Using competition law to address high medicines prices: excessive pricing doctrine

Prof. Frederick Abbott

Florida State University College of Law

Knowledge Network for Innovation and Access to Medicines

Global Health Centre – Graduate Institute

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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

Excessive Pricing as a Cause of Action

- Typically a form of "abuse of dominant position" (e.g., Article 102, EU TFEU) or monopoly - not requiring agreement between undertakings
- Dominant position defined in manner generally applicable in competition law (e.g., market share and capacity to sustain elevated price)
  - For pharmaceuticals “market” can constitute single drug (e.g., where no or limited effective substitutes)
- CJEU has prescribed two step analysis (*United Brands v. Commission*, 1978)
  - Price excessive (e.g., because no reasonable relationship to economic value of product), cost of production compared to selling price recognized as acceptable methodology, and;
  - Either (a) unfair in itself or (b) unfair when compared to competing products
- At present, excessive pricing “as such” not recognized in U.S. antitrust law, but excessive pricing may be signal of underlying market defect

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
- In general, 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 law enforcement may not be "first best" solution to high pharmaceutical prices, but may be "best available" solution

Times Are Changing (hesitantly)

- Competition authorities, administrative and judicial bodies, and institutions have shown increasing willingness to address excessive pricing “as such” - general trend is positive
- So far, authorities have intervened in cases involving unjustifiable large increases in prices of generic products, e.g., where production costs have not increased, but prices in dominated market have significantly increased
- Competition authorities remain skeptical of addressing excessive pricing by originators because of perceived obstacles
  - Uncertainty regarding methodologies for establishing costs -- deterred by perceived complexity
  - Concerns regarding potential adverse effect on future R&D -- reluctance to question patent system, notwithstanding abuses

Paradigm generics excessive pricing case

- *CMA v. Pfizer and Flynn*
  - See 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

Competition authority finds excess

- 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

Competition authority meets jurisprudential resistance

- 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
- 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
- CMA pursuing appeal

Trend toward gradual acceptance

- OECD Policy Roundtable, Excessive Prices (2012)
  - Expresses substantial caution about extending excessive pricing doctrine
- OECD, Excessive Prices in Pharmaceutical Markets, Background Note by the Secretariat, 27-28 November 2018
  - Acknowledges increased acceptance by competition authorities
  - Accepts utility of excessive pricing actions in limited cases, in particular generic products with large increases and substantial barriers to entry
  - Recognizes recent attention to potential for excessive pricing actions against originator products
  - OECD Background Note recommendation is for sector investigations by drug regulatory authorities and advocacy for national legislation/action

Basis of hesitation

- Risk from Type 1 error (acting improvidently) greater than risk from Type 2 error (failing to act)
- Risk of interfering with benefits of competitive market processes greater than the potential for improving market function
  - Concerns expressed regarding investment and R&D
- Judicial and administrative authorities lack sufficient expertise to analyze pharmaceutical market
- Activities better left to sector regulatory authorities
- Judicial and administrative authorities are not price control administrators

Excessive Pricing: Core Doctrine

- 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
  - Legislative and jurisprudential treatment
  - Methodology for construction of "reasonable price" through determination of cost basis including risk-adjusted R&D costs
- Abuse of market power manifest by injury to welfare of individual consumers and/or purchasing groups
- Patents and market exclusivity provide basis for dominance within therapeutic class (down to individual drug)
  - Consumer with life-threatening disease does not have freedom of choice - demand is inelastic

Determining What Is "Excessive": Methodologies

Establishing "reasonable price"

- Cost plus profit, adjusted for risk
  - Preferred approach
- Reference pricing: see, e.g., current U.S. legislative proposals
- Bargaining between monopoly supplier and monopsony purchaser
- Cost based on corporate assessments of acquisition targets
- Cost based on reporting of R&D and related expenditures to tax authorities
- Cost based on Securities and Exchange Commission reporting

Adjusting for risk

- Drug development risk varies in relation to unknowns
- *Basic research*
  - Government (e.g., NIH) funds basic research seeking to reduce unknowns and concomitant risk factors
  - Taxpayer-funded R&D costs should not be included within the calculation of reasonable price
- *Low risk R&D*: Most new pharmaceutical products are follow-on; different formulations, routes of administration, dosages, patient populations, etc., where cause of condition, mechanism of therapeutic action and toxicity profile is generally known
  - Favored by industry because of predictability in respect to future streams of income
  - Risk factors should be limited taking into account overall project costs

Adjusting for risk

- *High risk R&D*: Development of novel therapy based on identifying biological cause of disease and/or novel mechanism of treatment typically involves greater risk
  - Assumed there will be failures in project development and execution
  - Originators reduce risk by pursuing multiple targets (disease and mechanism of action)
  - Originators reduce risk by identifying and acquiring promising third-party portfolios
- Level of risk varies depends on structure of investigating institutions (e.g., single or multi-focus)
  - Multi-focus institutions typically subdivide budget among research units

Calculating Cost

- *Not* a black box
- Manufacturing costs generally known
- Certain costs should be excluded: opportunity cost of capital, executive salaries above reasonable limits, tax incentives
- Originator companies maintain carefully monitored budgets and internal capital allocations
  - R&D departments are not given "blank checks“
  - Originators typically subdivide R&D efforts among disease targets and/or therapeutic types: related costs are identifiable
- Costs of developing successful new therapeutic product should reasonably take into account failures reasonably proximate to the approved product
- Capital markets and originator companies constantly place values on R&D streams both to establish share price on public exchange and/or price of acquisition target
- The "mystery" of R&D costs is deliberately maintained

Supra-baseline “Excess”

- After determining cost must establish what constitutes a price "excessive" in relation to it
- Establishing an acceptable norm of profitability can be accomplished by comparison with others in the same industry, or with others in other industries
- Difficulty with comparing other Pharma originators is that historical pricing practices may reflect excess
- Abbott article illustrates methodology for calculating reasonable price based on expectation of sales over time, leaving choice of multiplier in determining excess
- In recent cases where the medical community and public have been "shocked" by pricing practices, may not be difficult to determine that prices are excessive, but establishing reasonable price plus profit may be necessary for remedial purposes

Addressing Hesitancy

- Assumption underlying hesitancy to address excessive originator pricing is that enforcement will curtail investment in R&D and ultimately reduce potential for innovation
- This assumption is not based on historical precedent or economic analysis of effects of limiting "excessive pricing" in regulated pharmaceutical markets, but on postulate that pharmaceutical industry is dependent on ability to capture substantially greater than "normal" returns. It is an untested hypothesis
- Originators have strenuously resisted public examination of R&D costs, even under threat within high-stakes litigation. Why? Difficult to see how such information could benefit competitors
- Developing robust approaches by competition authorities will take practice in addressing cost accounting and other issues. Until this is tried, viability remains an issue

Remedial Measures

- Civil and criminal competition prosecution are alternatives
- Private civil actions an important potential means of enforcement (in the United States including triple damages)
- Civil remedies may be based on consent agreement (and judicial order or decree), or judicial/jury determination and order, including:
  - Reduction of price to reasonable level
  - Payment of monetary damages, with potential for reimbursement to payors
  - Judicial or administrative monitoring of price, with opportunity for seeking adjustment based on changed circumstances
  - Anti-circumvention controls
- Criminal penalties may include fines and/or imprisonment

Pursuing Low-Hanging Fruit

- Competition authorities have shown willingness to pursue excessive pricing actions against generic producers with market dominant positions substantially raising prices in the absence of changed economic circumstances (e.g., demonstrated increases in production costs)
- Prevalence of generic products enjoying "effective monopolies" is growing trend imposing substantial costs on consumers and public health systems
- Issues arising from determining risk-adjusted R&D costs do not arise, nor is there a threat to future R&D streams
- The meaningful threat in the hands of generic producers is withdrawal from the market
    - Governments must consider alternative means for producing necessary generics to counter this threat, including by subsidizing alternative private entrants or establishing national or international production capabilities

Gaps and Challenges

- 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

Additional Information

- Various sets of workshop presentations on using competition law to promote access to medicines, including causes of action generally available under competition law, mechanisms for securing evidence, case law and remedial measures are available at:

  http://frederickabbott.com/recent_presentations