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."

Learning from the Past

Use of TRIPS/Doha Flexibilities

Sources:

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

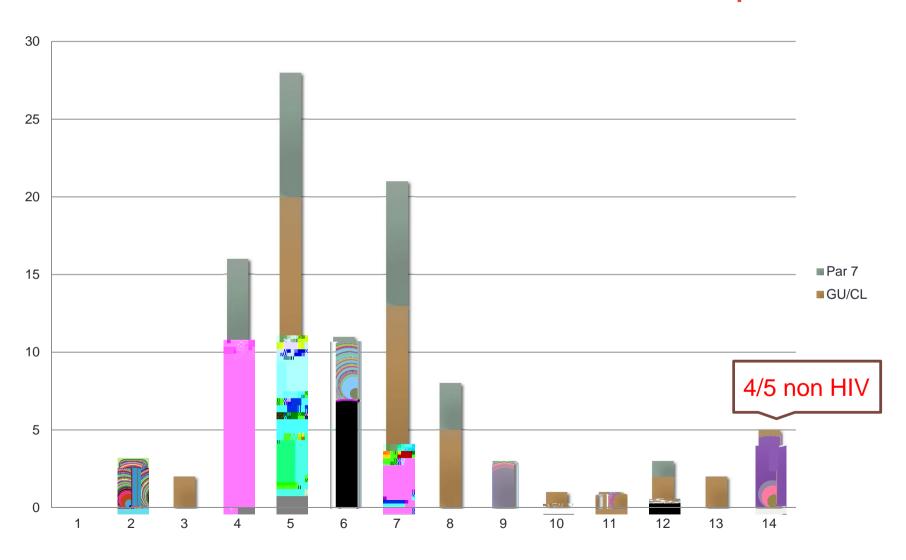
Use of TRIPS flexibilities

- 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



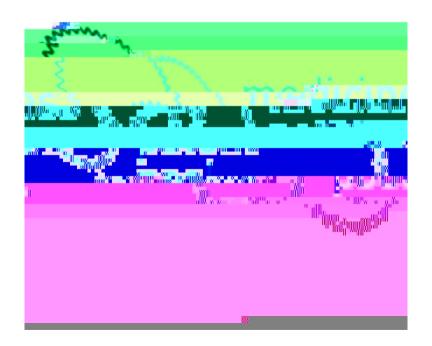
Learning from the past ...

Absence of pharmaceutical product patents in India

Use of Doha

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

2010



... is mostly learning from HIV/AIDS

Illuminating the Future

New Essential Medicines and Patents

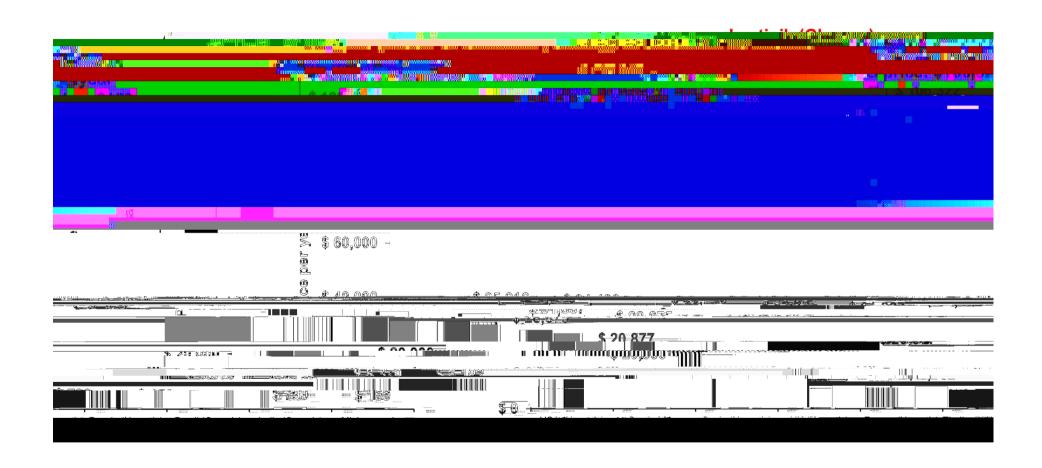
- Post TRIPS medicines are subject to patenting more widely
- For ARVs Medicines Patent Pool no such mechanism exists for other medicines
- 2015 WHO EML update contains new, patented and high priced essential medicines
 - Including biologics
- Huge challenges for access to these essential medicines

New essential medicines and patents

Price / cost of new essential medicines



Imatinib – for treatment of Leukaemia (CML and ALL)



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

 - New rules for financing of R&D for missing essential medicines innovation + access

Thank you!

