

EXCESSIVE DRUG PRICING AS AN ANTITRUST VIOLATION

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We have become all too familiar with a recurring pattern in pharmaceutical drug pricing. First, a report is published about an astonishing rise in the price of a pharmaceutical drug that patients need for a life-threatening illness or event.¹ Denunciations of price gouging then come quickly. Politicians send letters to the drug companies asking for explanations.² Congressional hearings are held.³ Corporate executives try to explain—they don't make so much

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¹ See, e.g., David Crow, *US Drugmaker Raises Price of Vitamins by More Than 800%*, FIN. TIMES, Dec. 10, 2017 (post-acquisition 809% increase of Niacor, prescription version of niacin, and 2,469% increase in SSKI, a respiratory drug); Adam Feuerstein, *Acadia Pharma Raised the Price of Its Only Drug Twice But Quarterly Sales Still Disappoint*, STATNEWS.COM (Feb. 28, 2018) (price of drug for treating symptoms of Parkinson's raised twice at end of 2017; annual cost now \$32,400, 35% more than when introduced in 2016; CEO says we are now better able "to appreciate and gauge the value of the drug that we're delivering"); Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html. For fuller treatment, see ROBIN FELDMAN & EVAN FRONDORF, *DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET* 1–12 (2017).

² See, e.g., Anjali Cordeiro & Makiko Kitamura, *Valeant Under Fresh Scrutiny with New Subpoenas on Prices*, BLOOMBERG (Oct. 15, 2015); Ed Silverman, *Lawmakers Demand Answers on a Huge Price Hike for an Old Drug*, STATNEWS.COM (Dec. 20, 2017) (reporting letter from three U.S. Senators questioning price increase of Kevevis, which sold for \$50 for 100 pills and now costs \$15,000; sharp price increase post-acquisition); Ed Silverman, *Lawmakers Demand Info on Opioid Overdose Antidote After a Big Price Hike*, STATNEWS.COM (Feb. 8, 2017); Ed Silverman, *Grassley Probes EpiPen Rival over Its \$4,500 List Price*, STATNEWS.COM (Mar. 8, 2017); James Swann, *Senate Panel Investigating Drugmakers About Price Hikes*, BLOOMBERG BNA (Nov. 4, 2015).

³ See, e.g., Associated Press, *Senate Initiates Inquiry into Spikes of Drug Prices*, N.Y. TIMES (Nov. 4, 2015), www.nytimes.com/2015/11/05/business/senate-initiates-inquiry-into-spikes-of-drug-prices.html.

(middle-men take the profit), they don't make enough (new drugs cost a lot to develop), pharmaceutical drug regulation is really to blame.⁴ They then offer some relief (maybe coupons to consumers to help with deductibles), but not much.⁵ It's all a version of what our parents told us—take your medicine, it will be good for you, it's not our fault if it tastes bad, that can't be helped.

But is it true that it can't be helped? Various public policy approaches have been advanced: allow (or require) government agencies to bargain over prices, require greater transparency in drug pricing, increase imports, forbid drug companies from issuing coupons to consumers, force drug companies to manufacture in the United States, reduce (or maybe eliminate) aspects of FDA regulation, jaw-bone pharmaceutical companies into lowering prices.⁶ Politicians and bureaucrats have stepped up the rhetoric—presidential candidates condemn,⁷ a president threatens,⁸ administrators form task for-

⁴ See, e.g., David Balto, *How PBMs Make the Drug Price Problem Worse*, THE HILL (Aug. 31, 2016), thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse; Eric Lipton & Katie Thomas, *Drug Lobbyists' Battle Cry over Prices: Blame the Others*, N.Y. TIMES (May 29, 2017), www.nytimes.com/2017/05/29/health/drug-lobbyists-battle-cry-over-prices-blame-the-others.html; Jonathan D. Rockoff, *Behind the Push to Keep Higher-Priced EpiPen in Consumers' Hands*, WALL ST. J. (Aug. 6, 2017), www.wsj.com/articles/behind-the-push-to-keep-higher-priced-epipen-in-consumers-hands-1502036741; Zachary Tracer, Robert Langreth & Anna Edney, *Big Pharma Is Pointing Fingers, and Hoping Trump Will Listen*, BLOOMBERG (Feb. 8, 2017).

⁵ See, e.g., Andrew Pollack, *Mylan Tries Again to Quell Pricing Outrage by Offering Generic EpiPen*, N.Y. TIMES (Aug. 29, 2016), www.nytimes.com/2016/08/30/business/mylan-generic-epipen.html (“So now, the company will essentially sell the same product under two names at two price points, in competition with each other. . . . [T]he generic would still be triple the price of the EpiPen in 2007, when Mylan acquired the product and began steadily raising its price.”); Ed Silverman, *Novo Nordisk Becomes Second Major Drug Maker to Limit Price Hikes*, STATNEWS.COM (Dec. 5, 2016) (“In an open letter discussing the cost of medicines, Novo Nordisk President Jakob Riis promised not to raise the list price of any medicine by more than single-digit percentages annually.”).

⁶ See Jared S. Hopkins, *Allergan CEO Pushes for Trump to Lead Drug Price Discussions*, BLOOMBERG (Feb. 22, 2017) (urging presidential negotiations similar to Kennedy's effort to restrain steel pricing); David Nather, *Washington Has Big Hopes, But Little Power, To Negotiate Drug Prices*, STATNEWS.COM (Jan. 6, 2016) (explaining problems of having CMS negotiate drug prices); STAT Staff, *Transcript: Trump Tells Pharma Execs 'We're Gonna Streamline the FDA'*, STATNEWS.COM (Jan. 31, 2017), (“One thing I really want you to do a lot of—I've seen this over the years, but a lot of the companies have moved out. They don't make the drugs in our country anymore. . . . So you have to get your companies back here.”); Ed Silverman, *To Lower Drug Costs, a Bill in California Would Prohibit Coupons*, STATNEWS.COM (Feb. 3, 2017).

⁷ See Thomas Kaplan, *Hillary Clinton Unveils Plan to Address 'Excessive' Increases in Drug Prices*, N.Y. TIMES (Sept. 2, 2016), www.nytimes.com/2016/09/03/us/politics/hillary-clinton-epipen-mylan.html (plan would impose fines on drug companies); Carolyn Y. Johnson, *Clinton Unveils Plan to Stop Price-Gouging on Old Drugs*, WASH. POST: WONKBLOG (Sept. 2, 2016), www.washingtonpost.com/blogs/wonkblog/files/2016/09/DrugPricingPlan.pdf?noredirect=on (would establish a new group to investigate “unjustified” price increases and respond with “an aggressive new set of enforcement tools”).

⁸ See, e.g., Adam Feuerstein & Damien Garde, *Trump Promised to Bring Pharma to Justice. His Speech Sent Drug Stocks Soaring*, STATNEWS.COM (May 11, 2018) (“We are going to see those prices go down. It will be a beautiful thing to watch.”); Ed Silverman, *Trump Promised*

ces⁹—and drug companies have rolled back price increases a bit (but have still raised prices overall).¹⁰ When effective federal action does not materialize, states try to fill the gap.¹¹ So far, though, either the proposals have made little sense or, even if sensible and adopted, have had little effect.

One might think that antitrust would be on the list of public policy tools to wield against high pharmaceutical prices, but it's not.¹² Of course, there have been antitrust enforcement efforts against various pharmaceutical practices

Drug Makers Would Lower Their Prices, But Not Every Company Got the Memo, STATNEWS.COM (July 3, 2018) (after Trump promises "'voluntary, massive drops in prices' in two weeks," Pfizer and Teva took "hefty price hikes on numerous medicines"); Dylan Scott, *Trump Promises Reforms on Drug Prices, Saying Companies 'Getting Away with Murder'*, STATNEWS.COM (Jan. 11, 2017) ("Our drug industry has been disastrous. They're leaving left and right.").

⁹ See Press Release, U.S. Food & Drug Admin., Statement by FDA Commissioner Scott Gottlieb (July 19, 2018), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613931.htm (announcing formation of a "new work group" to study allowing the short-term importation of lower-priced foreign versions of drugs subject to "sudden, significant price increases" in domestic markets); AMERICAN PATIENTS FIRST 23, U.S. DEP'T OF HEALTH & HUMAN SERVICES (May 2018), www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf (HHS "may undertake" a number of steps "to the extent permitted by law, in response to President Trump's call to action").

¹⁰ See Robert Langreth, Cynthia Koons & Jackie Gu, *After Raising Prices for 100s of Drugs, Industry Pledges Restraint*, BLOOMBERG (July 16, 2018) (although some drug makers announced price reductions or a decision not to raise prices, 255 brand drugs had price increases between Feb. 1, 2018 and July 15, 2018; 96% of the increases were below 10%, with 27% between 9 and 10%, based on list prices); Ed Silverman, *Under Pressure from Trump, Pfizer Agrees to Roll Back Price Hikes*, STATNEWS.COM (July 10, 2018) (after discussion with President Trump, deferring until the end of the year announced price increases on 40 drugs, the majority of which had exceeded 9%).

¹¹ See, e.g., MD. HEALTH-GENERAL CODE ANN. § 2-802 (prohibiting price gouging in sale of essential off-patent or generic drug; held unconstitutional in *Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018) (dormant commerce clause)); *Twenty States Passed 37 Bills to Curb Rising Rx Drug Costs in the Short 2018 Legislative Session*, NAT'L ACAD. FOR STATE HEALTH POL'Y (July 24, 2018) (detailing efforts), www.nashp.org/twenty-states-passed-37-bills-to-curb-rising-rx-drug-costs-in-the-short-2018-legislative-session/; Ed Silverman, *More State Lawmakers Are Pushing Transparency Bills for Diabetes Drugs*, STATNEWS.COM (Feb. 8, 2018); Ed Silverman, *Congress Isn't Acting to Curb Drug Prices, So States Are Stepping Up. Here's How*, STATNEWS.COM (Oct. 18, 2017) (reviewing state efforts).

¹² See COUNCIL OF ECONOMIC ADVISERS, REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD 5 (Feb. 2018), www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (although pointing out that in a "well-functioning competitive market, the price of a good is driven down to the cost of production," and that this principle applies to all markets, including pharmaceutical drugs, report makes no mention of using antitrust as a way to lower the price of drugs); DEP'T OF HEALTH & HUMAN SERVS., HHS BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS, 83 Fed. Reg. 22,692 (May 16, 2018) (same). Cf. Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs 1, 4 (July 16, 2018), www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-human-services-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf (focusing on preventing abuse of REMS process and spurring biologics competition, but noting the "limitations of antitrust enforcement" to address REMS abuses).

that elevate price above the competitive level. For almost 20 years the FTC has been challenging reverse payments (or pay-for-delay) made by branded pharmaceutical companies to generics in return for their promise to stay out of the market for some period of time, an enforcement effort that is ongoing.¹³ Product hopping has been successfully attacked by the New York State Attorney General.¹⁴ An investigation into collusion among generic drug manufacturers, underway at the Department of Justice, has resulted in criminal charges against two executives,¹⁵ along with a threat of a treble-damages action by the Justice Department to recover damages that the United States has sustained in overpaying for generic drugs.¹⁶ Forty-seven state attorneys general have filed a civil suit alleging damages to their governments and citizens arising out of generic company collusion.¹⁷

Nevertheless, the core problem remains. Prices for certain pharmaceutical drugs seem astonishingly high. Antitrust law outlaws non-competitive pricing in certain situations (cartels, for example), but can antitrust law be used to condemn high drug prices by themselves?

The conventional wisdom is that U.S. antitrust laws do not forbid high prices *simpliciter*, but I think that we are not forever condemned to that result. Closer examination of prior efforts to deal with excessive prices in other areas of the economy shows a willingness to take on excessively high prices, at least where the seller is exploiting what might be a temporary power to raise prices of much-needed products. Further, closer examination of antitrust case law shows that there is no direct precedent barring the courts from finding that raising prices to an excessive level is conduct that violates Section 2 of the Sherman Act. Indeed, decisions in the area of licensing of standard essential patents come close to condemning such pricing.

¹³ See Jonathan D. Rockoff, *Federal Trade Commission Questions Mylan on EpiPen*, WALL ST. J. (Jan. 30, 2017), www.wsj.com/articles/federal-trade-commission-questions-mylan-on-epi-pen-1485816270 (discussing the FTC's investigation of Mylan's alleged efforts to block Teva from getting approval for generic EpiPen). For a review of FTC and private litigation involving pay-for-delay and sham pharmaceutical patent enforcement, see Matthew Perlman, *Actavis at 5: Where Pay-For-Delay Litigation Stands*, LAW360 (Aug. 6, 2018).

¹⁴ See *New York v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

¹⁵ See Press Release, U.S. Dep't of Justice, *Former Top Generic Pharmaceutical Executives Charged with Price-Fixing, Bid-Rigging and Customer Allocation Conspiracies* (Dec. 14, 2016), www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer.

¹⁶ See Caroline Chen & David McLaughlin, *Generic-Drug Firms Fall as U.S. Threatens to Sue for Damages*, BLOOMBERG (Jan. 19, 2018) (quoting Assistant Attorney General Delrahim as saying, "To the extent that taxpayers have had to pay that bill, I think the taxpayers should recover").

¹⁷ See Erica Orden, *States Sue Generic-Drug Companies over Price-Fixing Allegations*, WALL ST. J. (Dec. 15, 2016), www.wsj.com/articles/states-sue-generic-drug-companies-over-price-fixing-allegations-1481820123.

My argument for antitrust consideration of excessive drug pricing begins with a more general discussion of the problem of high prices and two examples of a non-antitrust approach to this problem. I then focus on the current antitrust approach to excessive pricing and the assumed inapplicability of Section 2 of the Sherman Act to a monopolist's excessive pricing. I compare that approach to how U.S. courts and enforcers have handled standard essential patent licensing and how competition law enforcers outside the United States are now tackling the issue of excessive pharmaceutical drug pricing as an abuse of dominance. I then look at three examples of excessive pricing of pharmaceutical drugs, arguing that excessive pricing could be the basis of antitrust liability under Section 2 in each case. I conclude with some suggestions for how an antitrust enforcement program in this area might proceed.¹⁸

I. THE GENERAL PROBLEM

A. WHAT'S WRONG WITH HIGH PRICES?

The standard antitrust/welfare economics paradigm condemns high prices at least on the grounds of resource misallocation and deadweight welfare loss. Output is reduced, resources are misdirected to less desired goods or services, and the value of the preferred goods that are not produced is lost.¹⁹ Many scholars go beyond the deadweight welfare loss, condemning monopoly pricing because of the redistribution of the consumer surplus from consumers to producers, but some are indifferent to this redistribution.²⁰

Although monopoly pricing has been condemned as a general matter, not everyone agrees that monopoly pricing is always bad. Some economists and

¹⁸ Although I focus my argument on Section 2 of the Sherman Act, I do not mean to exclude the possibility that the FTC could proceed against excessive prices under Section 5 of the FTC Act as an unfair method of competition, using a stand-alone theory of liability. See *infra* note 103 and accompanying text. See also Harry First, *Unfair Drug Prices and Section 5*, CPI ANTI-TRUST CHRON. (Nov. 2015), ssrn.com/abstract=2699843.

¹⁹ The extent to which output is restricted depends, of course, on the particular product in question. Goods with a highly inelastic demand (like certain pharmaceutical drugs) might experience a small reduction in output but an extreme increase in price.

²⁰ Compare, e.g., Robert H. Lande, *Wealth Transfers as the Original and Primary Concern of Antitrust: The Efficiency Interpretation Challenged*, 34 HASTINGS L.J. 65, 69–70 (1982) (“[T]he antitrust laws were passed primarily to further what may be called a distributive goal, the goal of preventing unfair acquisitions of consumers’ wealth by firms with market power.”) with ROBERT H. BORK, *THE ANTITRUST PARADOX* (1978) (indifference to distribution between producers and consumers). There is an additional distributional consideration. Not only will consumers bear the brunt of a price increase (in one way or another—for pharmaceutical drugs, perhaps through higher insurance premiums), but the increase can have important distributional effects if the higher priced goods can be purchased only by wealthier consumers. For a macro view of the overall effect of “overcharges” on the distribution of income, see Rory Van Loo, *Consumer Law as Tax Alternative 6*, N.C. L. REV. (forthcoming) (Feb. 25, 2018 manuscript, on file with author) (estimating that “removing overcharge [throughout the economy] would reduce the top households’ share of income from 20% closer to 15%”).

courts have focused on the dynamic benefits of monopoly pricing. Monopoly pricing can incentivize innovation and investment, offering greater reward for risky endeavors. Monopoly pricing also carries with it the seeds of its own destruction, signaling firms that there are extra profits to be made if they enter. A dynamic economy might thrive on some degree of monopoly pricing, at least for some limited amount of time.²¹

Whatever the antitrust view of high prices, there is an additional argument that can be made against high prices, but it is one to which antitrust is often indifferent. High prices can be seen as unfair in certain situations. Common discourse confirms this view—“profiteering,” “price gouging,” and “manipulation” are labels often attached to certain kinds of pricing decisions. These terms are used when sellers take advantage of the situation in which buyers find themselves, often in times of shortage or because of a particular need. For one reason or another, buyers are at the mercy of a seller that can easily take advantage of the situation to hold up the buyer and demand more for its product or service than it should be worth. Sellers can exploit buyers.

The law is rich with examples of efforts to deal with this problem of fairness, efforts that far predate the elaboration of welfare economics. The common law imposed duties of reasonable pricing on those who pursued “public” or “common callings,” such as innkeepers, carriers, ferrymen, and even surgeons.²² Legislation widened the group to include grain elevator operators, railroads, water companies, and the like.²³

This legal response to high prices has taken a number of forms beyond general common law duties or public utility regulation, of course, but I want to focus on two that show both a willingness to take on high prices in situations relevant to drug prices as well as some of the problems in doing so—post-World War I shortages and electric utility surge pricing.

²¹ See *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (“The opportunity to charge monopoly prices—at least for a short period—is what attracts ‘business acumen’ in the first place; it induces risk taking that produces innovation and economic growth.”) (emphasis added).

²² See Bruce Wyman, *The Law of the Public Callings as a Solution of the Trust Problem*, 17 HARV. L. REV. 156 (1904); Charles K. Burdick, *The Origin of the Peculiar Duties of Public Service Companies*, 11 COLUM. L. REV. 514, 515 (1911).

²³ See, e.g., *Munn v. Illinois*, 94 U.S. 113 (1876) (grain elevators); *Spring Valley Water Works v. Schottler*, 110 U.S. 347 (1884) (water); *New Orleans Gas-Light Co. v. Louisiana Light & Heat Producing & Mfg. Co.*, 115 U.S. 650 (1885) (lighting); *Georgia R.R. & Banking Co. v. Smith*, 128 U.S. 174 (1888) (railroads); see also Edgar Watkins, *The Law and The Profits*, 32 YALE L.J. 29 (1922) (discussing price regulation by governments since Hammurabi, usually done in emergency situations).

B. POST-WORLD WAR I SHORTAGES

In 1917 Congress enacted the Lever Food and Fuel Control Act to deal with the problem of high pricing of certain “necessaries”—foods, feeds, fuels, and fertilizer—at a time when there were shortages of these products. The Act made it a violation to charge an “unjust or unreasonable” price for these necessities or to conspire “to exact excessive prices” for them.²⁴ The Lever Act was passed as a wartime measure, set to lapse on a declaration from the President that the state of war was at an end.²⁵ Rather than allowing the law to lapse, however, in 1919 Congress extended the statute and made its violation criminal.²⁶

The Lever Act did not survive constitutional challenge. In *United States v. L. Cohen Grocery Co.*, decided in 1921, the Supreme Court posed the question whether the words “unjust or unreasonable” in the Act fixed an “ascertainable standard of guilt and are adequate to inform persons accused of violation thereof of the nature and cause of the accusation against them.”²⁷ The Court held that they did not, a result so clear, the Court wrote, that “their mere statement . . . render[s] elaboration on the subject wholly unnecessary.”²⁸

But the Court did elaborate a bit. “[T]he section forbids no specific or definite act,” the Court wrote, and therefore leaves open “the widest conceivable inquiry, the scope of which no one can foresee and the result of which no one can foreshadow or adequately guard against.”²⁹ The Court also cited to the difficulties that the lower courts had in prosecutions of retail grocers, for example, trying to figure out whether the seller’s profit was the critical factor making the prices “excessive,” or whether the critical factor was the price that the seller paid for the goods, or whether the seller was exceeding the profit “established generally in the trade.”³⁰

Although the Court did not have much difficulty reaching its decision in *L. Cohen Grocery*, the case was actually decided in the middle of a scrum of difficult cases dealing with legislative efforts to control not only high pricing but anticompetitive conduct more broadly. The decisions in these cases are hard to reconcile, and the Court struggled with them. The line that eventually

²⁴ Food Fuel and Control Act, Pub. L. 64–41, 40 Stat. 276, 277 (1917) (repealed 1921).

²⁵ See Beirne Stedman, *Lever Act as a Civil Remedy*, 8 VA. L. REG. 641 (1923) (statute enacted to prevent profiteering immediately following World War I).

²⁶ 40 Stat. 276, amended by Food Control and the District of Columbia Rents Act, Pub. L. 66–63, 41 Stat. 297, 298 (1919).

²⁷ *United States v. L. Cohen Grocery Co.*, 255 U.S. 81, 89 (1921).

²⁸ *Id.*

²⁹ *Id.*

³⁰ See *id.* at 90 n.1. The Court subsequently refused to distinguish *L. Cohen Grocery* on the basis that it was a criminal prosecution, holding that even civil enforcement could not survive a due process attack. See *A.B. Small Co. v. Am. Sugar Ref. Co.*, 267 U.S. 233, 238–39 (1925).

emerged was that the surrounding commercial practice or common law understanding could fill in the notice gap in what was otherwise vague language.

In *Nash v. United States*, for example, the Court was willing to uphold the Sherman Act as constitutional, despite the vagueness of the rule of reason as adopted in *Standard Oil* two years earlier.³¹ On the other hand, in *Cline v. Frink Dairy*, the Court was unwilling to uphold a Colorado antitrust law that provided a defense to price-fixing agreements where the defendant's purpose was to make a "reasonable profit" and there was no other way to do so.³² The Court in *Cline* pointed out that the interpretation of the Sherman Act was informed by the common law understanding of what restraints of trade might be "reasonable."³³ The Colorado statute, however, involved "so many factors of varying effect" that it would be "an utterly impracticable standard for a jury's decision."³⁴

Similarly, in *Edgar A. Levy Leasing Co. v. Siegel* the Court upheld the New York State Emergency Housing Laws that allowed tenants in certain cities to defend against claims for unpaid rent when that rent was "unjust" and "unreasonable" and "oppressive."³⁵ The housing law was enacted because of a shortage of rental housing in the New York City area after World War I, which allowed landlords to "[take] advantage of the situation to exact . . . whatever exorbitant rents the necessities of the occasion would bring forth."³⁶ The Court eventually drew a distinction between the New York housing statute and the Lever Act on the ground that the real estate market was more stable than the commodities market, making valuations simpler, and so the housing law gave more guidance as to whether the rent charged was unjust and unreasonable.³⁷

Although the constitutional boil over these cases has subsided, these cases do provide some useful lessons. First, whether seen as a constitutional or a policy matter, the cases remind us that some guideposts are necessary when prohibiting excessive prices, although these guideposts need not be spelled out in a statute but can come from business practice and court decisions.³⁸

³¹ *Nash v. United States*, 229 U.S. 373 (1913).

³² See *Cline v. Frink Dairy Co.*, 274 U.S. 445 (1927).

³³ As Taft had so brilliantly displayed in *United States v. Addyston Pipe & Steel Co.*, 85 F. 271 (6th Cir. 1898), which he quoted in *Cline*, 274 U.S. at 461-63.

³⁴ *Cline*, 274 U.S. at 465.

³⁵ *Edgar A. Levy Leasing Co. v. Siegel*, 258 U.S. 242, 249 (1922).

³⁶ *People ex rel. Durham Realty Corp. v. La Fetra*, 130 N.E. 601, 604 (N.Y. 1921).

³⁷ See *A.B. Small Co. v. Am. Sugar Ref. Co.*, 267 U.S. 233, 241-42 (1925). The New York statute also provided that increases over a prior year's rent were "presumptively unjust, unreasonable and oppressive." *Edgar A. Levy Leasing Co. v. Siegel*, 130 N.E. 923, 925 (N.Y. 1921) (McLaughlin, J., dissenting).

³⁸ See *United States v. Nat'l Dairy Prods. Corp.*, 372 U.S. 29, 35-36 (1963) (holding Section 3 of the Robinson-Patman Act, criminalizing sales at "unreasonably low prices," was constitu-

Second, these cases remind us that the legislative willingness to protect consumers from excessive pricing did not depend on the existence of monopoly power as that concept has come to be applied in antitrust cases. Rather, the government acted to prevent the exploitation of consumers when sellers, in a time of shortage, had the power to raise prices on necessary products, such as food and housing. Applying Section 2 to exploitation in the pricing of pharmaceutical drugs would actually target a more limited set of cases than legislatures in the past have targeted. Third, these cases show that there is a rich history of using basic law enforcement tools to attack excessive pricing.

C. ELECTRICITY PRICE SURGES AND MANIPULATION

The regulation of electricity pricing in the United States has undergone a long, expensive, and interesting evolution, from full federal and state regulatory agency control of pricing to today's very mixed system that has injected market institutions into electricity pricing in wholesale and retail markets.³⁹ The movement from regulated rates to market-set rates, however, has hardly been smooth.

Critical to the movement to market-set pricing has been the establishment of electricity pricing exchanges in wholesale markets.⁴⁰ These exchanges (run by independent system operators and regional transmission organizations) have created time-of-day auction markets where generators bid available capacity into the market and distribution companies bid for electricity based on their demand at a specific time of day. The exchanges are supervised in a general way by state and federal regulators, but the prices are set by supply and demand.

The outcomes of these market-set prices, however, have not always seemed desirable. Take what happened on June 26, 2000. On that day a price spike occurred in parts of New York State's day-ahead electric power market. For five consecutive hours (from 1:00 pm through 6:00 pm), Consolidated Edison paid more than \$1,000 per MWH for electricity. That price spike resulted in a

tional, distinguishing it from *L. Cohen Grocery* on the ground that "the standard held too vague in *Cohen* was without a meaningful referent in business practice or usage").

³⁹ For a description, see, for example, PAUL L. JOSKOW & RICHARD SCHMALENSEE, *MARKETS FOR POWER: AN ANALYSIS OF ELECTRIC UTILITY DEREGULATION* (1983) (early efforts); Severin Borenstein & James Bushnell, *The US Electricity Industry After 20 Years of Restructuring*, 7 *ANN. REV. ECON.* 437 (2015).

⁴⁰ See THE ELECTRIC ENERGY MARKET COMPETITION TASK FORCE, *REPORT TO CONGRESS ON COMPETITION IN WHOLESALE AND RETAIL MARKETS FOR ELECTRIC ENERGY* 53–84 (2007), www.ferc.gov/legal/fed-sta/ene-pol-act/epact-final-rpt.pdf (describing wholesale markets); NEW YORK STATE DEP'T OF PUBLIC SERV., *STAFF REPORT ON THE STATE OF COMPETITIVE ENERGY MARKETS: PROGRESS TO DATE AND FUTURE OPPORTUNITIES* 5–27 (2006), www3.dps.ny.gov/pscweb/WebFileRoom.nsf/ViewCat?ReadForm&View=ArticlesByCategory&Cat=Staff+Reports&Count=10 (describing New York wholesale markets).

30 percent increase in the average wholesale price of electricity for the month and is estimated to have increased the cost of electricity by more than \$100 million over the price for electricity on the same day but at a different time.⁴¹

Of course there were good reasons for the spike. It was hot. People cranked up their air conditioners. Increased demand called on more expensive peaking generators. Because price was set at marginal cost, all the electricity demanded during that period was priced at the high cost of the marginal megawatt hour.

Nevertheless, despite free-market arguments to the contrary, the New York Independent System Operator (NYISO) adopted a bidding cap after this incident, setting the cap at the highest price received that day, \$1,300 per MWH.⁴² A cap, now reduced to \$1,000 per MWH, remains in effect today.⁴³

In addition to being concerned about price surges that are responsive to legitimate high demand for electricity, the electricity exchanges have been concerned about the possibility of price manipulation through bidding strategies that can be particularly effective in periods when demand spikes. These bidding strategies can either be to withhold capacity from the market at certain times (on the ground that a generating unit is “out of service”) or strategically to put in an “unjustifiably high” bid that could “substantially distort or impair the competitiveness” of the market.⁴⁴ How to tell whether a bid was unjustifiably high? The NYISO will compare the bid to a “reference bid,” which is basically the price at which the operator bid the particular generating unit at the same time the previous year.⁴⁵ If the bid is 300 percent (or \$100 per MWH) higher, the bidder will be required to “mitigate” its bid and take a lower amount.⁴⁶

Electricity thus provides another interesting example of governmental willingness to intervene in certain specific situations to prevent excessive pricing, again in a product that we would consider a necessity. The market regulator involved (the independent system operator) generally relies on market forces to set prices, but it has still sought to prevent excessively high prices when markets don't produce the outcomes it seeks. As in the post-World War I cases, these high prices are not necessarily the result of monopoly power as

⁴¹ See Harry First, *Regulated Deregulation: The New York Experience in Electric Utility Deregulation*, 33 LOY. U. CHI. L.J. 911, 911–12 (2002).

⁴² See *id.* at 919.

⁴³ See N.Y. INDEP. SYS. OPERATOR, INC., MKT. ADMIN. AND CONTROL AREA SERVS. TARIFF, Attachment F, § 21.4 (Apr. 26, 2018), nyisoviewer.etariff.biz/ViewerDocLibrary/MasterTariffs/9FullTariff.pdf.

⁴⁴ See *id.*, Attachment H, §§ 23.2.3.1, 23.2.4.1.1, 23.2.4.1.2.

⁴⁵ See *id.* § 23.3.1.2.1.1.

⁴⁶ See *id.* § 23.4.2 (default bids).

we would define it for antitrust analysis. Rather, sellers find themselves able to exploit buyers because of the way these markets have been designed. Government intervention, if properly done, can correct market imperfections by establishing rules that produce better results. In the case of electricity, the NYISO's tariff rules provide relatively clear guideposts for telling producers when rates are excessive, an approach that satisfies the policy concerns articulated in the Supreme Court's early 20th century cases discussed above.

II. ANTITRUST'S CURRENT APPROACH TO HIGH PRICES

A. THE CONVENTIONAL WISDOM

The conventional wisdom in antitrust is that monopoly pricing is not a violation of Section 2 of the Sherman Act. The Supreme Court said so most recently in *linkLine*: “[A]ntitrust law does not prohibit lawfully obtained monopolies from charging monopoly prices.”⁴⁷ For this proposition, the Court relied on a similar statement in *Trinko*, which actually pressed the point further.⁴⁸ Charging monopoly prices is not only “not unlawful,” the Court in *Trinko* wrote, “it is an important element of the free-market system.”⁴⁹ The opportunity to charge monopoly prices, “at least for a short period” incentivizes the risk taking “that produces innovation and economic growth.”⁵⁰ This is why the possession of monopoly is not a violation of Section 2 unless “accompanied by an element of anticompetitive conduct.”⁵¹ Similar statements can be found in lower court opinions as well.⁵²

Closer examination of this line of authority, however, suggests that a different result might be possible: that is, excessive pricing could satisfy the monopolistic conduct requirement. In fact, there is no case holding that a monopolist's conduct in raising its price to an excessively high amount, or even that the charging of a monopoly price, is lawful under Section 2.

I start with *linkLine*. In *linkLine* the Court was presented with a claim that AT&T had tried to squeeze the plaintiffs out of the retail market for high-speed internet connection by keeping a small spread between the price it charged the plaintiffs for interconnection to the local loop and the price it was

⁴⁷ *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 454 (2009).

⁴⁸ *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *See, e.g.*, *Rambus Inc. v. FTC*, 522 F.3d 456, 464 (D.C. Cir. 2008); *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995); *Ball Mem'l Hosp., Inc. v. Mutual Hosp. Ins.*, 784 F.2d 1325, 1339 (7th Cir. 1986); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 274 n.12 (2d Cir. 1979) (“Nor is a lawful monopolist ordinarily precluded from charging as high a price for its product as the market will accept.”).

charging consumers for internet access, the market in which it competed with the plaintiffs.⁵³ The plaintiffs had alleged only that the wholesale price was “high” in relation to the retail price, not that the defendant was charging a monopoly price at wholesale or that its price was excessive.⁵⁴ The purpose of AT&T’s price squeeze was to exclude the plaintiffs from the internet service provider market, not to extract monopoly profits from them as consumers.⁵⁵

The Supreme Court rejected the plaintiffs’ theory on two grounds: the defendant had no “antitrust duty to deal” with the plaintiffs at wholesale (so the wholesale price was irrelevant) and, as it appeared to the Court, the plaintiffs had not alleged that the low retail price was predatory under the *Brooke Group* test.⁵⁶ The case was “thus nothing more than an amalgamation of a meritless claim at the retail level and a meritless claim at the wholesale level.”⁵⁷

Given the plaintiffs’ allegations, and their theory of competitor exclusion rather than consumer harm, the Court’s expansive statements about the freedom of “lawfully obtained monopolies” to charge “monopoly prices” is raw dictum.⁵⁸ The Court relied on *Trinko* for this proposition, but *Trinko* doesn’t make the case any stronger. *Trinko* itself was not about charging high prices (Verizon’s regulated prices were actually low) but about dealing in ways that were intended to harm its competitors. Indeed, *Trinko* cited no cases in support of its view that charging high prices is a fine idea.

Alcoa is another case that has been cited for the proposition that a monopolist is “free . . . to charge a monopoly price.”⁵⁹ Closer examination shows, however, that the case is, at most, ambiguous on the point.

In *Alcoa* the government, as part of its proof that Alcoa had violated Section 2, presented evidence that Alcoa had earned exorbitant profits on the sale of virgin aluminum ingot,⁶⁰ a contention that the district court had rejected.⁶¹ Hand wrote that Alcoa’s profits actually might not be “extortionate” as a factual matter, but then resolved the issue by holding that it was enough for the

⁵³ Pac. Bell Tel. Co. v. linkLine Commc’ns, Inc., 555 U.S. 438, 442 (2009).

⁵⁴ *Id.*

⁵⁵ *Id.* at 443.

⁵⁶ *Id.* at 449, 451.

⁵⁷ *Id.* at 451.

⁵⁸ *Id.* at 454.

⁵⁹ See Donald F. Turner, *The Definition of Agreement Under the Sherman Act: Conscious Parallelism and Refusals to Deal*, 75 HARV. L. REV. 655, 667 (1962) (citing United States v. Aluminum Co. of Am. 148 F.2d 416, 429–30 (2d Cir. 1945)).

⁶⁰ See United States v. Aluminum Co. of Am., 44 F. Supp. 97, 286 (S.D.N.Y. 1941) (noting that the government had made two accusations “which were much emphasized,” that Alcoa charged “extortionate prices” and made “exorbitant profits”).

⁶¹ See United States v. Aluminum Co. of Am., 148 F.2d 416, 426 (2d Cir. 1945) (*Alcoa*).

government to prove that Alcoa had a monopoly on ingot.⁶² Were the fairness of profits relevant, that would be an “excuse” for the defendant to prove, but Hand held the issue “irrelevant anyway” because “it is no excuse for ‘monopolizing’ a market that the monopoly has not been used to extract from the consumer more than a ‘fair’ profit.”⁶³

Does Hand’s resolution of this issue imply the opposite, that monopoly pricing, if proved, would violate the Sherman Act because the defendant would be “extracting” from consumers *more* than a fair profit? Or does it just mean that monopoly can’t be justified by reasonable pricing?

The next part of the court’s opinion indicates that Hand likely meant that low prices are no defense to monopolization and was not considering whether rent extraction is itself a violation. Hand pointed out that if agreements fixing prices are “unconditionally condemned,” then a monopolist’s pricing should also be condemned, because price-fixing agreements “are only steps toward that entire control which monopoly confers.”⁶⁴ But even though collusive control of pricing would violate Section 1, Hand does not rest liability under Section 2 on a monopolist’s control of pricing (without regard to whether the prices set are extortionate or not). Instead, Hand’s interpretation of Section 2 relies on grammar and on policy. Grammatically, “monopolizing” is a verb, so just being a monopoly (and having control over its prices) should not be enough for liability. As for policy, although having only one firm in the market “may expose the public to the evils of monopoly,” nevertheless, “the successful competitor, having been urged to compete, must not be turned upon when he wins.”⁶⁵ But this solicitude appears more based on a concern for fairness in a market system that prizes competition rather than on a desire to incentivize firms to seek monopoly. After all, because “the Act makes ‘monopolizing’ a crime, as well as a civil wrong, it would be not only unfair, but presumably contrary to the intent of Congress” to penalize a firm that has a natural monopoly, or becomes a monopolist by “force of accident,” or that outlasts its rivals through “superior skill, foresight, and industry.”⁶⁶

Hand ultimately rested liability on exclusion, arguing that Alcoa’s course of conduct, “indefatigably pursued,” was an “abuse,” enabling it to maintain its control of the aluminum ingot market.⁶⁷ Even the court’s consideration of the

⁶² *Id.* at 427.

⁶³ *Id.*

⁶⁴ *Id.* at 428.

⁶⁵ *Id.* at 430.

⁶⁶ *See id.*

⁶⁷ *See id.* at 430–31 (“[W]e can think of no more effective exclusion than progressively to embrace each new opportunity as it opened, and to face every newcomer with new capacity already geared into a great organization, having the advantage of experience, trade connections and the elite of personnel”).

government's price-squeeze claim in the case was focused on exclusion, just like the Supreme Court's subsequent consideration of the price squeeze in *linkLine*. Unlike in *linkLine*, however, the court in *Alcoa* was willing to find liability for pricing monopolized ingot above a "fair price," but not because it was illegal to sell a monopolized product at a monopoly price, but because of the exclusionary impact of Alcoa's price squeeze on downstream competition in the aluminum sheet market.⁶⁸

Although these decisions, carefully read, do not actually reject Section 2 liability for excessive pricing, commentators have readily taken the view that monopoly pricing is perfectly lawful under Section 2. The canonical article is Donald Turner's article on agreement under the Sherman Act.⁶⁹ In this article Turner is trying to distinguish the proper treatment of interdependent consciously parallel decisions on basic price (which he calls pure oligopoly pricing) from other kinds of interdependent pricing decisions.⁷⁰ He argues that pure oligopoly pricing under Section 1 should not be a violation of Section 1 (without regard to how one defines "agreement" under Section 1) in part because pure monopoly pricing is not illegal under Section 2: "If monopoly and monopoly pricing are not unlawful per se, neither should oligopoly and oligopoly pricing [be unlawful]. . . ."⁷¹ Turner's case law support for the proposition that monopoly pricing is not unlawful, however, is *Alcoa* and two other cases that he reads broadly, even though none of them involved the legality of excessive pricing under Section 2.⁷²

⁶⁸ See *id.* at 436–38. It was this consideration of high prices that the Court in *linkLine* swept away in a footnote. See *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 452 n.3 (2009). Note that Hand rejected the price-squeeze claim in the aluminum cable market because aluminum cable competed with copper cable and there was no proof that a reduction in ingot prices would have left enough "spread" for independent aluminum cable fabricators to compete with Alcoa. See *Alcoa*, 148 F.2d at 438. This is a further indication that Hand was focused on exclusion, not monopoly pricing.

⁶⁹ See Turner, *supra* note 59. For more recent affirmations that Section 2 does not reach excessive pricing, see, for example, the United States submission to the OECD, *Excessive Prices 2* (Oct. 2011), www.justice.gov/sites/default/files/atr/legacy/2014/05/30/278823.pdf (DAF/COMP/WP2/WD(2011)65); cf. Jonathan B. Baker, *Exclusion as a Core Competition Concern*, 78 ANTITRUST L.J. 527, 533 n.24 (2012) (Sherman Act does not reach exploitative offenses such as charging higher prices). For articles that criticize high pharmaceutical prices but that make the same assumption about Section 2, see Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 285–89 (2016) (addressing the problem of excessive pricing from a global competition law and policy perspective), and Jennifer L. Graber, Note, *Excessive Pricing of Off-Patent Pharmaceuticals: Hatch It or Ratchet?*, 92 N.Y.U. L. REV. 1146, 1183–84 (2017) (even though Section 2 does not apply to excessive pharmaceutical prices, Section 5 of the FTC Act might).

⁷⁰ See Turner, *supra* note 59, at 663, 673. By "basic price," Turner means price before discounts, quality extras, transportation, "and the like." *Id.* at 673.

⁷¹ *Id.* at 667–68.

⁷² See *id.* at 667 n.15 (referring to *Alcoa*, *American Tobacco Co. v. United States*, 328 U.S. 781 (1946) (exclusionary agreements), and *United States v. United Shoe Mach. Corp.*, 110 F. Supp. 295 (D. Mass. 1953) (lease-only policy)).

Turner's real argument is based not on case law but on policy. Interpreting the Sherman Act to prohibit monopoly pricing (or to prohibit pure oligopoly pricing) is "wholly unsupportable" because it would invoke a "purely public-utility interpretation of the Sherman Act" and require the courts "to act as price regulators for all businesses possessing substantial monopoly power."⁷³ Instead, Turner favored a "no fault" monopolization offense for significant and persistent monopolies, and saw nothing in the language, legislative history, or precedent under Section 2 that would preclude it:⁷⁴ "The evils of monopoly are largely independent of the manner in which it is achieved or maintained. Even innocently obtained monopoly can and likely will produce monopoly pricing."⁷⁵ The proper remedy, Turner argued, was not to enjoin the high pricing, but to end the monopoly through dissolution or divestiture.⁷⁶

The policy argument that Turner raises against making monopoly pricing itself unlawful is the same one to which the Court refers in *linkLine* in its discussion of administrability.⁷⁷ It is not without merit. In part it goes to the argument the Supreme Court was addressing in its constitutional cases—can we come up with some institutionally administrable approach to reprehend monopoly pricing?

Of course, administrability is not the only policy argument that a prohibition on excessive pricing raises. Courts do need to be concerned about the effect of such a prohibition on incentives and with whether high prices will self-destruct without judicial intervention because high prices invite entry.⁷⁸ If high prices carry the seeds of their own destruction, courts might justifiably be hesitant to get involved.

The important point to take away from a review of the conventional wisdom regarding Section 2's ability to reach excessive pricing is that a fresh consideration of the policy arguments that excessive pricing raises is not foreclosed as a matter of law. If one believes that antitrust law is basically a matter of common law development,⁷⁹ bounded at some point, of course, by

⁷³ *Id.* at 668–69.

⁷⁴ Donald F. Turner, *The Scope of Antitrust and Other Economic Regulatory Policies*, 82 HARV. L. REV. 1207, 1220–21 (1969).

⁷⁵ 3 PHILLIP AREEDA & DONALD F. TURNER, ANTITRUST LAW ¶ 614, at 35 (1978).

⁷⁶ Turner, *supra* note 74, at 1214 ("I believe it would be sounder economic policy to apply divestiture remedies to the most serious, persistent, and economically significant monopolies . . .").

⁷⁷ See *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 452–53 (2009).

⁷⁸ See United States submission to the OECD, *Excessive Prices*, *supra* note 69, at 4 ("High prices also typically attract new market entry, by producers lured by the lucrative profits to be made, thus promoting output.")

⁷⁹ See, e.g., *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 899 (2007); *cf. Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2413 (2015) ("By contrast with the Sherman Act, the patent laws do not turn over exceptional law-shaping authority to the courts.")

statutory language and legislative purpose, then the courts should be able to question the premises for not reaching excessive pricing under Section 2 when done to exploit consumers. No precedent forces a court to reject such a claim.

B. SEPs AND FRAND LICENSING

One reason why courts should reconsider the ready assumption that Section 2 does not reach excessive pricing is because we do actually condemn high prices in many areas of antitrust law. Firms can't merge if we think we can predict that the merged firm could raise its prices unilaterally,⁸⁰ and the government has brought suit against mergers that it believes will put the merged firm in a stronger bargaining position that will enable it to raise its prices to the detriment of consumers.⁸¹ Cartelists who agree to raise prices go to jail. Their firms are then sued for treble-damages for the overcharges, overcharges that are based on the difference between the prices they charge and the "but-for" competitive price, something that economists are often called on to figure out. Buyers that pay too much because of a defendant's violation of Section 2 can sue for the overcharge.⁸² Monopolists that price below variable cost and then raise their prices to monopoly levels can be sued for predatory pricing.

These are familiar examples of antitrust's concern with high prices, but there is one less familiar area in which high prices (rather than exclusion or collusion) have been an antitrust concern—the licensing of standard essential patents (SEPs) that carry a commitment to license on fair and reasonable terms (FRAND). Breach of this commitment has drawn FTC and private enforcement, as well as Justice Department and Patent and Trademark Office attention, and the high prices have been asserted as a type of competitive harm.

FRAND licensing obligations have arisen in the context of the establishment of industry standards that allow interoperability among diverse products. These standards have been adopted through the efforts of private industry standard-setting organizations (SSOs) and have been particularly important in

⁸⁰ See U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 6.1 (2010), www.ftc.gov/os/2010/08/100819hmg.pdf ("A merger between firms selling differentiated products may diminish competition by enabling the merged firm to profit by unilaterally raising the price of one or both products above the pre-merger level.").

⁸¹ See *United States v. AT&T Inc.*, 310 F. Supp. 3d 161 (D.D.C. 2018) (alleging that merger of video program provider and distributor would lead to net increased prices to consumers of at least \$286 million annually) (District court rejects government claim as not supported by the evidence).

⁸² See *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 489 (1968) ("We think it sound to hold that when a buyer shows that the price paid by him for materials purchased for use in his business is illegally high [because of a Section 2 violation] and also shows the amount of the overcharge, he has made out a prima facie case of injury and damage within the meaning of § 4 [of the Clayton Act].").

high technology industries, such as electronics and communications equipment, where common platforms are necessary if firms are to manufacture compatible but competing products.

SSOs have required FRAND commitments to diminish opportunistic behavior by patent holders. Once a standard is set, implementers of that standard are likely to make substantial investments in standards-compatible products and to become effectively locked into the standard. Absent a FRAND commitment, patent holders could exploit (hold up) licensees for high royalties, not because of the intrinsic innovative value of the patent but because of the value of the investments that the potential licensee has made.⁸³

The FRAND commitment was meant to curb exploitation, but patent holders have not always abided by their commitments, and litigation has been a frequent result. In this litigation (even in contract litigation) the focus has been on high prices as a competitive harm, although the antitrust cases are often framed around what might be seen as enabling conduct so as to avoid tackling directly the legality of the excessive pricing.

One example is a Sherman Act suit brought against Qualcomm by Broadcom, a manufacturer of chipsets for mobile phones using the Wide Band Code Division Multiple Access standard (WCDMA), a telephony standard for which Qualcomm's patents were essential.⁸⁴ Broadcom alleged that Qualcomm had monopolized the WCDMA technology market by making a "false promise" to license its WCDMA essential patents on FRAND terms, a promise on which the relevant standards development organizations relied when adopting the WCDMA standard.⁸⁵ Instead, Broadcom alleged, Qualcomm had refused to license its technology on FRAND terms.⁸⁶

The district court dismissed the complaint, but the court of appeals reversed, finding that Broadcom's allegation of deception satisfied Section 2's conduct requirement.⁸⁷ But the court's policy concerns were not focused on

⁸³ See, e.g., Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991 (2007). During the Obama administration the Antitrust Division had been concerned about the possibility of patent holdup and the ability of SEP holders to obtain "unwarranted higher royalties" that increase prices to consumers. See U.S. Department of Justice & U.S. Patent & Trademark Office, *Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary FRAND Commitments* 4 (2013), www.justice.gov/atr/page/file/1118381/download. In the Trump administration, however, the Antitrust Division shifted its views and became skeptical that holdup actually exists. See Makan Delrahim, Assistant Att'y Gen., Antitrust Div., U.S. Dep't of Justice, Speech at USC Gould School of Law, *Take It to the Limit: Respecting Innovation Incentives in the Application of Antitrust Law 3-7* (Nov. 10, 2017), www.justice.gov/opa/speech/file/1010746/download.

⁸⁴ See *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007).

⁸⁵ See *id.*, 501 F.3d at 315.

⁸⁶ See *id.*

⁸⁷ See *id.* at 313.

the evils of deception. (In fact, it wasn't clear from the complaint whether the deception was anything more than the failure to license at FRAND rates.) Rather, the court focused on the ill effects of Qualcomm's high pricing: "In [its] unique position of bargaining power, the patent holder may be able to extract supracompetitive royalties from the industry participants."⁸⁸ Qualcomm's alleged deception "harms the competitive process by obscuring the costs of including proprietary technology in a standard[.]"⁸⁹

Two FTC cases show a similar concern for excessively high royalties in the context of FRAND licensing of SEPs. The first was brought in 2008 against Negotiated Data Solutions (N-Data).⁹⁰ *N-Data* involved the standard-setting process, but not a commitment to license on undefined FRAND terms. Rather, in the course of an SSO's adopting an Ethernet standard that allowed backward compatibility, N-Data's predecessor had promised to license the patents covering the technology to any requesting party for a one-time fee of \$1,000.⁹¹ The relevant patents were later assigned to another company, and eventually to N-Data.⁹² The later assignees, although aware of the commitment, decided that the patents were worth more and set out to collect the higher royalties from a group of target companies that included many large computer hardware manufacturers.⁹³ The royalties demanded represented a "substantial increase" over the original \$1,000 fee.⁹⁴

The FTC's complaint charged that N-Data's practices were "unfair methods of competition" in violation of Section 5 of the FTC Act.⁹⁵ The "threatened or actual anticompetitive effects," the FTC asserted, included "increased royalties" for the manufacture or sale of products that implement the standard.⁹⁶ As the Commission explained, N-Data's efforts to "exploit the power it enjoys" over firms locked into the standard were inherently "oppressive" and adversely affected competition because of its "adverse impact on prices" for the technology N-Data controlled.⁹⁷

⁸⁸ *Id.* at 310.

⁸⁹ *Id.* at 314. For a more recent antitrust case making similar allegations, see *Microsoft Mobile Inc. v. InterDigital, Inc.*, No. 15-723-RGA, 2016 U.S. Dist. LEXIS 49498, at *2-3 (D. Del. Apr. 13, 2016) (alleging monopolization of technology markets by falsely promising to license its SEPs on FRAND terms and then demanding "exorbitant royalties") (denying motion to dismiss).

⁹⁰ Complaint, Negotiated Data Sols. LLC, FTC Docket No. C-4234 (Sept. 23, 2008), www.ftc.gov/sites/default/files/documents/cases/2008/09/080923ndscomplaint.pdf.

⁹¹ *See id.* ¶¶ 12-13.

⁹² *See id.* ¶¶ 23, 33.

⁹³ *See id.* ¶ 28.

⁹⁴ *See id.*

⁹⁵ *Id.* ¶ 38.

⁹⁶ *Id.* ¶ 37.

⁹⁷ *See* Analysis of Proposed Consent Order to Aid Public Comment 5, Negotiated Data Sols. LLC, FTC File No. 051-0094 (Jan. 23, 2008) [hereinafter Analysis of Proposed Consent Order, N-Data], www.ftc.gov/sites/default/files/documents/cases/2008/01/080122analysis.pdf.

A similar concern for excessively high royalties can be found in the FTC's 2013 complaint against Google. In this case the alleged unfair method of competition was Google's breach of commitments to license certain SEPs on FRAND terms, commitments to which its newly acquired subsidiary, Motorola Mobility, had previously agreed.⁹⁸ The breach was alleged to be the likely result of Google's prosecution of claims for infringement of its SEP patents before the International Trade Commission and the courts, seeking, respectively, exclusion orders and injunctions.⁹⁹

Of course, patent holders are generally thought to be able to seek this sort of relief when their patents are infringed, so why are such relief requests an "unfair method of competition" when FRAND-committed SEPs are involved? The Commission explained: Threats to use injunctions to deprive implementers of future sales allowed Google to "demand licensing terms that tended to exceed the FRAND range."¹⁰⁰ Although the Commission pointed to a number of anticompetitive effects that could arise from Google's breach of its FRAND commitment, such as undermining the integrity of the standard-setting process and raising rivals' costs in the handset market, the "substantial consumer injury" the Commission alleged was higher prices:¹⁰¹ "If Google's practices are allowed to continue, many consumer electronics manufacturers will agree to pay unreasonable royalties simply to avoid an injunction or exclusion order. Manufacturers will likely pass on some portion of these costs to end consumers."¹⁰²

The three cases involving SEPs and FRAND licensing are not direct precedent for applying Section 2 to excessive pricing. For one, neither *N-Data* nor *Google* were decided as Sherman Act cases. The Commission charged the respondents in both cases with engaging in "unfair methods of competition" in violation of Section 5 of the FTC Act on the basis of its stand-alone authority to prosecute anticompetitive conduct that harms consumers but may not violate the Sherman Act.¹⁰³ Nor was either case solely about price raising (al-

⁹⁸ See Complaint ¶ 1, Motorola Mobility LLC, FTC Docket No. C-4410 (July 24, 2013), www.ftc.gov/sites/default/files/documents/cases/2013/07/130724googlemotorolacmpt.pdf.

⁹⁹ See *id.* ¶¶ 25–27.

¹⁰⁰ *Id.* ¶ 25.

¹⁰¹ See *id.* ¶ 30. The Commission in *N-Data* also was concerned about the impact of N-Data's behavior on the standards-setting process and on innovation. See Analysis of Proposed Consent Order at 6, *N-Data*, *supra* note 97.

¹⁰² Complaint, Motorola Mobility LLC, *supra* note 98, ¶ 30.

¹⁰³ See Analysis of Proposed Consent Order at 4–5, *N-Data*, *supra* note 97; Analysis of Proposed Consent Order to Aid Public Comment at 4, Motorola Mobility LLC, File No. 121-0120 (Jan. 3, 2013), www.ftc.gov/sites/default/files/documents/cases/2013/01/130103googlemotorolaanalysis.pdf. The extent to which the Commission can go beyond the Sherman Act under Section 5 remains a highly contested issue, one that was not resolved by these cases because they were settled by consent. For a case combining Section 2 and a Section 5 stand-alone claim, see Complaint, *FTC v. Qualcomm*, No. 5:17-cv-00220 (N.D. Cal. Jan. 1, 2017) (alleging that SEP

though the other competitive effects were only sketchily described). Finally, neither the two FTC cases nor *Broadcom* had to confront the administrability issue of deciding whether the prices were “excessive.” Instead they were able to focus on specific acts of deception or opportunism that were associated with the price-raising conduct, and that could be enjoined without deciding under what circumstances prices should be considered excessive.

Nevertheless, the animating antitrust concern of these three cases was the exploitation of consumers through the charging of high prices. The SEP holders in these cases were able to extract monopoly rents because they controlled something “essential” to their licensees and then acted either deceptively or opportunistically to exploit that power. Put in an antitrust framework, there was monopoly power, plus anticompetitive conduct, and harm to consumer welfare.

C. EXCESSIVE PRICING OUTSIDE THE UNITED STATES

If we look at competition law outside the borders of the United States, we see that the United States is an outlier in the world in its view that a monopolist’s conduct in pricing excessively is not an antitrust violation. The law in most other countries is otherwise.

The prime contrary example is the European Union, where Article 102 of the Treaty on the Functioning of the European Union (TFEU) prohibits “abuse” of a dominant position, with a specific clause to catch the imposition of “unfair” selling prices or trading practices.¹⁰⁴ Many countries follow the EU’s approach. China’s condemnation of abuse of dominance includes selling at “unfairly high prices,” or “other abusive practices” as determined by the enforcement authority.¹⁰⁵ South Africa specifically condemns, as an abuse of dominance, the charging of an “excessive price.”¹⁰⁶ India prohibits a dominant firm from imposing “unfair” prices in the purchase or sale of goods or services.¹⁰⁷ Korea prohibits a dominant firm from pricing “unreasonably” or “unreasonably interfering” with the business activities of other enterprises.¹⁰⁸ Japan prohibits “private monopolization” as in the United States, but also con-

licensing practices enable Qualcomm to maintain its monopoly in chips market and to obtain “elevated royalties” that act as a tax on manufacturers and raises price to consumers). The district court denied a motion to dismiss the complaint, but without reaching the stand-alone theory. *See* *FTC v. Qualcomm Inc.*, 2017 WL 2774406, *9 (N.D. Cal. 2017) (effect of Qualcomm’s licensing policy is to reduce competitors’ sales and diminish their incentives to invest and innovate).

¹⁰⁴ Consolidated Version of the Treaty on the Functioning of the European Union art. 102, 2016 O.J. (C 202) 1.

¹⁰⁵ Anti-Monopoly Law of the People’s Republic of China (promulgated by the Standing Comm. Nat’l People’s Cong., Aug. 30, 2007, effective Aug. 1, 2008), ch. 3, art. 17.

¹⁰⁶ Competition Act 89 of 1998 § 8 (S. Afr.).

¹⁰⁷ The Competition Act, 2002, No. 12, Acts of Parliament, 2003 (India).

¹⁰⁸ Monopoly Regulation & Fair Trade Act, Act. No. 3320, Dec. 31, 1980, art. 3-2 (S. Kor.).

demns unfair trade practices, which include “engaging in transactions at an unjust price” and dealing with another party on terms that “unjustly restrict” the other party’s business.¹⁰⁹

Despite having the legal authority to condemn excessive pricing, jurisdictions outside the United States have historically been quite cautious in attacking high prices. The European Commission, for example, has taken the same approach to FRAND overcharges as has the FTC, focusing on the SEP-holder’s conduct in seeking injunctions to force higher rates rather than attacking the rates themselves as “unfair,” and it has rarely used its authority to reprehend high prices directly.¹¹⁰ The South Africa Competition Commission has brought a few high-profile cases for excessive pricing, but the Competition Appeals Court has turned them away.¹¹¹ The Chinese antitrust enforcement authority (the NDRC) brought a case against Qualcomm for excessive pricing of its SEPs, but pointed to the licensing conduct that it felt enabled Qualcomm to raise its prices rather than finding that the prices themselves were excessive.¹¹² Japan has focused more on buyer abuse than seller abuse, so has had “few cases of excessively high prices.”¹¹³ As Frédéric Jenny concluded in his 2016 study of excessive pricing in European jurisdictions, “[M]ost competition authorities will only exceptionally enforce this type of provision, preferring to focus on exclusionary practices.”¹¹⁴

“Only exceptionally,” though, is not never. In fact, competition agencies have become increasingly active in pursuing excessive pricing cases, particularly in pharmaceutical pricing. In 2016, for example, the Italian Competition Authority, following two years of investigations and hearings, issued a decision against Aspen, a multinational pharmaceutical company, for excessive price increases on four off-patent drugs used mainly for treating various forms

¹⁰⁹ Act Concerning Prohibition of Private Monopolization and Maintenance of Fair Trade, Act No. 54 of Apr. 14, 1947, as amended, art. 2 (9) (Japan).

¹¹⁰ The leading European Union case is *United Brands Co. v. Commission*, Case 27/76, *United Brands Co. v. Comm’n*, 1978 E.C.R. 207 (CJ). For a review of the case law developing the *United Brands* test, see Marco Botta & Klaus Wiedemann, *EU Competition Law Enforcement vis-à-vis Exploitative Conducts in the Data Economy: Exploring the Terra Incognita* 9–12 (Max Planck Inst. for Innovation & Competition Res. Paper No. 18-08, 2018), ssrn.com/abstract=3184119.

¹¹¹ See, e.g., *Competition Comm’n v. Sasol Chem. Inds. Ltd.*, 2015 (5) SA 471 (CAC) (S. Afr.); *Harmony Gold Mining Co. v. Mittal Steel S. Afr. Ltd.*, 2007 ZACT 21 (CAC) (S. Afr.).

¹¹² See Decision on Administrative Penalty, National Development and Reform Commission of the People’s Republic of China: Penalty No. 1, Bureau of Price Supervision and Anti-Monopoly, General Office (2015), jjs.ndrc.gov.cn (Nat’l Dev. & Reform Comm’n Feb. 9, 2015).

¹¹³ Tadashi Shiraishi, *The Exploitative Abuse Prohibition: Activated by Modern Issues*, 62 ANTITRUST BULL. 737, 747 (2017).

¹¹⁴ Frédéric Jenny, *Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment* 47 (Sept. 11, 2016) (unpublished manuscript), dx.doi.org/10.2139/ssrn.2880382.

of leukemia in children and the elderly.¹¹⁵ The Authority found that Aspen had increased its prices for these drugs between 300 and 1500 percent and realized profits (price in excess of costs) between 100–150 percent and 350–400 percent.¹¹⁶ After reviewing a number of other factors related to the “economic value” of the drugs, the Authority concluded that the price increases were “unfair” and an abuse of dominance under Article 102 of the TFEU, fining Aspen more than €5 million.¹¹⁷ In May 2017, following the Italian Competition Authority’s decision, the European Commission opened an investigation into Aspen for violating Article 102 of the TFEU, alleging “very significant and unjustified price increases” of its cancer medications.¹¹⁸ One month later the South African Competition Commission also opened an investigation into Aspen, as well as into Roche and Pfizer, for excessive pricing in a variety of cancer drugs.¹¹⁹ And in July 2017 the NDRC, one of the Chinese competition agencies, fined two Chinese companies for the “sharp rise” in the price of a bulk tuberculosis drug ingredient (in one case, an increase of 19 times over the previous year’s price).¹²⁰

Perhaps the most active competition authority in the area of excessive drug pricing, however, has been the UK’s Competition and Markets Authority (CMA). Since 2013 the CMA has opened three separate investigations into excessive drug pricing, of which one has been decided and two remain under investigation.¹²¹

¹¹⁵ See Italian Competition Auth., Case A480—Price Increase of Aspen’s Drugs ¶¶ 69, 71 (Oct. 14, 2016) (*Aspen*), www.en.agcm.it/dotcmsdoc/pressrelease/a480_eng.pdf. The case is discussed in Elisabetta M. Lanza & Paola R. Sfasciotti, *Excessive Price Abuses: The Italian Aspen Case*, 9 J. EUR. COMP. L. & PRAC. 382 (2017). The Italian First Grade Administrative Court affirmed the decision in 2017. See *id.* at 383.

¹¹⁶ See *Aspen*, *supra* note 115, ¶¶ 184, 309.

¹¹⁷ See *id.* ¶¶ 189, 401.

¹¹⁸ See Press Release, European Commission, Commission Opens Formal Investigation into Aspen Pharma’s Pricing Practices for Cancer Medicines (May 15, 2017) (IP-17-1323).

¹¹⁹ See Media Release, Competition Comm’n of South Africa, International Pharmaceutical Companies Investigated for Cancer Medicine Prices (June 13, 2017), www.compcom.co.za/wp-content/uploads/2017/01/International-pharmaceutical-companies-investigated-for-cancer-medicine-prices.pdf. The Commission dropped its investigation of Aspen four months later, on the ground of low sales in South Africa, but continued its investigation of Roche and Pfizer. See Media Release, Competition Comm’n of South Africa, Update: Pharmaceutical Investigations (Oct. 4, 2017), www.compcom.co.za/wp-content/uploads/2017/01/Update-Pharmaceutical-Investigations.pdf. For an earlier South African Competition Commission excessive drug price prosecution, which resulted in a settlement, see Complaint, *Hazel Tau v. GlaxoSmithKline*, S. Afr. (Pty) Ltd. 2002 (Competition Comm’n) (S. Afr.), www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf.

¹²⁰ See National Development and Reform Commission, Administrative Penalty Decision No. 2017 [1], (July 28, 2017) (on file with author).

¹²¹ For cases under investigation, see Press Release, Competition & Mkts. Auth., Drug Company Accused of Abusing its Position to Overcharge the NHS (Nov. 21, 2017), www.gov.uk/government/news/drug-company-accused-of-abusing-its-position-to-overcharge-the-nhs (alleged 6000% increase over a 10-year period in the price of liothyronine, a drug used to treat

The decided case involves phenytoin sodium, a prescription drug primarily used to treat epilepsy.¹²² Phenytoin sodium was originally synthesized in 1908, but is now off patent, superseded by newer drugs with fewer side effects.¹²³ Although the demand for the drug is declining, approximately 10 percent of epilepsy patients in the United Kingdom still use it. The reason for this continuing demand is clinical guidance from a number of sources (including the government) that because even slight changes in epilepsy medication can give rise to severe problems, patients who are stabilized on a particular manufacturer's version of this drug should stay on it and not be switched to another medication or even to another brand of the same medication.¹²⁴

In 2012 Pfizer “debranded” the drug, selling it under its generic name and thereby removing it from National Health Service (NHS) price regulation. Pfizer then immediately raised the drug's price by 488 percent to more than 1300 percent, depending on dosage size.¹²⁵ Prior to 2012, the NHS had spent approximately £2 million annually on the drug. After the debranding, and despite falling demand, the NHS spent substantially more for the drug than before (£50 million in 2013, £42 million in 2014, and approximately £37 million in 2015).¹²⁶

The CMA concluded that the prices charged were excessive, having regard to the costs incurred and a reasonable rate of return.¹²⁷ Using a methodology similar to the one that the Italian Competition Authority employed in *Aspen*, the CMA calculated Pfizer's direct and common costs, decided on a reasonable rate of return (6 percent), and then determined the excess of price over cost, concluding that Pfizer's prices ranged from 29 percent to more than 700 percent over cost, depending on dosage, with an average of 443 percent, amounts that were clearly sufficient to be “excessive.”¹²⁸ The CMA then found that the prices were also “unfair,” both because there were “no non-cost

hypothyroidism) (investigation opened in October 2016; Statement of Objections issued in November 2017); Press Release, Competition & Mkts. Auth., Pharmaceutical Company Accused of Overcharging NHS (Dec. 16, 2016), www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs (alleged 12,000% increase in a 10mg pack price of hydrocortisone over an 8-year period and a 9500% increase in the 20mg tablet dosage) (investigation opened in March 2016; Statement of Objections issued in December 2016).

¹²² See Unfair Pricing in Respect of the Supply of Phenytoin Sodium Capsules in the UK, Decision of the Competition & Mkts. Auth., CMA CE/9742-13, § 1.5 (Dec. 7, 2016) (*Pfizer*), www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products#non-confidential-infringement-decision.

¹²³ See *id.*

¹²⁴ See *id.* §§ 3.28–3.42.

¹²⁵ See *id.* § 3.173, tbl.3.5.

¹²⁶ See *id.* § 5.398.

¹²⁷ See *id.* § 1.33.

¹²⁸ See *id.* §§ 5.125, tbl.5.8 (4-year period); 5.127.

factors [that] would increase [their] economic value . . . beyond [their cost]”¹²⁹ and because they were “unfair” in themselves, noting that the drug is off-patent and that the substantial price increases after de-listing were not the result of any change in “costs, investments, or risk.”¹³⁰ Concluding that Pfizer had infringed Article 102 of the TFEU, the CMA fined Pfizer more than £84 million (approximately \$106 million).¹³¹ It also ordered Pfizer to change its prices in a way that has “regard to” the CMA’s decision, but it did not set a specific price.¹³² It did note, however, that nothing in its order precluded Pfizer from earning a profit greater than the reasonable rate of return of 6 percent.¹³³

Pfizer and its distributor then appealed the decision to the Competition Appeal Tribunal, which set it aside in part.¹³⁴ Although agreeing that the CMA had correctly defined the market (phenytoin sodium capsules) and that Pfizer had a dominant position in that market, the Tribunal disagreed with how the CMA determined whether the prices were “excessive” and with the approach it took to whether the prices were “unfair,” both of which are required under European case law interpreting Article 102.¹³⁵

With regard to excessiveness, the Tribunal rejected the idea that there is a single test or methodology for assessing whether a price is excessive, and particularly objected to the CMA’s reliance on a theoretical “cost plus” approach to this issue.¹³⁶ What needed to be determined was a “benchmark price” that would have been charged “in circumstances of normal and sufficiently effective competition” in the “real world,” not the price that one might theoretically charge under “idealised competition.”¹³⁷ This price would depend on examining comparable products and companies, as well as placing Pfizer’s prices “in their commercial context,” neither of which the CMA did.¹³⁸

¹²⁹ *Id.* §§ 5.261–5.262.

¹³⁰ *Id.* § 5.356.

¹³¹ *See id.* §§ 7.6–7.62, tbl.7.1.

¹³² *Id.* at Annex B, § 1(c). *Compare Aspen*, *supra* note 115, at 58 ¶ (b) (requiring Aspen to “carry out all which is necessary to define fair prices” of the drugs in question).

¹³³ *See Pfizer*, *supra* note 122, at Annex B § 1(d).

¹³⁴ *See Pfizer Inc. v. Competition & Mkts. Auth.*, [2018] CAT 11 (*Pfizer v. CMA*), www.catribunal.org.uk/sites/default/files/2018-08/1275-1276_Flynn_Judgment_CAT_11_070618.pdf. The Competition Appeal Tribunal is the body with initial jurisdiction over appeals on the merits from CMA decisions.

¹³⁵ *See* Case 27/76, *United Brands Co. v. Comm’n* 1978 E.C.R. 207, 301 (¶ 252) (CJ). Although the Tribunal did not decide whether the penalties were appropriate, it did indicate that had a violation been proven, it would likely have had difficulty approving the amount of the penalty, *see Pfizer Inc. v. CMA*, *supra* note 122, ¶ 461.

¹³⁶ *Pfizer Inc. v. CMA*, *supra* note 122, ¶ 310; *see also id.* ¶ 294 (discussing Advocate General Wahl’s opinion in the *Latvian Copyright* case).

¹³⁷ *Id.* ¶¶ 310, 318.

¹³⁸ *Id.* ¶¶ 318, 324.

As for unfairness, the Tribunal agreed with the CMA that the amount of the price increase and the impact on buyers were among the factors that could be considered.¹³⁹ Where the CMA erred, however, was in not making an adequate comparison to prices charged in other jurisdictions or for other products (particularly the drug in tablet rather than capsule form, even though capsules and tablets were in different product markets).¹⁴⁰ Finally, the CMA erred in not factoring in the benefit that the patient gets from the drug,¹⁴¹ which the Tribunal said should be considered part of the “economic value” of the product.¹⁴² Taking account of the value of the product to a consumer—“what the product is worth”—is necessary before deciding whether the price was “unfair.”¹⁴³

The Tribunal also made clear its uncertainty about using competition law to deal with excessive pricing: “Cases of pure unfair pricing are rare in competition law,” the Tribunal wrote.¹⁴⁴ “Authorities find them difficult to bring and are, rightly, wary of casting themselves in the role of price regulators.”¹⁴⁵ Even so, the Tribunal wrote that “there is no reason in principle why competition law cannot be applied, provided this is done on the correct legal basis and the analysis of evidence is sound.”¹⁴⁶

The *Pfizer* case is a good illustration of the uncertainties surrounding efforts to deal with excessive pricing. After *Pfizer*, one would be hard-pressed to argue that we now have clear guidance on what should be required to prove that a firm has charged excessive prices. If anything, the Tribunal’s approach suffers from the vague standards it inherited from *United Brands* (what is “normal and sufficiently effective competition”? what is “economic value”?) and an unarticulated theory of harm. Still, jurisdictions around the world recognize, perhaps grudgingly, that excessive high pricing can be dealt with as a competition law matter. And this leads to the rhetorical question: If the EU, or the Italian Competition Authority, or the UK competition law enforcers are trying to take on this task, why can’t the FTC or a federal district court?

¹³⁹ *Id.* ¶ 369.

¹⁴⁰ *Id.* ¶¶ 379, 402.

¹⁴¹ *Id.* ¶ 419 (“Placing a precise monetary value on patient benefit is not straightforward but it appears to us that a qualitative assessment would be possible and should have been attempted by the CMA rather than simply assessing this value as nil.”).

¹⁴² *Id.* ¶ 407.

¹⁴³ *Id.* (“[W]e find the outright rejection of any value at all to patients surprising. . . . We think there is clearly some economic value to be derived from the therapeutic benefit to patients of phenytoin capsules.” *Id.* ¶ 412.).

¹⁴⁴ *Id.* ¶ 3.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

These cases also provide another caveat. They show that an antitrust inquiry into excessive pricing is not easy or quick. The CMA opened its investigation in May 2013 but did not adopt a Statement of Objections until 2015 and took another year to issue its decision.¹⁴⁷ The Tribunal's decision was handed down in June 2018, and is not even the end of the matter (the Tribunal remitted the matter to the CMA for further proceedings, and the Tribunal's decision might be appealed to the Court of Appeal). This type of intensive examination shows both antitrust's strength as a tool for dealing with high pharmaceutical drug prices and antitrust's weakness. An antitrust approach offers the possibility of a careful inquiry, but it is time consuming. It is not a quick fix.

III. APPLYING ANTITRUST TO EXCESSIVE DRUG PRICING

A. INTRODUCTION

The problem of high pharmaceutical drug prices encompasses many different types of drugs. Newly introduced drugs intended for widespread use, such as treatments for hepatitis C, cholesterol-lowering inhibitors, and biologic drugs for various cancers, can cost tens of thousands of dollars per year.¹⁴⁸ Some studies show that new drugs can exhibit substantial post-launch price increases over time, even when competitors enter the market.¹⁴⁹

Rather than take on a general approach to all pharmaceutical drug pricing, however, the following discussion focuses on increases in the price of three drugs that share certain common traits and which I think are the most obvious targets for antitrust enforcement because of high prices. The purpose of this discussion is not to argue that the overall conduct of the drug makers in question could be considered an effort to maintain monopoly power in violation of Section 2 (although their overall conduct might make out such a case). Rather, I want to isolate some indicative factors that I think are relevant to an analysis of excessive pricing in this area, approaching the analysis of this conduct as

¹⁴⁷ See Case Timetable, Unfair Pricing in Respect of the Supply of Phenytoin Sodium Capsules in the UK, Competition & Mkts. Auth., CMA CE/9742-13, www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products#case-timetable.

¹⁴⁸ See Dhruv Khullar & Anupam Jena, *Why Some Drug Prices Should Be High*, STATNEWS.COM (Mar. 17, 2016); Robin C. Feldman & Connie Wang, *May Your Drug Price Be Ever Green* 9–11 (Univ. Cal. Hastings Coll. of L. Res. Paper No. 256, 2018), ssrn.com/abstract=3061567; cf. Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 859 (2016) (Table 1 describes the average drug prices for top-selling drugs). For hepatitis C treatment, see Joseph Walker, *Gilead Cuts Pills' Price to \$24,000*, WALL ST. J., Sept. 25, 2018, at B2 (introduction of authorized generic, cutting price by more than 60% of branded product, but still costing \$24,000 for a full course of treatment).

¹⁴⁹ See Noa Gordon et al., *Trajectories of Injectable Cancer Drug Costs After Launch in the United States*, 36 J. CLIN. ONCOLOGY 319, 322–23 (2018) (study of 24 patented drugs).

one would approach any Section 2 monopoly case, that is, through a rule of reason methodology.¹⁵⁰

B. POST-ACQUISITION PRICE SURGES

1. *Daraprim*

Daraprim, known generically as pyrimethamine, is used mainly to treat toxoplasmosis, a parasite infection that can cause serious or even life-threatening problems for babies born to women who become infected during pregnancy.¹⁵¹ It is also used for people with compromised immune systems, such as AIDS patients and certain cancer patients, and can be used to treat malaria.¹⁵² Dosages vary, depending on the illness. Toxoplasmosis may require more than 100 tablets over the course of eight weeks;¹⁵³ one of the treatments for a particular illness to which HIV-infected patients are susceptible could require more than 150 pills over the course of six months.¹⁵⁴

The FDA approved Daraprim in 1953. It has long been made by Glaxo-SmithKline, which sold the U.S. marketing rights to CorePharma in 2010.¹⁵⁵ In 2014 Impax Laboratories bought Core and affiliated companies for \$700 million.¹⁵⁶ In August 2015, Impax sold Daraprim to Turing Pharmaceuticals for \$55 million.¹⁵⁷ Turing was a start-up run by former hedge fund manager Martin Shkreli.¹⁵⁸

Immediately on acquisition, Turing raised the price of Daraprim from \$13.50 per tablet to \$750 per tablet.¹⁵⁹ Based on possible dosage, this means that the price of the HIV-related treatment mentioned above would have increased from about \$2,000 to about \$112,000, roughly a 5500 percent increase. Shkreli vigorously defended the price increase (“I think profits are a great thing to sustain your corporate existence”¹⁶⁰) and promised to use the

¹⁵⁰ See *United States v. Microsoft Corp.*, 253 F.3d 34, 58–59 (D.C. Cir. 2001).

¹⁵¹ See Pollack, *supra* note 1.

¹⁵² See *id.*

¹⁵³ See *FDA Labels: Pyrimethamine*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (2014), aidsinfo.nih.gov/drugs/445/pyrimethamine/40/professional.

¹⁵⁴ See *Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents*, U.S. DEP’T OF HEALTH & HUMAN SERVS. B-9–B-10 (2018), aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf.

¹⁵⁵ Pollack, *supra* note 1.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ See CNBC Television Interview by Meg Tirrell with Martin Shkreli, Turing Pharma Founder & CEO, *Turing CEO: Drug Priced Where We Could Make ‘Comfortable Profit’* (Sept. 21, 2015), www.cnbc.com/video/2015/09/21/turing-ceo-drug-priced-where-we-could-make-comfortable-profit.html.

profits for future research into new drugs for toxoplasmosis (an irrelevant promise even if true).¹⁶¹ Shkreli became the instant poster-boy for abusive pharmaceutical pricing.

These facts make Daraprim a good case for testing a Section 2 theory based on excessive pricing as exploitative conduct, improperly transferring surplus from consumers to producers. First, there is a price spike—a sharp, substantial increase in price—unexplained by anything other than opportunistic behavior. Second, the price increase is so substantial as to likely be unrelated to the cost of production, including any possible “reasonable” return on investment. Third, the drug is long off-patent, and there is no indication of any innovation being involved in what Turing did. Fourth, new entry did not occur, nor was there any indication that new entry was likely within any reasonable time. Indeed, these were the factors that were present in the excessive pricing cases that the Italian Competition Authority and the CMA decided involving *Aspen* and *Pfizer*.¹⁶²

This being a Section 2 case, there is also the requirement that Turing have monopoly power in a relevant market, which would likely be Daraprim, although there may be substitutes for Daraprim for some uses (this may be the case for treating pneumocystis pneumonia, an HIV-related disease¹⁶³). Whatever Daraprim’s share of various markets might be, a behavioral approach to Daraprim’s market power does point to its having monopoly power, given that it was able to raise price substantially (far in excess of a SSNIP) and keep it at that level without attracting entry.¹⁶⁴

There are a number of puzzles in the Daraprim story. One is why the prior owners did not raise the price. Some have suggested that reputational effects might explain why a prior owner did not raise prices but a later owner did.¹⁶⁵

¹⁶¹ *Id.*

¹⁶² See *supra* text accompanying notes 115–133.

¹⁶³ See U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 154, at B-1–B-10.

¹⁶⁴ See *United States v. Microsoft Corp.*, 253 F.3d 34, 57–58 (D.C. Cir. 2001) (use of direct proof to show monopoly power). As of 2018, Turing’s corporate successor was still charging \$750 per pill, but its revenue apparently peaked in 2016, in part because the need for the drug declined and in part because the negative publicity over its pricing led insurers to place greater restrictions on the use and reimbursement for the drug. See Damian Garde & Adam Feuerstein, *Three Years After Steep Price Hike, Martin Shkreli’s Drug Company Is Losing Money, Documents Show*, STATNEWS.COM (July 17, 2018).

¹⁶⁵ See Concurring Statement of Commissioner J. Thomas Rosch, *FTC v. Ovation Pharmaceuticals, Inc.*, FTC File No. 081-0156 (Dec. 16, 2008) (arguing that sale of a drug by a reputationally constrained manufacturer to one that was not could be challenged under Section 7 of the Clayton Act as the acquisition of monopoly, when the buyer subsequently raised its price by 1300 percent), www.ftc.gov/os/caselist/0810156/081216ovationroschstmt.pdf; cf. *Flynn Pharma Ltd. v. Competition & Markets Auth.*, [2017] CAT 1, ¶ 44 (parties arguing against interim relief on ground that once they were forced to lower the price of the drug phenytoin pending appeal, reputational damage would prevent them from subsequently raising the price

Perhaps that might have been true when GSK, a multinational company selling branded pharmaceutical products, owned Daraprim, but it seems unlikely for Daraprim's subsequent owners, CorePharma (a generic pharmaceutical producer at the time) and Impax (a "specialty" pharmaceutical company).¹⁶⁶ In any event, although it is hard to assess the prior owners' business strategies and the constraints they felt on their pricing conduct, Shkreli's decision was based on strategy, not efficiency. Seeing the possibility of successfully raising prices by a very large amount may be some form of "superior skill," but it is not the kind that should serve as a defense in a monopoly case.¹⁶⁷

A second puzzle is why the price rise did not attract entrants, which is what economists expect and which is one argument for leaving excessive prices alone. One reason is that even though Daraprim is off-patent, patents are not the only barrier to entry. FDA approval must also be obtained, but approval is not instantaneous, and new manufacturers may find themselves having difficulty getting the drug manufactured.¹⁶⁸ Another reason might be the potential for Turing to adopt an entry-detering pricing strategy. If the market is small enough, the manufacturing cost low enough, and the current generic manufacturer has sufficient capacity, it is easy enough for a current seller to deter entry by virtue of its ability to drop price to cost if a new competitor enters. Operating in the shadow of this entry-deterrence strategy, it might make little sense for another firm to invest in getting an additional generic to market when it can so easily find its investment undercut by extremely low prices.

Of course, Turing might raise defenses. Turing might argue that the price increase was necessary to get a reasonable return on its investment, that is, on the price it paid for Daraprim; but that defense would just mean that

even if they won the case on appeal), www.catribunal.org.uk/cases/127411216-ir-flynn-pharma-limited-and-another.

¹⁶⁶ See *CorePharma*, CRUNCHBASE.COM, www.crunchbase.com/organization/corepharma-llc; *About Impax*, IMPAXLABS.COM, www.impaxlabs.com/about/. Core itself had raised the price from the \$1 per pill that Glaxo had charged to \$13.50 per pill. See Joel Hruska, *Drug Company Reneges on Promise to Reverse 5,400-percent Price Hike on Daraprim*, EXTREME TECH (Nov. 25, 2015), www.extremetech.com/extreme/218598-drug-company-reneges-on-promise-to-reverse-5400-percent-price-hike-on-daraprim.

¹⁶⁷ See *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (1945).

¹⁶⁸ See Jeremy A. Greene et al., *Role of the FDA in Affordability of Off-Patent Pharmaceuticals*, 315 JAMA 461, 461 (2016) ("The agency's fiscal year 2014 performance report noted that none of the approximately 1500 applications for generic drugs submitted in fiscal year 2014 had been approved by the end of that year."). Turing might also have pursued various tactics to make it difficult for new firms to gain FDA approval. See Michael A. Carrier, Nicole L. Levidow & Aaron S. Kessel, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECH. L.J. 1379, 1381–86 (2017) ("Turing required institutions and individuals to set up accounts through Daraprim Direct Comments from Turing executives suggest that a primary goal of the Daraprim Direct system was to make it impossible for anyone other than registered clients to obtain the drug, including generic manufacturers wishing to obtain samples for use in bioequivalence studies needed to obtain Food and Drug Administration (FDA) approval of their applications for generic versions.").

Daraprim's seller had capitalized the monopoly profits and was getting them from Turing (or, perhaps, splitting them with Turing), surely not an attractive defense to a monopolization charge under Section 2.¹⁶⁹ Turing might also argue that the appropriate benchmark is not the cost of production, but the value of the product to the consumer, an issue that the UK Competition Appeal Tribunal raised in *Pfizer*.¹⁷⁰ But this is not a useful approach to take to excessive pricing. By definition, a sufficient number of consumers "valued" the product at the price Turing set—\$750 per tablet—so that it was profitable for Turing to sell it at that price, something that is true for all monopoly pricing. But surely the antitrust laws are not designed to allow a monopolist to capture all the surplus between the competitive price—\$13.50 a pill—and the \$750 a pill that Turing was able to charge to some. The correct antitrust approach, if "consumer welfare" means anything, is that consumers should get the benefit of a price near the competitive level, and not be forced to pay a price that is 55 times that amount, even if the product is "worth it" to some at that price. Consumer willingness to buy is not the appropriate antitrust measure of whether a price is reasonable.¹⁷¹

Daraprim is the easiest case for antitrust enforcement against excessive pricing. The anticompetitive effect in the form of excessively high prices is clear. The drug is off-patent, so there should be no reason to worry about reducing incentives for innovation, and there is no indication of some other type of risky investment of the sort that the Court in *Trinko* was worried about disincentivizing. There are no likely procompetitive justifications. The only justification that Shkreli seemed to advance was, "I could do it, so I did."

2. *Calcium EDTA*

Calcium EDTA is a decades-old intravenous treatment for severe and life threatening cases of lead poisoning. Severe lead poisoning cases are relatively uncommon (only 50 serious cases in the United States in 2015, for example), but hospitals need to keep this drug on hand for emergencies, particularly

¹⁶⁹ Cf. *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013) ("If the basic reason [for the settlement agreement] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.").

¹⁷⁰ See *supra* note 143 and accompanying text.

¹⁷¹ See David Gilo, *A Coherent Approach to the Antitrust Prohibition of Excessive Pricing by Dominant Firms*, in *EXCESSIVE PRICING AND COMPETITION LAW ENFORCEMENT* 113 (Frédéric Jenny & Yannis Katsoulacos eds., 2018) (rejecting argument that excessiveness should be judged based on demand considerations because "if . . . excessiveness is determined by consumers' willingness to pay, then no price will ever be considered excessive, because a monopoly would never want to charge a price higher than what consumers are willing to pay.").

urban hospitals where the chances for cases of lead poisoning are greater.¹⁷² The drug has long been off-patent.¹⁷³

Graceway Pharmaceuticals manufactured the drug from the mid-2000s through 2011.¹⁷⁴ In 2011 Graceway went into bankruptcy and was purchased by Medicis Pharmaceutical.¹⁷⁵ Medicis had production problems with the drug, leading to the stopping of its production.¹⁷⁶ In 2012, Valeant Pharmaceuticals acquired Medicis for \$2.6 billion and took steps to fix the problems in producing Calcium EDTA and to restart production.¹⁷⁷

In 2012 a box of 50 mg Calcium EDTA sold for \$950.¹⁷⁸ By January 1, 2014, Valeant had increased the price to \$7,116.¹⁷⁹ By December of 2014 the price had increased to \$26,927.¹⁸⁰ One box of five ampules is necessary to treat one young child for five days for severe lead poisoning.¹⁸¹ By contrast, in 2016 a company in France was selling 50mg of the drug for about \$75.¹⁸²

Valeant justified its price increase as enabling it “to provide to the market consistent availability of a product with high carrying costs and very limited purchase volume of 200 to 300 units per year.”¹⁸³ Valeant also pointed out that it “must purchase sufficient supplies of needed ingredients in advance and this can amount to three to five times more than recent annual sales.”¹⁸⁴ Valeant continued: “Given [the drug’s] relatively limited shelf life, the company takes substantial carrying cost risk and has written down at its own expense approximately half of purchased quantities in the past few years.”¹⁸⁵

¹⁷² See Christina Mattina, *Valeant’s Steep Price Hikes Continue with Lead Poisoning Drug*, AJMC.COM (AM. J. MANAGED CARE) (Oct. 13, 2016), www.ajmc.com/newsroom/valeants-steep-price-hikes-continue-with-lead-poisoning-drug.

¹⁷³ See *List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic*, U.S. FOOD & DRUG ADMIN. 10 (2018), www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM564441.pdf.

¹⁷⁴ See Letter from Michael J. Kosnett, Consultant, Cal. Poison Control Sys. & Timur S. Durrani, Assistant Med. Dir., Cal. Poison Control Sys., to Elijah E. Cummings, Ranking Member, House Comm. on Gov’t Oversight and Reform (Jan. 28, 2016) [hereinafter Kosnett & Durrani Letter to Cummings], freepdfhosting.com/293789e0a0.pdf.

¹⁷⁵ See *id.*

¹⁷⁶ See Ed Silverman, *Huge Valeant Price Hike on Lead Poisoning Drug Sparks Anger*, STATNEWS.COM (Oct. 11, 2016).

¹⁷⁷ See *id.*

¹⁷⁸ See *id.*

¹⁷⁹ See *id.*

¹⁸⁰ See *id.*

¹⁸¹ See Kosnett & Durrani Letter to Cummings, *supra* note 174, at 2.

¹⁸² See *id.* at 3.

¹⁸³ Silverman, *supra* note 176.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

The Calcium EDTA story shares many similarities with Daraprim. First, like Daraprim, it looks like Valeant has monopoly power in Calcium EDTA. Perhaps more so than for Daraprim, there do not appear to be alternate therapies available to buyers. And Valeant was able to raise its price substantially without attracting entry. Second, this is another price-spike case, although the price rise was not quite as immediate as Daraprim's. Third, the post-acquisition price increases are so startlingly large as to give rise to the inference that its price is unrelated to costs or to any investment risk. To be sure, the justifications Valeant gave—high carrying costs and limited sales—are plausible, but it isn't clear why the carrying costs or risks increased so much over what Graceway had faced in the years when it sold the drug. Fourth, the drug is off-patent so incentives for innovation are not at issue. Finally, the drug's high prices have not attracted entry, probably because of its small market and low manufacturing cost (the chemical is widely available), making entry unattractive in the shadow of an entry-deterrence pricing strategy.

One difference with Daraprim is the availability of the drug in other markets. The public record is unclear on this point for Daraprim, but Calcium EDTA does seem to be available outside the United States.¹⁸⁶ As the Competition Appeal Tribunal wrote in *Pfizer*, geographic price comparisons can provide a benchmark against which excessiveness might be assessed.¹⁸⁷ Whether the lower prices in other jurisdictions reflect differences in regulatory regimes, which would make comparisons problematic, would, of course, need to be assessed.¹⁸⁸

Another point of difference with Daraprim is that the price increase did not follow immediately on acquisition but came after Valeant fixed production shortages that occurred when Medicis owned the drug. Immediate price increases, or surges, should be one of the indicative factors for an excessive pricing case because such surges raise an inference of exploitation rather than efficiency, but later increases may have explanations other than exploitation. In the case of Calcium EDTA, the record points more toward exploitation. Valeant's "disruptive" pricing strategy of acquisition followed by extreme price increases was well-known and may have even inspired Shkreli to adopt the strategy for Daraprim. On the other hand, there may be more facts behind

¹⁸⁶ See Kosnett & Durrani Letter to Cummings, *supra* note 174, at 3 ("Hospitals in Canada and Europe continue to be able to acquire CaEDTA ampules for treatment of their severely lead-poisoned patients at a small fraction of the cost of the Valeant brand drug sold in the United States.").

¹⁸⁷ See *Pfizer Inc. v. Competition & Mkts. Auth.*, [2018] CAT 11, ¶¶ 294, 297–298, catribunal.org.uk/sites/default/files/2018-08/1275-1276_Flynn_Judgment_CAT_11_070618.pdf.

¹⁸⁸ See *id.* ¶¶ 401–402 (pointing out need to account for different regulatory regimes that could keep prices low in other jurisdictions).

fixing the shortage of Calcium EDTA than the public record reveals, facts that might give some credence to an economic justification for the price increase.

C. GRADUAL PRICE INCREASES IN A BRAND-PROTECTED MARKET: EpiPEN

The EpiPen is an auto-injector device for rapidly delivering epinephrine to a patient. It is used for emergency treatment of anaphylaxis, a serious and potentially life-threatening allergic reaction to insect bites and food allergies. Epinephrine itself is not patented but the injector is.¹⁸⁹ A dose of epinephrine dispensed in an EpiPen costs about \$1 to produce.¹⁹⁰

The EpiPen injector was invented in the 1970s by an employee working on auto-injectors for a company designing products for the military. That company was eventually acquired by Meridian, which is now a subsidiary of Pfizer and which owns the patent on the auto-injector. Mylan acquired the marketing rights to the EpiPen in 2007 when it bought Merck KGaA's generics business. Meridian (Pfizer) manufactures EpiPens for Mylan.¹⁹¹

In 2012 Mylan and the holders of the patent on the injector settled a patent infringement suit they brought against Teva, a generic manufacturer.¹⁹² In the settlement Teva agreed not to enter the market until 2015, which was ten years before the patent's expiration. Teva had production problems, however, and was unable to enter the market at the agreed upon time.¹⁹³

When Mylan bought the marketing rights to the EpiPen in 2007, annual revenues from the product were \$200 million. By 2015 revenues had risen to over \$1 billion. Key to this increase was the passage in 2013 of the School Access to Emergency Epinephrine Act, called the "EpiPen" bill even though the statute did not mention the EpiPen by name.¹⁹⁴ This legislation gave fund-

¹⁸⁹ See *List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic*, *supra* note 173, at 10. Epinephrine, known as adrenaline, was the subject of a famous decision on patentability. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911) (L. Hand, J.).

¹⁹⁰ See Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen into a Billion-Dollar Business*, BLOOMBERG (Sept. 23, 2015).

¹⁹¹ See generally Lydia Ramsey, *The Strange History of EpiPen, the Device Developed by the Military That Turned into a Billion-Dollar Business*, BUSINESS INSIDER (Aug. 27, 2016), www.businessinsider.com/the-history-of-the-epipen-and-epinephrine-2016-8; Kevin Smetana, *EpiPen Inventor Helped Millions and Died in Obscurity*, TAMPA BAY TIMES (Sept. 24, 2009), web.archive.org/web/20130201055705/http://www.tampabay.com/news/humaninterest/epipen-inventor-helped-millions-and-died-in-obscurity/1038756.

¹⁹² See Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53, 60–62 (2017).

¹⁹³ See *id.* at 64–66 & n.84 (reporting FDA rejection of Teva's application for approval to market injector).

¹⁹⁴ School Access to Emergency Epinephrine Act, Pub. L. No. 113-48, 127 Stat. 575 (2013). See also Valerie Jarrett, Senior Advisor & Assistant to the President for Intergovernmental Affairs & Pub. Engagement, *President Obama Signs New EpiPen Law to Protect Children with Asthma and Severe Allergies, and Help Their Families to Breathe Easier*, THE WHITE HOUSE

ing preferences for schools maintaining emergency supplies of epinephrine,¹⁹⁵ thereby not only substantially increasing sales of the EpiPen but also solidifying its brand reputation.

Mylan faced some limited competition. Auvi-Q entered the market in 2013 with a smaller injector that came with audio instructions.¹⁹⁶ Auvi-Q entered at about the same price as EpiPen (or higher), withdrew from the market in 2015 after dosage problems arose,¹⁹⁷ but returned in 2017—with a \$4,500 list price for two injectors.¹⁹⁸ Adrenaclick offered an auto-injector that was slightly different than Mylan's, but had problems with insurance company coverage.¹⁹⁹ In 2017 Mylan responded to the public outcry over its pricing by offering an authorized generic version of the EpiPen for \$300,²⁰⁰ and CVS began an aggressive campaign to offer an authorized generic version of Adrenaclick for \$109.99.²⁰¹ In 2018 the FDA finally approved Teva's application to produce a generic version of the EpiPen,²⁰² but the future impact on the price of Teva's product is unclear.²⁰³ At least for now, Mylan continues to maintain its monopoly share of the market for epinephrine injectors.²⁰⁴

(Nov. 13, 2013), obamawhitehouse.archives.gov/blog/2013/11/13/president-obama-signs-new-epipen-law-protect-children-asthma-and-severe-allergies-an.

¹⁹⁵ See School Access to Emergency Epinephrine Act, Pub. L. No. 113-48, § 2, 127 Stat. 575 (2013).

¹⁹⁶ See Katie Thomas, *Brothers Develop New Device to Halt Allergy Attacks*, N.Y. TIMES (Feb. 1, 2013), www.nytimes.com/2013/02/02/business/auvi-q-challenges-epipen-with-a-new-shape-and-size.html.

¹⁹⁷ See Ed Silverman, *An EpiPen Alternative Is About to Return to Your Local Pharmacy*, STATNEWS.COM (Oct. 26, 2016).

¹⁹⁸ See Ed Silverman, *Grassley Probes Epipen Rival over Its \$4,500 List Price*, STATNEWS.COM (Mar. 8, 2017) (also offering the drug for \$360 in cash to people without insurance).

¹⁹⁹ See Katie Thomas, *Why the Lone EpiPen Competitor Hasn't Taken Off*, N.Y. TIMES (Nov. 1, 2016), www.nytimes.com/2016/11/02/business/also-ran-to-epipen-reaches-for-a-closing-window-of-opportunity.html.

²⁰⁰ See Anne Steele, *Mylan Launches Cheaper Generic EpiPen Alternative*, WALL ST. J. (Dec. 16, 2016), www.wsj.com/articles/mylan-launches-cheaper-generic-epipen-alternative-1481896300.

²⁰¹ See Nathan Bomey, *CVS Targets EpiPen with Cheaper, Generic Version*, USA TODAY (Jan. 12, 2017); *A More Affordable EpiPen Alternative*, CVS PHARMACY, www.cvs.com/content/epipen-alternative (promoting Adrenaclick authorized generic as a “more affordable EpiPen alternative”).

²⁰² See Press Release, U.S. Food & Drug Admin., FDA Approves First Generic Version of EpiPen (Aug. 16, 2018), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm617173.htm.

²⁰³ See Jonathan D. Alpern & William M. Stauffer, *Does a Generic EpiPen Mean Lower Prices? Don't Hold Your Breath*, STATNEWS.COM (Sept. 7, 2018) (data show that a single generic “has minimal impact on price” and that “when there is only one generic manufacturer competing, continued price hikes can still occur”; because of complexities in producing the auto-injector, another generic EpiPen is unlikely to be on the market soon).

²⁰⁴ According to IMS data, in 2015 Mylan had 89% of revenue in the epinephrine injector market and 91% of prescriptions written; for 2016, 92% of prescriptions written (on file with author). See also Carrier & Minniti, *supra* note 192, at 56 n.25 (2017) (market shares from

What caught the public's attention with regard to the EpiPen was the extent of the price rises over time. A two-pack of EpiPens sold for about \$100 in 2007; by 2016 the same two-pack sold for about \$600.²⁰⁵ Much of the price increase has come since 2013, when the price rose from about \$265 to about \$600,²⁰⁶ a price rise that seems to have coincided with the passage of the EpiPen bill and Teva's anticipated entry.²⁰⁷

For all the public attention that this increase has garnered, however, analyzing this as a case of excessive pricing is more difficult than the other two cases. This is not a case of an immediate price spike, in contrast to Daraprim or Calcium EDTA, so this indicator of exploitation is less clear. Indeed, gradual price rises over time may be a broader phenomenon exhibited in many drugs post-launch.²⁰⁸ Nevertheless, the overall price increase has been substantial, and still appears to be far above cost. (In fact, Mylan has sold EpiPens to schools for substantially lower prices under exclusive dealing agreements.²⁰⁹) Further, Mylan is not the innovator of the auto-injector so the incentive/reward story is unclear. Indeed, the innovation story is further muddied by the uncertain validity of the patents that protect the auto-injector and the settlement of the Teva patent litigation.²¹⁰ On the other hand, without regard to patent validity, Mylan may have a plausible claim that its auto-injector is a superior product, given the problems that competitors have had in producing a successful product.²¹¹ Finally, although there has been some entry, the new entrants have not proven to be effective competitors, for various reasons.²¹² Indeed, it appears that the EpiPen trademark itself is a substantial

2008–2011); Chelsea Rice, *Despite Woes, EpiPen Still Dominates the Market*, ATHENAHEALTH.COM (Sept. 12, 2017) (based on 130,000 prescriptions, alternatives to EpiPen had a 32.5% market share as of August 2017, but the alternatives included Mylan's own generic), www.athenahealth.com/insight/despite-woes-epipen-still-dominates-market; Ed Silverman, *EpiPen Prescriptions Continue to Climb, But Market Share Dropped*, STATNEWS.COM (Oct. 25, 2016) (reporting drop in share of prescriptions in September 2016, from 96% to 92%).

²⁰⁵ See Andrew Pollack, *Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic*, N.Y. TIMES (Aug. 24, 2016), www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html.

²⁰⁶ See Silverman, *supra* note 204 (chart).

²⁰⁷ See *id.*

²⁰⁸ See Gordon et al., *supra* note 149 (study of 24 patented drugs).

²⁰⁹ See Ike Swetlitz & Ed Silverman, *Mylan May Have Violated Antitrust Law in Its EpiPen Sales to Schools, Legal Experts Say*, STATNEWS.COM (Aug. 25, 2016); see also BioRidge Pharma, LLC, Certification Form: EpiPen Auto-Injectors School Discount Program (Sept. 10, 2016), [www.web.archive.org/web/20160910011637/http://www.bioridgepharma.com/pdf/2_Auto_Injectors_PHJ62812\(3\)_FINAL-NPS_edits_v6.pdf](http://www.web.archive.org/web/20160910011637/http://www.bioridgepharma.com/pdf/2_Auto_Injectors_PHJ62812(3)_FINAL-NPS_edits_v6.pdf).

²¹⁰ For discussion of the Teva settlement, see Carrier & Minniti, *supra* note 192, at 60–63.

²¹¹ See Meghana Keshavan, *5 Reasons Why No One Has Built a Better EpiPen*, STATNEWS.COM (Sept. 9, 2016).

²¹² See Press Release, U.S. Food & Drug Admin., *supra* note 202 (“The path to developing generic drug-device combination products like this one [the EpiPen] is challenging These

entry barrier, particularly in a market where the risk of buying an ineffective product can be death.²¹³ How willing would any of us be to purchase a product with a lower price when the life of our child is at stake?

A full rule of reason analysis of EpiPen's pricing and the structural barriers to competition in the market, along with possible efficiencies, would be worthy subjects of investigation for government enforcement agencies. Indeed, it has been reported that the FTC opened an investigation into Mylan's activities in January of 2017, an investigation that may be focused on the 2012 Teva settlement, as well as on the slight changes that Mylan may have made in the auto-injector as a form of product hopping.²¹⁴ This behavior could very well be exclusionary, and worthy of condemnation, but it is ironic that an investigation impelled by substantial and apparently unjustified price increases can't focus on the core harmful behavior because of an overly narrow view of the scope of U.S. monopoly law.

IV. CONCLUSION

How is it that we can't seem to use the antitrust laws in the United States to tackle the problem of excessively high pharmaceutical drug pricing? The problem is easy enough to identify, as recent cases show, and is ongoing. Martin Shkreli may have left the scene, but his decision to raise the price for Daraprim by 5500 percent continues to draw praise and even imitation from at least one drug company executive.²¹⁵

Antitrust condemns "the evils of monopoly" and seeks to push prices down to the competitive level. Many pharmaceutical drugs are priced far above that. We may argue over whether antitrust is *only* about consumer welfare, but it is at least about consumer welfare. These high drug prices redistribute wealth from consumers to producers, something we normally condemn. Add to this the fact that we are not just talking about abstract "consumers," but about sick people in need of pharmaceutical drugs, often to survive.

[complex generic] products can be hard to copy, and therefore sometimes don't face timely generic competition once patents and exclusivities are no longer a block to approval.") (quoting FDA Commissioner Scott Gottlieb).

²¹³ See Thomas, *supra* note 199 ("EpiPen is like Kleenex—it's ubiquitous," said Brian Chapman, a consultant for ZS Associates, a pharmaceutical marketing firm. "What they've done with that brand has been amazing.').

²¹⁴ See David McLaughlin et al., *Mylan Faces U.S. Antitrust Investigation on EpiPen*, BLOOMBERG (Jan. 30, 2017) (product hopping and agreements to delay entry); Rockoff, *supra* note 13 (efforts to delay Teva's entry).

²¹⁵ See David Crow, *Pharma Chief Defends 400% Drug Price Increase as A 'Moral Requirement'*, FIN. TIMES (Sept. 11, 2018) (quoting chief executive of Nostrum Laboratories that there is a "moral requirement to sell the product at the highest price" and that "I agree with Martin Shkreli") (raising price of bottle of antibiotic nitrofurantoin from \$472 to \$2,392), www.ft.com/content/48b0ce2c-b544-11e8-bbc3-ccd7de085ffe.

Our failure to address this problem is even more perplexing in light of the historical willingness to take on excessive pricing in other sectors of the economy when sellers opportunistically raise the prices of products that are critical to consumers. True, these efforts have most often used statutory or regulatory approaches rather than antitrust, although the FTC has used Section 5 of the FTC Act to police deviations from FRAND pricing in the area of consumer electronics. In hesitating to use antitrust against excessive pricing of pharmaceutical drugs, though, the United States is an international outlier. Governments outside the United States are increasingly trying to use their antitrust laws to rein in excessive drug pricing as an abuse of dominance, albeit with some mixed results, while the idea is not even under discussion in the United States.

The explanation for this blind spot in U.S. antitrust enforcement lies first in an unexamined assumption that Section 2 of the Sherman Act does not reach monopoly pricing itself. Many cases say so, but a closer look at past Section 2 cases indicates that no case has ever so held. If the courts feel free to develop the Sherman Act as a matter of common law, they are free to bring excessive pricing into the ambit of Section 2.

What holds the courts back is a policy problem, not a legal one. In my view, the courts' consensus by dictum rests on three beliefs—that entry will take care of monopoly pricing faster than judicial intervention; that it is too difficult to determine what price is “excessive”; and that it is unduly interventionist to remedy that problem in an antitrust court. The entry argument is the weakest of the three. The other two are more difficult.

With regard to entry, economics scholarship has questioned assumptions about easy entry generally in the economy and specifically in pharmaceutical drugs.²¹⁶ In the three cases examined in this article, entry has either been difficult or non-existent. In the excessive drug pricing cases that the Italian Competition Authority and the CMA examined, the assumption of ready entry did

²¹⁶ See, e.g., COUNCIL OF ECON. ADVISERS ISSUE BRIEF, BENEFITS OF COMPETITION AND INDICATORS OF MARKET POWER 4–6 (2016) (discussing increasing concentration across a number of industries, increasing rents, and declining rates of entry; suggesting that “barriers to entry may have increased in many industries”); Ernst R. Berndt et al., *The Landscape of US Generic Prescription Drug Markets, 2004–2016* (Nat'l Bureau of Econ. Research, Working Paper No. 23640, July 2017) (showing high concentration in generic drug markets, with average HHIs over 4000, but with entry decreasing after 2013 and exits increasing; notes the “notable lack of detailed data to document actual patterns of firm entry and exit in important sectors of the U.S. economy”); Ariel Ezrachi & David Gilo, *Excessive Pricing, Entry, Assessment, and Investment: Lessons from the Mittal Litigation*, 76 ANTITRUST L.J. 873 (2010) (excessive prices do not necessarily attract new entrants because rational potential entrants consider post-entry rather than pre-entry price); Michal Gal, *Monopoly Pricing as an Antitrust Offense in the U.S. and the EC: Two Systems of Belief About Monopoly?*, 49 ANTITRUST BULL. 343, 356 (2004) (“modern economics” recognizes that markets may not self-correct expeditiously).

not hold true. But why rely on assumptions one way or the other? Conditions of entry are frequently litigated in antitrust cases, so why not in this area as well?

Figuring out when pricing is excessive is a harder question. Once the defendant is shown to have monopoly power in a relevant market, antitrust courts in the United States would proceed under the general rule of reason framework used in Section 2 cases. The three case studies presented earlier (as well as the European cases) can help isolate some of the indicative factors that might show excessive pricing. These factors would include: (1) the timing of the price increase, whether as an immediate price spike or a more gradual increase (which creates an inference of anticompetitive effect); (2) the amount of the increase over previous prices; (3) whether the price increase was opportunistic as opposed to being based on changed cost factors or the need to reward investment in risky enterprise; (4) the relationship of price to an appropriate benchmark (cost of production or a relevant comparator, such as the price in a different geographic market); (5) the potential impact on innovation (which will vary depending on the product and the industry); and (6) the conditions of entry and other structural aspects of the market.

Although these factors can be helpful in guiding analysis, each contains a broad element of judgment. To some extent we now tolerate this type of judgment in rule of reason cases, recognizing that judicial development and industry practice can help fill in the contours of what is considered reasonable, as the Supreme Court eventually recognized in the post-World War I constitutional cases. Indeed, today we find ourselves in a position similar to the one that the United States faced in 1898 when Judge Taft surveyed domestic and foreign jurisdictions to decide which contracts should be considered illegal restraints of trade under the then-new Sherman Act.²¹⁷ U.S. courts could follow Taft's example and draw on decisions outside the United States to help develop their approach to excessive pricing by monopolists, but without being bound by the legal framework that Article 102 of the TFEU requires in the European Union.

Enforcement agency guidelines or policy statements, or even rule-making, could provide further guidance on excessive pricing.²¹⁸ These tools of the reg-

²¹⁷ See *United States v. Addyston Pipe & Steel Co.*, 85 F. 271 (6th Cir. 1898) (reviewing cases from England, Canada, and Australia, from the U.S. Supreme Court and the federal courts, and from 18 state courts), *aff'd*, 175 U.S. 211 (1899).

²¹⁸ See Comment of Rohit Chopra, Comm'r, Fed. Trade Comm'n, Hearing #1 on Competition and Consumer Protection in the 21st Century, Docket ID FTC-2018-0074 (Sept. 6, 2018) (arguing that FTC should make greater use of participatory rulemaking as a way of dealing with the ambiguities of the rule of reason and increasing democratic input into antitrust rules), www.ftc.gov/system/files/documents/public_statements/1408196/chopra_-_comment_to_hearing_1_9-6-18.pdf.

ulatory state were not available at the turn of the 20th century when federal courts first encountered legislative efforts to control excessive pricing, but we are quite familiar with them today. Such enforcement guidelines could, for example, use screens that would give parties safe harbors in terms of how much of a price increase would not be considered excessive (much as HHIs provide safe harbors for certain mergers), draw on historic pricing patterns to provide some benchmarks against which to judge price spikes (much as we do in electricity pricing), and make clear the factors that the agencies would look to when deciding whether to bring such a case.²¹⁹ This type of approach would go far to deal with the concerns for administrability that have bothered U.S. courts.

The third problem is that of remedy. How can courts or agencies write an injunction that tells defendants how they cannot price in the future? Or, to put it another way, what sort of remedy will an enforcement agency seek that can avoid casting courts in the role of price regulator tasked with monitoring a defendant's pricing? In the *Aspen* and *Pfizer* cases discussed above, the Italian and UK enforcers basically told the drug companies that it was up to them to figure out how to conform to the law.²²⁰ Whether this is adequate guidance for the parties, or for subsequent court enforcers, remains to be seen. Perhaps the most that can be said here is that courts and agencies have faced similar problems in other types of pricing cases, such as predatory low pricing, but those problems have not been considered as a reason to disable courts or agencies from considering such claims.²²¹

Finally, even if excessive pricing could be the subject of a Section 2 case, would antitrust law be a good vehicle for remedying excessive pricing of pharmaceutical drugs? There are some obvious institutional problems in using antitrust to deal with this issue. The case-by-case development of standards is a slow and expensive process, even when augmented by guidelines, and does not always produce clarity. Antitrust enforcement against excessive pricing of pharmaceutical drugs will necessarily be more sporadic and more expost than a regulatory scheme would be, but these may count as virtues. Anti-

²¹⁹ See Gilo, *supra* note 171, at 30–31 (suggesting that price less than 20% above benchmark price might be considered a safe harbor).

²²⁰ See *supra* note 132 and accompanying text.

²²¹ See, e.g., Decision & Order §§ I.K, IV.A.6, Intel Corp., FTC Docket No. 9341 (Oct. 29, 2010), www.ftc.gov/sites/default/files/documents/cases/101102inteldo.pdf (forbidding certain bundled sales below “consent order cost,” computed as a three-quarter rolling average of product cost of sales minus depreciation, “using the quarter in which assembly and testing of the shipped units of the Relevant Product is completed and the two immediately following quarters”); Borden, Inc., 102 F.T.C. 1147 (1983) (consent order forbidding Borden from selling ReaLemon brand reconstituted lemon juice at a price such that net revenue would be below variable cost in any quarter, defining elements of total and variable cost, as well as net revenue) (predatory pricing case).

trust is less likely to be captured by the pharmaceutical industry and more consistent with relying on market mechanisms, indeed as we are trying to do in other, more regulatory schemes. But if antitrust enforcement works, it may allow us to avoid more intrusive regulatory schemes, such as more general pharmaceutical price regulation, schemes that may carry larger risks to innovation and entrepreneurial freedom.

Every proposal advanced in this area has problems, and it is doubtful that any one proposal will be *the* solution. But the real mystery is why we have taken antitrust law off the table. At their core, the antitrust laws are directed against the harmful conduct of monopolists, and particularly the harmful conduct of monopolists that leads to high prices, misallocates resources, and extracts money from consumers and gives it to producers for no other reason than they are in a position to take it. Unless we prefer to do nothing at all, we should embrace the opportunity to use antitrust law this way, making it truly a “consumer welfare prescription.”²²²

²²² *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (citing ROBERT H. BORK, *THE ANTI-TRUST PARADOX* 66 (1978)).