



Health-related patent landscaping: patent information needs & current policy concerns

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Campaign for Access to Essential Medicines

Médecins Sans Frontières (MSF)

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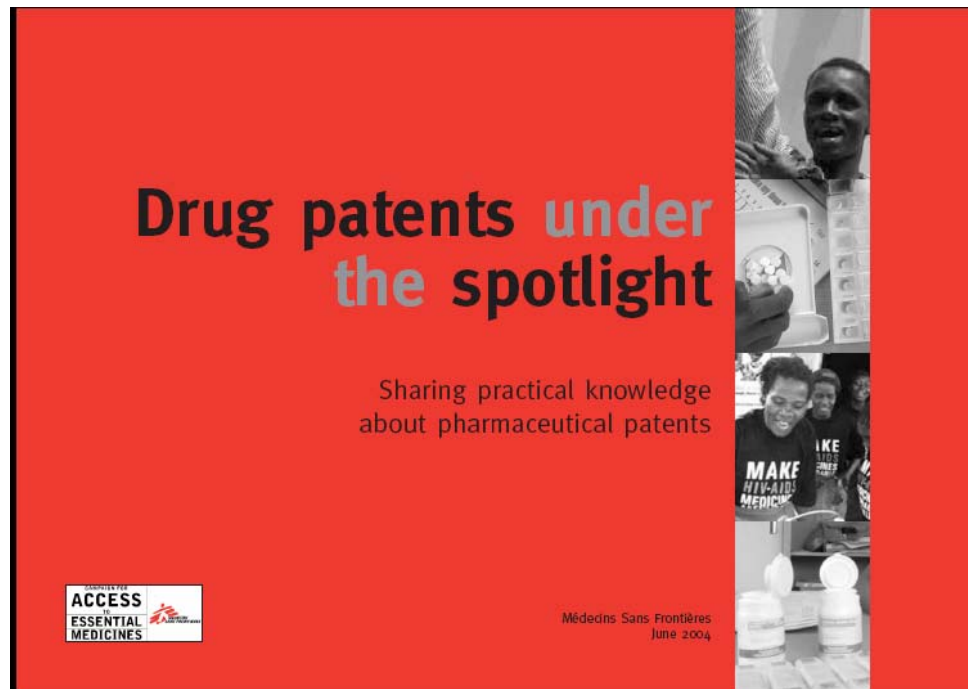
MSF's patent information needs

- MSF traditionally procuring quality generic medicines at best possible price
- Patent information needs began in relation to HIV/AIDS medicines
- MSF currently providing antiretroviral treatment to more than 100,000 patients in over 30 countries
- 85% of ARVs MSF buys are generics



MSF patent landscaping

- Identifies basic patents covering essential medicines procured by MSF in a selected number of countries
- Points out at difficulties in getting access to patent information



MSF patent landscaping (con't)

INN(s)	Originator's Trade mark	Patent holder(s) (manufacturer)	Basic patent priority date	International patent application	Representative European corresponding patent
Abacavir (racemic mixture)		Wellcome (GSK)	27.06.1988 (GB8815265)	No	EP0349042
Abacavir (enantiomer)	Ziagen	Wellcome (GSK)	22.12.1989 (US455201)	No	EP0434450
Didanosine - ddi Improved oral formulation	Videx	USA Gov (BMS) BMS	26.08.1985 (US769016) 22.07.1991 (US733547)	WO87/01284 No	EP0216510 EP0524579
Efavirenz	Stocrin/Sustiva	Merck (MSD, BMS)	07.08.1992 (US926607)	WO94/03440	EP0582455
Indinavir (including sulfate) (related) Indinavir	Crixivan	Merck (MSD) Merck	08.11.1991 (US789508) 07.05.1993 (US059038)	WO93/09096 WO94/26717	EP0541168 EP0696277 (withdrawn)
Lamivudine - 3TC (including enantiomer) enantiomer crystalline form	Epivir Epivir Epivir	IAF Biochem (GSK) IAF Biochem Glaxo	08.02.1989 (US308101) 02.05.1990 (GB9009861) 03.06.1991 (GB911902)	No WO91/17159 WO92/21676	EP0382526 EP0625150 (rejected) EP0517145
Nelfinavir mesylate	Viracept	Agouron (Roche)	07.10.1993 (US133543)	WO95/09843	EP0722439
Nevirapine Syrup formulation	Viramuna Viramuna	Boehringer Boehringer	17.11.1989 (US438923) 25.08.1997 (US60056803)	No ?	EP0429987 ?
Ritonavir Combination w/ lopinavir	Norvir Kaletra	Abbott Abbott	29.12.1992 (US998114) 13.12.1995 (US72226)	WO94/14436 WO97/21685	EP0674513 EP0882024
Saquinavir	Fortovase	Hoffmann-La Roche	11.12.1989 (GB8927913)	No	EP0432695
Stavudine - d4T Pro-drug	Zerit	Yale Univ. (BMS) BMS	17.12.1986 (US942666) 06.05.1988 (US190809)	No No	EP0273277 EP0340778 (withdrawn)
Zidovudine - AZT	Retrovir	Glaxo Wellcome	16.03.1985 (GB8506869)	No	EP0196185
AZT - 3TC combination Tablet formulation	Combivir	Glaxo Wellcome Glaxo Wellcome	16.05.1991 (GB9110624) 31.10.1996 (GB9622681)	WO92/20344 WO98/18477	EP0513917 EP0941100 (expected grant 28.05.03)
AZT + 3TC + abacavir Tablet formulation	Trizivir Trizivir	Glaxo Wellcome Glaxo Wellcome	30.03.1995 (GB9506490) 29.04.1998 (GB9809213)	WO96/30025 WO99/55372	EP0817637 EP1083932 (under examination)

MSF patent landscaping (con't)

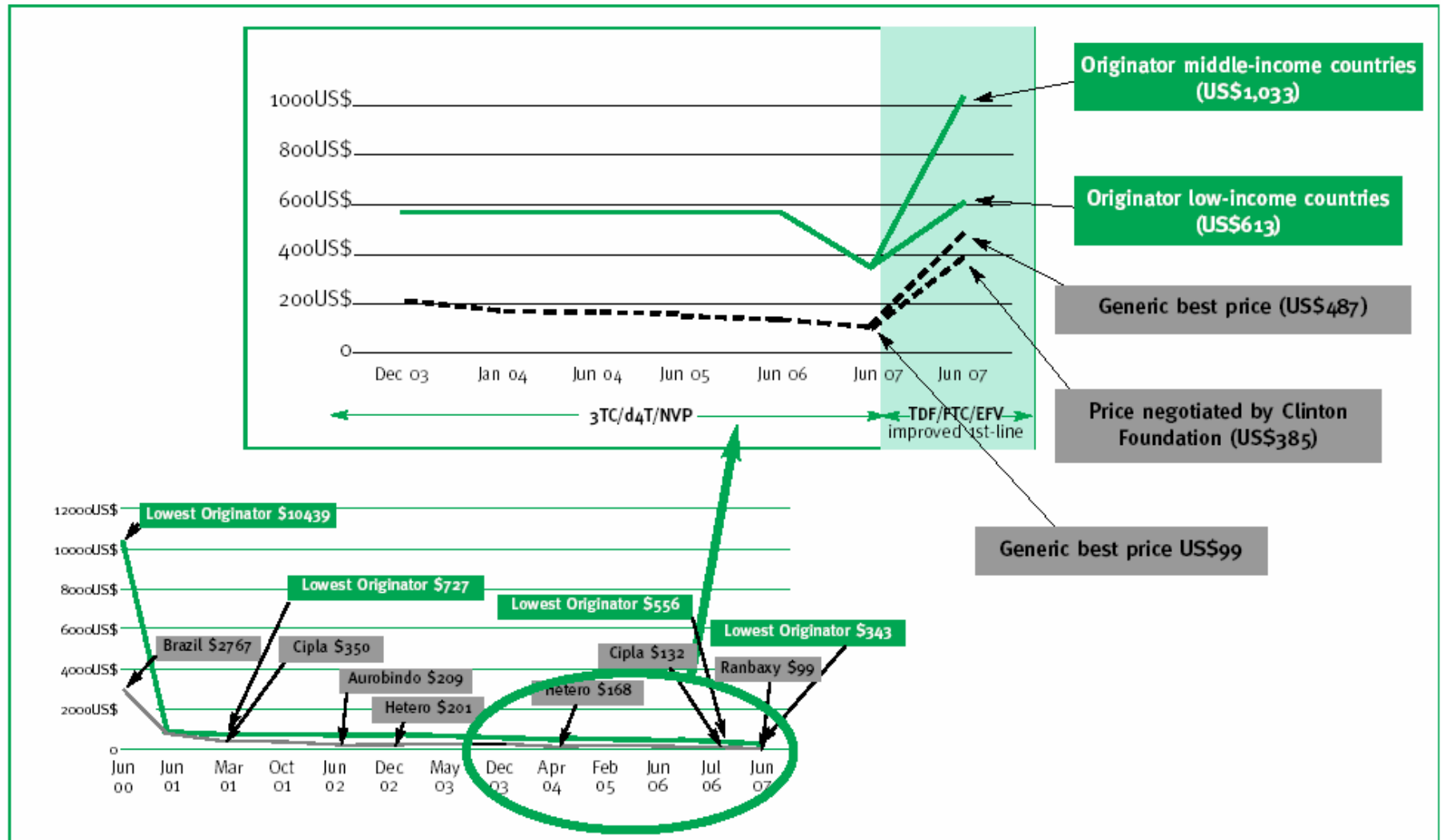
INN(1)	Originator's Trade mark	Patent holder(2) (manufacturer)	Basic patent priority date (number)	International patent application	Representative European corresponding patent	Expected(o) patent expiry date (patent number) in		
						Bradi(3)	Cambodia(4)	China(5)
Amphotericin B liposomal	Fungizone	Clin Mathieson (Bristol Myers Squibb)	28.12.1954 (US478014)	No	No	No	No	No
	Ambisome	Vestar (Gilead-Nektar)	12.11.1987 (US119518)	No	EP0317120	No	No	No
Artemeter+ Lumefantrine (benflutemol)	Coartem/Riamet(13)	Ciba-Geigy (Novartis)	08.08.1990 (CN106722)	WO92/02217	EP0500823	No	No	abandoned? (CN1058717)
Azithromycin crystalline dihydrate	Sumamed	Pfizer (+Pfizer)	06.03.1981 (YU592)	No	GB2094293	No	No	No
	Zithromax	Pfizer	09.07.1987 (PCT/US87/01612)	WO89/00576	EP298650	No	No	08.07.08 (CN1030422)
Ciprofloxacin tablet formulation(12)	Cipro, Ciproxin	Bayer	03.09.1980 (DE3033157)	No	EP0049355	No	No	No
	Cipro, Ciproxin	Bayer	21.01.1986 (DE3601566)	No	EP0230881	No	No	abandoned? (CN1013839)
Fluconazole (general) specific		ICI	02.06.1980 (GB8017959)	No	EP0044605	No	No	No
	Diflucan	Pfizer	06.06.1981 (GB8117379)	No	EP0069442	No	No	No



Why is information on medicines patents needed?

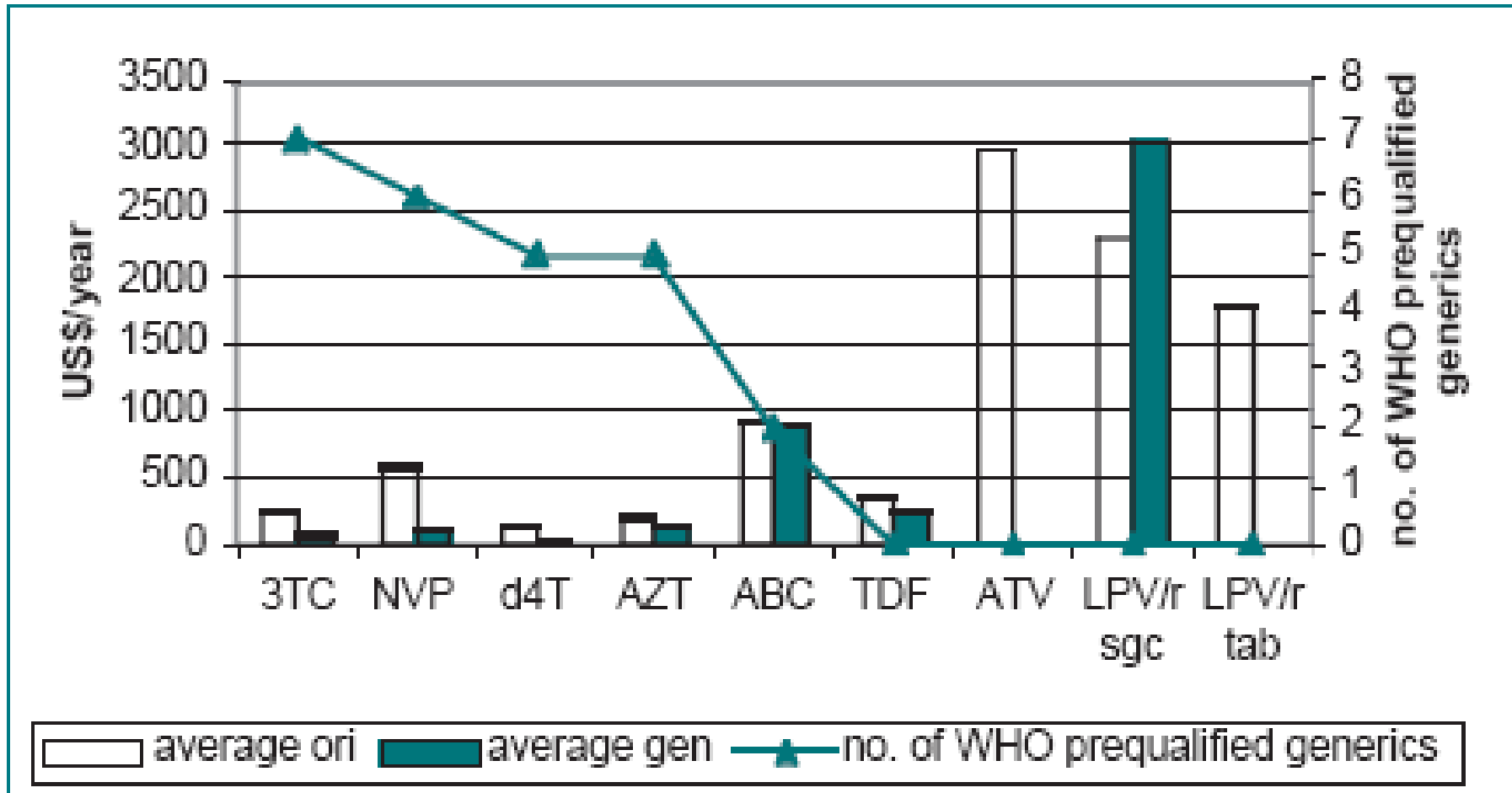
- Patented medicines generally more expensive than generic medicines
- Patenting of medicines increasing worldwide with TRIPS implementation
- International procurement organizations (UNICEF, IDA, GFATM, NGOs) need to know where generic medicines can be sourced and supplied

Effects of generic competition

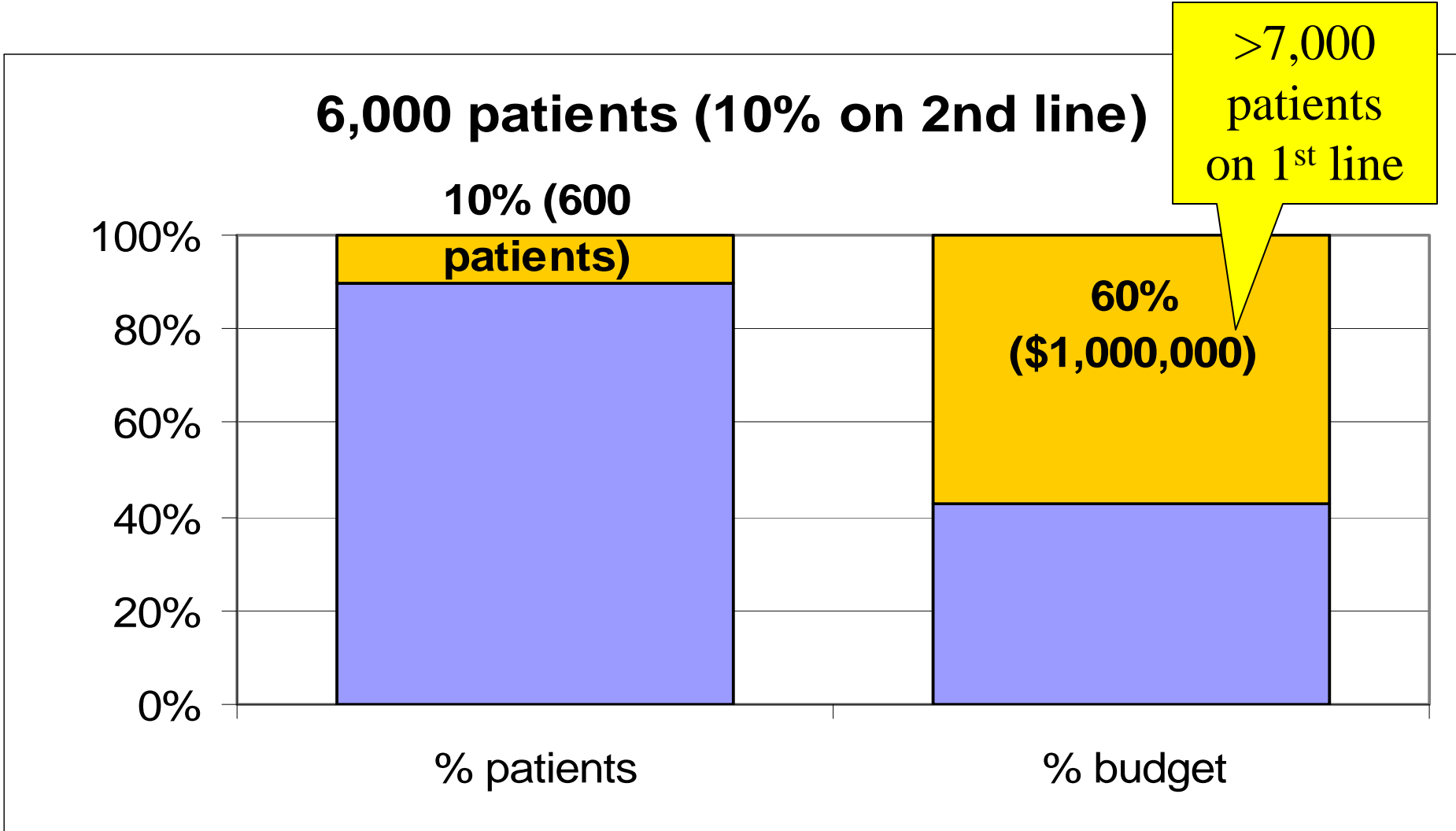


Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest prices per patient per year. Improved first line: tenofovir (TDF) + emtricitabine (FTC) + efavirenz (EFV)

Prices decrease as competition increases



Impact of 2nd line :
 Treatment of 10% of patients accounts for 60% of budget





Difficulties to obtain patent information

- International patent databases do not include all developing countries
- Lack of electronic searchable databases in some developing countries
- Need to check legal status and payment of annual fees at national level
- Translation issues in some countries



Patents on lamivudine (3TC) and access problems to FDC in China

- FDC- fixed dose combination, 2 or 3 drugs in one pill
- In most countries MSF uses 3-in-1 FDC: d4T/3TC/NVP
- Benefits of using FDC
 - Improves adherence: simple to take, must take all 3 meds
 - Low price (less than USD 100 per patient per year)
- No 3-in-1 FDC in China so far—why?
 - Exclusive rights on 3TC
 - No product patent, but
 - A group of process patents
 - Several kind of other regulatory exclusive rights (administrative protection, new drug protection, data exclusivity) which expired end of 2006
 - Blocked local production, generic registration and importation
 - 2007: GSK statement that process patents still valid "extend to all finished products of lamivudine"



What kind of patent information is needed?

- Which patents constitute a barrier to generic competition? (i.e. related to the active ingredient, an essential manufacturing process, an improved formulation, a combination, etc.)
- In which countries have patent applications been applied? Patents effectively granted?
- Which patent applications have been opposed, amended, rejected or revoked? (legal status needs to be updated regularly)



Patent oppositions in India

Name of Medicine	Patent holder.	Date & place of opposition	Signatories	Status
Imatinib mesylate	Novartis	26/09/05 Chennai	Cancer Patient AID Association	Rejected, appeal on-going
Lamivudine + Zidovudine	GSK	30/03/06, Kolkata	MNP+/INP+	Application withdrawn
Nevaripine Hemihydrate (syrup)	BI	09/05/06 Delhi	PWN & INP+	Pending
Tenofovir Disoproxil Fumarate	Gilead science	09/05/06 Delhi	DNP+ & INP+	Reduced to process claims
Abacavir	GSK	13/07/06 Kolkata	INP+	Application withdrawn
Amprenavir	GSK	13/ 07/06 Delhi	UPNP+ / INP+	Pending

Patent oppositions in India (2)

Name of medicine	Patent holder	Date & Place of opposition	Signatories	Status
Atazanavir	Novartis	27/07/06 Chennai	KNP+ & INP+	Deemed abandoned
Valgancyclovir	Roche	27/07/06 Chennai	TNP+ & INP+	Granted, appeal expected
Lopinavir	Abbott	04/08/06 Mumbai	DNP+, NMP+ & INP+	Pending
Lopinavir/Ritonavir (Soft Gel)	Abbott	04/08/06 Mumbai	DNP+ & INP+	Deemed abandoned
Tenofovir Disoproxil	Gilead science	05/09/06 Delhi	DNP+ & INP+	Pending
Ritonavir	Abbott	07/09/06 Mumbai	DNP+ & INP+	Pending
Efavirenz	BMS	02/02/07	DNP+	Pending

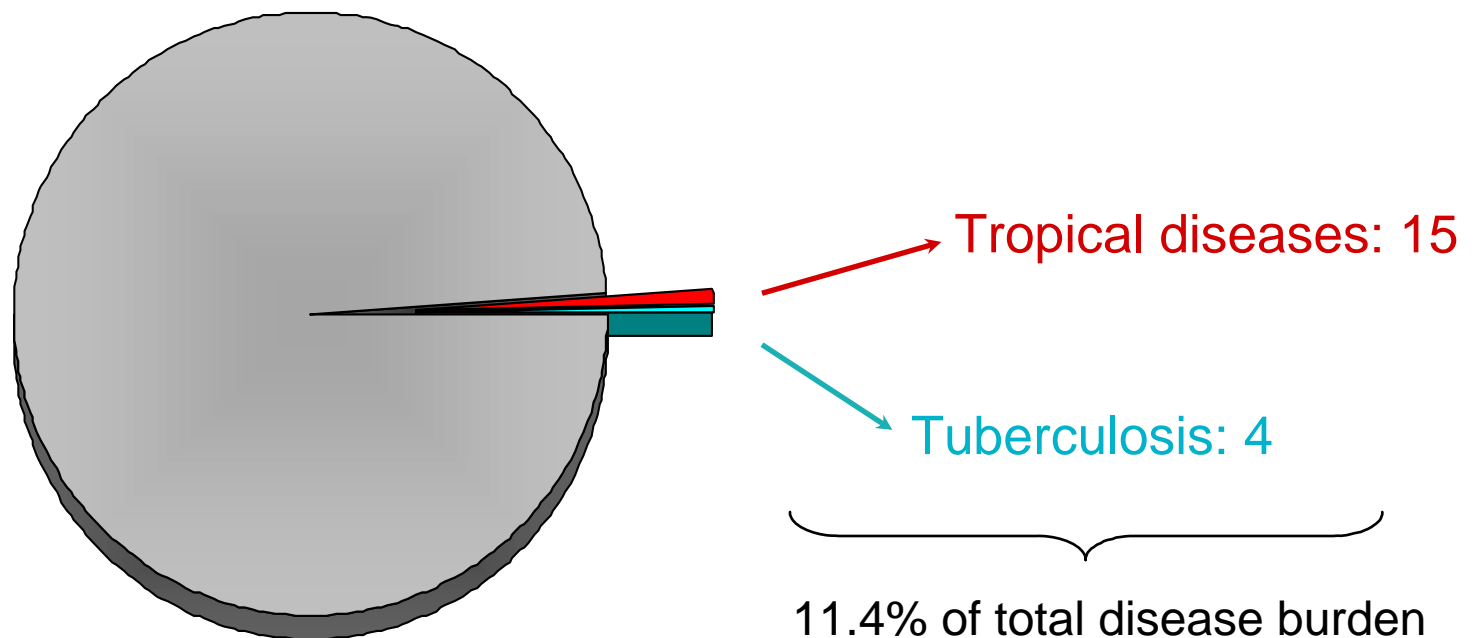


Public policy concerns

- Patents presumed valid until challenged
- Push for harmonisation of patentability criteria beyond TRIPS minimum standards
- Patents related to new forms of known compounds, new formulations, combination of known compounds used to extend monopoly rights
- Patents as obstacles to follow-on research & innovation
- No significant increase of R&D for neglected diseases despite TRIPS implementation

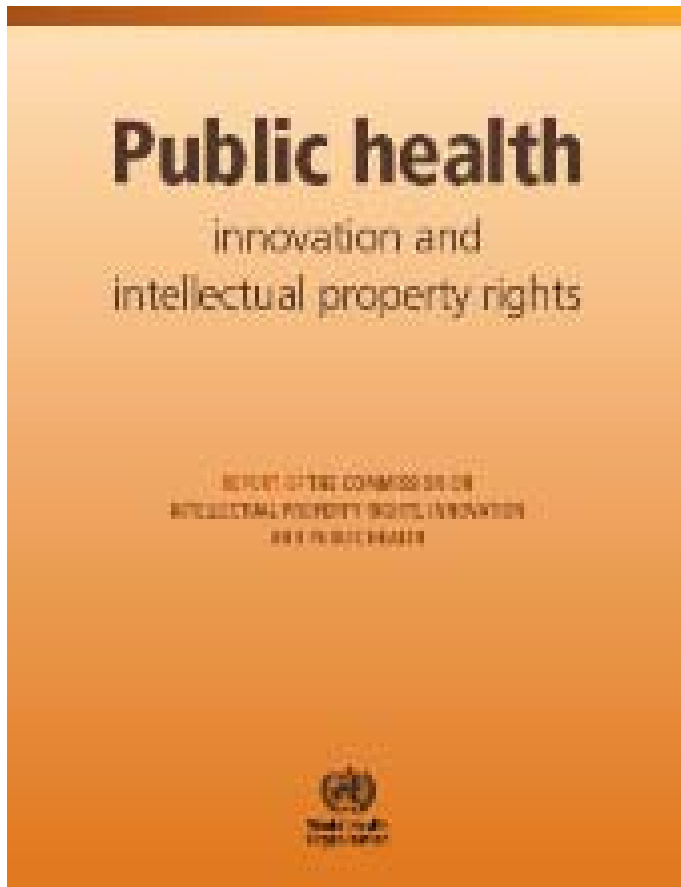
Fatal Imbalance

- 1975-1999: **1,393** new chemical entities marketed
- Only 1% of new drugs developed are for neglected diseases
- 1999-2004: + 163 NCEs, + 3 new drugs for neglected diseases





Bad Bargain?



- “There is no evidence that the implementation of the TRIPS agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II and particularly Type III diseases. Insufficient market incentives are the decisive factor.”

WHO Commission on Intellectual Property, Innovation and Public Health, April 2006



Conclusions

- Need for a patent landscaping on essential medicines:
 - identifying major patents in developing countries, in particular countries with pharmaceutical manufacturing capacity
 - including updated data on legal status & challenges
 - acknowledging the diversity of national patent legislations
 - providing technical advice on mechanisms to overcome patent barriers (oppositions and challenges, exceptions to exclusive rights, voluntary & compulsory licensing, patent pools, etc)