Fair and Equitable Pricing in Health: Competition Law and Access to Medicines

International Experiences and Access to Medicines: Synthesizing Trends and Reflecting on Paths Forward

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TRENDS IN COMPETITION LAW ENVIRONMENT AFFECTING ACCESS TO HEALTH PRODUCTS, INCLUDING PHARMACEUTICALS

- This presentation is based on materials compiled for the Supplement to the UNDP Guidebook for Low-and Middle-Income Countries: Using Competition Law to Promote Access to Health Technologies (forthcoming)

- Benefited from input from various stakeholders, including Competition Authorities in LMICs and HICs, and civil society. This includes the Brazilian (CADE) and Italian (AGCM) Competition Authorities represented on this panel

- The first subject matter of the UNDP Supplement is pandemic impact, but do not address here because subject of separate panel tomorrow

Expanding Universe of Active Authorities

- While the EU and US remain the predominant jurisdictions for prosecutions of anticompetitive conduct in the health products sector, substantially higher levels of enforcement activity in Latin America and Asia (and particularly, China) since publication of UNDP Competition Guidebook in 2014

- The leading subject matter for competition enforcement almost certainly remains efforts by patent owning originator companies to delay entry of generic competition

    - Subject of earlier US FTC and EU Competition Directorate studies

Delay of Generic Market Entry

- "Reverse payments" cases continue, with new attention to alternative forms of compensation to cash, such as delaying introduction of "authorized generics" and settlement of tangentially related litigation on favorable terms. Also, prosecution for "sham" patent litigation

- Reverse payments cases involve allegations of unlawful agreements between undertakings and/or abuse of dominant position

- Court of Justice of European Union (CJEU) recently rendered decision, *Generics (UK) v CMA*, CJEU Judgment (Fourth Chamber), Case C-307/18, 30 January 2020, similar to US Supreme Court decision in *FTC v Actavis*, 570 US 136 (2013), holding that patent ownership does not insulate anticompetitive conduct within scope of the patent

Evidence-Gathering and Independence

- European Union recognized shortcomings of disparate enforcement procedures in various member states in adopting ECN+ Directive (Directive (EU) 2019/1 “to empower the competition authorities of the Member States to be more effective enforcers and ensure the proper functioning of the internal market”)
- Emphasized importance of maintaining political independence of competition authorities
- Strengthened obligations to maintain compulsory process for securing evidence without undue restrictions on competition authorities

Originators and IP Only Part of the Problem

- Anticompetitive behavior among generic producers a major focus of attention, including agreements to rig procurement (bidding) processes, limit output, fix prices
- Very large-scale cases currently pursued in the United States by States Attorney Generals and Department of Justice (including criminal investigations and individual defendants)
  - 51 US States and Territories filed third lawsuit in June 2020 stemming from the ongoing antitrust investigation into a widespread conspiracy by generic drug manufacturers to artificially inflate and manipulate prices, reduce competition, and unreasonably restrain trade for generic drugs sold across the United States
  - The first Complaint, still pending in the U.S. District Court in the Eastern District of Pennsylvania, was filed in 2016 and now includes 18 corporate Defendants, two individual Defendants, and 15 generic drugs

China

- Major developments in China as former 3 regulatory authorities consolidated into single agency, State Administration for Market Regulation (SAMR), responsible for competition law enforcement
- Resulted in re-drafting of major sets of regulations and guidance documents
- In addition to prosecutions for market abuse, active in policing mergers and acquisitions. Has moved toward conditional approvals, e.g., requiring divestitures where appropriate

Brazil and South Africa

- Brazilian competition authority (CADE) active. Several cases involving unlawful agreements between undertakings to restrict competition, in pharmaceutical and medical devices markets. Public interest groups pursuing complaint lodged with CADE regarding excessive pricing of sofosbuvir (Hep C Treatment) by Gilead. CADE active in reviewing mergers and acquisitions, including imposing conditions
- South African Competition Authority issues report criticizing health products regulatory authority (SAHPRA) for creating unnecessary obstacles to parallel importation and generic drug regulatory approval. Recommends greater coordination with competition authority ("SAHPRA's mandate must be broadened to consider competition principles when registering and licensing health products.")

Italy and the United Kingdom

- Italian Competition Authority with major success in *Aspen/Cosmos* case on excessive pricing of anti-cancer drugs. Judicial authorities render well-crafted decisions showing deep understanding of market structure and dynamics. *Aspen Italia et al. v. Italian Competition and Market Authority*, Council of State (Italy), Section Six, N. 01832 / 2020 REG.PROV.COLL., N. 08447/2017 REG.RIC., 13/03/2020
- UK Court of Appeals overturns substantial part of unfortunate prior decision of Competition Appeal Tribunal, in particular rejects multiple methodology test for unfairness prong that was inconsistent with CJEU (*United Brands*) jurisprudence. UK Court of Appeals decision poorly drafted, raising various ambiguities for future prosecutions. Returned to CMA for further investigation and analysis. *CMA v Pfizer & Flynn*, Court of Appeal (Civil Division), Case No: C3/2018/1847 & 1874, Neutral Citation Number: [2020] EWCA Civ 339, date: 10/03/2020

Transparency

- Attention to the transparency question has been heightened, particularly in light of the new Pharmaceutical Strategy for Europe (2020)
  - "There is a lack of **transparency** (in particular in R&D costs) and **consensus on costing principles**. Better understanding and greater clarity are fundamental as a basis for policy debates on the pricing of niche medicines and 'fair return' on research contributions." … "Commission will foster transparency of price information to help Member States take better pricing and reimbursement decisions, also considering possible knock-on effects for innovation."
- Improving the transparency of markets for medicines, vaccines, and other health products, WHO Resolution, Seventy-Second World Health Assembly, WHA72.8, Agenda item 11.7 28 May 2019

TIAs Redux

- Proliferation of competition chapters in trade an investment agreements (TIAs), including among LMICs
- Predominately address process issues, but ultimately may interfere with Independence of competition authorities
- Caution should be exercised regarding these commitments

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