DEVELOPMENTS AND TRENDS IN COMPETITION LAW AND PRACTICE

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USING COMPETITION LAW TO PROMOTE ACCESS TO MEDICINES AND OTHER HEALTH TECHNOLOGIES

5TH GLOBAL CONGRESS ON INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST

SEPTEMBER 28 2018

THE ROLE OF COMPETITION LAW

- Global pharmaceutical market characterized by multiple failures
  - Political
  - Economic
  - Regulatory
  - Scientific

Necessitates competition law approach broader than uni-dimensional attention to elimination of producer restraints

PUBLIC HEALTH AND (NON-) SELF-CORRECTING MARKETS

- Early US Supreme Court jurisprudence under Sherman Act focused on consumer protection
- Transition to Chicago School approach in 1980s emphasized self-correcting nature of markets and removal of producer restraints
- Producer-restraint focus continues to permeate discourse among competition authorities, courts and academia
- Markets characterized by legislative grants of exclusive rights and other regulatory barriers (e.g., extended approval processes) are not "self-correcting"

COMPETITION AUTHORITIES AND SECTOR INQUIRIES

- Various approaches to health and pharmaceutical sector inquiries – activity in this area has expanded dramatically since UNDP initiated its work program 5+ years ago
- EU Competition Directorate undertook deep analysis of role of patents and other market exclusivity mechanisms – report in 2009 http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/
  - Instituted continuous monitoring of validity challenge settlements
  - Dutch government investigating price impact of patent extensions and regulatory exclusivity rules
- EU Competition Directorate pursuing excessive pricing probe of South Africa's Aspen Pharmaceutical (2017) – refers to exceptional circumstances
- UK Competition and Markets Authority leading excessive pricing efforts – discussed separately

COMPETITION AUTHORITIES AND SECTOR INQUIRIES

- Italian Competition Authority active, including fining Aspen Pharmaceutical for excessive pricing violations regarding anticancer drugs (2016)
- French Competition Authority launches pharmaceutical sector inquiry November 20, 2017: http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=663&id_article=3068&lang=en

  "As part of its advisory powers, the Autorité de la concurrence is launching a vast sector-specific inquiry on the functioning of competition in the medicinal products and medical biology sectors.

  In particular it will look at the distribution of pharmaceuticals, their price regulation mechanism, as well as at the business development opportunities available to pharmacists."

  ,"… a sector-specific inquiry looks at the overall functioning of a sector and leads to the submission of an opinion, which has only a consultative value."
- Dutch Pharmaceutical Accountability Foundation (NGO) asks Authority for Consumers and Markets (ACM) to take action against the medicines manufacturer Leadiant Biosciences for excessive pricing of chenodeoxycholic acid (CDCA)

COMPETITION AUTHORITIES AND SECTOR INQUIRIES

- South Africa
  - Competition Commission undertaking private healthcare sector inquiry http://www.compcom.co.za/healthcare-inquiry/
  - Competition forms part of IP Policy reform (2018)
  - "Competition law and policy have, in the recent past, been applied to cases involving IP and the public interest. Building on this recent history, a joint effort is recommended, along with the Competition Commission, to clarify the remit and scope of the intersection between competition law and IP."
  - Additional pharmaceutical competition enforcement actions under review
  - UNDP organized multi-country consultation, Pretoria 2016

COMPETITION AUTHORITIES AND SECTOR INQUIRIES

- China's competition authorities (MOFCOM, National Development and Reform Commission (NDRC) and the State Administration for Industry and Commerce (SAIC)), undertaking pharmaceutical industry review accompanied by enforcement actions
- Competition Commission of India (CCI) undertaking baseline study/survey in the pharmaceutical sector and healthcare delivery systems/services
  - CCI opens proceedings against Roche (Trastuzumab)(2016/7)
- Malaysia – UNDP and MyCC hosted September 2017 Workshop for ASEAN Competition, Health and IP Authorities
  - Market Review on Priority Sector under Competition Act 2010: Pharmaceutical Sector, 27 December 2017
  - UNDP provided comments MyCC draft Intellectual Property Rights and Competition Law Guidelines (May 2018)
- ISAGS-UNISUR / Fiocruz / UNDP Consultation on Competition and Access to Health Technologie
  - Access to Health Technologies, Patents and Prices: Capacity Strengthening Consultation on the Use of Competition Law to Promote Affordable Access, 5-7 December 2017, Rio de Janeiro, Brazil

United States:
State Atty's Gens v. Mylan et al.

- 46 attorneys general accusing 18 companies of conspiring to fix prices for more than a dozen drugs…"collusion was so pervasive that it essentially eliminated competition"
- Bid-rigging for pharmaceutical benefit manager (PBM) and public procurement
- Agreements to allocate customers and restrict output
- Informal enforcement mechanisms

- Illustrates that anticompetitive behaviors not limited to originators and patents
- Artificial short supply used to dramatically raise prices
- Generics producers are easier targets for competition authorities because of lesser political influence

Status:

- October 31, 2017: amended complaint filed, states can separate their actions from private actions
- June 5, 2018:
  - States can expand their allegations to include an overarching conspiracy among drug makers
  - The number of medications for which the states assert overpayment can be increased
- In discovery and pre-trial

CANADA:
Alexion Pharmaceuticals, Inc. v. Canada

- Patented Medicine Prices Review Board (PMPBP) review agency: prices for Soliris, or eculizumab, in 10 milligram dosages, excessive under Sections 83 and 85 of Canada's Patent Act
- Court of Appeals upheld determination:
  - Challenge to PMPRB powers rejected, because the complainant did not raise the issue before the agency and previous rulings upheld the constitutionality of the controls
  - Alexion to pay back about C$5.6 million ($4.4 million) in excess profits
- Supports previous jurisprudence on the constitutionality of federal pricing controls on prescription pharmaceuticals
  - Canada (Attorney General) v. Sandoz Canada: provisions challenged were validly enacted by Parliament

Status:

- Supreme Court: June 28, 2018: Alexion's leave to appeal refused

USA

- US Federal Trade Commission – Bureau of Competition - Health Care Division
- Persistent pursuit of bad actors; cases time-consuming, resource intensive, outcomes uncertain; operating under intense political scrutiny
- Extensive list of cases
  - *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
  - Federal Trade Commission (FTC) v. AbbVie, 2015 WL 8623076, Civ. No. 14-5151 (ED Penn. 2018)
    - On June 29, 2018, a US Federal District Court judge in Pennsylvania rendered a civil award of $448 million in favor of the US Federal Trade Commission (FTC) against AbbVie for abusing its monopoly power in the market for topical testosterone replacement therapies (TTRTs). Earlier, on September 15, 2017, the same judge found AbbVie to have engaged in sham patent litigation against Perrigo and Teva. AbbVie initiated patent infringement proceedings against Perrigo and Teva in response to Paragraph IV filings companies seeking early entry into the market for generic versions of AndroGel 1%.

UNITED STATES:
Pfizer, Inc. v. Johnson & Johnson
BIO on BIO

- Pfizer alleges:
- J&J coerced health insurers and hospitals into not covering biosimilar versions of biologic Remicade
  - Exclusionary contracts
  - E.g. Threatened to deny rebates for Remicade if health insurers covered rival biosimilar products
- Pfizer has lower-cost biosimilar product: Inflectra
- J&J cornered market, in violation of the Sherman Act and the Clayton Act

- Reflects emerging trend of biosimilars as the basis for pharmaceutical antitrust claims
  - Status:
- August 10, 2018: J&J's motion to dismiss denied
  - In Pretrial

CMA v. Pfizer and Flynn

- Globally most important current competition case from jurisprudential and access standpoint

  Frederick M. Abbott, *The UK Competition Appeal Tribunal's Misguided Reprieve for Pfizer's Excessive Pricing Abuse*, IIC - International Review of Intellectual Property and Competition Law, Vol. 49, No. 7 (2018), IIC (2018) 49:845-853

- UK Competition and Markets Authority (CMA) renders enforcement determination against Pfizer and Flynn for excessive pricing of anti-epilepsy drug (phenytoin sodium capsules)

- Through manipulation of National Health Service (NHS) drug cost reimbursement system, Pfizer effectively removes generic drug from price control system

  - transfers nominal ownership of registration to intermediary (Flynn) – "debranding" -- and together increase price by more than 2000%

- Pfizer executives expressly discuss public perception regarding "fleecing" of NHS, and engage Flynn to defend against anticipated backlash

CMA v. Pfizer and Flynn

- CMA determines Pfizer and Flynn maintain dominant position on market, and post-debranding price is excessive
  - Uses cost-plus benchmark for assessing level of price increase
  - Excessive prices "unfair in themselves" because lacking any objective justification
  - Pfizer and Flynn supply exactly same product from exactly same German factory
  - UK prices substantially higher than elsewhere in Europe (unfair in comparison to competing products – second approach unnecessary here, but for sake of completeness)
- Competition Appeal Tribunal (CAT) affirms finding of dominant position
- CAT rejects excessive pricing finding on grounds that CMA did not sufficiently explore alternative avenues for determining excessive price and unfairness, notwithstanding that CMA closely adhered to jurisprudence of Court of Justice of European Union (CJEU) from *United Brands* and subsequent

CMA v. Pfizer and Flynn

- CAT relies on opinion of Advocate General Wahl in recent *Latvian Copyright* excessive pricing case that went beyond CJEU jurisprudence by advocating multiple analytic approaches as "sanity check", citing US Supreme Court Justice Scalia on virtues of self-correcting markets
- CJEU did NOT use the AG's multiple approach in *Latvian Copyright* decision which appeared to relax requirements for finding of excessive pricing
    - Refusing to establish minimum threshold for cross-country comparison price differences demonstrating excess
- June 2018 CMA petitioned CAT for permission to appeal to UK Court of Appeal; if declined, apparently may appeal directly

CMA v. Pfizer and Flynn

- Why is CMA v. Pfizer and Flynn so important?
- Substantial degree of awareness among competition authorities and judges of jurisprudential developments, including historical regard for British legal system
    - We see jurisprudential influence in discussions around the world with Competition Authority officials, and with judges
    - Judges in India, Malaysia and South Africa are familiar with jurisprudence from the CJEU, and judges tend to be somewhat cautious in matters of doctrine
    - An adverse determination in *CMA v. Pfizer* could well have a substantial influence on an excessive pricing cases, e.g., in South Africa
        - South Africa's Competition Act provision on excessive pricing is based on CJEU's formula in *United Brands*

CMA V. ACTAVIS (UK)

CMA Press release

Pharmaceutical company accused of overcharging NHS

From: Competition and Markets Authority

Part of: Competition Act and cartels

Published:16 December 2016

The CMA has provisionally found that Actavis UK has broken competition law by charging excessive prices to the NHS for hydrocortisone tablets.

"In a statement of objections issued to the company today, the CMA has alleged that in doing so it broke competition law by charging excessive and unfair prices in the UK for the tablets."
Investigation proceeding

"The pharmaceutical company Actavis UK (formerly Auden Mckenzie) has increased the price of 10mg hydrocortisone tablets by over 12,000% compared to the branded version of the drug which was sold by a different company prior to April 2008. For example, the amount the NHS was charged for 10mg packs of the drug rose from £0.70 in April 2008 to £88.00 per pack by March 2016.

The company also increased the price of 20mg hydrocortisone tablets by nearly 9,500% compared to the previous branded price, equating to charges to the NHS of £102.74 per pack by March 2016, when it had previously paid £1.07 for the branded drug. De-branded (genericised) drugs are not subject to price regulation."

CMA v Concordia, Nov. 2017

On 21 November 2017 the CMA issued a statement of objections alleging that Concordia has breached UK and EU competition law by charging excessive and unfair prices in relation to the supply of liothyronine tablets in the UK.

EXCESSIVE PRICING: CORE DOCTRINE

- Effectively addressing high prices of patent- and marketing-exclusivity protected pharmaceuticals requires application of excessive pricing doctrine
- Inter-producer restraints are not the basis for elevated pricing; rather, taking unfair advantage of exclusivities authorized by legislature
- Generics industry also engages in excessive pricing when one or limited group of companies access sole supplier
- Competition authorities have approached excessive pricing cases cautiously with traditional reluctance to bring such cases (see 2011 OECD Report on jurisprudence)
- Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, UC Irvine Law Review, Volume 6, Issue 3, pp. 281-320, Dec. 2016

GAPS

- Investigative authority: powers to compel document production and testimony
- Transparency: *see* ILA Global Health Law Committee Report (2018) and UN Sec'y General's High Level Panel Report
    - Price trade secrecy and patent/exclusivity system issues
- Financial resources
- Caution regarding international negotiations

Let International Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity
IIC - International Review of Intellectual Property and Competition Law, March 2018, Volume 49, Issue 3, pp 259–266, https://doi.org/10.1007/s40319-018-0683-5