



Reforming the Patent System to Improve Access to Affordable Medicines in South Africa



Lotti Rutter, Treatment Action Campaign
HIV Clinicians Conference – Sept 2014



A conflict over a decade old...

“Everyone has the right to have access to health care services”

Section 27 of the South African Constitution



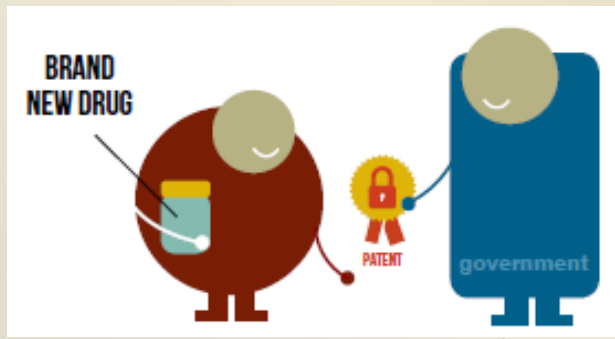


How do patents affects public health?



What is a patent?

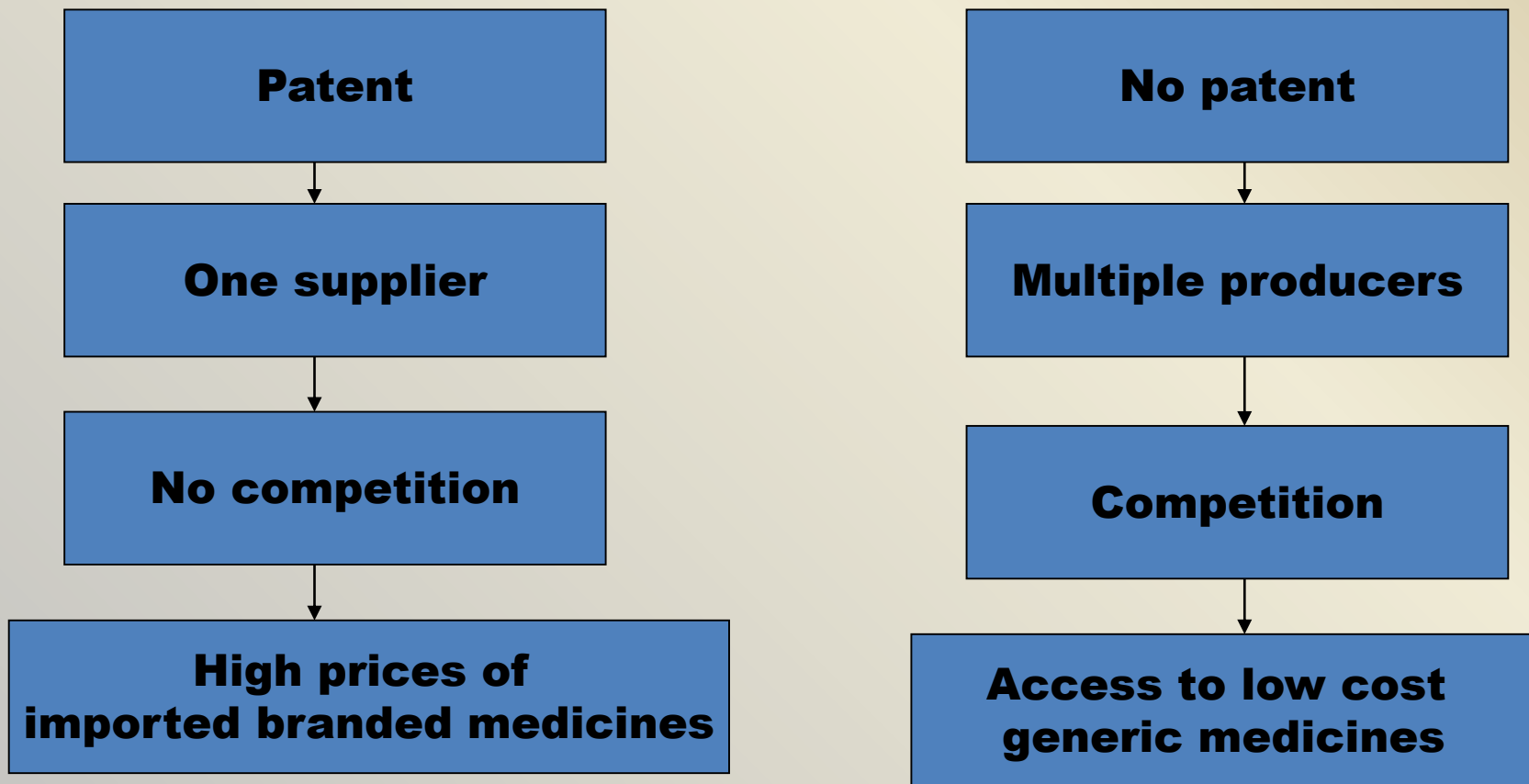
- A patent is a reward that is given to a company that allows it to sell a product with no competition from other companies. The patent lasts for 20 years.



- During this 20 year patent period, no other companies are allowed to make, sell, import or use the product.



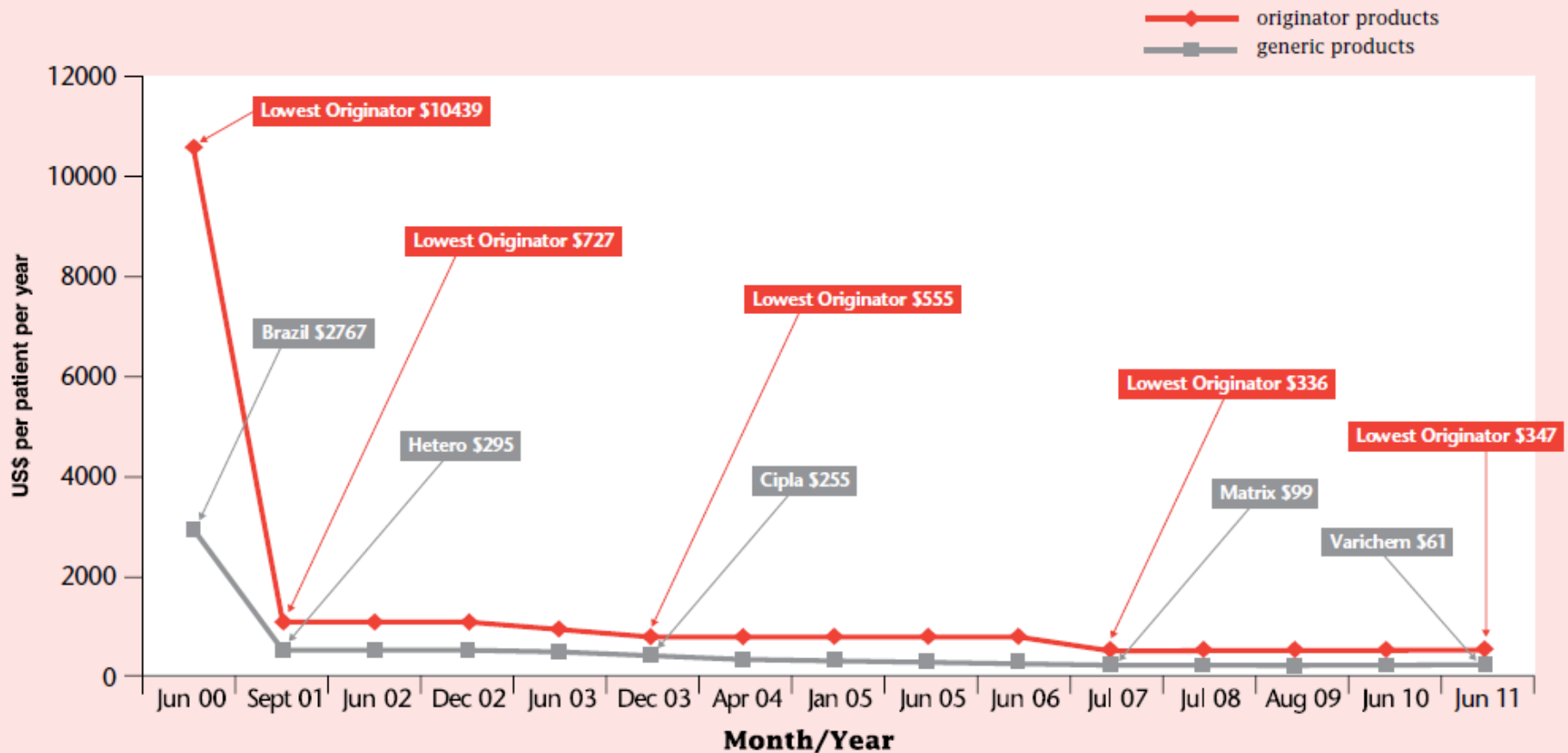
How do patents affect prices?



Competition cuts prices

Case Study: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.

The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.





Patents create “Neglected Diseases”

**MEDICINE
SANS FRONTIERES**

SIDE EFFECTS OF DRUG-RESISTANT TB DRUGS

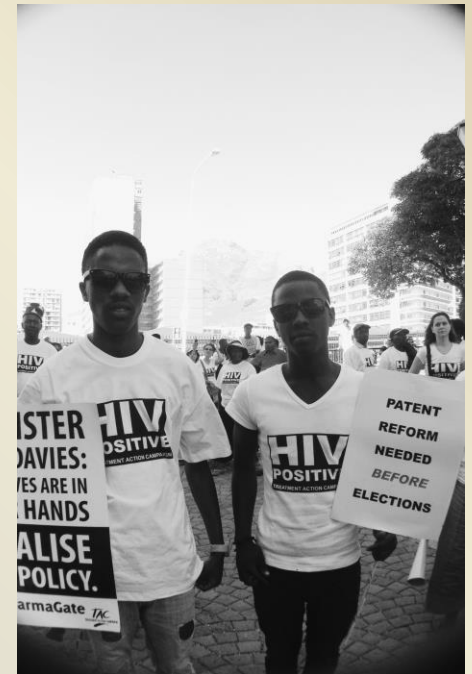
WE NEED BETTER TREATMENT NOW

deafness, hallucinations, loss of appetite, dizziness, weight loss, weight loss, TB, nausea, vomiting, fever, jaundice, suicidal feelings, psychosis, hallucinations, loss of appetite, dark urine, nausea, fatigue, vomiting, fever, side effects experienced for up to 2 years



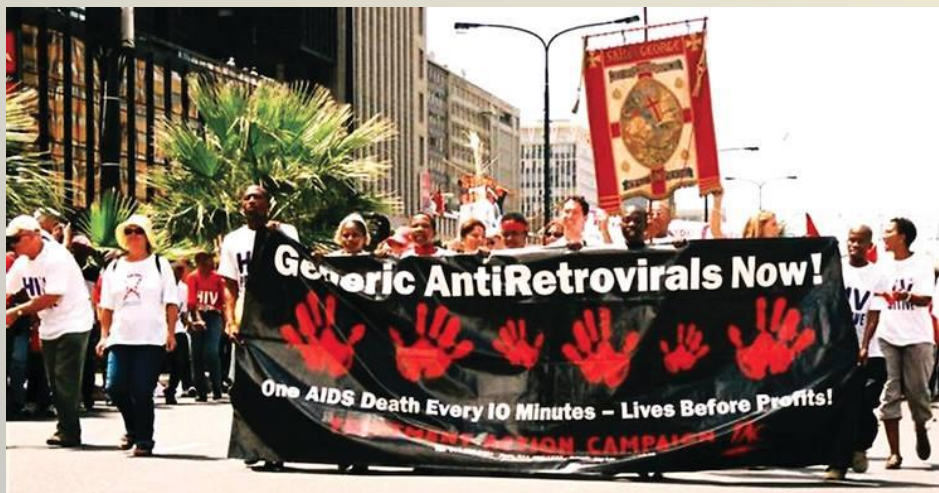
TRIPS Agreement

- WTO Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) signed 1995
- Standardized patent laws across the world
- Doha Declaration 2001—explicitly states that the TRIPS agreement should be interpreted in a way that protects access to medicines for all
- Countries are within their rights to take certain measures to limit intellectual property rights to protect public health
- These are called “**TRIPS flexibilities**”
- **South Africa yet to successfully enact any of these flexibilities in national law.**



Drug-by-Drug...

- Early 2000s: fluconazole defiance campaign
- 2002: Comp Com complaints over excessive AZT and NVP prices
- 2007: Comp Com case over price of EFV, lack of license for FDC
- 2008: complaint over Aspen-GSK merger, and effect on ABC price once off-patent





...Or System Change?

- **1997 Medicines and Related Substances Act:**
 - step forward for informing about generics medicines; international tendering;
 - Provisions allows for compulsory licensing (not used)
 - 39 pharmaceutical companies take Nelson Mandela to court— eventually back down
- **IP reform in South Africa:**
 - started by Dept. of Trade and Industry six years ago
 - seeks to define comprehensive policy on patents, and a balance between public health and private interests
 - Draft Policy released for public comment Sept. 2013





The campaign....

- “Fix the Patent Laws” campaign started in 2011, 10 years after the Doha Declaration was signed
- Aims to have Dept. of Trade and Industry include pro-public health language in national IP policy in order to take advantage of TRIPS flexibilities in national laws
- Coalition: TAC, MSF, SECTION27, and growing...





Campaign timeline...



- September 2011: Minister of the DTI told TAC & MSF that the DTI was developing an Intellectual Property Policy to address access to medicines
- May 2012: First promised that IP policy would be released for public comment in July
- Repeated missed deadlines to release policy—TAC hold picket at Africa IP Forum (Feb 2013)
- Memorandum delivered at WTO-WHO-WIPO workshop held by DTI in Pretoria (August 2013)
- Draft National Policy on Intellectual Property (DNPIP), 2013, released on September 4th for public comment.
- January 2014: Pharmagate scandal; FTPL marches in Pretoria, Cape Town
- One year after the DNPIP: regulatory impact assessment complete...but still no final policy!



What's wrong with South Africa's patent laws?



**FIX THE
PATENT
LAWS!**

**SOUTH AFRICA BLINDLY HANDS OUT DRUG PATENTS
EVEN WHEN THEY'RE NOT DESERVED**



THIS MAKES MEDICINES UNAFFORDABLE

SOUTH AFRICANS PAY THE PRICE

www.fixthepatentlaws.org

**FIX THE
PATENT
LAWS!**



SOUTH AFRICA BLINDLY HANDS OUT DRUG PATENTS
DRUG PATENTS= UNAFFORDABLE MEDICINES

**IN 2008 ALONE,
SOUTH AFRICA GRANTED**

2442

PATENTS ON MEDICINES

VS.

**FROM 2003-2008,
BRAZIL ONLY GRANTED**

273

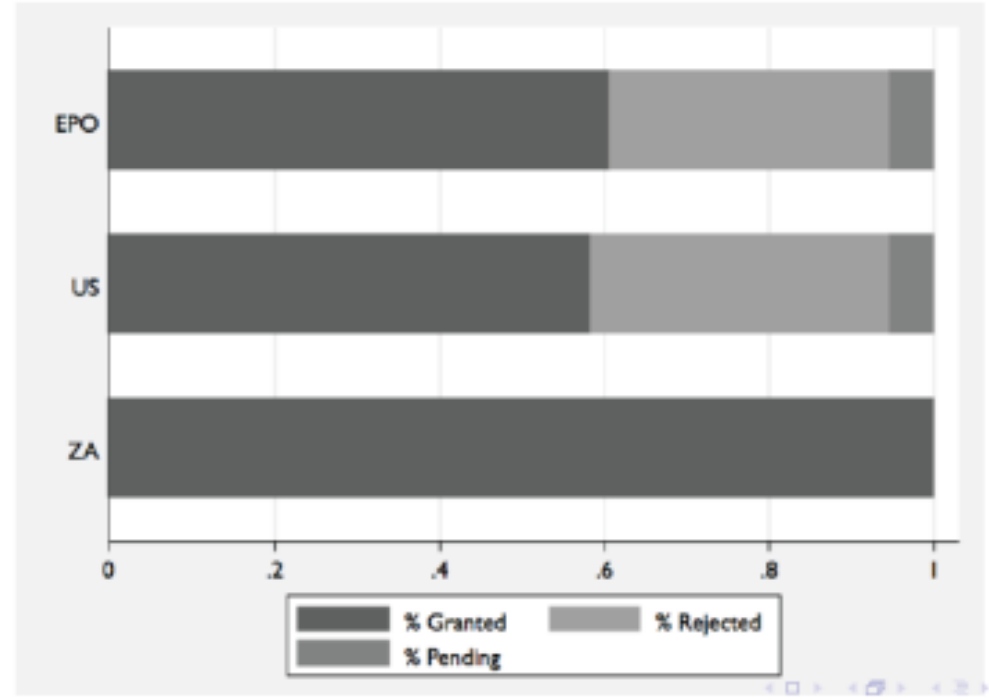
PATENTS ON MEDICINES

SOUTH AFRICANS PAY THE PRICE
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Outcomes at the EPO, in the U.S., and South Africa for identical twin pharmaceutical patent applications filed in each jurisdiction between 2000 and 2002

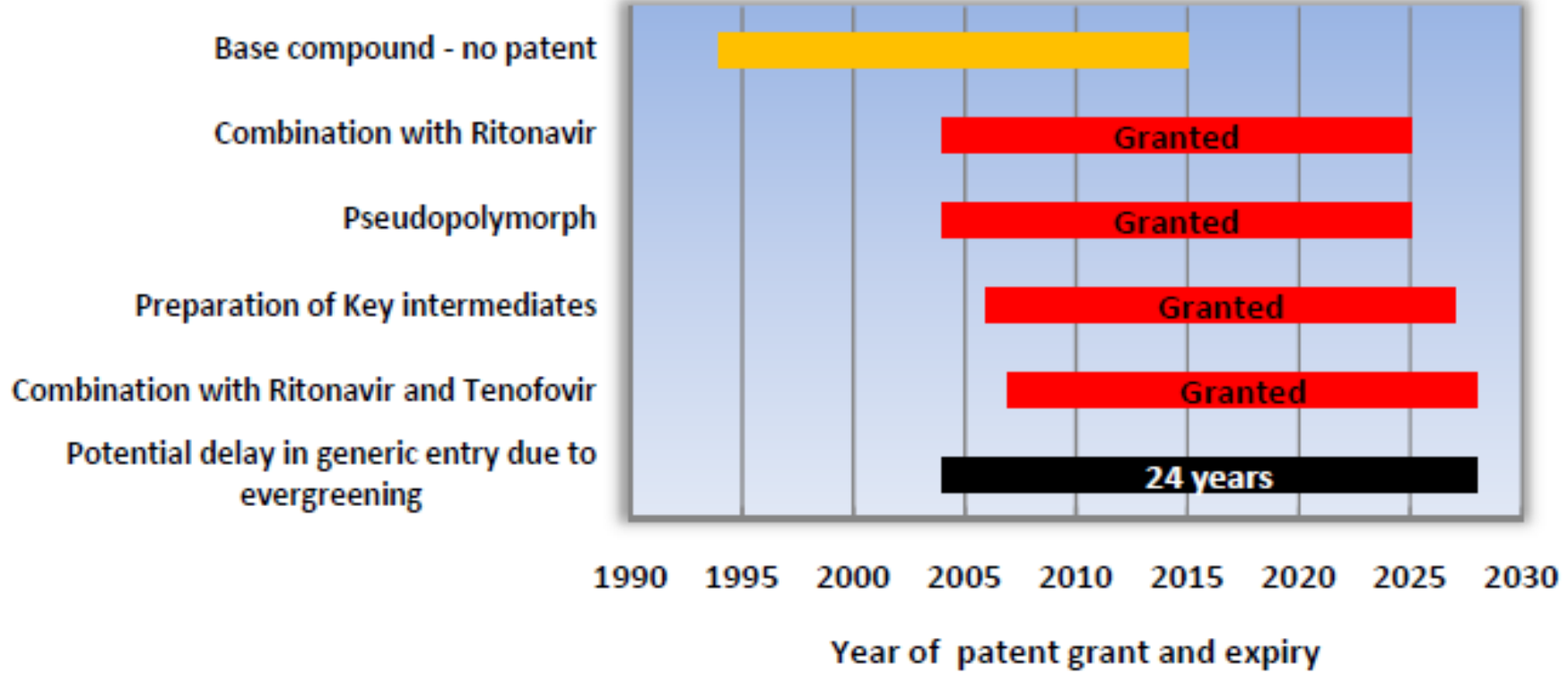


Of identical applications, South Africa grants 40% more patents than US & European Patent Offices.



Evergreening blocks competition

Darunavir Patent Status in South Africa





SOUTH AFRICA BLINDLY HANDS OUT DRUG PATENTS PATENT MONOPOLIES = UNAFFORDABLE PRICES

IF SOUTH AFRICA REFORMED HOW IT GRANTS PATENTS,



80% OF MEDICINE PATENTS WOULD BE REJECTED AND DRUG PRICES WOULD FALL

SOUTH AFRICANS PAY THE PRICE

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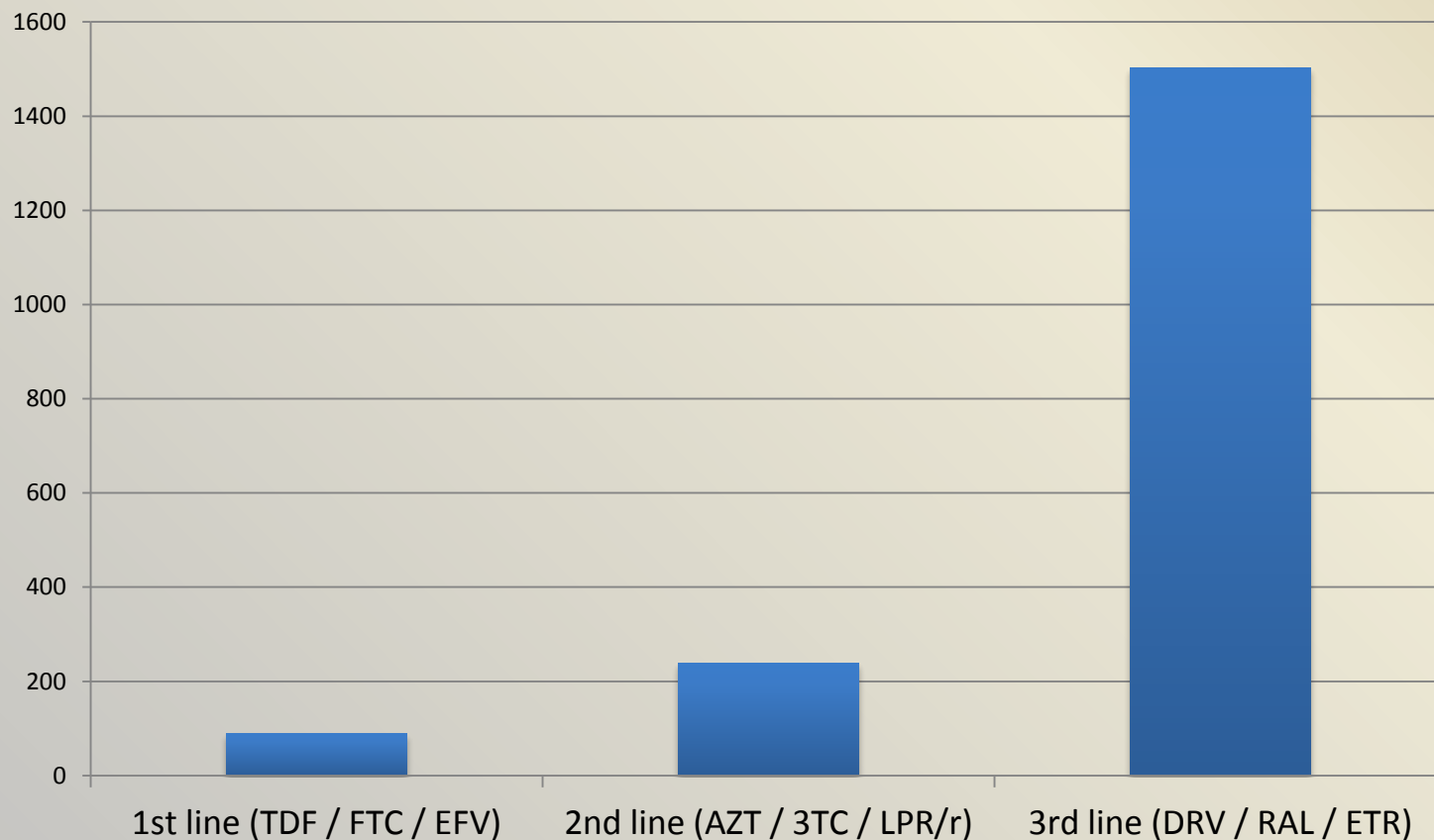
What does this mean for the cost of specific medicines?





Cost comparison ARV regimens

Monthly Cost of Standard ARV Regimens in Public Sector
(ZAR prices per person per month)





Hepatitis C

- Sofosbuvir - shorter in duration, more effective, less side effects than existing Hep C treatments (improved cure rates)
- US FDA approved at R10,000 per daily pill. R840,000 for the 12 weeks of treatment recommended for most patients, and R1,680,000 for the 24 weeks needed for a hard-to-treat strain of the virus.
- Patent opposition filed in India to try to block patenting of the drug – “old science, existing compound”
- Annual sales could surpass the record of around \$13 billion achieved by Lipitor, from Pfizer, in its peak year.





Hepatitis B



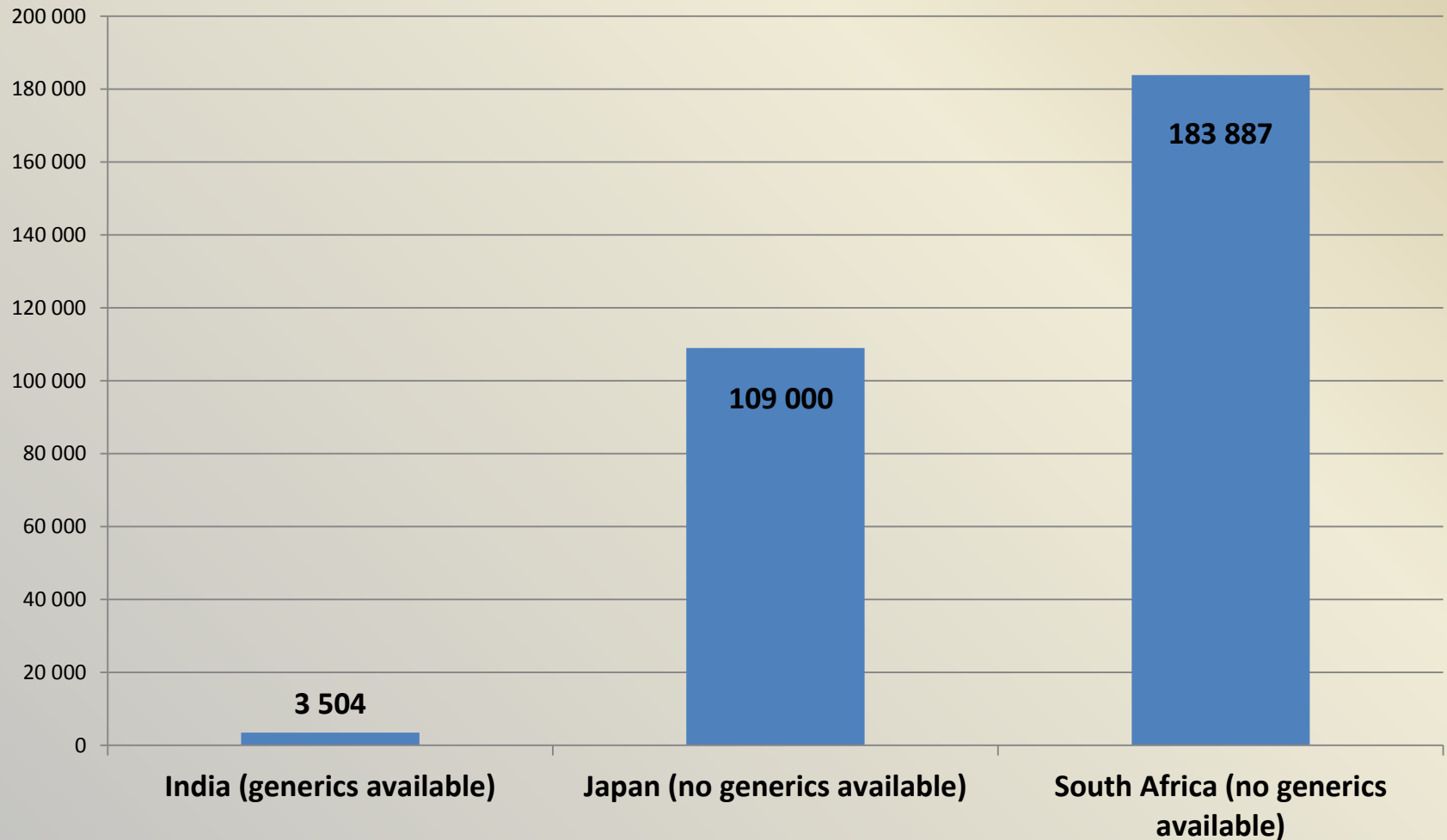
- Hepatitis B chronic infection affects approximately 8% of the population in Sub-Saharan Africa
- Entecavir used for those who don't tolerate tenofovir, have kidney impairment. Not available in public sector, nor on private formularies for HepB
- **R4,700-R5,500 per month in SA** (Bristol-Myers Squibb only manufacturer). In India, generics cost around R400-R800 per month!
- Initial patent expired 2011 in SA. Three secondary patents were granted, one still in force (expires 2022).
- Patent overturned in the U.S. can be filed in SA up until end 2014

Depression



- Aripiprazole - anti-psychotic (for schizophrenia, bipolar disorder)—one of the top-10 selling drugs globally
- Could have been off-patent in U.S. in 2009 (extensions run to 2015)—South African multiple pending patents could run until 2033.
- Cost of a 10mg tablet R35.60 in South Africa over 35x higher than generics available in India.

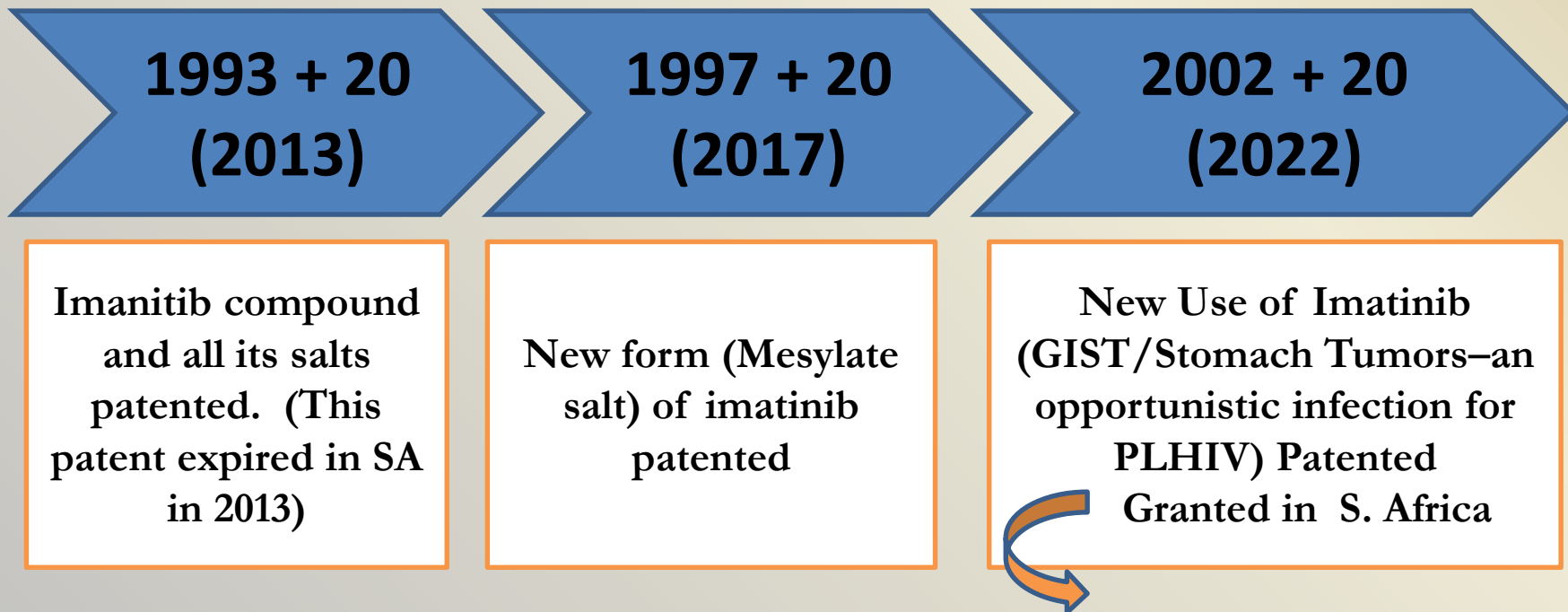
Lowest Possible Cost of aripiprazole 20mg dosage per day for 5 years (quoted in ZAR)





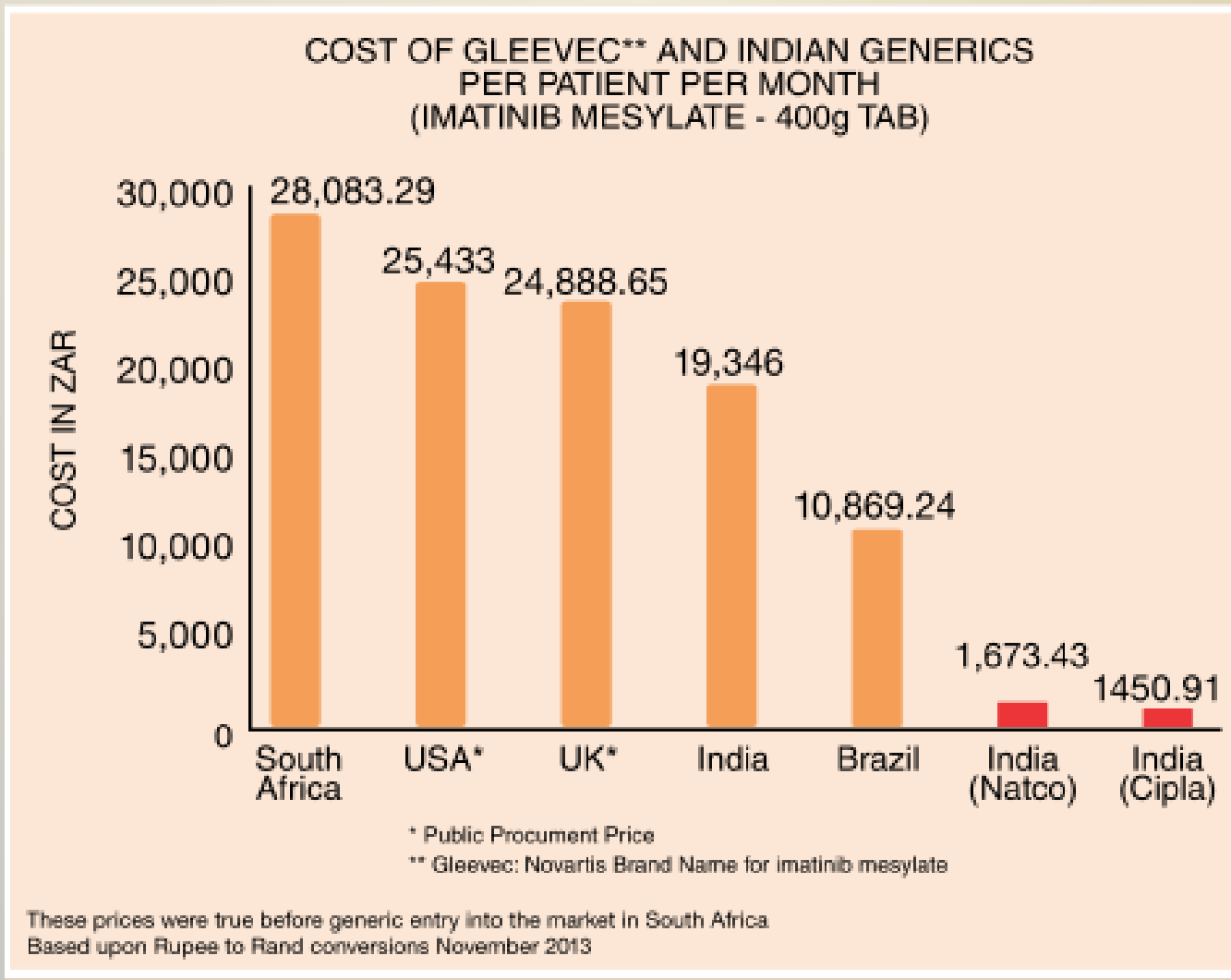
Cancer

Chronic Myeloid Leukemia (CML) drug 'imatinib' – Novartis





Before generic competition in SA






Generic imatinib: Still Priced Too High?

- Novartis charges 39% less in India than in SA
- Cipla's price in India is 91% less than in SA

MANUFACTURER	INDIA PPY	RSA PPY
Novartis	R 237,549	R 387,834
Novartis clone	--	R 214,109
Cipla	R 17, 816	R 208,780
Natco	R 20,902	--
Glenmark	R 10,694	--

Cost per person per year. (Amounts in ZAR)



Further competitors (and lower prices) will be blocked in South Africa by Novartis' secondary patents



R&D costs for imatinib

Novartis' imatinib:

1. Early Research Costs:

- 50% National Cancer Institute
- 30% Leukemia and Lymphoma Society
- 10% Oregon Health Sciences university;
- **Only 10% Novartis**

2. Tax Credits: Orphan Drug Credit for Novartis

3. Product costs:

Sales of Novartis' imatinib in 2012: **R46 billion**

Estimated Novartis Investment in R&D: R960 million

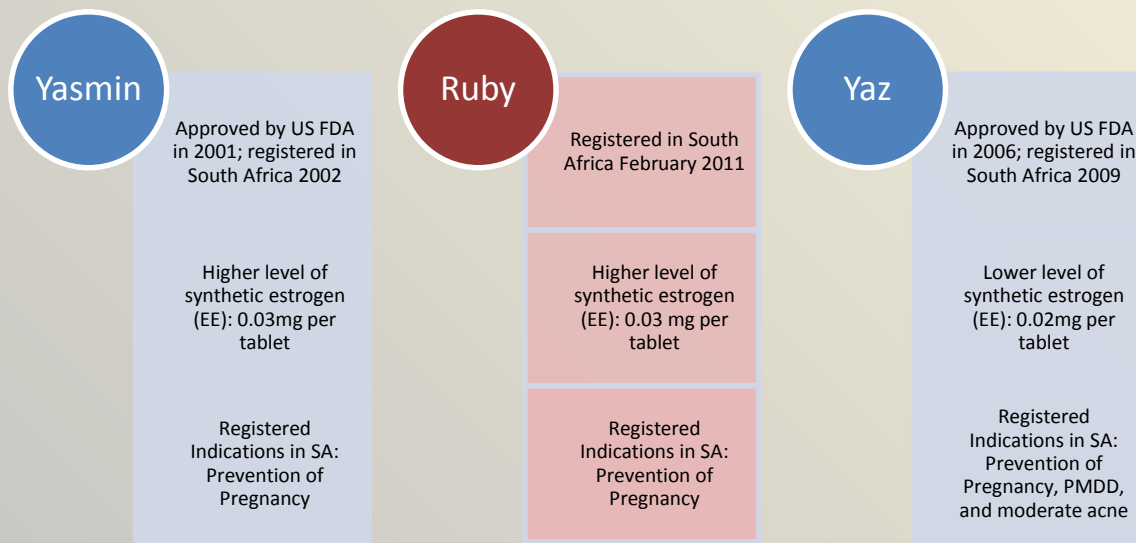
All money back every 13 days!!!





Oral contraceptive (DSP+EE)

- Bayer holds multiple patents on drospirenone clathrate/ethinyl estradiol (Yasmin/Yaz).
- Initial Yasmin patent expired 2011 in SA, secondary patents expire 2022 (size of synthetic hormone) and 2024 (dissolution profile).
- Ruby is a generic version of Yasmin, by manufacturer PharmaDynamics





Oral contraceptive (DSP+EE), continued

- PharmaDynamics 2011 launch of generic product at -30% lower price was halted through an interdict over secondary patent
- SA court case continues, even though generics available elsewhere, patent in question has been struck down in Europe and US.
- Secondary patents on Yasmin run to 2024
- PharmaDynamics has incurred over R10million in legal fees, millions of rand in lost sales—will make it difficult to realize lower prices even if they are given right to launch product



Oral contraceptive (DSP+EE) Sales

Manufacturer	Brand Name	Units Sold in SA (Oct 2012-Sept. 2013)^	Annual revenue in ZAR (Oct. 2012-Sept. 2013)^	Price per pack of pills in private sector*
Bayer	Yaz	793 559	89 404 172	R139.80
Bayer	Yasmin	903 531	84 196 100	R115.62
Pharmadynamics	Ruby	0	0	R80.93

If everyone on Yasmin had made the switch to Ruby, South African women would have saved over R11 million per year in total.



DR-TB: Linezolid Access Barriers

- Pfizer’s initial linezolid patent in SA expired 2014
- No alternative generic registered yet—MSF special access granted in June 2014.

Purchaser	Supplier	Price (600 mg tablet)
SA Government	Pfizer	R 287.9*
SA Private Sector	Pfizer	R 715.24**
MSF	Hetero	~R80 ***

* Expired SA DOH antibiotics tender
 **Single Exit Price
 ***only available to MSF in South Africa

*A 6-month supply of linezolid in the private sector costs approximately **R123,000 per patient –one drug was eating up 10% of entire MSF Khayelitsha budget***



Will the Story Repeat with New DR-TB drugs?

- **Bedaquiline**
 - US FDA Approval in 2012
 - Clinical access program ongoing in South Africa pending full registration—limited number of sites
 - SA registration fast-tracked in Dec. 2012—still pending
 - SA price unknown...but lowest announced price for any country \$900 for a course of treatment
 - At least 4 patents granted in SA (expire between 2025-2027)
 - including use for treating DR-TB in combination with other TB drugs
- **Delamanid**
 - Registered by the EMA in 2013
 - Will Otsuka register in South Africa?
 - At least 7 patents in SA (expire between 2025-2032)—including on use with other TB drugs

****Will combination patents hinder research into better regimens??****





The impact of the patent system on the economy





Investment



- If strict IP regimes lead to increased investment – South Africa should be awash in investment.
- Instead, following adoption of TRIPS 35 foreign pharmaceutical manufacturing plants shut down in SA
- Consolidated operations in regions with skilled labour, low costs of labour & production & other economic incentives
- Unlike SA, India proactively adopted TRIPS flexibilities that protect local industry– as such India’s domestic pharma industry realised FDI of US\$1 billion from April-June 2013 (*Novartis expansion*)
- SA realised less FDI than countries with weaker IP



Economic cost



- Pharmaceuticals are 5th largest driver of SA trade deficit / R5billion spent on procuring pharmaceuticals by DOH in 2012
- Cost driven by branded products – despite the fact that in quantity the majority of medicines are imported from India and majority of API from China.
- **Every Rand spent on branded medicines is money diverted from the wider health system**



Fixing South Africa's Patent Laws: Lessons From Other Countries





What Reforms Could SA Enact?

Other countries have used these reforms to make their patent systems work in the interest of public health:

- Patent examination system
- Stricter patentability criteria
- Patent opposition
- Improve Compulsory Licensing & Parallel Importation mechanisms
- Broad research exception





Where we are...

- DTI released draft policy almost one year ago
- Despite pressure – policy yet to be finalized & adopted
- Six years since the policy process began
- Crossed three ANC led administrations
- No timeline for completion has been given





The backlash: #PharmaGate



“The overall campaign is aimed at delaying the finalization of the IP policy...”



Industry's Arguments

“Patents do not impede access to medicines...”

“We do NOT want a debate over individual drug prices to become the focal point”

“South Africa is now ground zero for the debate on the value of strong IP protection. If the battle is lost here, the effects will resonate.”

“Proposed IP Policy Hurts the South African Economy... innovation will stall”





We need your help!

- Must continue to build pressure the government to finalize policy and fix our patent laws!
 - National IP Summit (20th October) – join, endorse, engage
 - Joint memorandum at IP Summit to government
 - Help us find additional individuals/patients with stories to tell
 - Help us to create a survey to find stories in the community (which medicines are the best/worst for different disease areas)



**FIX THE
PATENT
LAWS!**

**OUR LAWS
ARE IN
HANDS**

**POS
TREATMENT A**

PharmaGate **TAC**
TREATMENT ACTION CAMPAIGN

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