



REPUBLIC OF SOUTH AFRICA



# Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

## *Topic 8: Compulsory Licenses*

**Durban, South Africa  
January 29 to 31, 2013**

# **Enhancing Access to Medicines through Licenses**

**Regional Seminar on Patent-Related Flexibilities**

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**World Health  
Organization**

# Some underlying health facts

- Between 20 % and 60 % of the health budget in LIC goes to medicines expenditures
- In some countries, up to 80 to 90 % of medicines are purchased out-of-pocket as opposed to being paid for by health insurance schemes
- In 2009, in 36 out of 89 countries for which data are available out-of-pocket expenditures for health accounted for more than 50 per cent of total health spending
- Average availability of selected generic medicines in LMICs:
  - public sector less than 42 %
  - private sector almost 72 %



# What is a license?

**Contract between two parties = outcome of a negotiation process**

- **Patent holder allows the contracting party to use the patent (to exercise the patented invention)**
- **Against a payment of royalties or free-of-charge**
- **For a defined period of time**
- **Worldwide or in specific countries (defined territory)**
- **Subject to additional conditions**



Recent compulsory licenses & government use						
Country	Medicine	Indication	Measure	Period	Royalties	Remarks
India	trastuzumab; ixabelone; dasatinib	Breast cancer; leukemia	CL	2013	To be decided	Decision pending
Ecuador	abacavir/lam ivudine	HIV/AIDS	CL	2012	5%	Local prod.
Indonesia	Seven products	HIV/AIDS; hepatitis B	Gov use	2012	0.5%	Local prod.
India	sorafenib	Cancer	CL	2012	6%	Local prod.
Ecuador	ritonavir	HIV/AIDS	CL	2010	5%	Import; local prod.
Thailand	erlotinib; letrozole; docetaxel; clopidogrel; Lopinavir/ritonavir	Cancer, heart disease HIV/AIDS	Gov use	2006-2008	3-5%	Import
Brazil	efavirenz	HIV/AIDS	CL	2007	1.5%	Import & local prod.

# Example: India/sorafenib

## Anti-cancer medicine: sorafenib (Nexavar - Bayer)

Compulsory license issued on request of local generic company in 2012 for local production.

**Reason:** unaffordable price

- Generic price: USD 175/120 tablets
  - Originator price: USD 5500/120 tablets
- = 97% reduction

# Example: Brazil/efavirenz

## HIV/AIDS treatment: efavirenz (Merck Sharp&Dome)

Government issues a CL after protracted negotiations with the patent owner.

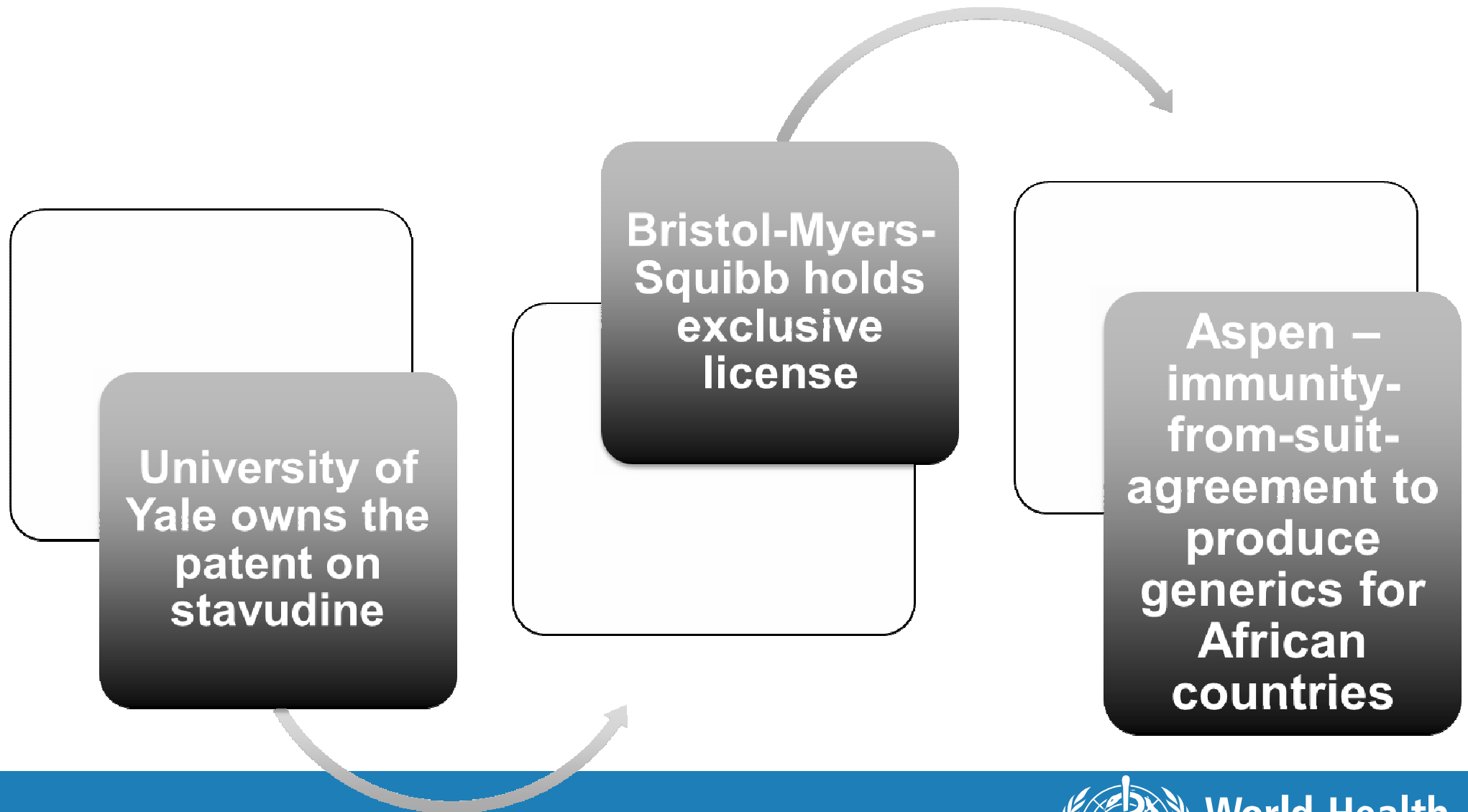
**Reason:** high price

- Generic price: USD 0.43 per dose
  - Originator price: USD 1.59 per dose
- = 73% reduction

But it took two years to set up local production...



# Example: South Africa/stavudine





# Example: oseltamivir

## Pandemic pressure leads to licenses:

### Problem:

- Threat of H5N1 (avian flu) pandemic: patent holder faced explosive demand
- Countries threaten to use compulsory licenses
- Some countries later discover that there is no patent
- one compulsory license issued, but finally not used

### Solution:

- Patent holder issues a worldwide call to apply for sub-licenses
- Royalty-bearing licenses granted to four generic companies
- Limited to pandemic preparedness (emergency situation) allowing for governmental stockpiling



# Socially responsible licensing

## Objective:

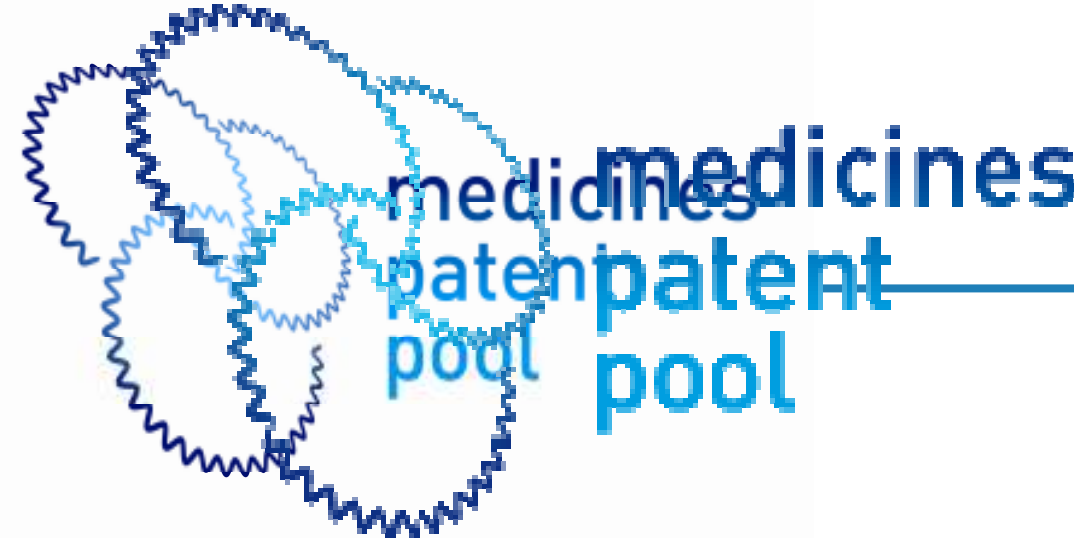
- To ensure that licenses are negotiated in a way that facilitates access to the licensed product in countries in need of affordable prices/for patients

Adds a **dimension of social responsibility** to the economic dimension of licensing without necessarily compromising the business (in developed countries)

- When is a license socially responsible?



Voluntary licenses						
Company	Medicine	Indication	Geographic scope	Number of Licensees	No of countries	Remarks
<b>BMS</b>	ATV ddl; d4T	HIV/AIDS	SSA, India	7 >3	48 50	immunity-from-suit
<b>Boehringer</b>	NVP/TPV	HIV/AIDS	All Africa, LDC, LIC; India	Several	75	immunity-from-suit agreements
<b>Gilead / MPP</b>	TDF (FDC) EVG/Quad COBI	HIV/AIDS	unlimited	Country list	112 100 103	
<b>MSD (Merck)</b>	EFV RAL	HIV/AIDS	SA SSA, LIC	6 2	1 60	EFV: No patents in SSA outside SA
<b>Roche</b>	SQV oseltamivir	HIV/AIDS; influenza	SSA; LDC Africa; China; India	13	65	oseltamivir for pandemic prepared.
<b>Tibotec (J&amp;J)</b>	DRV ETR RIL	HIV/AIDS	SSA; LDC; India Country list	2 2 5	65 65 112	
<b>ViiV (GSK&amp;)</b>	AZT; 3TC;	HIV/AIDS	SSA; LDC;	11	68	



Initiated by UNITAID in 2010  
with the objective to

- negotiate license agreements with companies regarding HIV/AIDS products, with the aim of sub-licensing these products to generic companies to increase access to treatment in low- and middle-income countries.
- assemble the necessary intellectual property rights regarding key HIV/AIDS products in order to develop new fixed-dose combination products that unite different products in one pill or formulation
- develop missing paediatric formulations of existing treatments.

# Medicines Patent Pool

## Achievements

- Expansion of territory for licenses
- License to Gilead's TDF (tenovofir) combination with other products.
- In collaboration with WIPO establishment of patent database for antiretrovirals

## Criticism

- But still limited territory excluding most middle-income countries
- Relation between royalties and actual patent coverage
- Transparency of the process
- Involvement of patient groups



# Trends & Challenges: Compulsory license

- established flexibility under TRIPS Agreement
- has been used by a number of countries to lower prices and make medicines more affordable with a recent increase in 2012
- initially focus on HIV/AIDS, now also medicines for non-communicable diseases



# Trends & Challenges: Voluntary licenses

- Competition policy, Medicines Patent Pool and industry's attention to performance ratings on Access to Medicines Index led to expansion: 7 out of 8 originator ARV companies grant licenses
- More recent agreements cover new and pipeline products, but limited to HIV/AIDS
- Average territory expanded from SSA, LDCs and LICs to up to 112 countries. (Upper)-middle-income countries still mostly excluded
- Trend towards lower royalties; except for agreements covering new products and more extensive territory
- Agreements have to ensure robust competition and include tech transfer where necessary



# Contact

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P. Beyer. Developing socially responsible intellectual property licensing policies – voluntary licensing initiatives in the pharmaceutical sector. *Research Handbook on Intellectual Property Licensing*. Edward Elgar, 2012 (forthcoming).

