Health Technologies, Market Exclusivities and Abuse of Dominance:

Methodology and Structure for Competition Law Enforcement

Prof. Frederick Abbott
Florida State University College of Law

IP Researchers Europe Conference

organized by the World Intellectual Property Organization (WIPO)

and the World Trade Organization (WTO)

and the School of Law, University of Geneva (UNIGE)

Geneva, June 28 and 29, 2019

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

Medicines Pricing and R&D

https://www.wsj.com/articles/abbvie-nears-deal-to-buy-allergan-for-more-than-60-billion-11561458504

BUSINESS

AbbVie Strikes Deal to Acquire Allergan for About $63 Billion

Drugmakers agree to one of the biggest mergers in the health sector this year

Allergan CEO Brent Saunders on the floor of the New York Stock Exchange in 2016. As of Monday's close, Botox maker Allergan has a market capitalization of $42.47 billion. **PHOTO:** BRENDAN MCDERMID/REUTERS

By Cara Lombardo, Jonathan D. Rockoff and Dana Cimilluca

Updated June 25, 2019 8:41 pm ET

AbbVie Inc. ABBV **3.89%** ▲ agreed to buy Allergan AGN **0.86%** ▲ PLC for about $63 billion in a bet by the two drugmakers that a combination will deliver new sources of growth that they have struggled to find on their own.

The takeover is worth about $188 a share in cash and stock, the companies said. The price represents a 45% premium over Allergan's closing share price Monday of $129.57. If not for a surge in the shares in recent days on expectations for a breakup of the company, the premium would be even bigger.

Buying Dublin-based Allergan would deliver a dominant position in the $8 billion-plus market for Botox and other beauty drugs, as well as a number of popular eye treatments, as AbbVie braces for the end of patent protection for the world's top-selling drug, Humira.

Medicines Pricing and R&D

The New York Times

Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.

By Danny Hakim

Jan. 6, 2018

Humira is the best-selling prescription drug in the world. You may have seen the commercials.

Because of Humira, a woman with rheumatoid arthritis can wash her puppy in the bathtub, another with colitis can stroll happily through a fair packed with food vendors, while a third suffering from psoriasis can go to the gym without hiding her neck.

But they probably wouldn't all look so relieved if they saw the bill. The price of Humira, an anti-inflammatory drug dispensed in an injectable pen, has risen from about $19,000 a year in 2012, to more than $38,000 today, per patient, after rebates, according to SSR Health, a research firm. That's an increase of 100 percent.

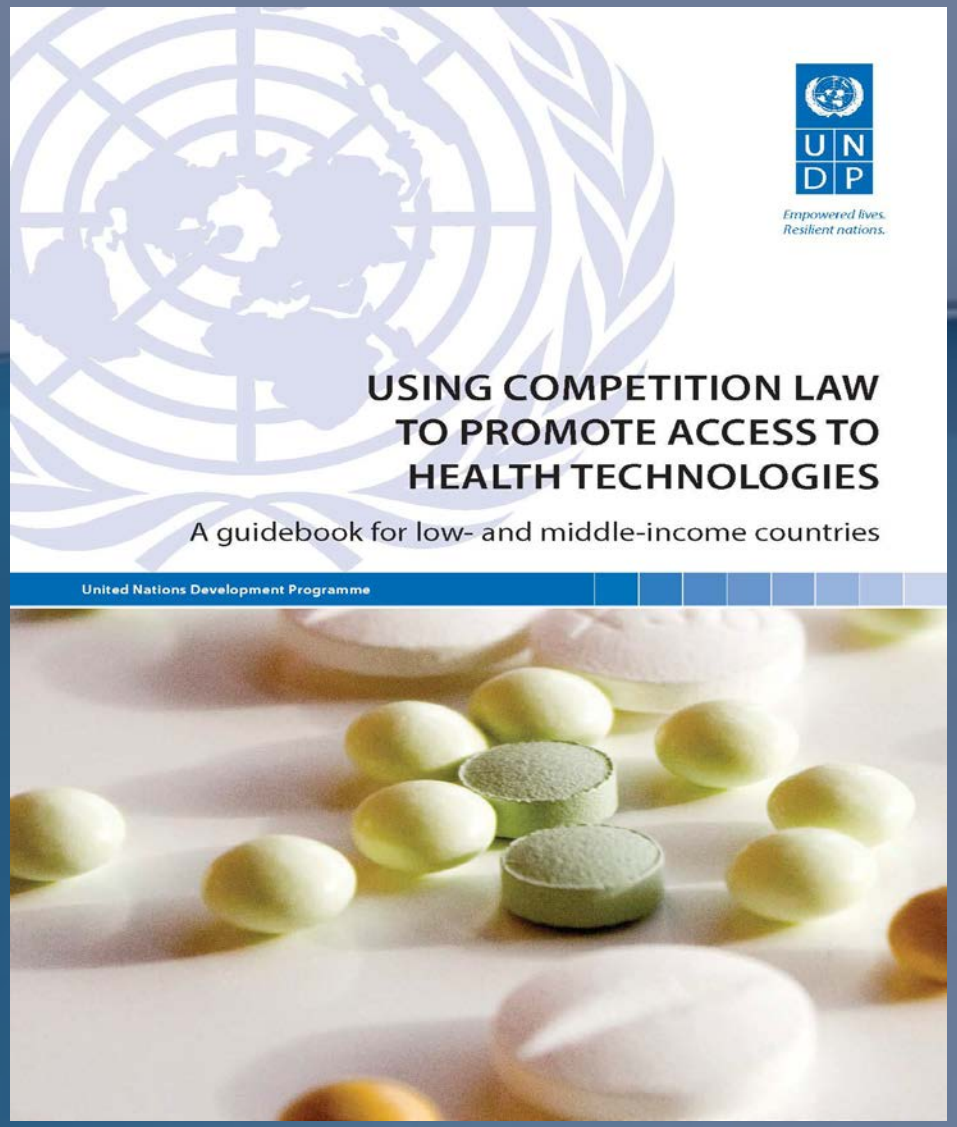
Pharma bosses probably miss Martin Shkreli, the reigning villain of the industry. If you'll recall, Mr. Shkreli, as chief executive of Turing Pharmaceuticals, acquired Daraprim, a drug used to fight infections in AIDS patients, and then raised the price overnight to $750 a pill from $13.50. He also trolled critics and spent $2 million on a one-of-a-kind Wu Tang Clan album, before his conviction on three securities fraud charges last year.

For a time, Mr. Shkreli's antics, along with the soaring price of EpiPens, sold by Mylan, deflected attention from the rest of the industry. A more typical play for drug companies — the Humira play — is to start at a high price and keep raising it ever higher, but incrementally.

"What they have done with Humira is just as unfair, just as morally wrong, but they did it over five years," said Ben Wakana, a former Obama administration spokesman who became executive director of Patients for Affordable Drugs, an advocacy group, because his younger brother couldn't afford Humira without the financial support of their parents.

"People are skipping doses, people are rationing, people are going into bankruptcy because of this drug," he said in an interview, arguing that Humira is both more expensive per dose and has a far higher volume than Daraprim.

UNDP



ISAGS-UNISUR / Fiocruz / UNDP Consultation on Competition and Access to Health Technologies

Presentations by Frederick M. Abbott at:

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

PowerPoints:

Frederickabott.com

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
  - *But see* decision by Judge Lucy Koh in *FTC v. Qualcomm* (2019)
  - Excessive royalty in context of essential standard patents coupled with abuse of market dominance

FTC Report: Excessive Pricing as a Cause of Action under Section 5 FTC Act

Federal Trade Commission
Report on Standalone Section 5 to Address High Pharmaceutical Drug and Biologic Prices

Congress directed the Federal Trade Commission ("FTC") to report to the House and Senate Appropriations Committees ("Committees") on the use of the FTC's standalone authority under Section 5 of the Federal Trade Commission Act to address high pharmaceutical prices. Specifically, the Committees requested that the FTC, in consultation with the U.S. Food and Drug Administration ("FDA"), examine Congress's intent regarding unfair methods of competition in 15 U.S.C. 45(n) and in the FTC's standalone Section 5 authority with regard to unreasonable price increases, including those that occur over multiple years, on off-patent pharmaceutical drugs and biologics when there are no alternatives available to the consumer, and when price increases are unreasonable, unavoidable, and not due to increased manufacturing costs of the product.[1] The Committees requested that the Commission submit a report within 120 days of the bill's enactment.

Section 5 gives the Commission authority to address both "unfair or deceptive acts or practices" ("UDAPs") and "unfair methods of competition." Although the directions for this report cite to the Commission's authority over unfair methods of competition under § 45(n), we note that this subsection pertains to "unfair or deceptive acts or practices," and not "unfair methods of competition" under 15 U.S.C. 45(a)(1). Consistent with the text of the bill, this report focuses on the FTC's ability to use its antitrust authority over unfair methods of competition to address unreasonable drug price increases. Although the FTC has not ruled out the possibility that, in certain extreme circumstances, an excessive price increase on a pharmaceutical product could constitute a UDAP, to date, it has not challenged an adequately disclosed price increase.

Part I of this Report provides an overview of the scope of the FTC's authority under Section 5(a) to address unfair methods of competition and the nexus to existing antitrust principles.[2] Part II explains how the Commission may combat high drug prices when a monopolist employs business practices that harm competition. For decades, the FTC has devoted substantial resources to anticompetitive practices in the pharmaceutical markets, which act to keep prices from being increased in violation of the law. However, the legal and economic analysis underlying the antitrust laws provides little basis for using standalone Section 5 to address high prices unaccompanied by exclusionary conduct, including high drug prices under the conditions of interest to the Committees. Part III briefly discusses other considerations that

[1] Joint Explanatory Statement published in the Congressional Record on Feb. 13, 2019 at H1831 https://www.congress.gov/116/crec/2019/02/13/CREC-2019-02-13-pt2-PgH1589-2.pdf that accompanied the Consolidated Appropriations Act, 2019, Pub. L. 116-6, incorporated by reference Senate Report 115-281 at 73 https://www.congress.gov/115/crpt/srpt281/CRPT-115srpt281.pdf that accompanied S. 3107, General Government and Financial Services Appropriations Bill, 2019.

[2] In a separate statement, Commissioners Chopra and Slaughter suggest that we should explore new ways of applying our standalone Section 5 authority to challenge "unreasonable" increases in drug prices for off-patent branded drugs. Their theories, however, neither define a clear legal standard under any aspect of Section 5, nor identify a case where a price increase alone would have violated their proposed application of Section 5. The theories would also require the FTC to decide acceptable pricing levels. Such a regime, which would involve barring excessive prices in the absence of anticompetitive conduct, would have the FTC act like a public utility commission, which sets rates, something for which we are ill equipped. This report outlines the contours of the FTC's Section 5 authority, as defined by prior litigation and policy work, and we will continue to use the full extent of our authority to vigorously challenge anticompetitive conduct that results in higher drug prices.

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

STATEMENT OF
COMMISSIONERS ROHIT CHOPRA AND
REBECCA KELLY SLAUGHTER
Federal Trade Commission Report on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes

June 24, 2019

Today, in response to a request from Congress, the Commission is issuing a report about its authority to address "unreasonable" price increases for off-patent pharmaceutical drugs and biologics and particularly those where consumers lack any therapeutic alternatives and where the price increases are "unreasonable, unavoidable, and not due to increased manufacturing costs of the product." The report does not fully outline the contours of Section 5 of the FTC Act as they relate to pricing practices under these specific circumstances,[1] so we write separately to provide our views.

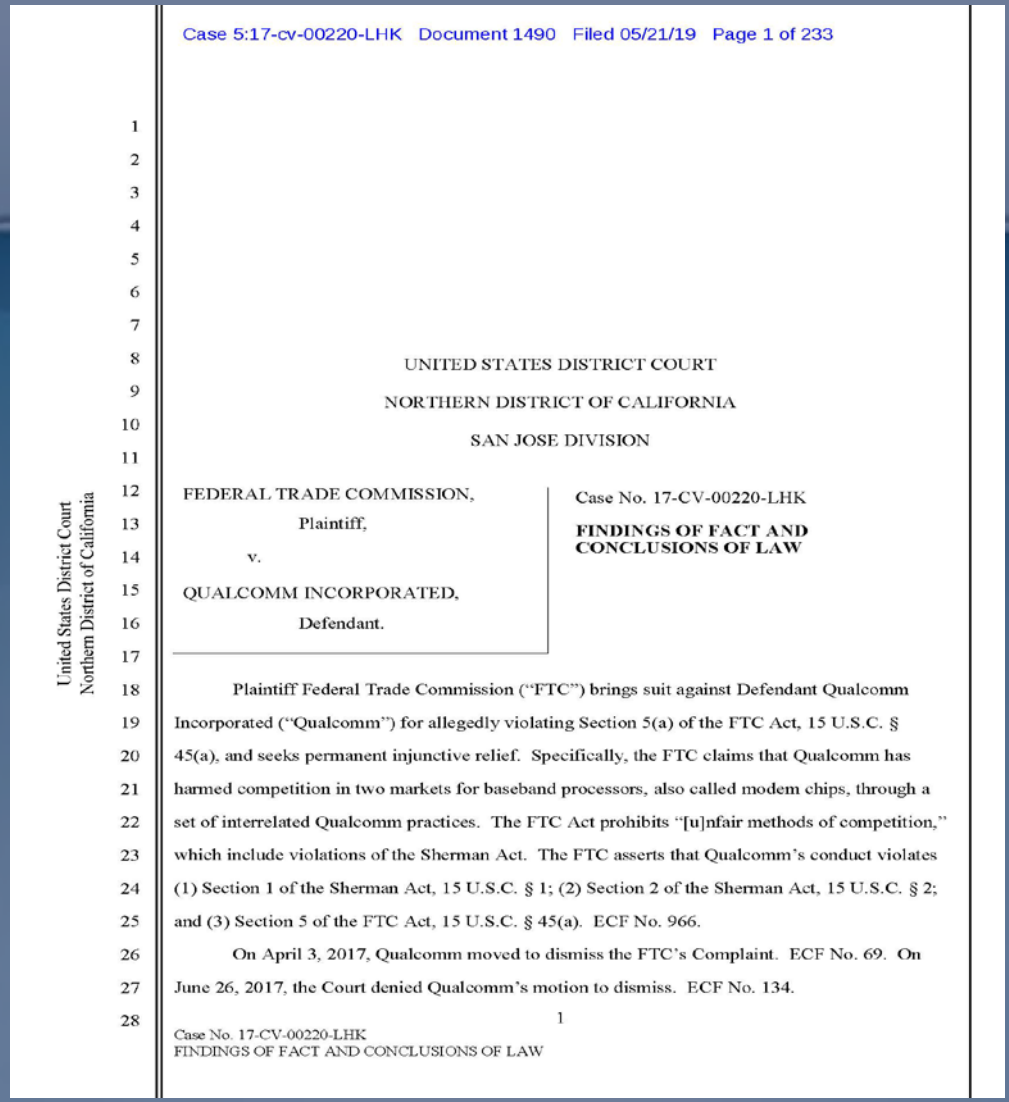
Congress is rightly concerned about exorbitant price increases on off-patent drugs. So are we. For decades, the Commission has challenged a number of illegal anticompetitive practices in the pharmaceutical industry that result in high drug prices. The Commission should consider ways to build on this work by addressing emerging and evolving practices that harm consumers. While the problem of excessive drug prices for off-patent pharmaceuticals involves a complex set of issues, the stakes are too high to rely on the agency's standard approach. The Commission needs to consider the full breadth of its statutory authority under Section 5.

The Commission's report to Congress repeats an oft-stated perspective regarding the dangers of interfering with market pricing mechanisms. While this view is appropriate in many instances, the unique characteristics of the pharmaceutical market can make the application of typical market pricing mechanisms unreliable. Entry barriers and the existence of consumers who have nowhere to turn because their lives depend on a particular drug are just a few of the complexities that make this industry atypical.

The conventional wisdom is that America's high drug prices are necessary to fuel innovation and attract entry for life-saving therapies. This is highly questionable, particularly when it comes to high priced off-patent drugs that invite, but do not receive, competition from therapeutic alternatives. Even for new drugs, studies have shown that, since the mid-1990s, about 85 to 90

[1] We do not contend that Section 5 is a general price-setting statute. Instead, we confine our remarks regarding the scope of Section 5 to the circumstances outlined in the Committee's request.

FTC v Qualcomm: Excessive Pricing as a Cause of Action – Essential Standards Patents



United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

FEDERAL TRADE COMMISSION,
Plaintiff,
v.
QUALCOMM INCORPORATED,
Defendant.

Case No. 17-CV-00220-LHK

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff Federal Trade Commission ("FTC") brings suit against Defendant Qualcomm Incorporated ("Qualcomm") for allegedly violating Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and seeks permanent injunctive relief. Specifically, the FTC claims that Qualcomm has harmed competition in two markets for baseband processors, also called modem chips, through a set of interrelated Qualcomm practices. The FTC Act prohibits "[u]nfair methods of competition," which include violations of the Sherman Act. The FTC asserts that Qualcomm's conduct violates (1) Section 1 of the Sherman Act, 15 U.S.C. § 1; (2) Section 2 of the Sherman Act, 15 U.S.C. § 2; and (3) Section 5 of the FTC Act, 15 U.S.C. § 45(a). ECF No. 966.

On April 3, 2017, Qualcomm moved to dismiss the FTC's Complaint. ECF No. 69. On June 26, 2017, the Court denied Qualcomm's motion to dismiss. ECF No. 134.

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 – British courts moving very slowly

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

Resistance at OECD

- At OECD Competition "Open Day" in February 2019 (Paris), former director of OECD Competition Division – John Davies, now consultant to pharma industry – sharply criticizes decision against Pfizer by UK Competition and Market Authority
  - Claims defending competition principles
- Rebuttal by author of CMA Report, Prof. Marsden
- Also intervention from floor by Prof. Abbott in support of CMA
- OECD risks impression that it is launch base for consultancies for industry
- None of the panelists addressed excessive pricing by originators

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
  - World Health Assembly Resolution
- 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