The UNITAID Patent Pool

Seeking Effective and Sustainable Innovation and Access for AIDS Drugs

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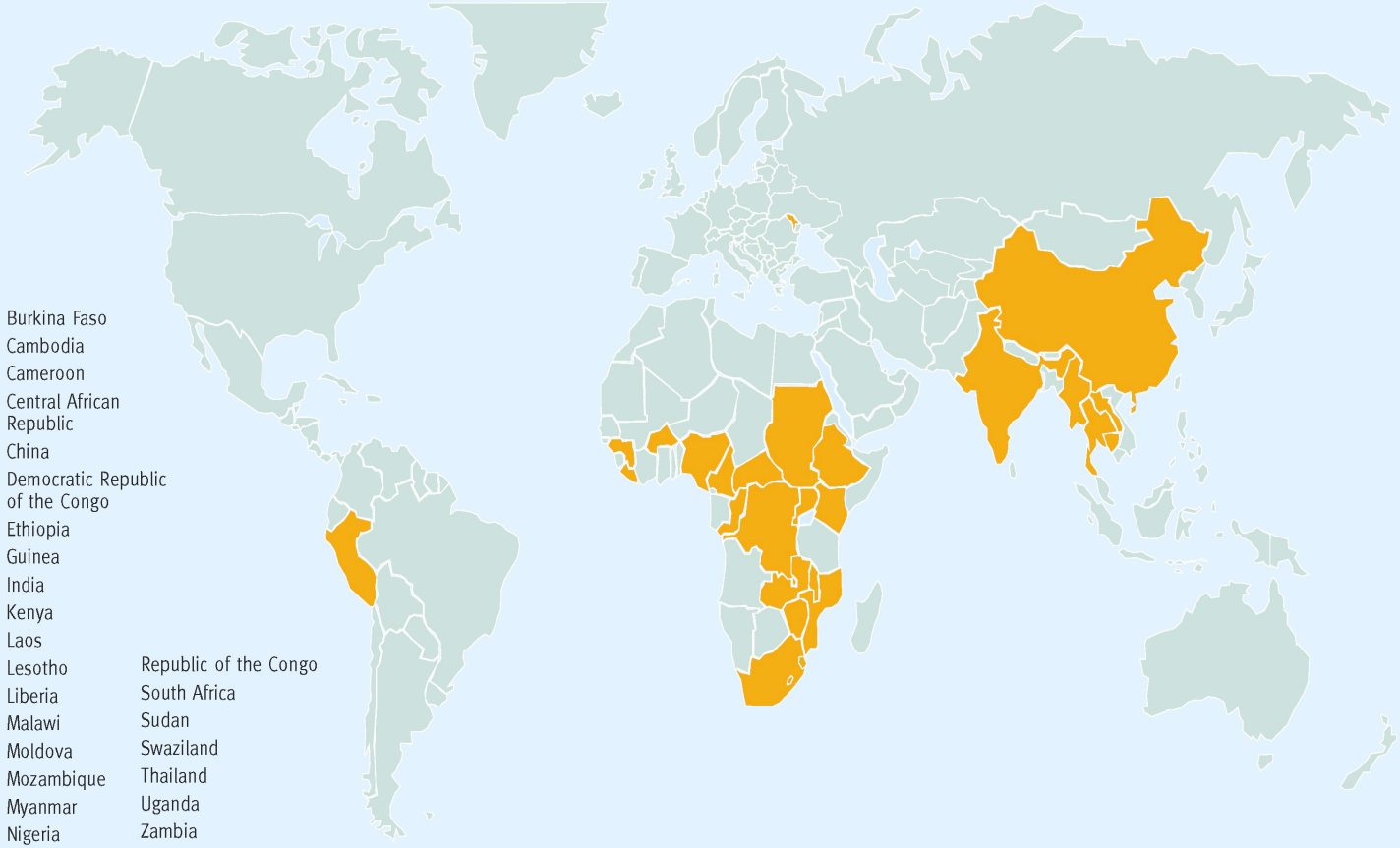
MSF HIV/AIDS TREATMENT PROGRAMMES

* data collected April 2008

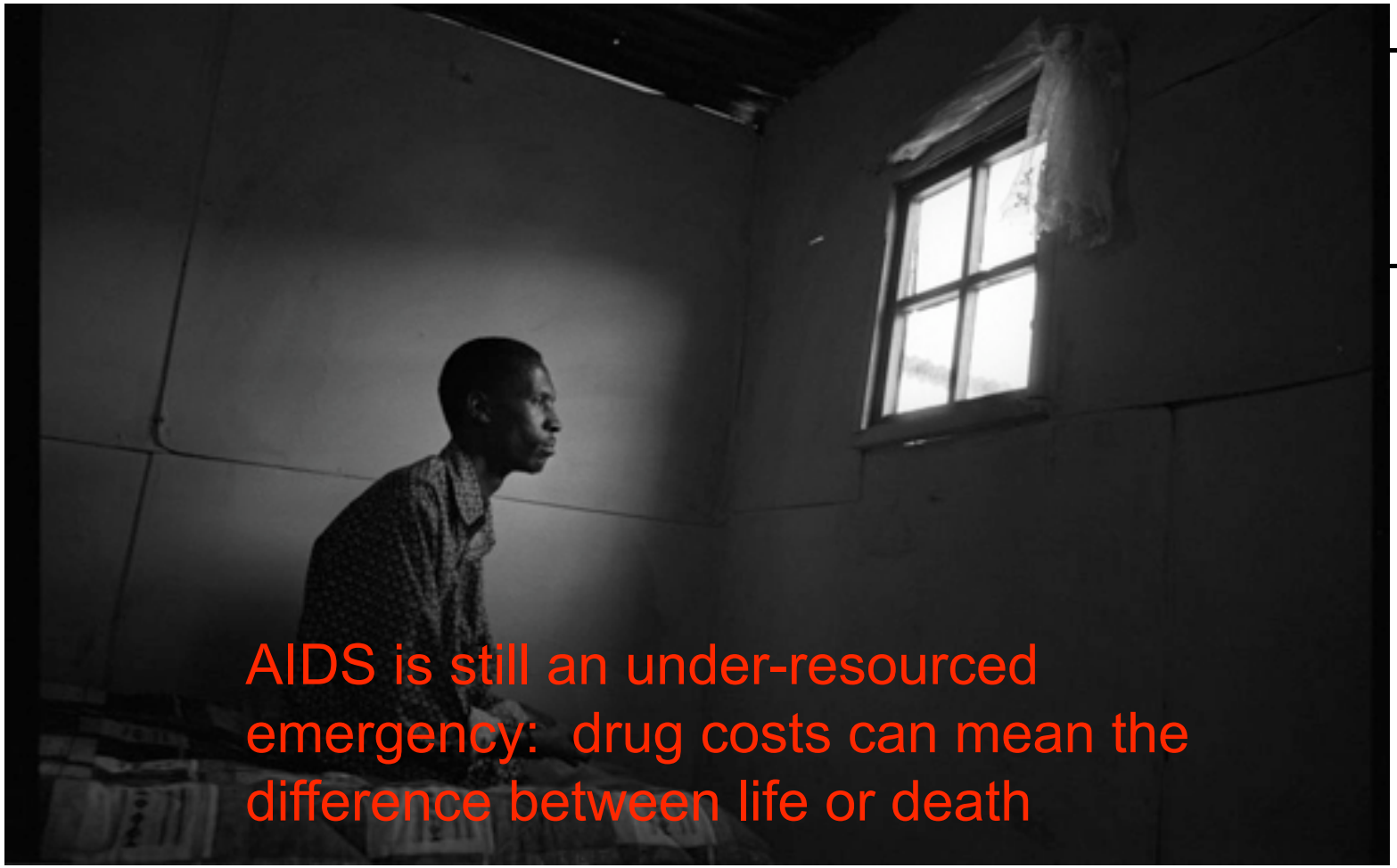


Burkina Faso
Cambodia
Cameroon
Central African Republic
China
Democratic Republic of the Congo
Ethiopia
Guinea
India
Kenya
Laos
Lesotho
Liberia
Malawi
Moldova
Mozambique
Myanmar
Nigeria
Peru
Republic of the Congo
South Africa
Sudan
Swaziland
Thailand
Uganda
Zambia
Zimbabwe

MSF PROGRAMMES ARE CURRENTLY PROVIDING ANTIRETROVIRAL TREATMENT TO MORE THAN 140,000 PATIENTS (10,000 OF WHOM ARE CHILDREN) IN 27 COUNTRIES*

Yet the needs remain enormous

- Only 1/3 of those in need with access to AIDS treatment in developing countries
- 2d and 3d line, pediatric formulations even less available



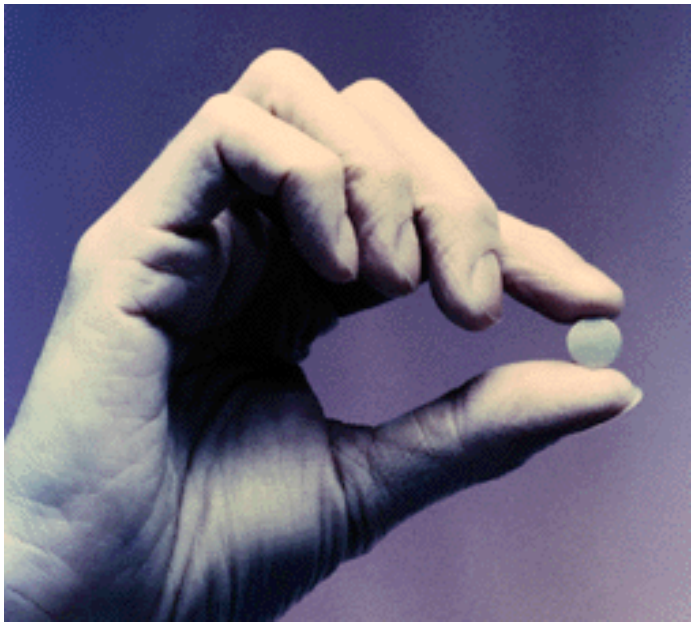
- Major funding shortfall
- For financial reasons, patients turned away; govts choosing cheaper regimens

Antiretroviral Treatment Scale-Up: Fixed Dose Combinations and the Absence of Patent Barriers

- Triomune (3TC, D4T, NVP) is a FDC produced by Cipla. It only exists in generic form.
- Only possible to create Triomune FDC because India's patent laws before 2005 did not recognize product patents for the 3 drugs.
- Initial cost of $350 pp/py (2001) and now $87 pp/py (2009).

Why Is An Affordable FDC Important?

- 75% of countries recommend a FDC as part of national guidelines.
- Simplified guidelines for widespread and accelerated roll-out.
- Improved adherence with smaller quantity of pills and fixed dosage.
- Drug costs are a limiting factor in achieving universal access.
- Drug costs increasingly important in tightening economic climate.



The Triomune Story

An imperfect story….

- Stavudine with poor long-term tolerability, and adherence issues. No longer recommended for use by the WHO.

….but one that would nevertheless be impossible with newer drugs today.

- Post 2005 modifications in Indian patent law limit generic competition of newer drugs.
- Many drugs needed in developing countries today are patented for ….


THIS PANDEMIC
IS WORSE THAN THE
HOLOCAUST DOCTOR
DENIALIST PLEASE!! GIVE
US ANTI-RETROVIRAL THERAPY
WE WILL DO COUNSELLING
FOR FREE!!!

Medical Needs

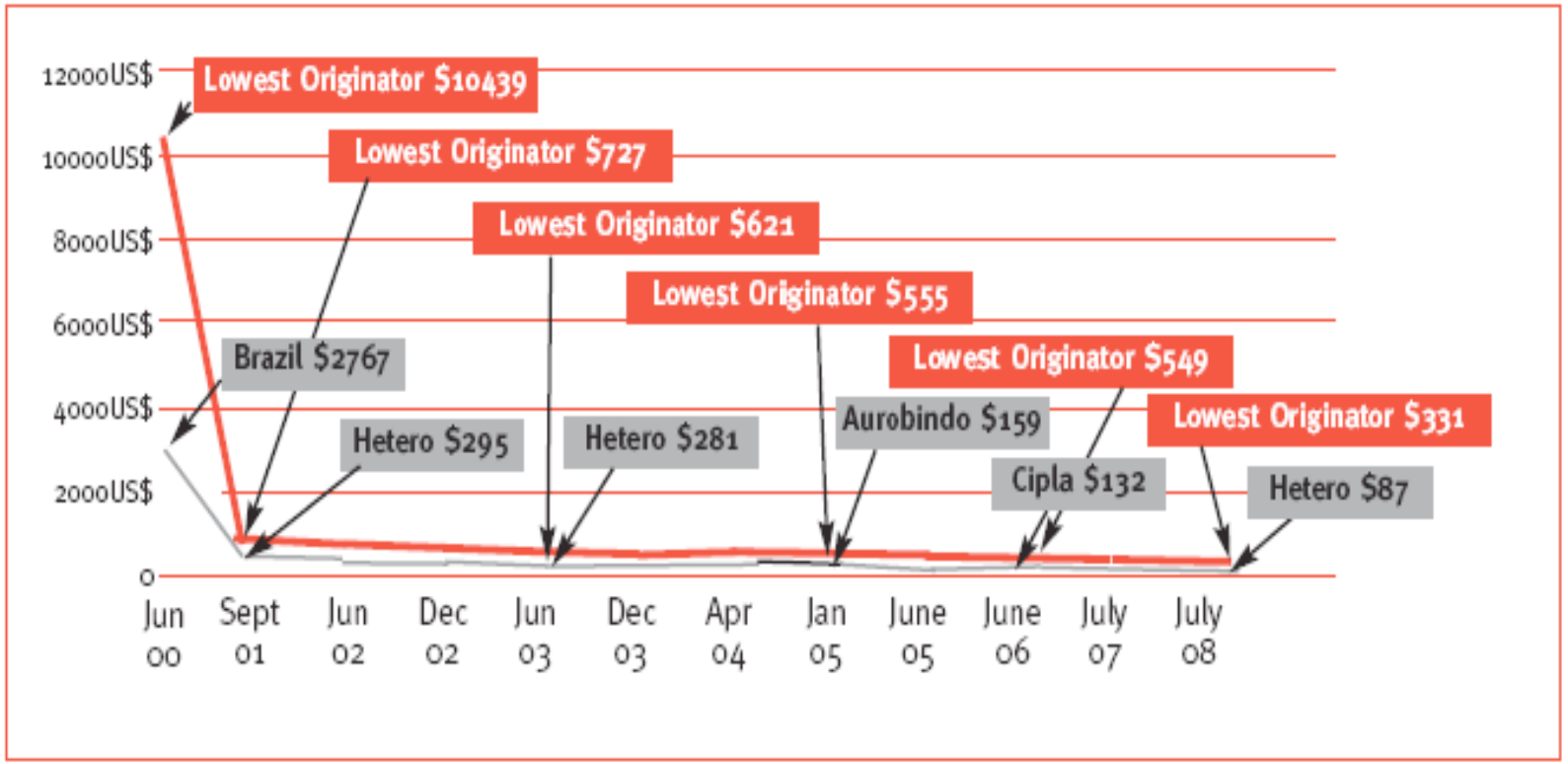
Do the drugs available **meet the needs** of the population in developing countries?

Are the **right combinations** available?

Are the drugs **formulated for children and adults** in developing countries? (Refrigeration requirements, lifespan, taste, etc.)

Are the drugs **affordable** for developing country populations?

“Generics fuel AIDS Program” (WSJ 31 July 2008)



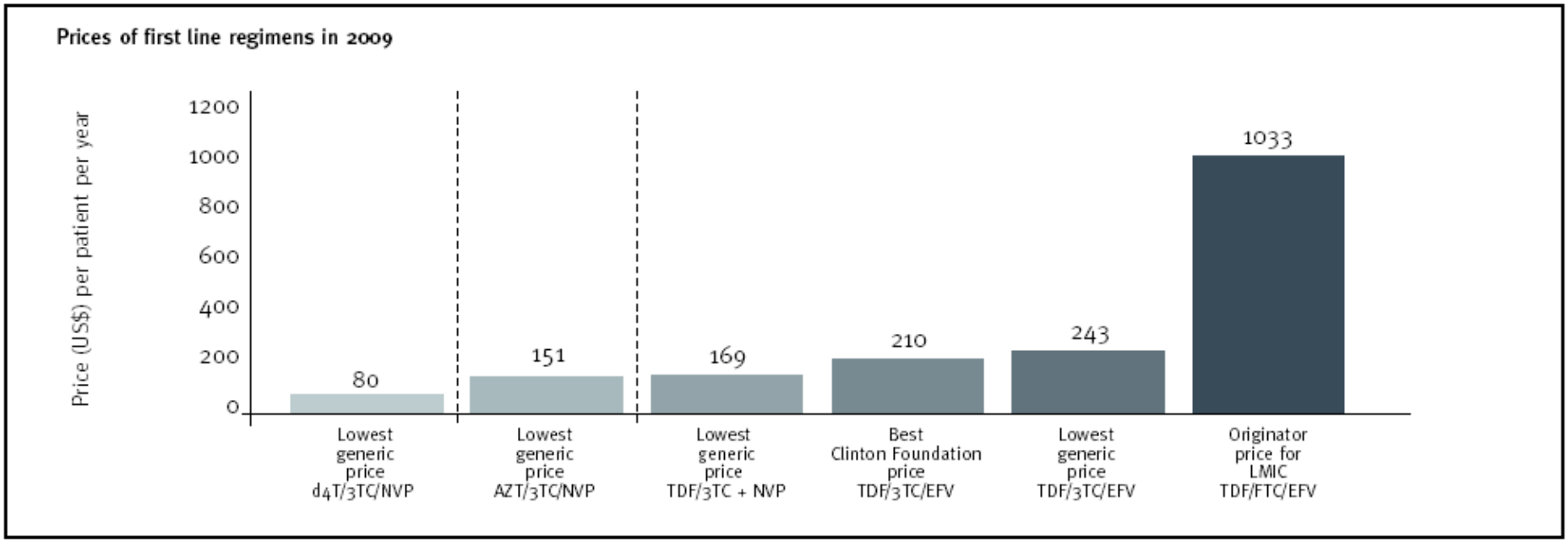
But …Times Have Changed

- 2005: WTO TRIPS Agreement fully implemented globalizing patent rules

- Medicines become patentable everywhere
  - India started granting product patents following amendment of the Patents Act in 2005
  - Brazil, Thailand

Need for newer drugs: a better first line regimen

- stavudine no longer best care -



Source: MSF briefing document: HIV/AIDS treatment in developing countries: the battle for long term survival 2009

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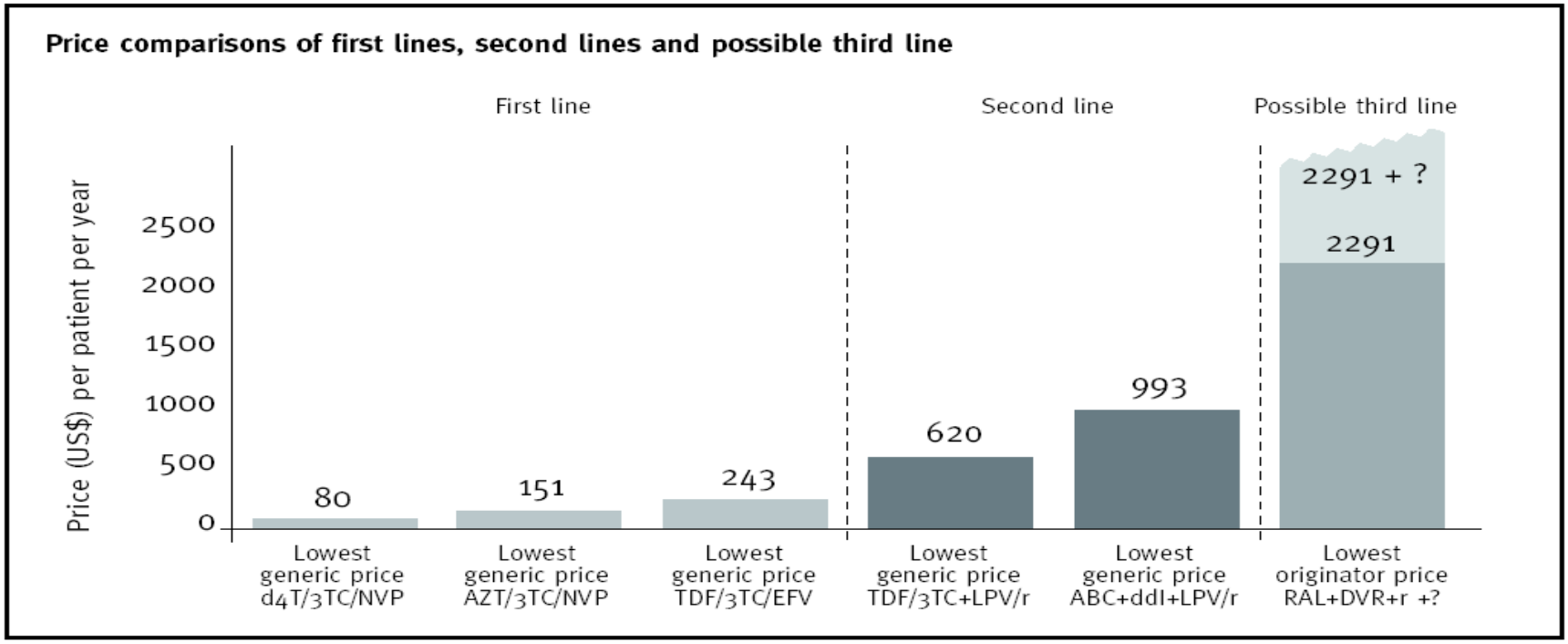
CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

Need for newer drugs: switch to new regimens to keep people alive



Flexibilities Exist and Must Be Used

- **Delayed implementation** for developing countries (2005 for India, 2016 for LDCs)

- **Parallel Importation** (Article 6: open to member states)

- **Compulsory Licensing** (Article 31: use without authorization of rights holder)
  - Reasonable effort to obtain authorization; limited scope and duration; inform the rights holder and provide remuneration
  - Primarily for the *domestic market* of the invoking nation

- **Doha Declaration (2001)**
  - "The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health"
  - Reaffirmed TRIPS flexibilities: compulsory license, *not only in cases of emergency*; the right to determine what constitutes national emergency or extreme case of urgency, (easier and faster CL); the right to determine national parallel importation regimes; extension of TRIPS deadline for LDCs to 2016

- **August 30th Agreement (2003): the "expeditious solution" for countries without manufacturing capacity to CL conundrum**
  - Temporary waiver of CL *domestic use* restriction to address public health problems.
  - But with limitations and arduous process

Health Before Patents

Limitations on Available Mechanisms for Innovation and Access

- Differential pricing
  - Discounts not steep enough and not as effective as generic competition
  - No solution to patent barriers for innovation (i.e., FDCs, pediatric formulations)
- "Voluntary" licenses
  - Restrictions limit full effect of generic competition e.g., trade in API, export
  - Rare and often response to threats e.g., CL or legal action
- Compulsory and government use licensing
  - Dramatic price decreases
    - Thailand => EFV price 1400 Baht (45$) to 615 Baht (19$) a bottle.
    - Brazil => EFV 77% price drop ==> increase of patients from 23.300 to 75.000
  - But: Harsh international criticism (Section 301, trade pressures) and company retaliation (e.g. Abbott refusal to make new drugs available in Thailand)
- Limitations on patentability
  - LDC's exclude product patents when patented
  - India – strict patentability criteria (Section 3d); patent grant oppositions
    - But: efforts to weaken Indian generic pharmaceutical production – Novartis' challenge to Section 3d of Indian Patents Act, political efforts by US Chamber of Commerce, USPTO and Pfizer to weaken Section 3d, etc.

Why a Patent Pool?

- Newer ARVs and 2d, 3d line ARVs more expensive and out of reach
- Need for drugs responsive to patient needs
- In TRIPS era, generic competition no longer reliable for lower prices
- *Current system threatens scale up of treatment access, availability of appropriate drugs, long-term survival*

- **Need for more systematic approach … NOW**

Patent Pool for Innovation and Access
Primary Needs

- Access:
  - **Decrease price of newer first-, second-, and third-line ARVs** by increasing the number of generic producers

- Innovation:
  - Encourage the development of first- and second-line **FDCs** by overcoming patent barrier
  - Encourage the development of **pediatric** first- and second-line formulations
  - Encourage the development of formulations **adapted to developing country needs**

Make It Happen Campaign / MSF - Campaign for access to essential medicines - Microsoft Internet Explorer

Fichier Edition Affichage Favoris Outils ? Précédente Rechercher Favoris Média Ouvrir Liens

Adresse http://www.msfaccess.org/main/access-patents/make-it-happen-campaign/ OK

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

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LatestNews

MSF leads WTO workshop on medicine detainment by customs... read more

Vacancy: Access & Innovation Officer MSF South Africa for more details click here

MSF calls for 'sustainable solutions' in response to UNAIDS progress report... read more

Novartis attacks Indian patent law again threatening future access to affordable medicines read more

Medical need, not purchase power, should determine the global response to the Influenza A (H1N1) pandemic read more

Treating Too Few, Too Late Read about the case for starting ARV treatment earlier in developing countries click here

Make It Happen Campaign

The cost of HIV medicines is rising all the time, meaning that many people with HIV will not be able to afford life-saving medicines. Unless.....

There is a way to produce new drugs at affordable prices: Join us in pushing for the patent pool. This way drug companies share their drug patents with the pool, so they still get their royalties ....but at the same time other companies can get hold of these patents to make cheaper drugs. Everyone wins.

Help us push for the pool: write a letter to drug companies asking them to put their drug patents in the pool.

TAKE ACTION: Write to drug companies

Send an **email** to the drug companies with the patents we need, urging them to put the patents in the pool.

UNITAID, The international drug financing agency, is in the process of setting up a patent pool . To make it work, the drug companies have to agree to put their patents in the pool. So send your letter and help us ... **MAKE IT HAPPEN**!!!

Campaign Update

AccessNews

Special Activism Edition Jan 2009!

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Press releases (related)

30 September 2009
MSF calls on drug companies to pool HIV patents

21 July 2009
AMFm - New global subsidy for malaria medicines must ensure quality of care – says MSF

20 July 2009
Optimise now, or pay more later...Sub-optimal treatment threatens long-term survival of people living with HIV/AIDS

all press releases RSS

Key publications (related)

28 July 2009
Missing ARVs for HIV/AIDS treatment in 2009: Unitaid Patent Pool Briefing

19 July 2009

Terminé, mais il existe des erreurs sur la page. Internet

What Molecules Should Be in the Pool?

MSF's Perspective

Company	Patents Requested	Headquarters
Abbott	Lopinavir (LPV) Ritonavir (r)	US (Abbott Park, Chicago, Illinois)
Bristol-Myers Squibb	Didanosine (ddI) Atazanavir	US (New York, NY)
Gilead Sciences	Tenofovir (TDF) Emtricitabine (FTC) GS-9350 Elvitegravir	US (Foster City, San Francisco, CA)
Merck	Efavirenz (EFV) Raltegravir	US (Whitehouse Station, NJ)
Pfizer	Maraviroc (MVC)	US (New York, NY)
Sequoia Pharmaceuticals	SPI-452	US (Gaithersburg, MD)
Johnson & Johnson / Tibotec	Darunavir Etravirine Rilpivirine	US (Langhorne, PA)
Boehringer Ingelheim	*Nevirapine (NVP)* *Tipranavir*	*Germany*
GlaxoSmithKline (GSK)	*Lamivudine (3TC)* *Abacavir* *Fosamprenavir* *S/GSK 1349572*	*England*

Why these drugs?

- **FDCs**
  - First-line regimens: need for TDF-based triple combinations
  - Second-line regimens: LPV/r or ATZ/r, Darunavir/r
- **Pediatric ARVs**
  - Of 22 approved ARVs: 6 have no pediatric indication, 7 have no pediatric formulations available
  - Patent barriers not the only issue: need additional incentives (i.e., clinical trials, funding for purchase to guarantee market)
- **New classes of drugs**
  - Would otherwise be blocked for 20 year patent term
    - **Integrase inhibitors:** raltegravir, elvitegravir
    - **Entry inhibitors:** maraviroc (MVC)
    - **New booster to avoid ritonavir monopoly :** GS 9350, SPI 452
    - **New NNRTIs:** rilpivirine, etravirine

No patents yet in the pool

But interest among companies

> *We believe if structured appropriately, UNITAID's patent pool can play a critical role in expanding access to antiretroviral treatment for patients around the world by encouraging the development of new fixed-dose combinations and pediatric formulations, lowering prices, while respecting intellectual property.*
>
> - Gregg Alton, Gilead senior vice president

Terms and conditions being decided

Details of the licenses, remuneration and governance structure crucial

Middle income countries a key sticking point

An Effective Pool, Not a Pool at Any Cost

- **AVOID UNNECESSARY PATENTS**: TRIPS flexibilities, public health safeguards, strict patentability criteria
- Cannot hamper **ACCESS TO COMPULSORY LICENSES** and other available mechanisms for access and affordability

- Based on **MEDICAL NEEDS**: must include the right drugs, including newer medicines
- Based on **ECONOMIC REALITIES**: must have a broad enough market, i.e. with middle income countries as both manufacturers and beneficiaries so that there are economies of scale attractive for generic producers
- Based on **ACCESS NEEDS**: low-income and middle-income developing countries must be beneficiaries given the wide income disparities and need for lower cost treatments and adapted medicines in middle-income countries

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CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

Conclusion

- The medicines patent pool is a unique opportunity.
- The pool can provide a sustainable solution for access and innovation shortfalls due to patent barriers.
- Voluntary approach to inclusion of patents in pool can avoid confrontation and litigation.
- Doing nothing is not an option: patent barriers can mean life or death for millions.
- The patent pool must be effective: based on medical needs and serving people living with HIV/AIDS in the whole of the developing world.

The Patent Pool

Because patients cannot wait 20 years for the right drugs.

And we know what they are.

For more information, please visit: www.msfaccess.org.