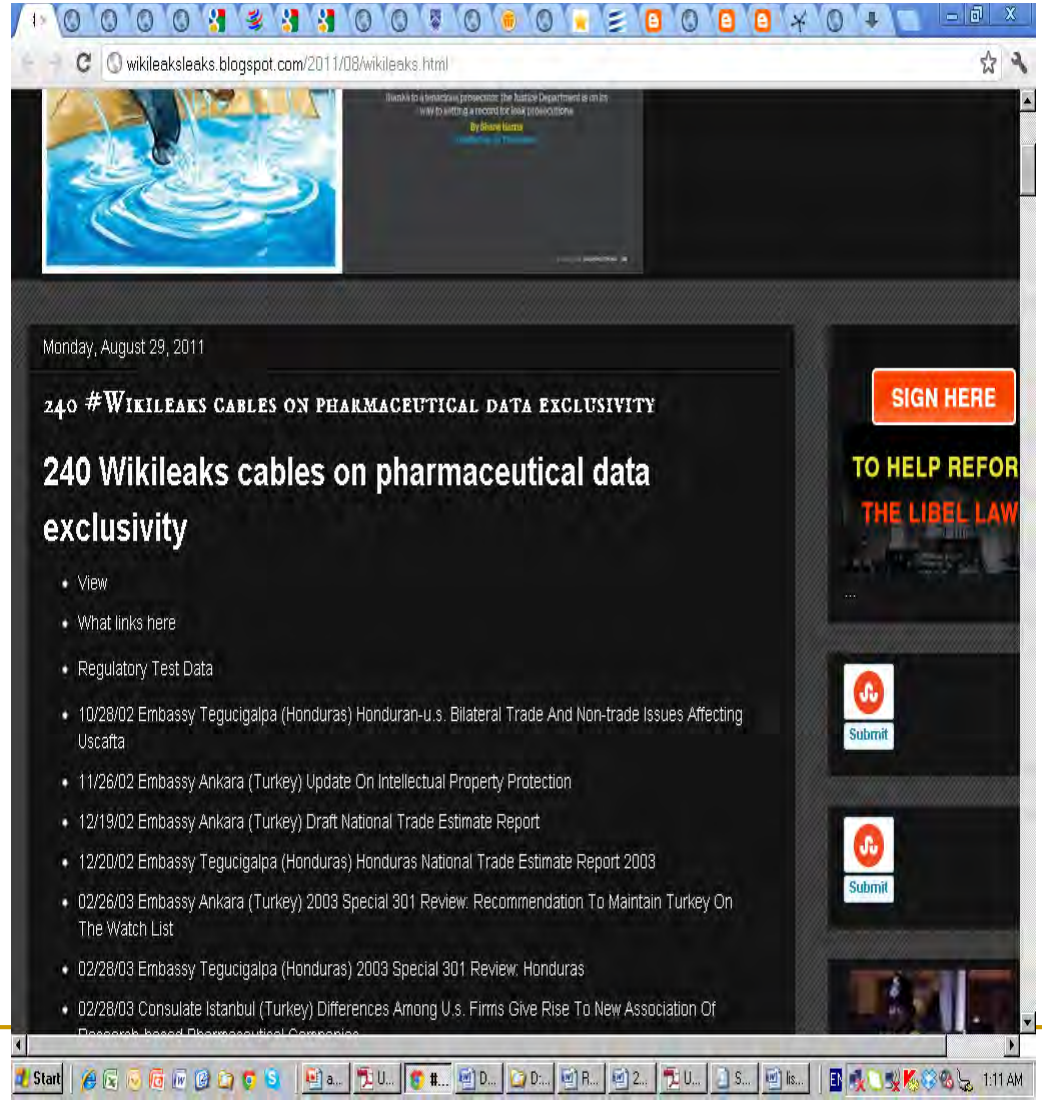
Pfizer v. Philippines

Pharma v. Brazil

Pharma v. Argentina

Implementing TRIPS flexibilities – a reality check: **lobbying, trainings, etc**

- **US and EU/MNC organised trainings:**
  - Training of Judges
  - Training of patent examiners, offices
  - Training of customs officials, police
- **Lobbying with law and policy makers**
- **Trade sanction threats: USTR, Special 301**



Lobbying and training

Pfizer tie-up for India meet a mistake: US patent office

JOE C MATHEW
New Delhi, 17 March

The United States Patent and Trademark Office (USPTO) said it made a "mistake" by allowing US-based drug maker Pfizer to co-sponsor a public discussion programme on sensitive issues related to intellectual property rights in India last year.

In response to a blog post that talked about a "USPTO-Pfizer collaboration

US patent office to train Indian judges on IPR-related issues

JOE C MATHEW
New Delhi, 13 September

THE United States Patent and Trademark Office (USPTO) will train Indian law enforcement officials and members of the judiciary on issues related to intellectual property rights (IPR) from this week.

The five-day workshop, beginning September 15, will be held in Mumbai in association with the Maharashtra Judicial Academy. It would have a three-day session on IPR and a two-day training session on digital piracy, an academy official said.

This is the first time the state judicial academy is joining hands with USPTO to conduct refresher and training programmes for members of the judiciary.

THE FIVE-DAY WORKSHOP BEGINNING SEPTEMBER 15, will be held in Mumbai in association with the Maharashtra Judicial Academy. It will have a three-day session on IPR and a two-day training session on digital piracy

"The IPR session is planned for district and session judges. For digital piracy workshop, public prosecutors, CBI officials and law enforcers, including police personnel, will be included," the official added.

The academy, the first of its kind in Maharashtra, was opened two years ago to train the judicial members in the state.

USPTO, an agency under the US government's department of commerce, runs similar training programmes world over primarily through its Global Intellectual Property Academy.

IPR violations is one of the major concerns of the US and is a key reason for keeping India, among several other nations, in the US government's "priority watch list" that indicates the level of IPR protection offered by the trading partners.

The Special 301 Report of the Office of the United States Trade Representative released in May complained that India continued to have a weak legal framework, and an ineffective IPR enforcement system. The report wanted India to take action on its draft optical disc law and combat widespread optical disc piracy.

It had also sought improvement of India's IPR regime by providing for stronger patent protection, to address concerns such as provisions of India's patent law that limit the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery.

It also wanted India to take steps to improve the efficiency of judicial proceedings, and strengthen its criminal enforcement regime, by encouraging the imposition of deterrent-level sentences for IPR violations and by giving prosecution of IPR offences a greater priority.

The Special 301 Report has stated that the US looks forward to increased engagement with India to address these and other matters.

THE TIMES OF INDIA

SC judge under attack from health activists

TNN | Sep 6, 2011, 08.28 AM IST

NEW DELHI: Two years ago, Justice Markandeya Katju of the Supreme Court had withdrawn from hearing a patent dispute vitally concerning pharmaceutical majors. Justice Dalveer Bhandari, the head of the bench that has since been dealing with the case, is now under attack, this time from health activists.

Though he did not himself give any reason for it, Katju's recusal in 2009 from the appeal filed by Novartis was then widely attributed to an article written by him in a legal journal conceding, much to the embarrassment of multinational companies, that "many of the medical drugs available in the market are too costly for the poor people in India" and that "ways and means should therefore be thought out for making these drugs available to the masses at affordable prices".

In what seems virtually a reversal of the situation, the health activists demanded on Monday, on the eve of the next hearing of the case, that the government should seek Justice Bhandari's recusal as he had participated in at least two international conferences for judges organized by the US-based Intellectual Property Owners Association (IPOA), whose members include Novartis, among a host of pharmaceutical and IT giants.


"We did not develop this medicine for Indians...We developed it for western patients who can afford it"
- Marijn Dekkers, Bayer CEO
BAYER

Priority Watch List

- Algeria
- Argentina
- Chile
- China
- India
- Indonesia
- Kuwait
- Russia
- Thailand
- Ukraine
- Venezuela

Watch List

- Barbados
- Bolivia
- Brazil
- Bulgaria
- Canada
- Colombia
- Costa Rica
- Dominican Republic
- Ecuador
- Egypt
- Greece
- Guatemala
- Jamaica
- Lebanon
- Mexico
- Pakistan
- Peru
- Romania
- Switzerland
- Turkey
- Turkmenistan
- Uzbekistan
- Vietnam

In a victory for U.S. pharma, India pledges to abandon compulsory licensing, trade group says

by *Tracy Staton* | Mar 8, 2016 11:26am

Has India given up the compulsory license fight? According to a U.S. trade group, officials have privately promised not to grant any more of the licenses, which force branded drugmakers to allow generics companies to knock off their on-patent drugs.

As *Reuters* reports, the U.S.-India Business Council assured the U.S. Trade Representative that it's no longer open to compulsory license requests from domestic drugmakers. The disclosure came in a USIBC submission to the trade rep, which is working on an annual report about international trade barriers.

Under Indian law--and World Health Organization protocols--the government is allowed to open the door to early generic competition when a medicine is too pricey for local use, but important to public health.

The threat of compulsory licensing became all too real in 2012, when

Patent Oppositions in India

What Happened To The Indian Official That Rejected The US Drug Company Gilead's Patent Application In 2015

By MANDAKINI GAHLOT AND VIDYA KRISHNAN | 10 May 2016

the globe to question how they will pay for the drug. The World Health Organization (WHO) estimates there are more than

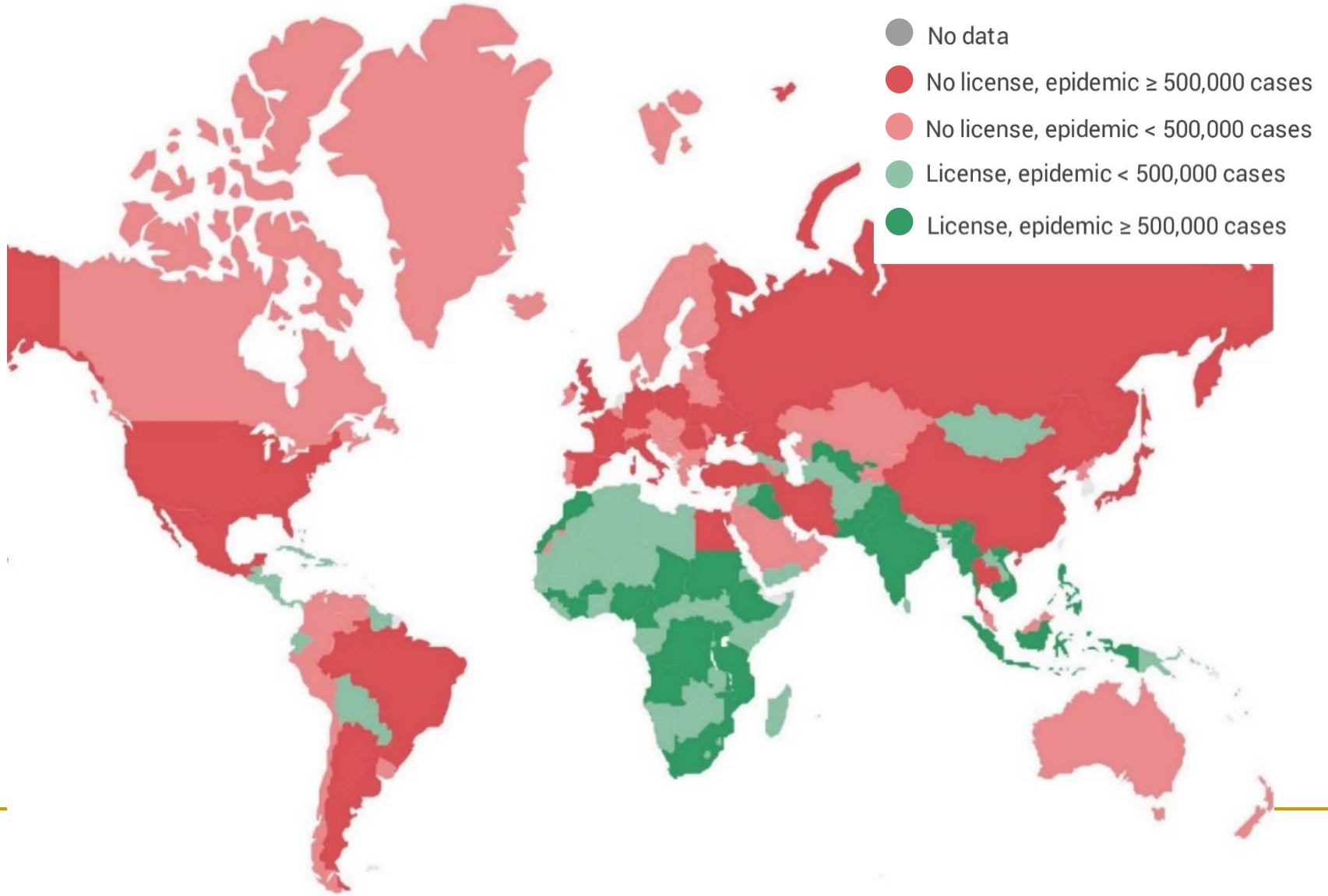
Developing country generic industry: merged and acquired

Target company	Acquirer	Country of origin	year	Amount (USD)
Matrix lab	Mylan Inc	US	August 2006	$736 million
Dabur Pharma	Fresenius Kabi	Singapore	April 20, 2008	$219 million
Ranbaxy Laboratories Limited	Daiichi Sankyo	Japan	June 11, 2008	$4.6 billion
Shantha Biotech	Sanofi Aventis	France	July 27, 2009	$783 million
Orchid Chemicals (injectible business)	Hospira	US	December 16, 2009	$400 million
Piramal Healthcare (domestic formulation)	Abbott Laboratories	US	21 May 2010	$ 3.72 billion

Source: compiled from various news reports

Voluntary Licenses: Medicines Patent Pool

Voluntary licences: Divide and Conquer?



Most Indian generics take the licenses…is there hope for independent production?

Free Trade Agreements and TRIPS-PLUS provisions

- For developed countries, TRIPS and TRIPS flexibilities were a compromise
  - United States
  - Japan
  - European Free Trade Association (EFTA)
  - European Union

When WTO TRIPS was being negotiated

- Developing countries were told – don't worry there are enough safeguards
- Doha Declaration: TRIPS Agreement can and should be interpreted to fulfil obligations for medicines for ALL
- FTAs severely hamper and undermine these safeguards

Back to the Future?
So, what's happening in your country?