USING COMPETITION LAW TO ADDRESS ACCESS AND INNOVATION BARRIERS IN THE PHARMACEUTICAL SECTOR

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REASONS FOR USING COMPETITION LAW

- Traditional legislative political process is strongly influenced by financial and other interests that make protection of the public interest difficult
- In principle, competition authorities act independently of executive or legislative direction in specific cases
- Private civil actions may further depoliticize

DIRECT PRICE CONTROLS AN ALTERNATIVE

- Cost-plus disfavored by industry, at least with respect to production
- Corrupt practices problematic
- Political resistance in the US a barrier

DIFFICULTIES WITH CASE-BY-CASE ENFORCEMENT

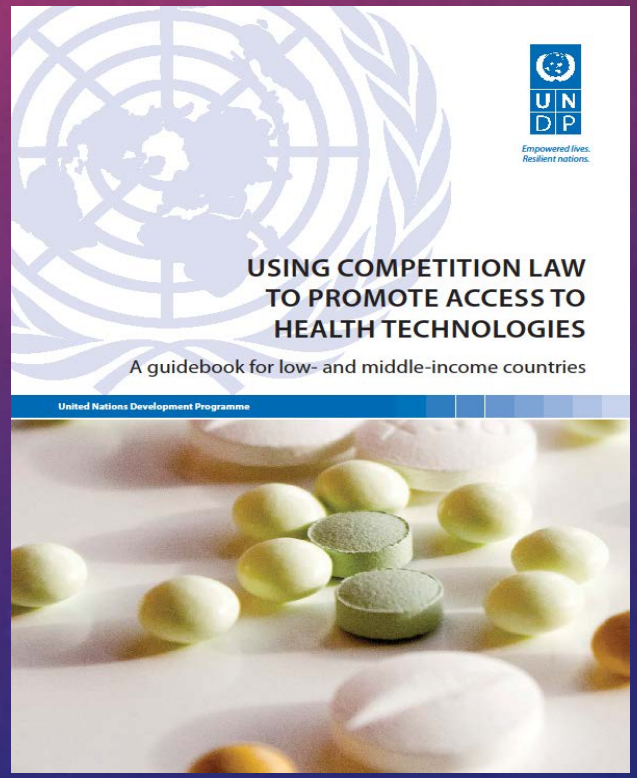
- Court proceedings, including preparation, typically expensive and lengthy
- Defendants highly capitalized
- Doctrinal uncertainties inhibit
- Triple damages in the United States help to offset barriers

EMBEDDED REGULATORY APPROACHES

- Canadian Patented Medicines Prices Review Board model
- US Hatch-Waxman Act para. iv certification process
- FTC competition enforcement, affirmation in *FTC v. Actavis*

UNDP COMPETITION LAW EFFORTS

- Guidebook on Use of Competition Law to Promote Access to Health Technologies (2014)
- Pharmaceutical Sector Inquiries in ASEAN Region
- Training Programs



EXCESSIVE PRICING DOCTRINE

- Competition authorities and courts traditionally reluctant to address excessive prices “as such”
  - Difficult to determine the reasonable price for a pharmaceutical product based on R&D involving risk, and consequently difficult to determine what is an excessive price over that reasonable price
  - Judicial authorities not well-equipped as price regulators
- Objections not persuasive: addressed in article (Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health)
- Transparency implicated in establishing R&D costs

CASE DEVELOPMENTS

- UK Competition and Markets Authority (CMA) in December 2016 imposes fine of £90 million on Pfizer and Flynn for excessive pricing relating to "de-branding“ (on appeal)
- *FTC v. Mallinckrodt*, Settlement, fine $100 million and compulsory technology license, January 2017
  - Extraordinary case involving unlawful abuse of monopoly position with respect to vital children's medicine, and charging of excessive prices
  - City of Rockford, Illinois, follow-on to recover excessive payments

TRANSPARENCY

- In ASEAN countries pricing information difficult to obtain because of confidentiality obligations imposed on purchasers
  - Competition authorities can compel, but this is a second-best option
- Pursuing database on patent coverage, market exclusivity and terms

PARALLEL IMPORTS AND REGULATORY TAKINGS

- International exhaustion issue addressed in South Africa Medicines Act proceedings leading ultimately to Doha Declaration
- Currently before US Supreme Court, *Impression Products v. Lexmark*
- Filing of Amicus Brief
- US Import Authorization Legislation
- Surfacing of unconstitutional takings issue by originators
  - Appears taken seriously within congressional branch