



Intellectual Property and Access to ARVs

Goa, India
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Key Issues and Agenda

- Patents remain a key driver of the financial returns to innovation in the pharmaceutical sector but also create business conditions that limit access to medicines
- This session considers several responses that address public health concerns
 1. The case for transparency in patent filings and existing IP estates
 2. The UNITIAD Patent Pool as a means to expand access to medicines
 3. Licensing programs as a bridge between IP and the needs of developing countries



Panelists

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Intellectual Property (IP) protections for ARVs create challenges for the WHO and other Public Health Institutions serving the developing world

- The WHO sets ARV treatment guidelines on an international basis (covering over 125 countries), but groups responsible for procurement and supply of ARVs must still determine how IP considerations affect the choice of
 - Products
 - Producer
 - Country of manufacture
 - Country of sale
- International purchasing and tender programs are not able to access a well accepted publicly available database that answers these questions
- Lack of transparency on basic IP data can lead to sub-optimal product choices and purchasing patterns



Patent Transparency & The IP Enforcement Climate

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Patent Transparency Milestones: 2000-2010

- 2000 - UNAIDS and WHO - Patent situation of HIV/AIDS-related drugs in 80 countries.
- 2001 - Attaran and Gillespie White - Do patents for antiretroviral drugs constrain access to AIDS treatment of Africa?
- 2003 - Medicines Sans Frontieres - Drug patents under the spotlight.
- 2005-8 - UNDP, WHO and EPO - Patent landscape of essential medicines in developing countries (unpublished).
- UNITAID (unpublished)

Problems with Patent Transparency

- Lack of information online for developing and least developed countries.
- Inaccurate data.
- Patent clusters.
- Patent holders obfuscate key search terms so patents cannot be detected.
- Patent holders do not divulge information (contrary to the patent social contract) e.g. Tamiflu.
- 'Moving goalposts' - information continuously needs updating.

Improvements in Patent Transparency

- A growing number of developing country patent offices now have searchable databases or electronic patent journals:

Argentina, Brazil, China, Colombia, Cuba, Egypt, India, Indonesia, Mexico, Pakistan, Thailand and the Philippines.

The Way Forward

In an ideal world:

- Patent holders would share information.
- Patent offices would make patent data easy to access for different technologies.

The Way Forward

In reality, it is unlikely we will have a perfect transparent patent information system in the foreseeable future.

Generic suppliers could help improve the situation by creating a patent 'transparency pool':

- create a centralised patent information database with agencies working to improve access;
- to avoid re-inventing the wheel, delays and inefficiencies.

The New IP Enforcement Climate

- The enforcement agenda is being ratcheted up as IP holders look for new ways to preserve their assets and keep a comparative advantage.
- The new enforcement agenda is conflating criminal counterfeiting and civil patent infringement to create a new layer of protection.

The New IP Enforcement Climate

- Governments are lending support to the enforcement strategy:

“We’re going to aggressively protect our intellectual property. Our single greatest asset is the innovation and the ingenuity and creativity of the American people. It is essential to our prosperity and it will only become more so in this century.”

President Barack Obama, 11 March 2010

The EU Commission is “committed to improve the international legal framework for IP protection”...“ACTA is one way to reach that goal. There was no intention to duplicate TRIPS. Rather, we want to go beyond it. TRIPS is the floor, not the ceiling.”

EU Commission Trade Directorate Negotiator, Luc Devigne (IP Watch 22 April 2009).

The Enforcement Agenda

- EU border seizures of generic drugs.
- Anti Counterfeiting Trade Agreement (ACTA).
- India-EU Trade Investment Agreement.
- Kenyan, Ugandan and Tanzanian Anti-counterfeiting legislation.

Responding to the IP Enforcement Agenda

- India, Brazil China and Ecuador commence a WTO dispute consultation on EU seizures of generic drugs.
- Civil society pressure on governments that ACTA threatens the public interest.
- Intellectual Property Owners Association (US) now seeking to narrow the scope of ACTA given the threat of conflating criminal counterfeiting with civil infringements of IP.

IP and Access to Medicines

For this discussion, we define access to ARVs as the ability of the public sector to procure formulations of the drugs recommend by the WHO treatment guidelines at the lowest available prices.

1

IP must not prevent production by the low-cost producers

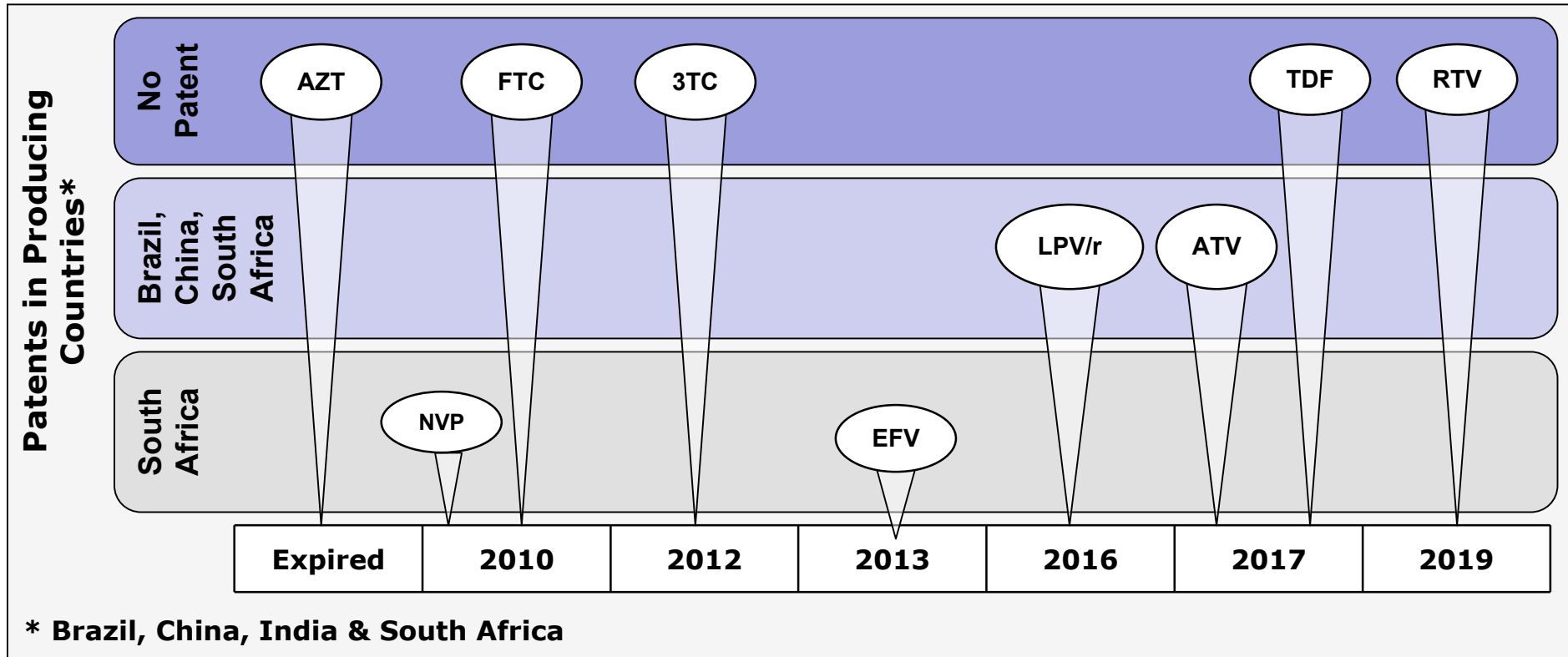


2

IP allows sale from low-cost producers to LI and LMI markets



Five of the nine ARVs recommended by the WHO have not yet achieved patent protection in any producing countries

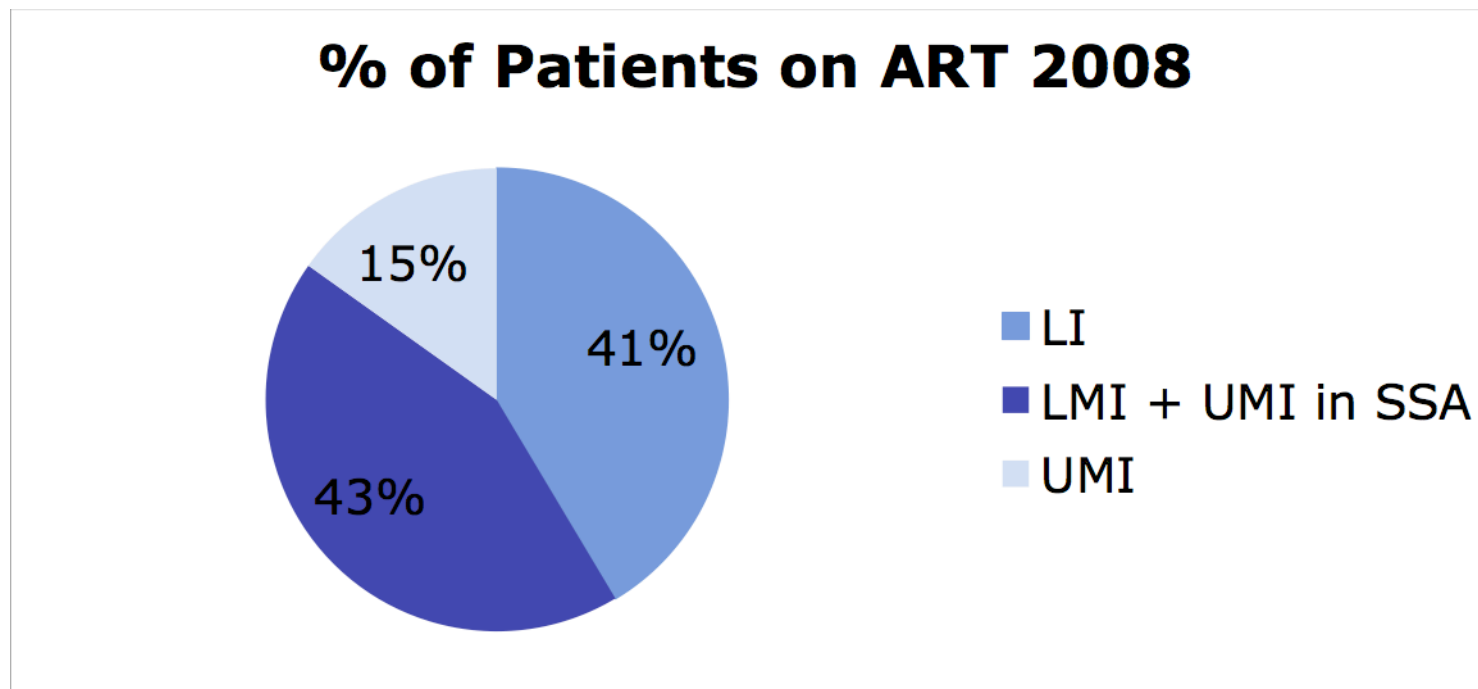


None of the nine recommended ARVs have received patent protection in India – although the ATV application is still pending

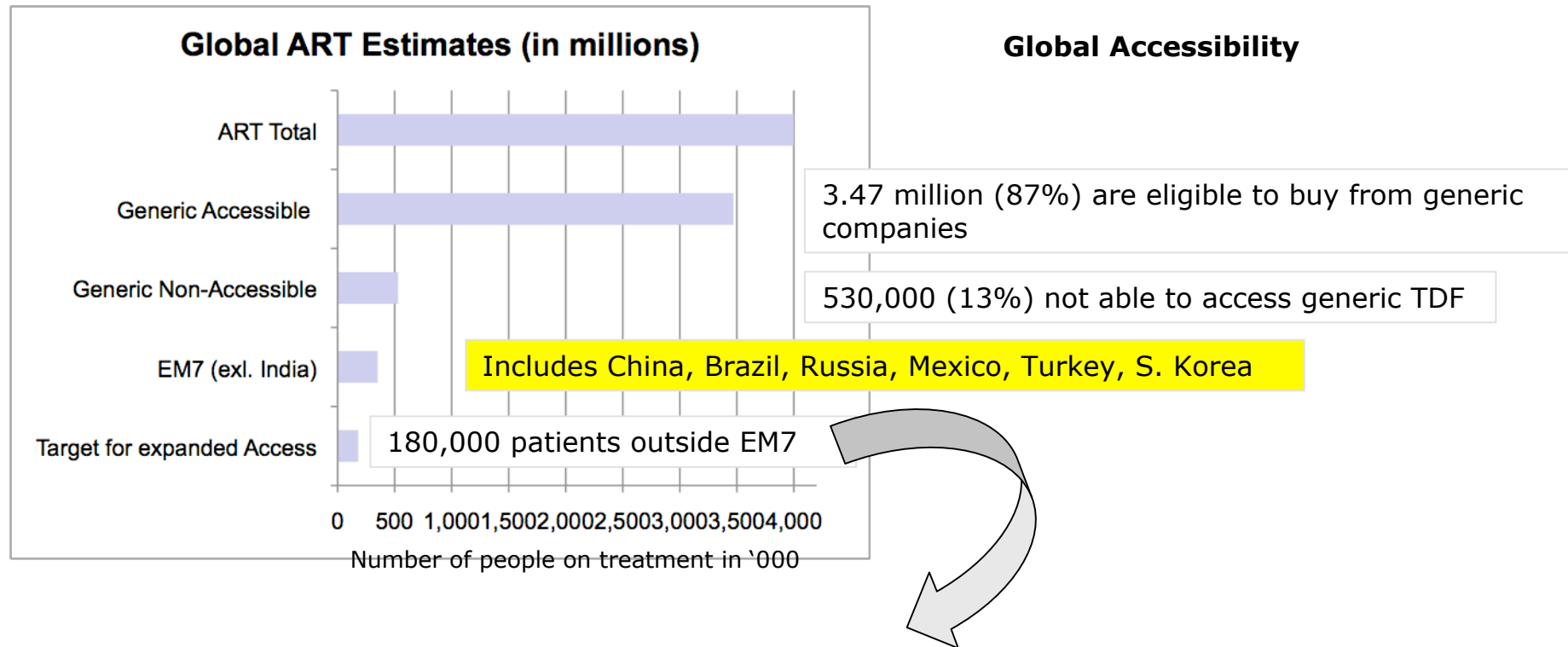
Licensing arrangements mediate the impact of IP on Access

Most licensing agreements include LI, and LMI countries plus UMI countries in SSA.

- lower income, <\$975; 41 countries
- lower middle income, \$976–\$3,855; 55 countries
- upper middle income, \$3,856–\$11,905 ; 46 countries















Patient populations with access to Generic TDF



Only 180,000 patients in countries outside the EM7 are currently excluded from access to generic TDF under Gilead's licensing program

Licensing status of key ARVs

	Years to Patent Expiry	3+ generic suppliers to SSA	Licenses or Non-Asserts Granted
AZT	Expired	✓	8 companies in SA & India
FTC	2010	✓	13 companies in SA, India & China
TDF		✓	13 companies in SA, India & China
3TC		✓	8 companies in SA & India
EFV		✓	5 licensees in SA to serve SSA
NVP	2010	✓	10 in SA & India
Etravavirine		✗	Aspen & Emcure
TMC278		✗	FDA Filing Q3-2010; Broad licensing expected
GS9350		✗	In Phase III; Broad licensing expected
ATV		✗	Aspen, Emcure, Ranbaxy,
DRV		✗	Aspen, Emcure
LPV/r		✗	None: Priced similar to generics
H/S RTV		✗	None: Priced below generics
Elvitegravir		✗	In Phase III; Broad licensing expected
RAL		✗	None

2010 Year 2027

Summary of licensed and unlicensed ARVs Supplied to the Developing World.

Licensing Results Between Innovators and Generic Manufacturers for ARVs in the Developing World

Generic Licensee	Country	Abbott		B I*		BMS*		Gilead			GSK				Merck		Roche	Tibotec	Total Licensed	Approved			
		LPV/r	RTV	NVP	ATV	ddl	d4T	FTC	TVA	TDF	ABC	CBV	EPZ	3TC	TRV	AZT	EFV	IDV		SQV	DRV	Individual	FDC
Addis	Ethiopia																	0		1	0	0	
Alkem	India									0			4					0		2	1	0	
Apotex	Canada												0							1	0	1	
Aspen	S. Africa			3	0	0	2		0	0	0	3		2		2	0		0	0	13	5	1
Aurobindo	India	4		4		3	3	3	4	3	4	4	4	4	4	3				5	14	4	
Barr	US					4														0	1	0	
Beximco Pharmaceuticals	Bangladesh																	0		1	0	0	
Biotech Laboratories	S. Africa										0		0		0				3	0	0		
CAPS Holdings	Zimbabwe																	0		1	0	0	
Cipla	India	4								4	4	4			4	3	4			1	8	3	
Cipla MedPro	S. Africa			0							0		0			3			4	1	1	0	
Combinopharm	Spain														4				0	1	0	0	
Cosmos	Kenya			0						0		0		0			0		5	0	0	0	
Emcure	India			3	3		4			0		4				4			4	5	1	1	
Feza	S. Africa										0		0		0				3	0	0	0	
Gemini	US			0															1	0	0	0	
Hetero	India			4			4			1		4		4		4	4	4	1	8	4	4	
Huahai	China			4															0	1	0	0	
JB Chem. (Unique Pharma)	India									0									1	0	0	0	
MacLeods	India			4								4		4		4			0	3	0	0	
Matrix Labs	India	4		4		4	4	4	4	3	4	4	4	4	4	4	4		1	14	8	8	
Medchem Int'l	India									0									1	0	0	0	
Memphis	Egypt			0															1	0	0	0	
Ranbaxy	India			4			4			2	4	4		4	4	4	4	4	1	10	5	5	
Regal Pharmaceuticals	Kenya																	0	1	0	0	0	
Shasun	India									0									1	0	0	0	
Shelys Pharmaceuticals	Tanzania																	0	1	0	0	0	
Sonke (Ranbaxy link)	S. Africa										0		0		0				3	0	0	0	
Strides	India			4			4			0	4	4		4		4			1	8	5	5	
Thembalami (Ranbaxy link)	S. Africa			0							0		0		0	0			5	0	0	0	
Universal	Kenya			0														0	2	0	0	0	
Vanchem	Zimbabwe																	0	1	0	0	0	
Total Licensed		0		8		6		13				23				4		10	2	68	78	30	

* B I and BMS have made "non-assert"/"immunity from suit" statements replacing/complementing licensing activities	Legend:	0	=	40	License Agreement (product not yet approved)
		1	=	1	Licensee is tentatively or fully approved by the FDA for this product
		2	=	4	Licensee is WHO pre-qualified for this product
		3	=	12	Licensee has met WHO pre-qualification and FDA tentative or full approval
		4	=	61	Generic Manufacturer has WHO pre-qualification or FDA approval but no license

Source for license agreements: Company web sites, press releases and press reports
 Source for FDA tentative approvals (as of 15May10): <http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/AsiaandAfrica/ucm119231.htm>
 Source for WHO pre-qualified products (as of 15May10): <http://apps.who.int/prequal/>

Innovators often focus on the following factors in choosing licensees

