Trends in the Development and Use of Competition Law to Promote Access to the Benefits of Health Technologies

A Dialogue: Trends and Strategies in the Use of Competition Law to Promote Innovation of and Affordable Access to Health Technologies

In cooperation with the Government of Namibia and the Namibia Competition Commission

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Methodology

- Research undertaken to identify developments in competition law post-2014
- Desk research
- Request for third-party submissions
  - Competition authorities, civil society, other interested persons
  - Positive response
- Review by multiple national competition authorities and multilateral institution actors with expertise in area

Identification of Recent Trends

- Response to the COVID-19 pandemic
- Legislative and regulatory changes
- Sector studies
- Prosecutions initiated by competition authorities
- Cases initiated by private parties, including nongovernmental organizations
- Merger and acquisition review

COVID-19: Price Gouging

- Pandemic presents multiple competition impacts, potential and actual
- Price gouging, a form of abuse of dominant position, the subject of numerous complaints
  - Shortages of PPE and attendant consumer impacts (e.g., face masks, disinfectant, laboratory testing, etc.)
    - See, e.g., South Africa Competition Tribunal finding against Dis-Chem for excessive pricing of surgical face masks (with fine), 2020
- Price gouging addressed by specific statutes in many jurisdictions, enforcement simplified in comparison to general competition enforcement (e.g., strong presumptions based on pre-existing price levels and percentage of increase)
- As supplies expand price gouging becomes more difficult to sustain (often a transitory event-driven phenomenon)

COVID-19: Supply Rationalization and M&A

- Supply-side exemptions adopted by, e.g., European Union, to allow sharing of information among actual and potentially competing suppliers to allow for rationalization of production to meet spikes in demand and address scarcity
- Actual and potential impacts on healthcare providers (e.g., hospitals and clinics) providing impetus for consolidation with potential long-term impact on local markets (reduced competition and price effects)

COVID-19: Pharmaceuticals

- Regarding pharmaceuticals (including vaccines) exceptional response by governments
  - Extraordinary levels of subsidization for R&D and production/purchasing
- Terms and conditions of supply (e.g., vaccines) largely left to negotiation between private firms and procurers (mainly government purchasing)
- Environment for potential anticompetitive behaviors present
  - Dominant position of suppliers
  - Absence of substitutable products
  - Supply shortage
- Complex competition law issues potentially raised

Continuation of Pre-2014 Trends with Geographic Tilt

- Major trend involves diversification of enforcement activity beyond traditional high-income country (HIC) authorities to low- and middle-income countries (LMICs)
  - *E.g.*, Brazil, Chile, China, Colombia, Mexico, Peru, South Africa
    - See also Chile Pharmaceutical Sector Study
  - HIC authorities remain very active (US FTC & DOJ, EU Competition Directorate, EU member states, UK)
  - Civil society active in initiating cases in LMICs (see, e.g., Brazil) and sector study support (e.g., Malaysia)

Causes of Action: Control of Market Entry

- Delaying market entry of generic pharmaceutical products through various forms of abusive conduct
  - Anticompetitive buyouts of patent validity challenges
    - Both unlawful agreements between undertakings and abuse of dominant position
    - USA Sup. Ct. (FTC v. Actavis, 2013) and CJEU (Generics(UK) v. CMA, 2020) hold that patents do not insulate owners from prosecution for anticompetitive behavior
  - Sham patent litigation, e.g., CADE (Brazil) finds against Eli Lilly re cancer treatment (2015); FNE (Chile) secures commitments from GD Searle re celecoxib (2016)
  - Abuse of regulatory approval processes; Disparagement; Refusal of samples

Causes of Action: “Traditional” forms of misconduct in generics sector

- Anticompetitive conduct in generics markets
  - Bid rigging - Price fixing - Output restraints - Market allocation
- See, e.g., CADE (Brazil) finding against Aurobindo, Brasvit and others for abuses of public tender market for antiretroviral drugs with imposition of fines (2016); NRDC (China) finding of price fixing and market allocation for allopurinol tablets by Chongqing Quinyang (2016) (Chinese authority now consolidated as SAMR with revised regulatory framework)
- Anticompetitive conduct at various levels of supply chain: from producer to distributor to dispenser
- US Department of Justice and States Attorneys General provide details of extensive US generics industry anticompetitive behavior

Causes of Action: Excessive pricing prosecutions gain substantial impetus

- Excessive pricing prosecutions predominantly in Europe (first in South Africa)
- UK Competition and Markets Authority (CMA)
  - Starting with *CMA v. Pfizer/Flynn*; several recent determinations regarding other parties and products
- Italian *Aspen* case
  - Abuse of dominant position to force excessive price of anticancer drugs; Competition Authority decision affirmed by Council of State
- Dutch *Leadiant* case
  - Abuse of dominant position with grossly excessive pricing for drug essential to life, failure to negotiate in good faith

Causes of Action: Excessive pricing prosecutions gain substantial impetus

- Denmark
  - Case against *CD Pharma* (distributor) for excessive pricing of drug used during childbirth
- EU Commission
  - *Aspen* case first EU excessive pricing action in pharmaceuticals market
  - 6 off-patent oncology medicines
  - Dominant position, threats to withdraw from market, strategy to defeat reference pricing limitations
  - Aspen agrees to price undertakings (settled)

Merger and Acquisition

- Merger review a key function of competition authorities
  - Consolidation may lead to limiting the number of suppliers in a therapeutic class
  - Results of reviews often requirement to divest business or product line to maintain adequate competition in relevant market
  - M&A may lead to reductions in R&D projects and personnel with adverse effect on introduction of new therapies
  - Competition authorities have been very active in policing M&A, see detailed descriptions in particular of activities in Brazil, China and USA

International Commitments

- WTO rules allow wide flexibility in development and application of competition law
- There is a recent trend toward inclusion of competition chapters in trade and investment agreements (TIAs) (typically bilateral or regional)
- Most rules are “process” related or general commitments regarding overarching principles

International Commitments

- Consider recent ECN+ directive for Europe stressing the centrality of “independence” of competition authorities in the EU and its member states
- Recall history of LMICs under TIAs on matters such as requirements for patent and regulatory market exclusivity, and attendant political pressure (see UN Sec’y Gen High-Level Panel on Access to Medicines Report)
- What is advantage to increasing leverage of foreign trade and finance authorities? Consider alternative of continuing cooperation directly among competition authorities

Room for Improvement

- Promote and protect independence of competition authorities
- Assure availability of adequate investigative tools
- Consider mechanisms for streamlining competition enforcement actions
  - *Per se* rules and/or strong presumptions
- Increased intergovernmental cooperation at competition authority level logically on a regional basis (i.e. shared environment and experience)