Intellectual Property, Access to Medicines and Innovation: Perspective from Médecins Sans Frontières

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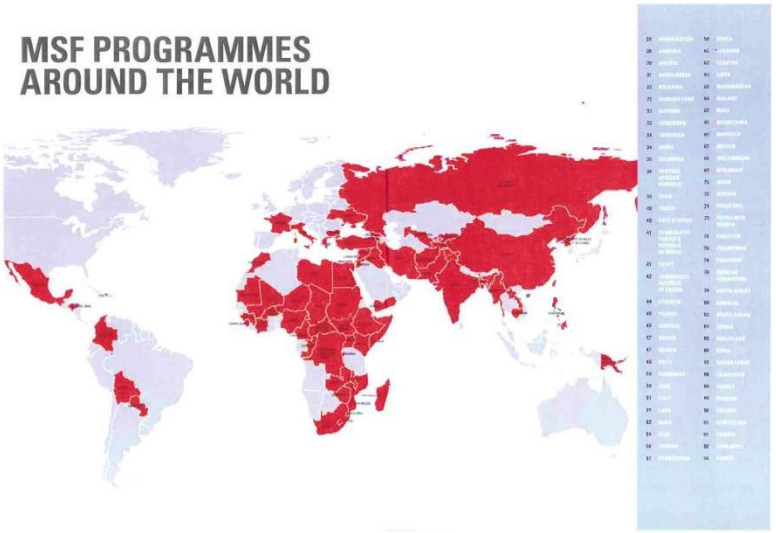
South Centre Side Event, WIPO SCP, June 29, 2016

MSF and Access to Medicines

Médecins Sans Frontières (MSF), founded in 1971, is an international, independent, medical humanitarian organization that delivers emergency aid to people affected by armed conflict, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries.



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Nobel Peace Prize Lecture 1999

Dr. James Orbinski

Médecins Sans Frontières International President

"*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.

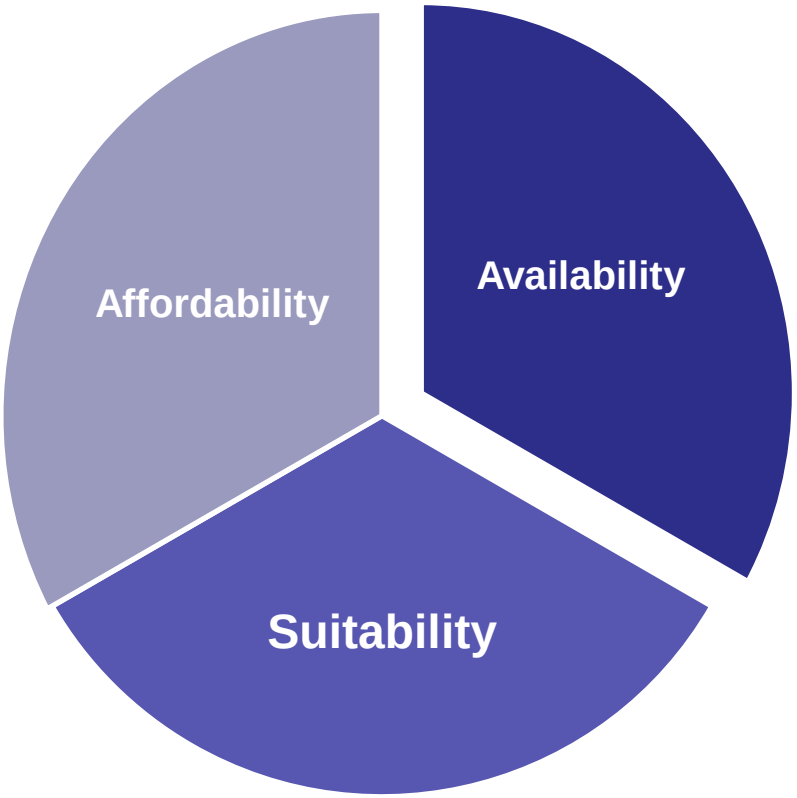
The challenge however, is not ours alone. It is also for governments, international government institutions, the pharmaceutical industry and other NGOs to confront this injustice.

What we as a civil society movement demand is change, not charity. "

Dimensions of Access and Innovation

- ☐ **Access to existing medicines**
- ☐ **Develop and access to new medicines**

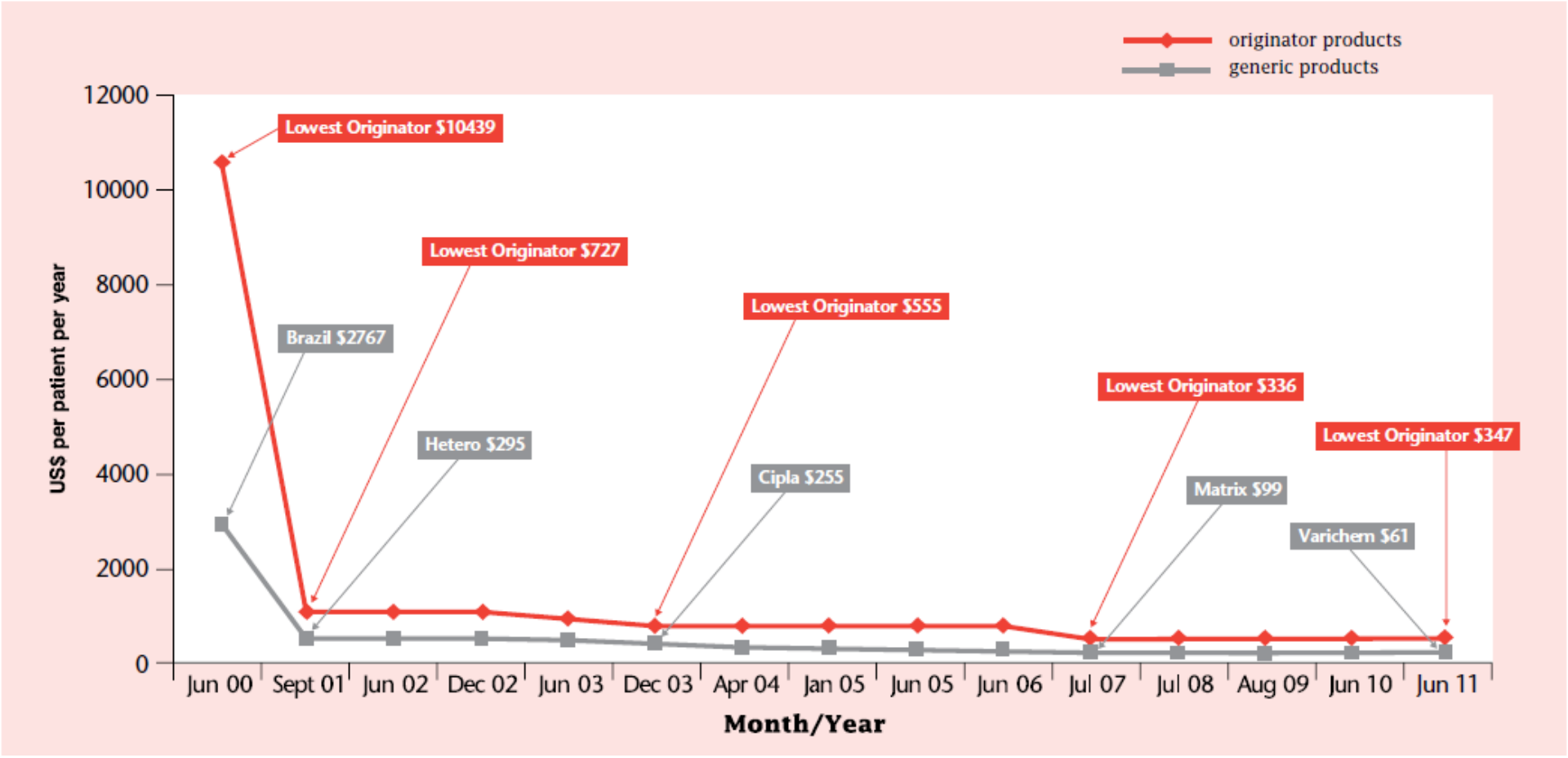
- The role of intellectual property, esp. patents
- Price
- Generic competition
- Follow up innovation
- Incentives for R&D for neglected population



Direct Effect on Prices of Medicines:
Competition = The Price of AIDS Drugs Fell by 99%

GRAPH 3: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.

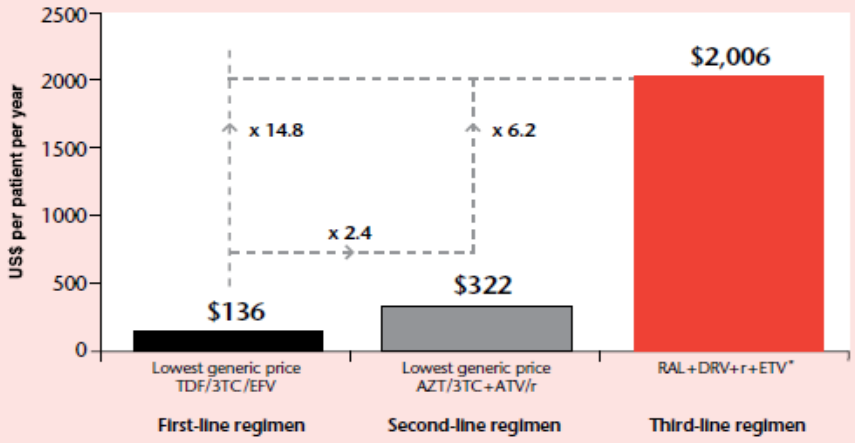
The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.



Source: MSF Untangling the Web of Antiretroviral Price Reductions, 15th Edition, July 2012

Today: Still Unaffordable

GRAPH 6: PRICE COMPARISON OF TREATMENT REGIMENS



*Note: The price of the third-line ARV regimen of US$2,006 was calculated by adding the three individual prices of the originator product.

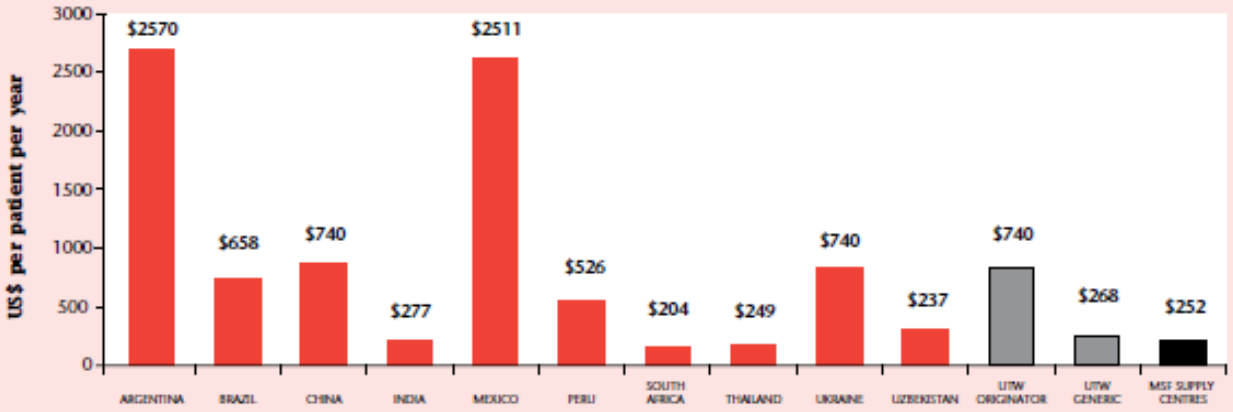
HIV

-The price of a third-line regimen is **more than 14 times higher** than the recommended first-line

- Middle income country dilemma with tiered pricing

Source: MSF Untangling the Web of antiretroviral Price Reductions, 17th Edition, July 2014

GRAPH 4: 2013 PRICE PER PATIENT PER YEAR LPV/R AS COMPONENT OF SECOND-LINE ARV REGIMEN



Sources: Argentina, Peru and Mexico: Antiretroviral Treatment in the Spotlight[28]; Thailand, Ukraine, Uzbekistan: The Global Fund Price and Quality Reporting[17]; Brazil, China, India, South Africa: responses to questionnaires sent from MSF to countries.

Key challenges to access and innovation

- New EML faces increasing challenges of patent barriers
- Patent ever-greening continued posing barriers to competition
- TRIPS-plus provisions harmful for public health
- Limitations on voluntary measures
- Political pressures on national laws and policies
- A broken model of incentivizing R&D

Are WHO Essential Medicines Lists better off from patent barriers?

New EMLs, New challenges

- New patented medicines in 2015 edition of WHO EML list --- *"…affordability is a major issue" – Nicola Magrini et al. 'Tough decisions on essential medicines in 2015'*
  - Hep C: daclatasvir, sofosbuvir
  - Cancer: trastuzumab, imatinib
  - TB: bedaquiline and delaminid
- Changing disease burden would see rising patent barriers to new EMLs with patent regime expansion

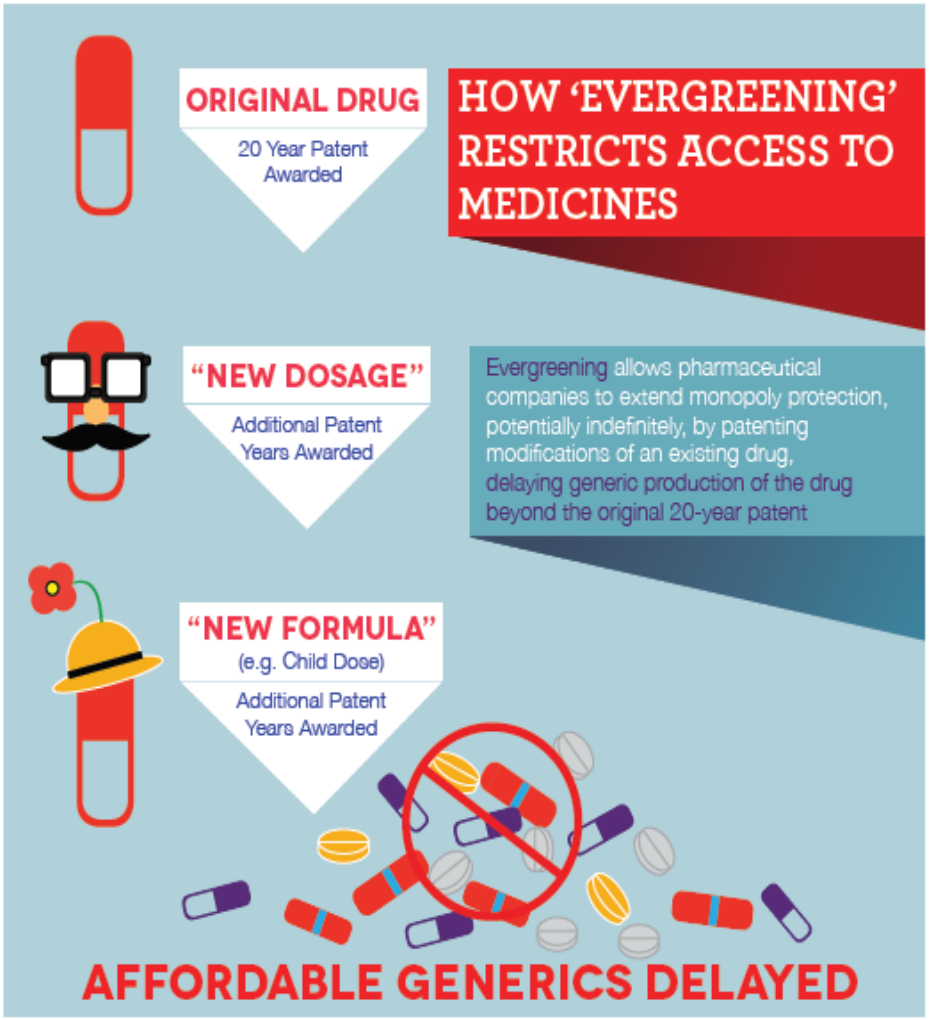
- WIPO report on patent-based analysis of WHO EML 2013
  - Disregarded the trend of disease burden and new development of EML
  - Contestable methodology – contestable conclusion
  - Wrong and limited usefulness of the data for public health decision making
  - Misleading and questionable on WIPO's mandate

MSF response: http://www.msfaccess.org/about-us/media-room/press-releases/msf-response-wipo-report-who-eml

What could patent ever-greening block access to affordable medicines?

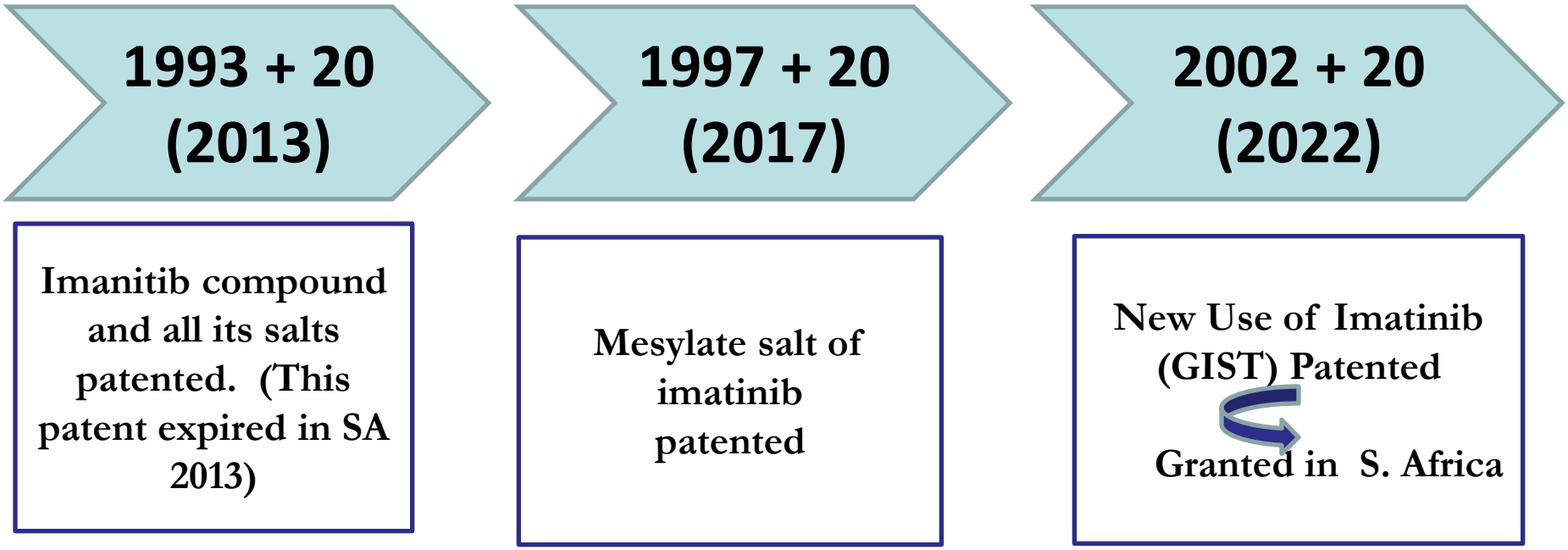
Impact of patent ever-greening

- **Case: *Novartis vs. Union of India***
  - 7 years case proceeding over rejection of Novartis patent application on Imatinib Mesylate (Gleevec), a drug treating leukaemia
  - Supreme Court final decision upheld the use of Sec. 3(d)
  - Political pressure continues especially from US

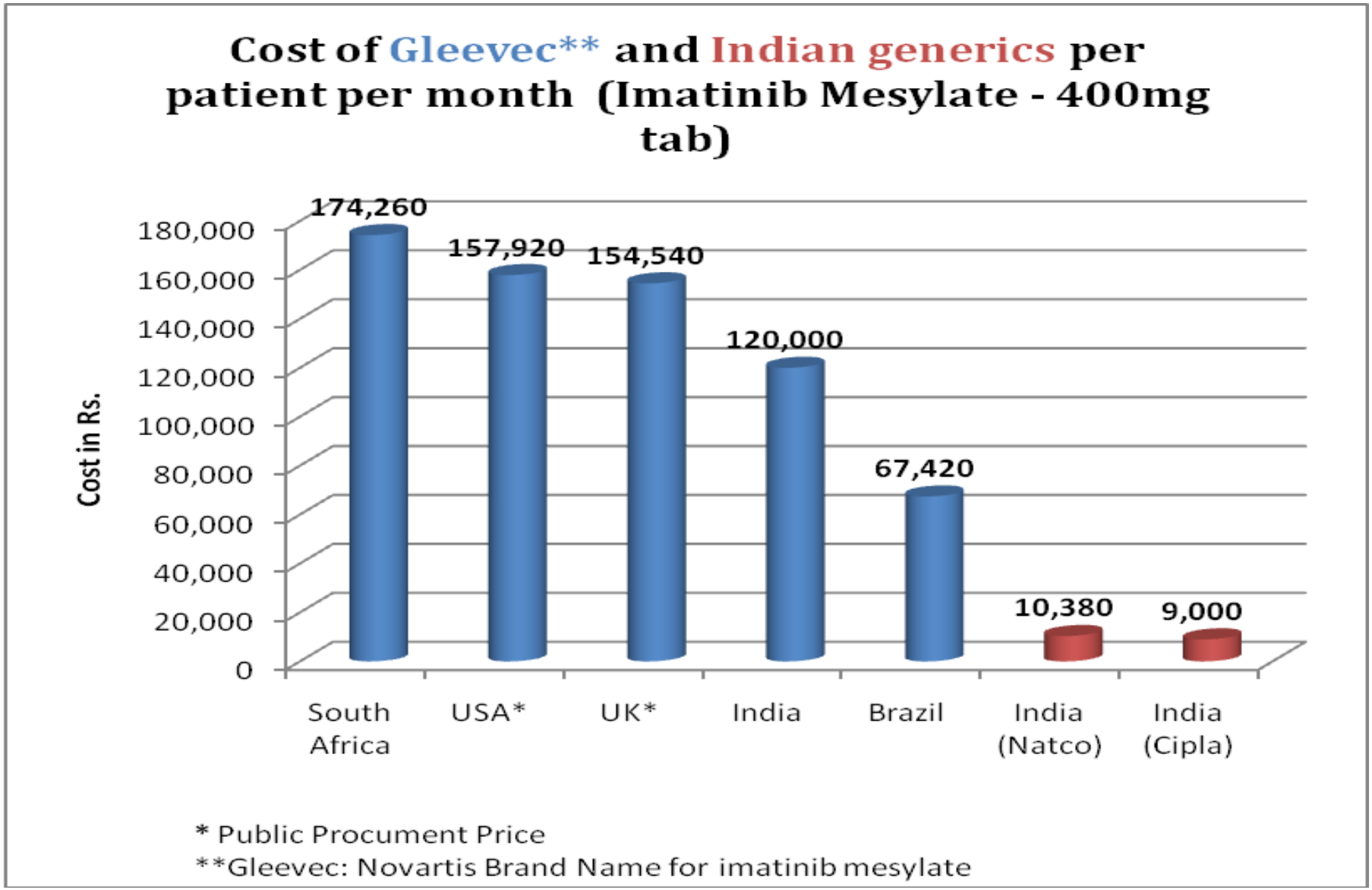


Effect of Ever-greening

- **Imatinib Mesylate Patents in South Africa**

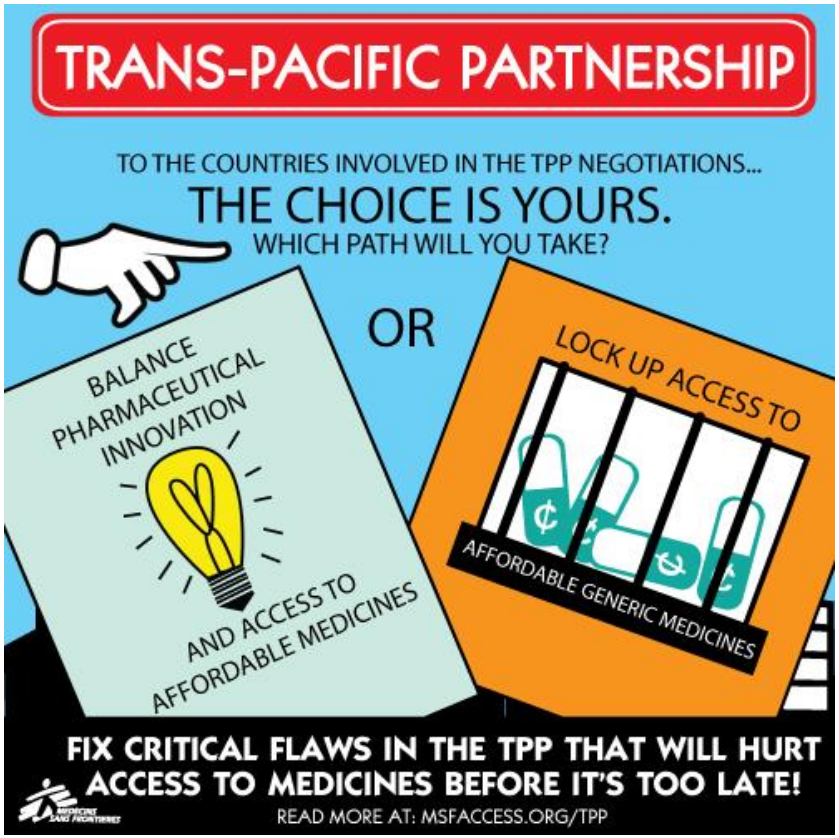


The Same Drug …
Before Generic Competition in South Africa



The route of TRIPS-plus provisions?

TPP Provisions affecting Access to Medicines



MSF Briefing and Open Letter to TPP countries:
•http://www.msfaccess.org/sites/default/files/TPP_IssueBriefing_July2014.pdf
•http://www.msfaccess.org/content/msf-open-letter-tpp-countries-dont-trade-away-health

MSF Open Letter to ASEAN on TPP:
http://www.msfaccess.org/content/msf-open-letter-asean-governments-dont-trade-away-health

•Lower requirements for patentability

• Expanded data exclusivity requirements --- at least 5 years for small molecule, 3 years for modifications, 5 years for combinations….

•Extend patent terms – beyond 20 years

•Introduce new forms of IP enforcement

• “Transparency and Procedural Fairness Chapter” restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs.

• Introduce Investor-State Dispute Settlement to risk substantive patent law flexibilities under attack

Could voluntary license bring the cure?

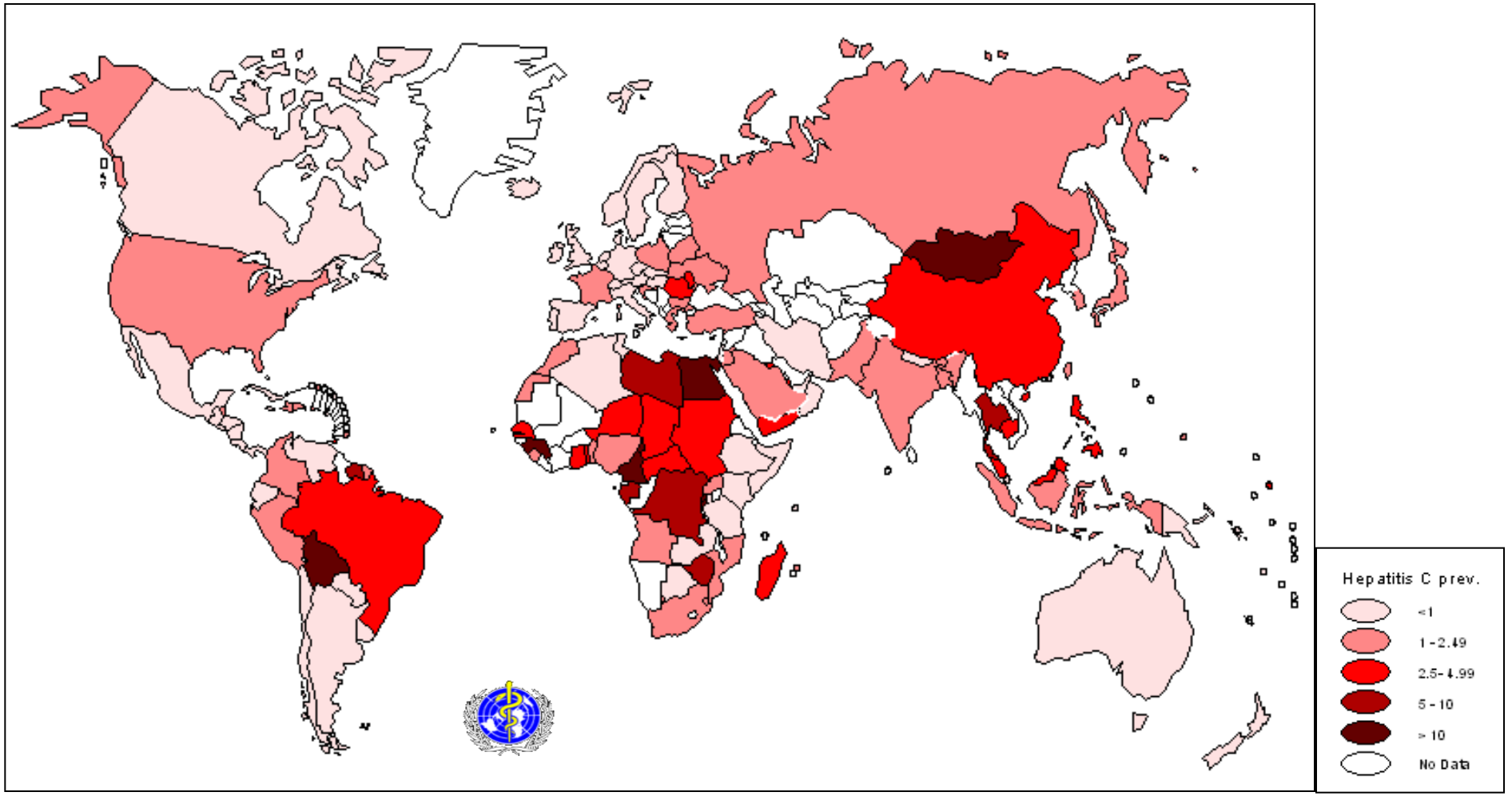
Issues with Voluntary License

- Transparency – Publication vs. secrecy
- Coverage:
  - Coverage for what? --- production, sale, API supply
  - Who is in and who is out? And why?
- Royalty rate: free? Tiered? Not tiered?
- 'Indirect coverage'? --- option for excluded countries; the use of CL; nexus with patent opposition?
- Termination: relation with tech transfer terms
- Anti-diversion: where is the limit?
- Framing : **does signing a VL bring access?**

New Challenges ahead with Access

Hepatitis C: global prevalence

About 180m people are infected with hepatitis C and 350,000 people die each year from related liver diseases



Cont. issues with Gilead's voluntary license

http://www.msfaccess.org/sites/default/files/MSF_assets/HepC/Docs/HepC_factsheet_GileadHCVTreatmentRestriction_ENG_2015.pdf

- Exclusion of many Middle-income countries
- Restriction on API sourcing by India generic companies

The Licensing Agreement Excludes the Following 50 MICs:

Albania	Columbia	Jordan	Montenegro	Tunisia
Algeria	Costa Rica	Kazakhstan	Morocco	Turkey
Argentina	Dominican Republic	Kosovo	Panama	Ukraine
Armenia	Ecuador	Lebanon	Paraguay	Venezuela
Azerbaijan	El Salvador	Libya	Peru	West Bank & Gaza
Belarus	Georgia	Macedonia	Philippines	Yemen
Belize	Grenada	Malaysia	Romania	
Bosnia Herzegovina	Hungary	Marshall Islands	Serbia	
Brazil	Iran	Mexico	St. Lucia	
Bulgaria	Iraq	Micronesia	Syria	
China	Jamaica	Moldova	Thailand	

Cont. issues with Gilead's voluntary license

http://www.msfaccess.org/about-us/media-room/press-releases/gilead-stop-blocking-access-hepatitis-c-treatment

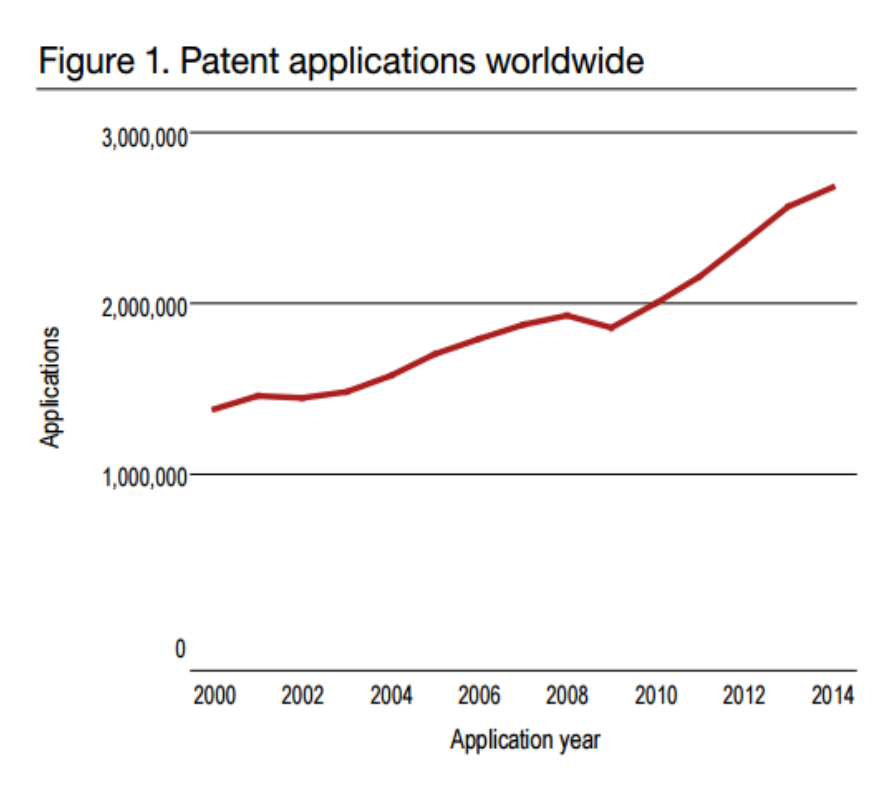
http://www.msfaccess.org/sites/default/files/HepC_Gilead_anti-diversion_FINAL.pdf

- 'Anti-diversion' programme in developing countries through its distributors and licensees (generics companies that have signed a voluntary license with Gilead).
- These policies violate patient privacy and autonomy, undermine confidentiality of patient data, introduce coercion and police upon medical providers.
- The policies may result in treatment interruptions for patients.

Is the patent centric model indispensable for medical innovation?

MSF new report: ‘Lives on the Edge’
https://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/R&D_report_LivesOnTheEdge_ENG_2016.pdf

Do more patents bring more innovation on medicines?

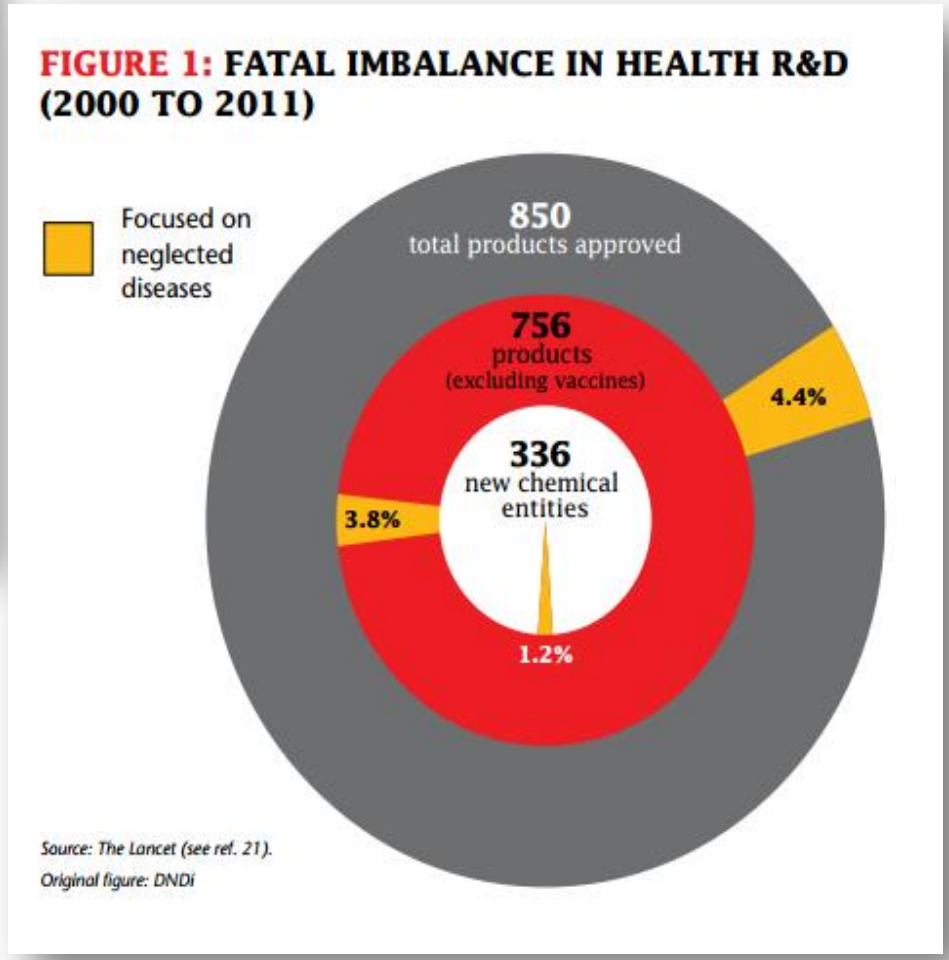


Source: WIPO World Intellectual Property Indicators, 2015

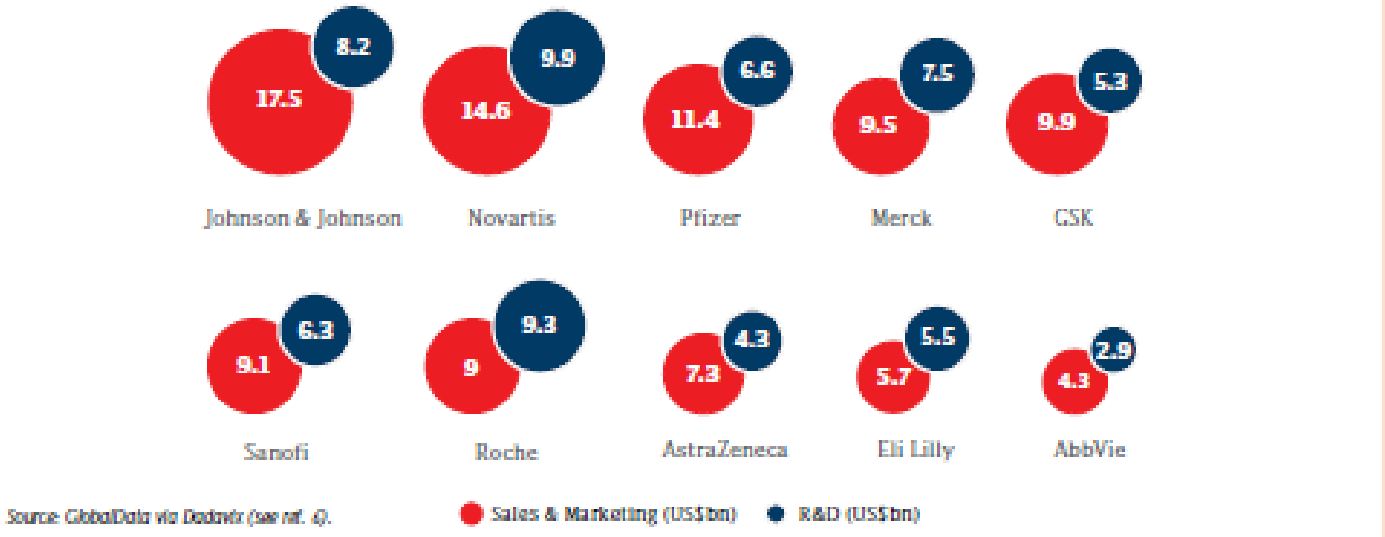
Global patent filings on pharmaceuticals have increased by 7.3% from 1995-2013.

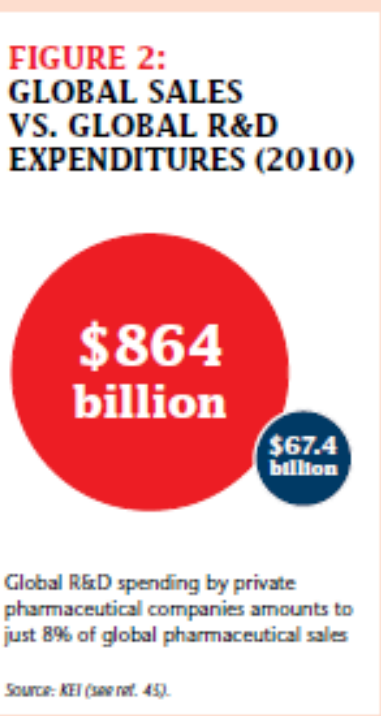
Source: WIPO World Intellectual Property Indicators, 2015

Source: MSF report, 'Live on the Edge: Time to align Medical R&D with People's Health Needs'; Ref. Pedrique B, et al. The drug and vaccine landscape for neglected diseases (2000- 11): a systematic assessment. [Online] Lancet: 2013; 1(6):e371.



Myth of R&D cost and prices of medicines

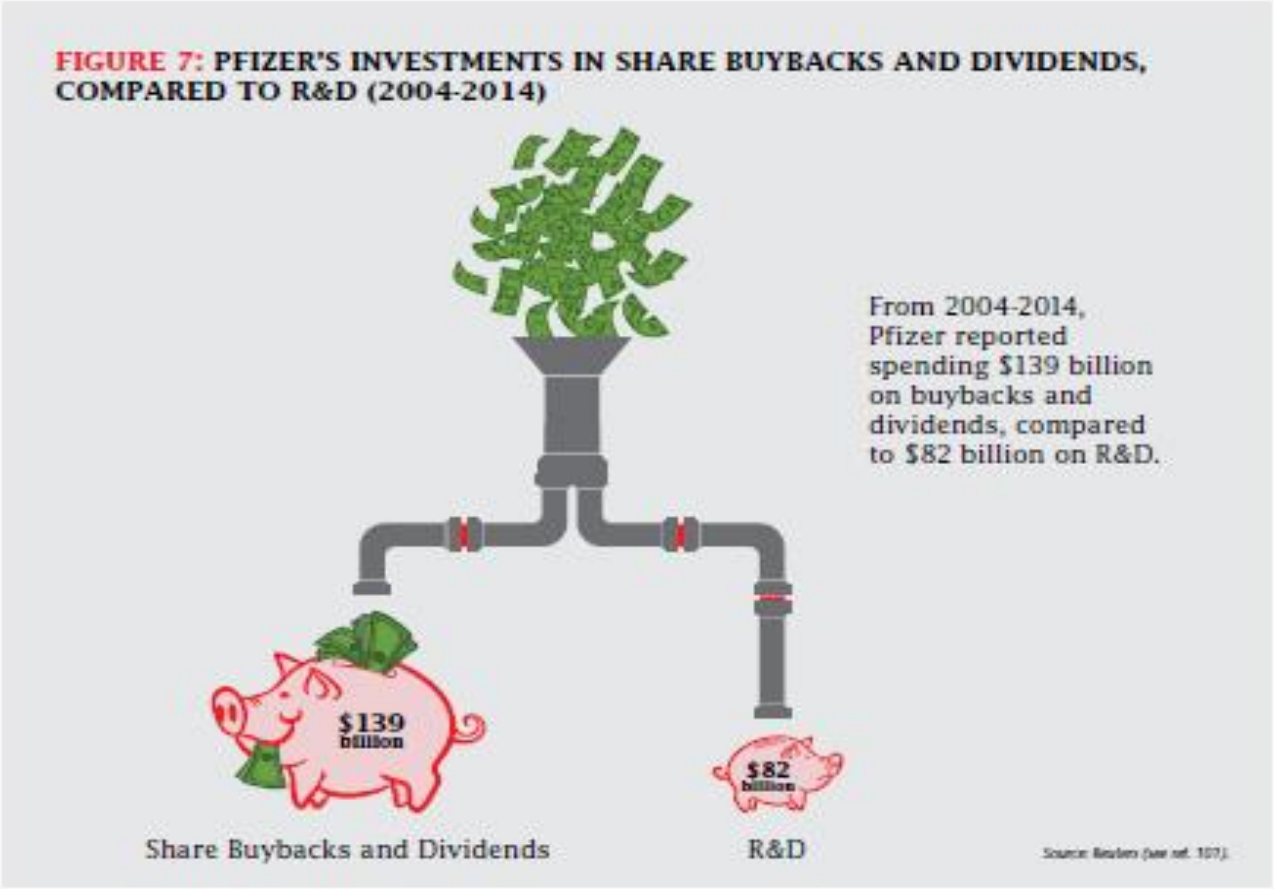




- The 5 largest pharma companies spent $60 billions on marketing

Myth of R&D cost and prices of medicines

- 2004-2015, 19 of the largest pharma companies spent $226 billions repurchasing their own shares = 51% of the R&D expenditure *(Lazonick W. et al, 2016)*



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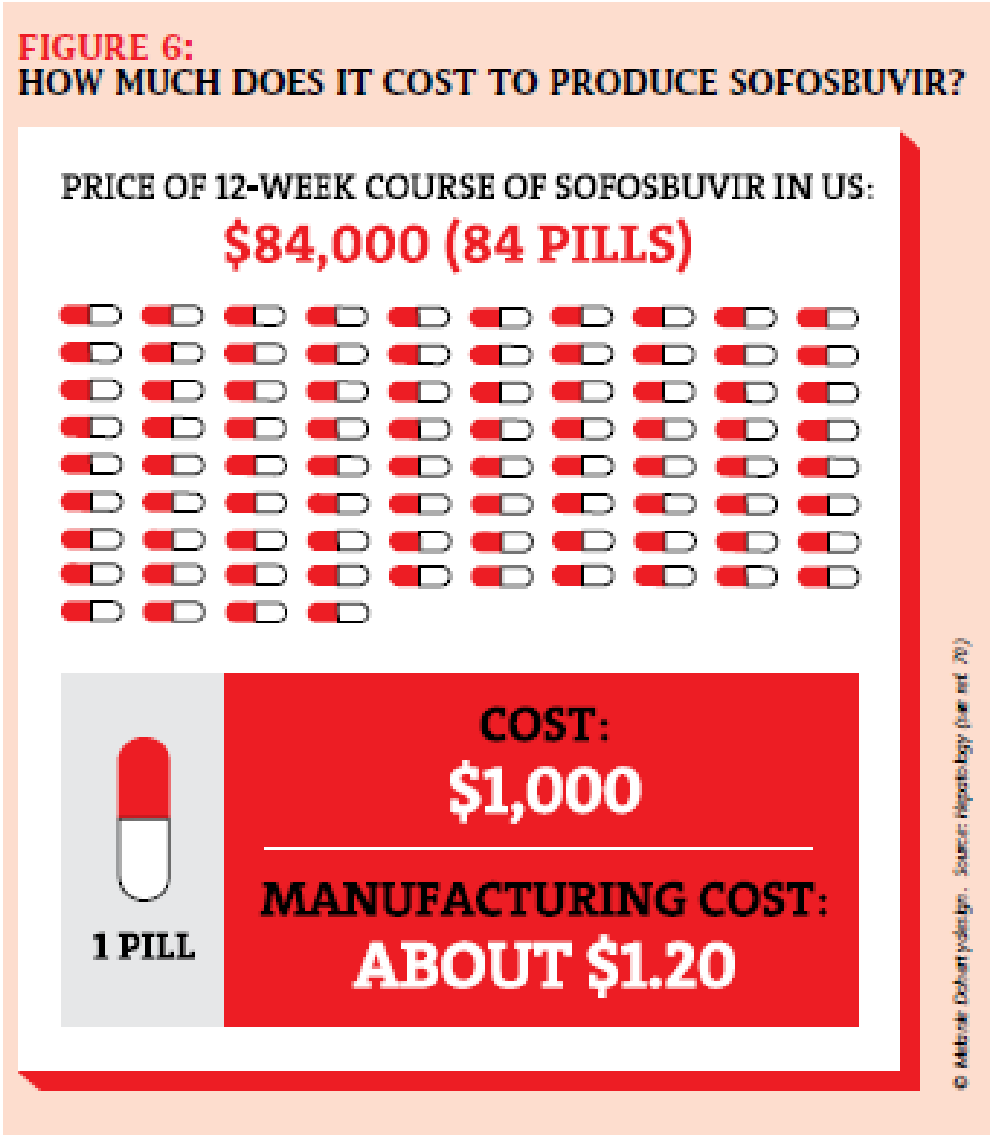
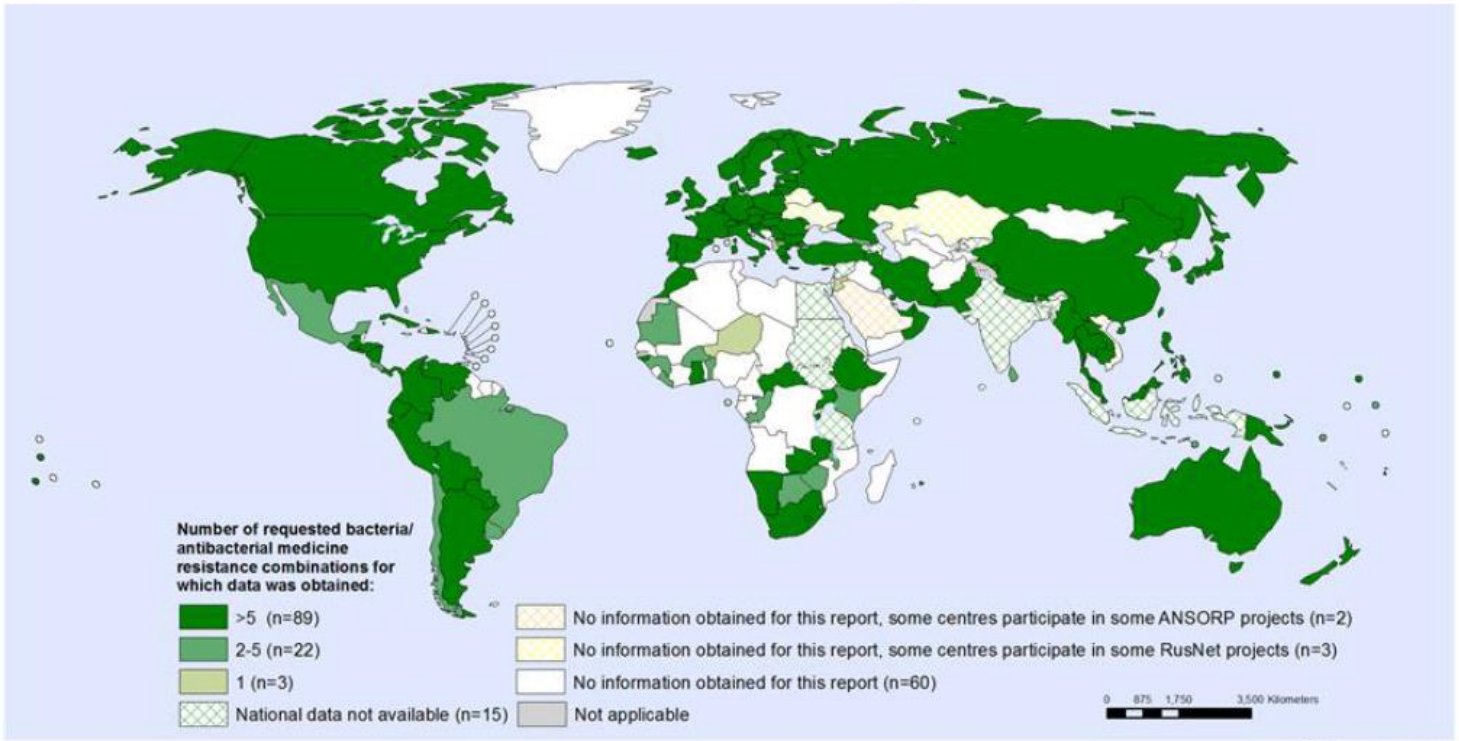


- Unjustifiable high launch price
- Voluntary tiered price leaves millions in need without access

Example: Antimicrobial Resistance - AMR

A truly global public health problem

Available National Data* on Resistance for Nine Selected Bacteria/Antibacterial Drug Combinations, 2013



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Health Statistics and Information Systems (HSI)
World Health Organization

World Health Organization

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*National data means data obtained from official sources, but not that data necessarily are representative for the populationor country as a whole

Source: WHO Global report on AMR, 2014

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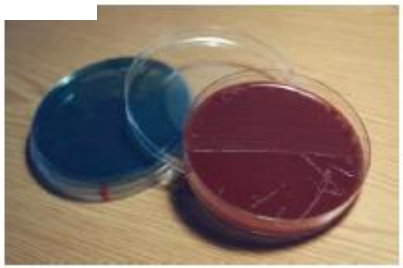
- Diagnostic methods are based on principles that are **over 75 years old!**
- Diagnostic devices not adopted to resource limited settings
- No promising pipeline of new antibiotics

Evaluation of a Commercial Microarray System for Detection of SHV-, TEM-, CTX-M-, and KPC-Type β-Lactamase Genes in Gram-Negative Isolates▽†

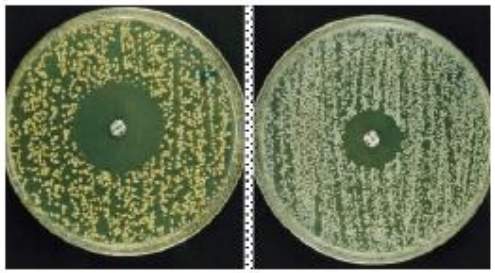
Andrea Endimiani,[1,2] Andrea M. Hujer,[1,2] Kristine M. Hujer,[1,2] Julian A. Gatta,[1] Andrew C. Schriver,[1] Michael R. Jacobs,[3] Louis B. Rice,[1] and Robert A. Bonomo[1,2,4,5]*

JOURNAL OF CLINICAL MICROBIOLOGY, July 2010, p. 2618–2622

~5-6 hrs
(6-7 hrs from DNA extraction)

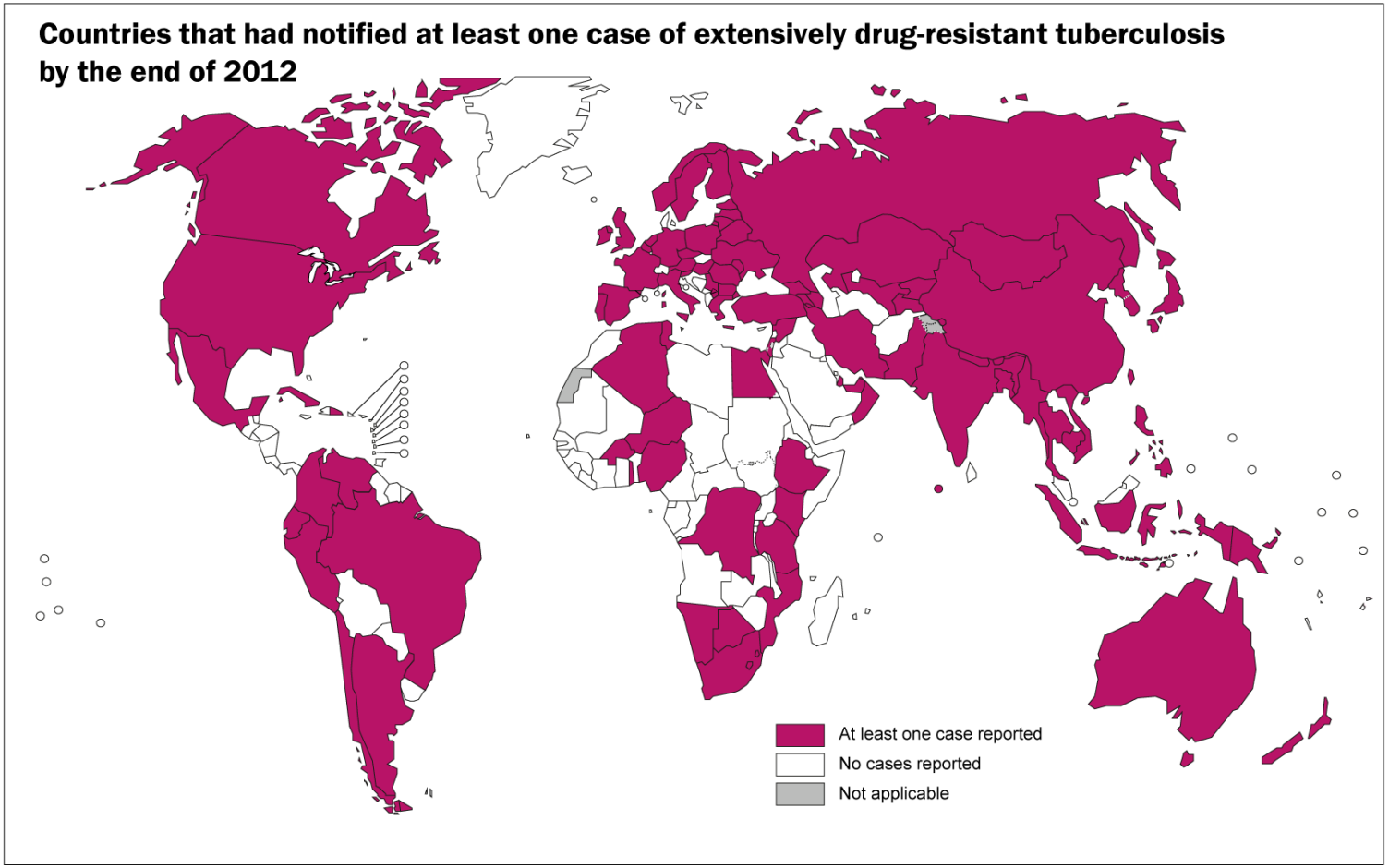


- **Why? Antibiotics market is less profitable**
- **Patent centric model does not work for AMR R&D**



Example: Drug-Resistant TB

The next epidemic in the making?



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Data Source: *Global Tuberculosis Report 2013*. WHO, 2013.

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The issues – Multi Drug Resistant (MDR)-TB treatment

- **Medicines:**
  - Old – 'newest' drug in current regimens was introduced 50 years ago; Two new drugs...no new regimens.
  - Expensive – Can cost up to $5000 in drug costs alone

- **Treatment:**
  - Long – Treatment takes two years and
  - Toxic – extreme side effects include deafness, psychosis, constant nausea and vomiting, weight loss and more; and
  - Complex – different treatment regimens for individual resistance patterns; about 5 different drugs (14,000 pills), including 8 months of painful injections
  - Inadequate – high default rates and low cure rates (~50%) contribute to further resistance; no paediatric formulations

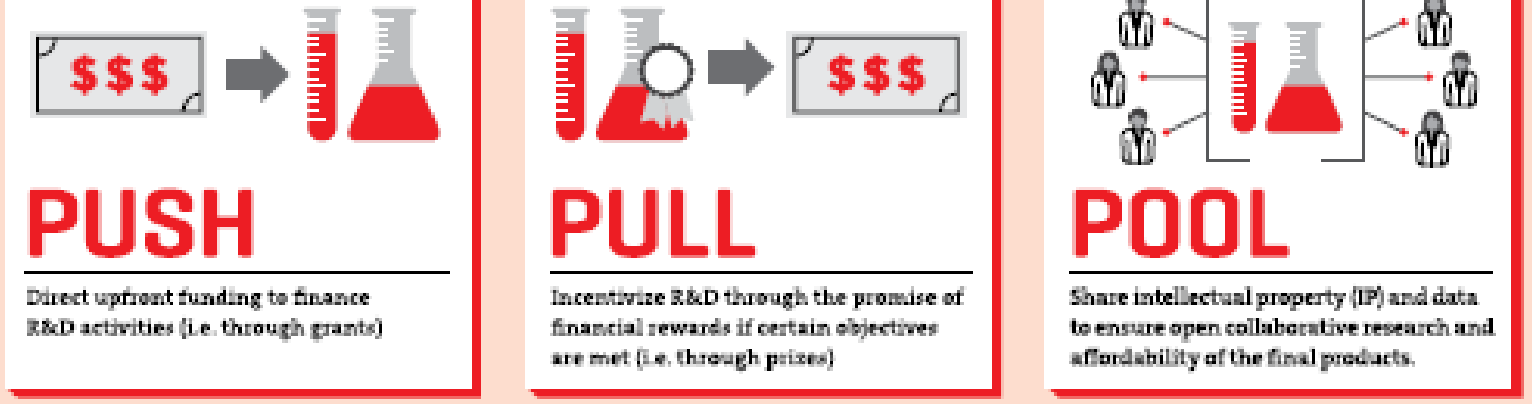
- **Funding:** Private funding decrease; lacking interests of accelerating clinical trial

- **Patent centric model does not work for TB R&D**

Time for TB to do something new

3P Project - Push, Pull and Pooling

FIGURE 9:
THE 3P PROJECT: AN OPEN, COLLABORATIVE APPROACH TO TB REGIMEN DEVELOPMENT



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