PUBLIC HEALTH, INTELLECTUAL PROPERTY, AND TRIPS AT 20:

Innovation and Access to Medicines; Learning from the Past, Illuminating the Future.

WHO-WIPO-WTO Joint Symposium
28 October 2015

Ellen ‘t Hoen LLM
Medicines Law & Policy

20 Years TRIPS and (almost 15 years) Doha Declaration on TRIPS and Public Health

"We agree that **the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.** Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement **can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.**

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

Learning from the Past

Use of TRIPS/Doha Flexibilities

Sources:

- Literature (legal, medical)
- Media
- Government publications
- Websites
- Procurement agencies

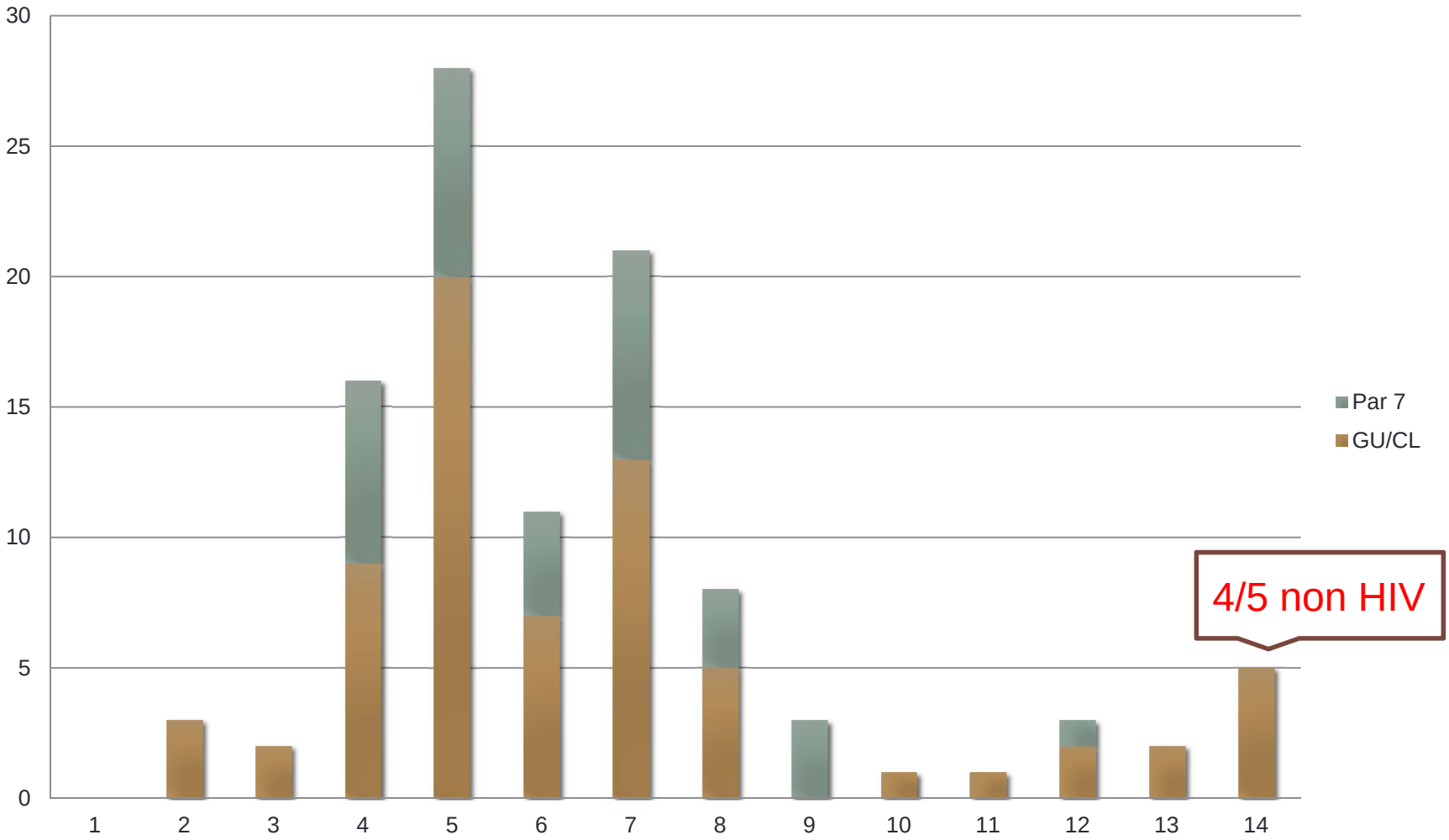
Use of TRIPS flexibilities

- Between 2001 – 2014
- 34 instances of compulsory licensing by 24 countries
- 48 instances of “government use” of patents by 34 countries
- 32 instances of use of the pharma waiver (par 7 mechanism) by 23 LDCs
  - Peak ‘04-’08
  - Context of procurement
  - Predominantly for HIV medication
  - Provided legal certainty to suppliers

The “almost” compulsory licenses

- 10 of the GU/CL not executed
  - 8 DCs, 2HICs
  - Reasons: no patent, discount, donation, VL for local production.
  - 1 pending (ARV in MIC)
  - 2 rejected
  - 5 concerned non-HIV products

Use of TRIPS flexibilities ‘01 – ’14 widespread



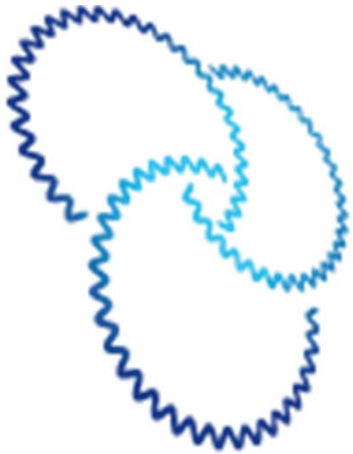
Learning from the past …

Absence of pharmaceutical product patents in India

Use of Doha

- Compulsory licensing/ Government use
- Paragraph 7 Doha (LDC extension)

2010



medicines patent pool

… is mostly learning from HIV/AIDS

Illuminating the Future

New Essential Medicines and Patents

- Post TRIPS - medicines are subject to patenting more widely
- For ARVs → Medicines Patent Pool – no such mechanism exists for other medicines
- 2015 WHO EML update contains new, patented and high-priced essential medicines
  - Including biologics
- Huge challenges for access to these essential medicines

New essential medicines and patents

Medicine	Company (originator)	Expiry date primary patent
Tuberculosis		
bedaquiline	Janssen	2023
delamanid	Otsuka	2023
terizidone		2024
Hepatitis C		
sofosbuvir	Gilead	2024 (‘28 prodrug)
simeprevir	Janssen	2026
daclatasvir	Bristol-Myers Squibb	2027
ledipasvir	Gilead	2030
ombitasvir	Abbvie	2030
Cancer		
bendamustine	Cephalon (US)	2026
imatinib	Novartis	2014 (2018 second.)
rituximab	Roche (others)	2008 (‘19-’20 –’30 form.)
trastuzumab	Roche	2009

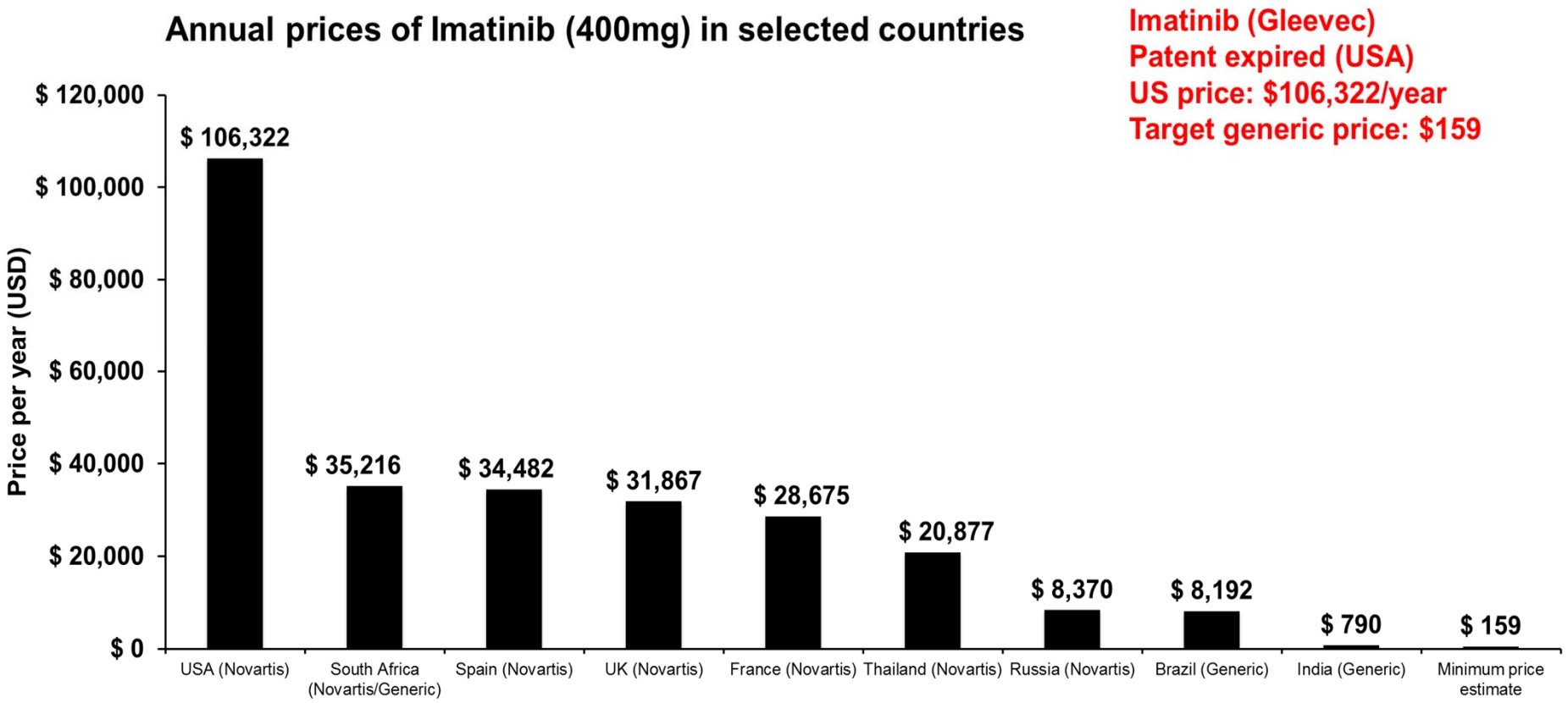
Price / cost of new essential medicines

Medicine	Originator price intro US	Cost of production[1]
Tuberculosis		
bedaquiline	$ 30,000 (6 month)	-
Hepatitis C		
Sofosbuvir (SOF)	$ 84,000 (12 week)	$68 -136
SOF+ledipasvir	$ 95,000 (12 weeks)	$ 193
simeprevir	$ 66,360 (12 weeks)	$130 - 270
daclatasvir	$ 63,000 (12 weeks)	$10 - 30
Cancer		
imatinib	$ 30.000 - >$100,000 (1y)	$ 119-159
rituximab		
trastuzumab	$54,000 (1 year)	$ 242

1. http://cid.oxfordjournals.org/content/early/2014/02/13/cid.ciu012.full (cost of production of HCV medicines)

Hill A. etal.,Target prices for mass production of Tyrosine Kinase Inhibitors (TKIs) for global cancer treatment access - Presented at 18th ECCO - 40th ESMO European Cancer Congress, 27th September 2015, Vienna, Austria [abstract number: 1203]

Imatinib – for treatment of Leukaemia (CML and ALL)



Thanks to A.Hill who Presented this at 18th ECCO - 40th ESMO European Cancer Congress, 27th September 2015, Vienna, Austria [abstract number: 1203]

Learning from the ancient past

- WHO Essential Medicines policy firmly rooted in generic policies
- Essential Medicines in some countries had special status with regards to patentability

Action for Essential Medicines: some recommendations

- The WHO designation “Essential Medicine” should have consequences
- Action is required to make new essential medicines affordable and available
- Today: Grant the LDC request for extension of Pharmaceutical waiver
- Licensing of patents in case of patent barriers to affordable pricing ➔

  - Governments can do this through compulsory licensing /government use
  - Collaborative models ➔ Essential Medicines Patent Pool
  - New rules for financing of R&D for missing essential medicines ➔ innovation + access

Thank you!

@ellenthoen