PATENTS AND HEALTH

WIPO Standing Committee on the Law of Patents

Geneva, 2 December 2015

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Medicines Law & Policy

Function of patents

… to encourage inventors to make an investment in time and money in research and development by providing exclusive rights for a limited time in exchange for an early public disclosure of the invention.

-Patent system is a social policy tool meant to create benefits for society.

-It also has significant societal cost.

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

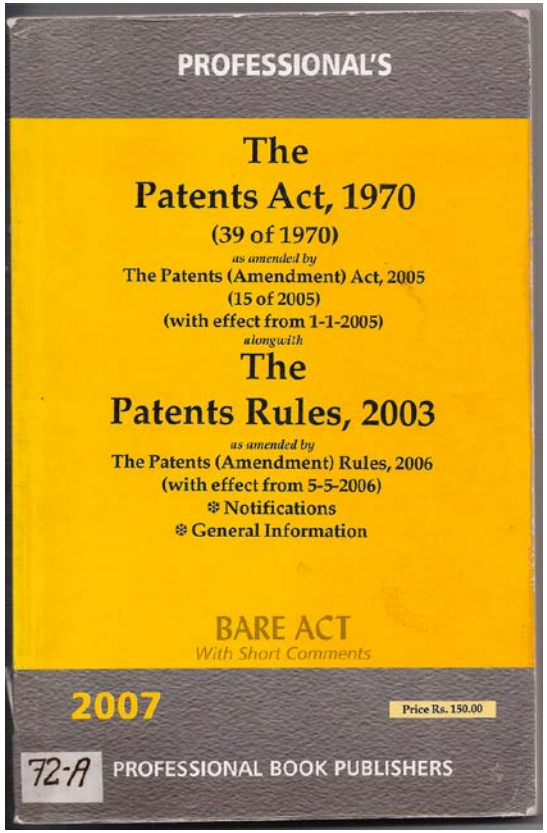
Health friendly IP has made a difference

Use of Doha Declaration:

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

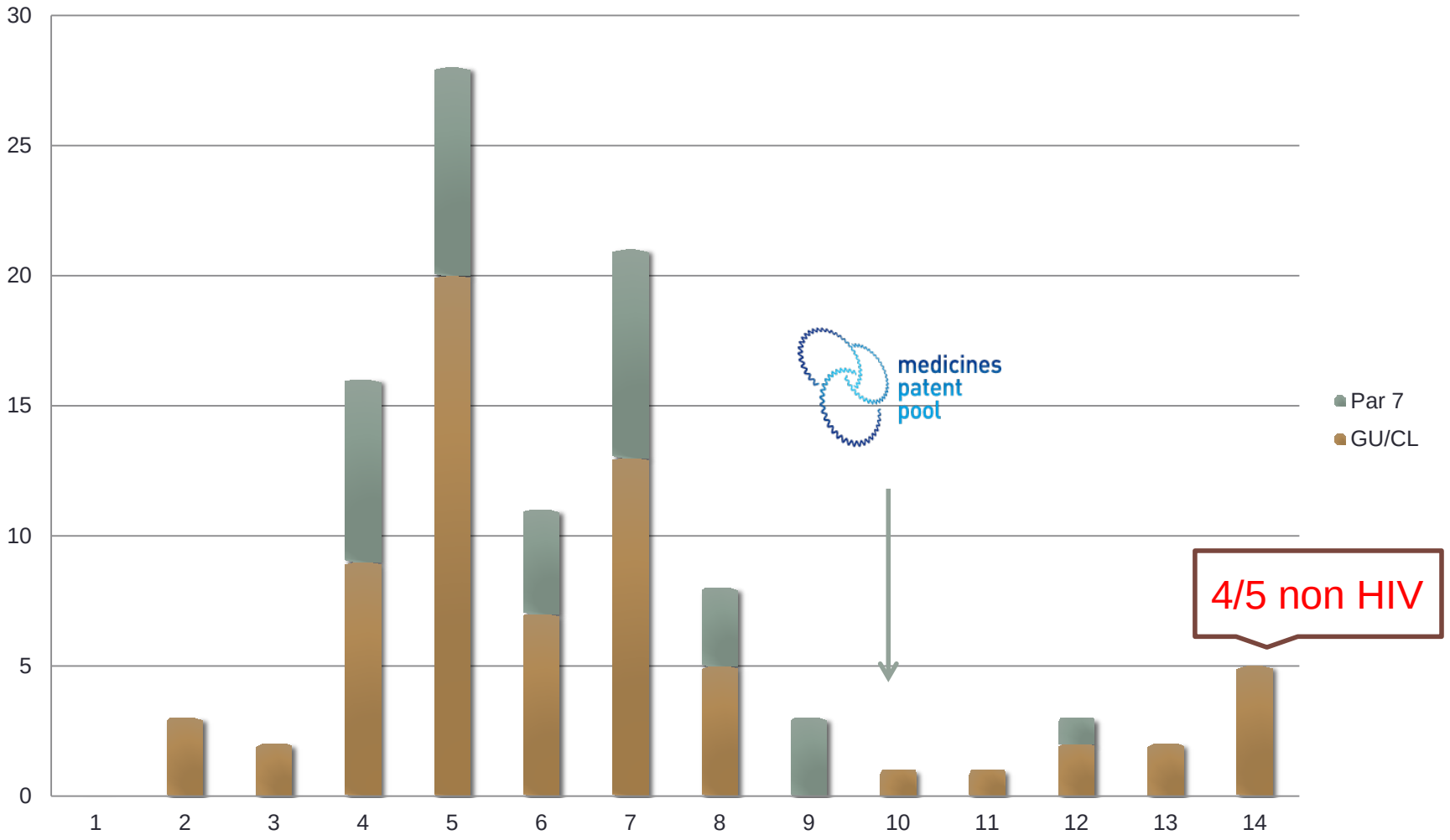
- **15.8 million people receive HIV treatment today**

- Absence of pharmaceutical product patents in India (1970 Patents Act)



… beyond HIV/AIDS ?

Use of TRIPS flexibilities ‘01 – ’14 widespread



The Medicines Patent Pool

- Licence agreements covering 12 priority antiretrovirals (ARVs) with six patent holders
- 59 sub-licences with 14 generic manufacturers.
- Generic companies have supplied > six million patient-years of ARVs in 117 countries (incl. 41 new countries).
- Savings of USD 79 million through lower prices of ARVs (equivalent to one-year of treatment for 625,000 people).
- New fixed-dose combinations and paediatric formulations.
- Expected to generate total savings of up to 1.4 billion by 2028.
- MPP branching out to hepatitis c and tuberculosis

http://www.medicinespatentpool.org/wp-content/uploads/MPP_Progress_and_Achievements_Report_EN_2015_WEB.pdf

Non-patent monopoly: regulatory data exclusivity

Regulatory Data Protection Periods		
Country	Pharmaceuticals RDP (Years)	Biologics RDP (Years)
Australia	5	5
Brunei	0	0
Canada	8	8
Chile	5	5**
Japan	8	8
Malaysia	5***	5***
Mexico	5	5**
New Zealand	5	5
Peru	5	5**
Singapore	5	5
United States	5	12
Vietnam	5	5
European Union	10	10

**Excludes further extensions for paediatric approval, orphan designation, new indications, and other incentives.*

***It is uncertain whether RDP will apply to biologics in Chile, Mexico and Peru. These countries do not specifically grant RDP to biologics.*

****Malaysia begins counting RDP from the date a product is approved and given data protection in its originator country and allows for up to five years RDP from that date.*

Source: http://www.raps.org/Regulatory-Focus/News/2015/02/11/21309/Trade-Talks-Stumble-over-Biologics-Data-Exclusivity/#sthash.9nLxqUdp.dpuf

Non-patent monopoly: the daraprim case

$750/pill pharma company reverses decision to lower drug price

Turing will offer hospitals and patients discounts, but high list price stands.

by **Beth Mole** - Nov 25, 2015 2:43pm CET

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Daraprim

- First marketed 1953
- No patents
- Generic available for < 2 cent a pill n global market
- Turing increased the price from $ 13.50 to $ 750 in US

FT on pricing

Financial Times The real cost of high pharmaceutical pricing:

… the licence to manufacture a treatment exclusively is not the same as one to print money. New medicines cannot come at any price — especially when the maker uses its legal monopoly to set swingeing charges for vital remedies. Doctors do not wish to withhold drugs that can save lives. But there is a limit to what stretched healthcare systems can afford.

http://www.ft.com/intl/cms/s/0/bc609266-611a-11e5-a28b-50226830d644.html#axzz3syFMHg38

New WHO 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

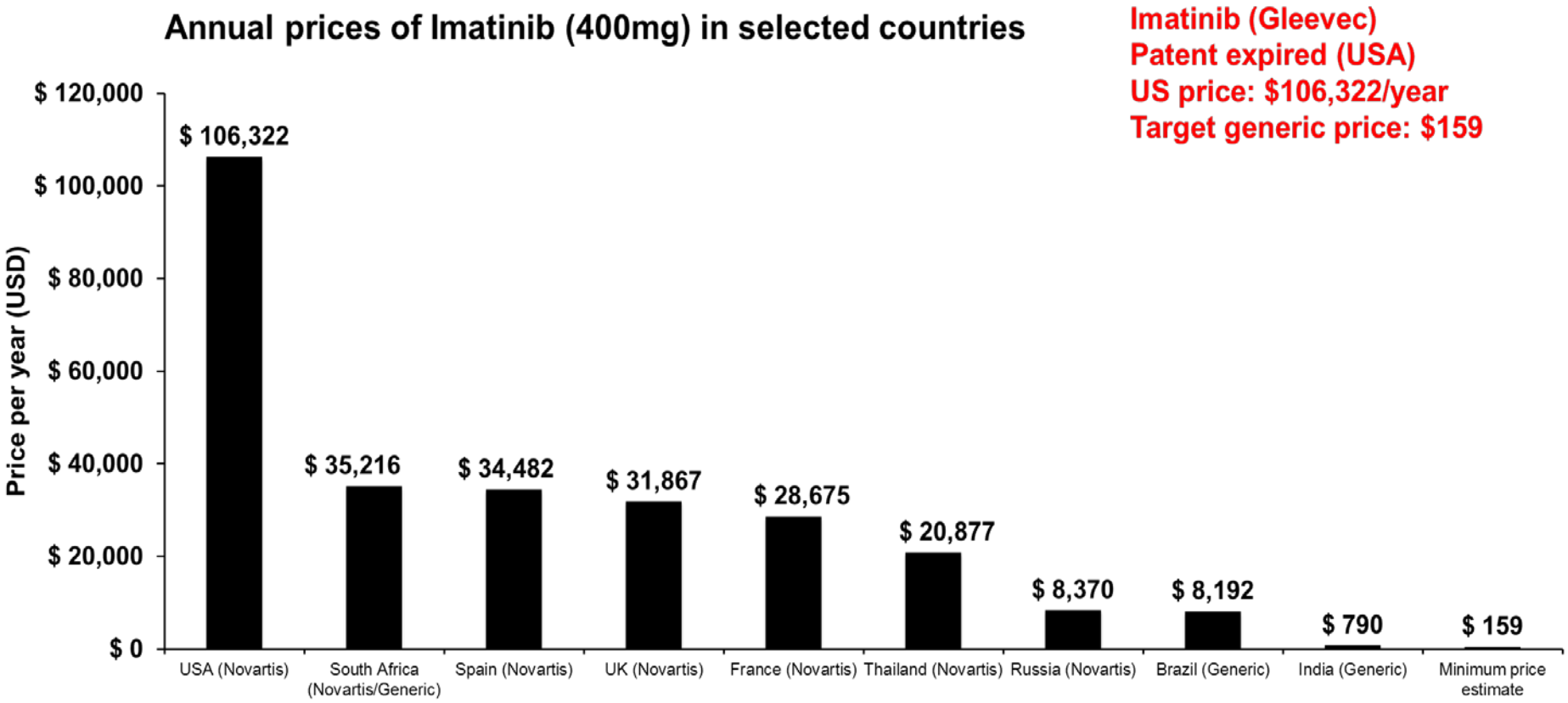
Price and production cost of new essential medicines

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)



Imatinib (Gleevec)
Patent expired (USA)
US price: $106,322/year
Target generic price: $159

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

Innovation *and* Access - Financing of R&D

- 2020 pharma spending will be US$ 1.4 trillion (30% increase from 2015)
- Spending on R&D is US$ 137 billion (2014 IFPMA)
- Reliance on high prices to fund R&D:
  - Important health needs unmet if profitability prospects drive R&D agenda (Ebola, antibiotics, medicines for children etc.)
  - Important new medicines increasingly unaffordable even in high income countries.

Need for Change

- New R&D framework – focus on health needs
- Greater diversity of financing mechanisms
- De-linkage models
- International collaboration and new rules → follow up of CEWG at WHO.

Access to new Essential Medicines

- The WHO designation “Essential Medicine” should have consequences
- Licensing of patents
  - Collaborative models ➔ Essential Medicines Patent Pool
  - Compulsory licensing /government use
- Protect flexibility in patent law - push back on TRIPS + agreements
- Invest in health – ensure uptake

Thank you!

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