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## Agreement on Trade-related Aspects of Intellectual Property Rights

- Minimum standards of protection: pharmaceutical patents
- 'Flexibilities' (Doha Declaration on TRIPS and Public Health)
  - Compulsory licenses
  - Parallel imports
  - Patentability standards
  - Exceptions

# TRIPS-plus protection in FTAs/EPAs

- Patent term extension
- Parallel imports
- Border measures
- Enforcement
- Data exclusivity

### TRIPS-plus obligations

• Do they generate aditional R&D investment in the EU or the partner country?

 Do they support efforts to meet governments' human rights obligations?

Are benefits and cost proportionate?

#### New molecular entities 1994-2016



Source: US FDA

#### High-Level Panel on Access to Medicines, Promoting Innovation And Access To Health Technologies (2016)

• FTAs exacerbate incoherence between IP and efforts of governments to meet their human rights obligations

### Disproportionate benefits & costs

- ...intellectual agreements lock us into a number of inefficiencies which have clear costs to Australia and yet which confer benefits on other countries that are either small or negligible.
- Australia: Pharmaceutical Patents Review. Draft Report (April 2013, p. 32)

• European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines

- 1. Stresses that access to affordable pharmaceutical products in poor developing countries...would contribute to poverty reduction, increase human security, and promote human rights and sustainable development;
- 2. Believes that EU policy should aim at maximizing the availability of pharmaceutical products at affordable prices in the developing world;

• 8. Asks the Council to support the developing countries which use the so-called flexibilities built into the TRIPS Agreement and recognized by the Doha Declaration in order to be able to provide essential medicines at affordable prices under their domestic public health programmes

 European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI))

- 51. Notes the fact that the WTO TRIPS agreement provides flexibilities to patent rights, such as compulsory licensing, which have effectively brought prices down; ...
- 98. Calls on the Commission and the Member States to make use of the flexibilities under the WTO TRIPS agreement and to coordinate and clarify their use when necessary;

# COMMUNICATION FROM THE COMMISSION

Trade, growth and intellectual property Strategy for the protection and
enforcement of intellectual property rights
in third countries

• Strasbourg, 1.7.2014COM(2014) 389 final

- The EU addresses these IPR challenges, in line with a European Parliament resolution [2007]...
- In particular, the EU:
- ensures that any multilateral and bilateral agreements reflect these objectives;
- supports the Doha Declaration on TRIPS and Public Health (implemented through
- Regulation 816/2006);