Unfair Drug Prices and Section 5

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I. INTRODUCTION

In August of 2015 Turing Pharmaceuticals, a start-up run by former hedge fund manager Martin Shkreli, acquired a drug called Daraprim, a 62-year old drug used to treat toxoplasmosis, a potentially life-threatening parasitic infection. Turing immediately raised the price of Daraprim from $13.50 per tablet to $750 per tablet. Shkreli vigorously defended the price increase (“I think profits are a great thing to sustain your corporate existence.”) and promised to use the profits for future research into new drugs for toxoplosmosis. If only Willy Sutton had thought of that argument when he was robbing banks.

Turing has not been alone in this strategy. According to a Wall Street Journal article published in April 2015, a number of pharmaceutical companies have been pursuing the same strategy of buying drugs and then immediately raising price. Valeant bought Isuprel and Nitropress, both staple drugs for heart problems that were off-patent but had not attracted generic competition. On the day of the acquisition Valeant raised the prices 525 percent and 212 percent respectively, increasing the annual costs of those drugs by $8.6 million for one hospital group alone (the Cleveland Clinic).

Mallincrodt bought Cadence Pharmaceuticals, which owned Ofirmev (an injectable form of acetaminophen); three months later it increased the price for a package of 24 vials by 2 ½ times. “It seemed like highway robbery,” an employee of the University of Utah health care system was quoted as saying; that system was now spending $55,000 per month instead of $20,000 to $25,000.

The day after Horizon Pharma bought the rights to Vimovo (a pain tablet) it raised the price by 597 percent; a year later it raised the price another 75 percent. Sixty tablets that had cost approximately $160 on December 31, 2013 cost more than $1600 by January 1, 2015.

The reports of these price increases brought cries of indignation, from presidential candidates and from Congress, but the question I want to address is whether the acquisition of these drugs should bring antitrust action, specifically, action by the Federal Trade Commission.
under Section 5 of the Federal Trade Commission Act. I think the answer should be yes. These acquisitions may fall short under traditional Clayton Act and Sherman Act analysis. But I think they are good candidates for a standalone Section 5 proceeding because this type of extortionate price raising goes to the heart of traditional antitrust concern—rent extraction, welfare loss, and redistribution of consumer surplus.

II. THE ARGUMENT FOR A SECTION 5 CASE

On first approach, it looks as though an FTC proceeding against these types of drug price increases would run into the buzzsaw of two significant antitrust doctrines. First, this is unilateral conduct without collusion. As a general matter we avoid reviewing such conduct because, as the Supreme Court has reminded us, we don’t want to chill or deter a single firm’s “vigorous competition through ordinary business operations.” Single-firm conduct is to be reached under Section 2, but only if the firm has monopoly power in a relevant market. Second, even if a firm has monopoly power, it is black letter law that high prices, in themselves, are not a Section 2 violation. As the D.C. Circuit has pointed out, “[e]ven if deception raises the price secured by a seller, . . . it is beyond the antitrust laws’ reach.”

Closer examination of antitrust doctrine, however, reveals some inconsistencies in these basic approaches. For one, when we look at asset acquisitions under Section 7—a form of “single-firm” conduct—we are directly concerned with unilateral price effects, that is, the likelihood that the acquiring firm, all by itself, will be able to raise price post-acquisition. For another, it turns out that there are cases in which we have been willingness to examine unreasonably high prices, although as an “unfair method of competition” under Section 5 and not technically as a Section 2 violation.

Start with Section 7. An obvious case in point is the FTC’s suit against Ovation Pharmaceuticals. In 2005 Ovation acquired Indocin IV, an off-patent injectable drug used to treat patent ductus arteriosus (“PDA”), a life-threatening heart condition that primarily affects low-birth-weight babies. Shortly after acquiring the drug, Ovation raised its wholesale price by 40 percent. In 2006 Ovation acquired Neoprofin, a patented injectable drug that was about to come onto the market and was approved for treating the same condition. Two days after acquiring Neoprofin Ovation raised the price of Indocin IV by nearly 1300 percent. The result was that a three-vial course of treatment using Indocin IV that had cost about $78 in 2005 cost $1500 six months later.
The Commission’s Section 7 concern, of course, was that the acquisition of Neoprofin removed a looming competitive constraint on Ovation’s pricing behavior, but the true harm that triggered the litigation was that Ovation had exploited consumers of Indocin IV in a way that the drug’s previous owner had not. But suppose that Neoprofin had not existed to constrain Ovation’s behavior and Ovation had raised its price, in two steps, by more than 1800 percent? Wouldn’t the economic harm still be the same—price raising, or “rent extraction,” in a way that produces a deadweight welfare loss and reduces consumer surplus?

Curiously, the Commission’s case against Ovation foundered because the district court held that Indocin IV and Neoprofin didn’t constrain each other’s pricing and so the two drugs weren’t in the same product market. I take this to mean that Indocin IV stood alone. Still even if Indocin IV was a “line of commerce,” a Section 7 case focused just on Indocin IV might have fallen short because the acquisition itself didn’t lessen competition (the new owner of Indocin IV was in the same position as the old).8 And perhaps a Section 2 case just involving Indocin IV would have fallen short because the bad conduct of the firm owning Indocin IV “only” consisted of setting high prices.9

But what if the FTC had framed the case initially just as an unfair method of competition arising out of Ovation’s ability to raise the price of Indocin IV so dramatically and hold it there for a substantial and significant non-transitory period? Why isn’t this price-raising harm enough? Shouldn’t this adverse economic conduct, unconstrained by marketplace competition, be sufficient for a “standalone” theory under Section 5 of the FTC Act?

This brings me to an important area where the FTC has been directly concerned with the imposition of unfair high prices—the licensing of standard-essential patents (“SEPs”). Beginning with the Dell case in 1996, the Commission has been scrutinizing the conduct of patentees involved in the standards setting process.10 In Dell this concern was reflected in a Section 5 case involving Dell’s manipulation of the standard-setting process by failing to disclose to the standard-setting organization that it had a patent on the standard the organization was about to approve. Later cases have focused on the conduct of patentees that have committed themselves to licensing their SEP patents on fair terms (known as “RAND” or “FRAND,” meaning fair, reasonable, and non-discriminatory).

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8 Commissioner Rosch thought that the original acquisition of Indocin IV could have been challenged under Section 7, based on FTC v. Procter & Gamble, 386 U.S. 568 (1967), but he did not discuss a possible standalone Section 5 case. See Concurring Statement of Comm’r J. Thomas Rosch, Federal Trade Comm’n v. Ovation Pharma., Inc., available at https://www.ftc.gov/system/files/documents/public_statements/418091/081216ovationroschtmt.pdf.

9 The Commission did include a monopolization count in its complaint, but based on the same product market definition as its Section 7 count. See Complaint, FTC v. Ovation Pharma., Inc. (D. Minn. 2008), at ¶¶ 42-46, available at https://www.ftc.gov/sites/default/files/documents/cases/2008/12/081216ovationscmp.pdf. The district court also dismissed the monopolization count for failure to prove the relevant market and the court of appeals did not consider the monopolization argument further. See 2010 U.S. Dist. LEXIS 95365 at *58-59.

The Commission has justified its concern for breach of FRAND commitments on the ground that royalty rates should not “overcompensate” the patentee.11 For example, in 2013 the FTC issued a complaint against Google alleging a violation of Section 5 arising from Google’s breach of commitments to license certain SEPs on FRAND terms, commitments to which its newly-acquired subsidiary, Motorola Mobility, had previously agreed. The specific conduct on which the FTC focused was Google’s willingness to prosecute patent infringement claims before the International Trade Commission and the courts, and to seek, respectively, exclusion orders and injunctive relief.12 Threats of injunctive relief, the Commission alleged, allowed Google to “demand licensing terms that tended to exceed the FRAND range.” The “anticompetitive effect” of this conduct, the Commission alleged, was “increas[ed] costs,” which the Commission termed a “substantial consumer injury”: “If Google’s practices are allowed to continue, many consumer electronics manufacturers will agree to pay unreasonable royalties . . . [and] will likely pass on some portion of these costs to end consumers.”13

The FTC made an even more direct attack on high licensing rates in the Negotiated Data Solutions case (N-Data), decided five years before the Google case was brought. N-Data involved the standard-setting process, but not a commitment to license on undefined FRAND terms. Rather, N-Data’s predecessor, in the course of an SSO’s adoption of an Ethernet standard, had promised to license the patents covering the technology to any requesting party for a one-time fee of $1000. The relevant patents were later assigned to another company, and eventually to N-Data. 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 targeted companies that included many large computer hardware manufacturers. The royalties demanded represented a “substantial increase” over the original $1000 fee.14

The FTC’s complaint charged that N-Data’s conduct was an “unfair method of competition” in violation of Section 5 of the FTC Act. The “threatened or actual anticompetitive effects,” the FTC asserted, included “increased royalties” for the manufacture or sale of products that implement the standard.15 As the Commission explained, even if N-Data’s conduct did not violate the Sherman Act, the conduct “threatened to raise prices for an entire industry.” Patent holders shouldn’t be allowed to “exploit the power [they] enjoy” over those practicing the standard.16

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13 Id. at ¶ 25, 28, 30.
15 Id. ¶ 37a.
16 N-Data, Analysis of Proposed Consent Order to Aid Public Comment at 5, available at https://www.ftc.gov/sites/default/files/documents/cases/2008/01/080122analysis.pdf. See Google/Motorola Mobility, Analysis of Proposed Consent Order to Aid Public Comment at 5 (“opportunistic breach of its licensing commitment had the tendency of leading to higher prices for consumers and undermining the standard-setting
So why should drug manufacturers be allowed to exploit the power they enjoy over patients who are dependent on their drugs? However important it is to prevent exploitation in communications equipment markets like cellphones—and it is economically quite important—surely it is at least as important economically and socially to prevent exploitation in pharmaceutical drug markets where both money and health are at stake.

Perhaps one difference between the high prices allegedly extracted by N-Data and Google/Motorola Mobility and the high prices of Daraprim and Indocin IV is that N-Data and Google had made contractual commitments not to exploit their monopoly power through high prices, but there was no such contractual agreement from Turing or Ovation. But could we say that drug companies have entered into a social compact with the American people that allows rewards for those who invest in pharmaceutical innovations but recognizes that price gouging is a breach of that compact?

The debate over patents for pharmaceutical drugs has always been shadowed by the concern that excessive prices can put medicine out of the reach of many who need it. We tolerate patents because we want new drugs, but the protection from competition we grant to these new drugs is not boundless. Could we at least take on the rather limited case of a Daraprim or Indocin IV and say that firms should not be able to raise prices so substantially post-acquisition where they have invested not a penny in researching or developing the drug but have simply taken advantage of a market opportunity that the innovating firm did not see or was unwilling to exploit?

A standalone Section 5 case would put this issue to the FTC. This would allow the Commission to explore the nature of the competitive constraints with regard to the drug involved. Perhaps the previous owner had been constrained by a concern for the reputational harm that a substantial and unjustified price increase might cause, whereas the new owner is not (which might have been the case for Indocin IV).\(^\text{17}\) Perhaps the new owner is able to exploit consumers because the size of the market is small and the new owner can deter entry by its ability to simply drop price to its low cost of production if a generic appears (which might be the case with Daraprim). And any procompetitive justifications could likewise be assessed by the Commission.

One obvious problem with taking on such cases would be to figure out how “substantial” a price rise would be considered exploitative, but I think that this, too, is a judgment that we can appropriately leave to the Commission, which actually has developed expertise in pharmaceuticals. It is not an impossible judgment to make. FRAND cases present a similar problem—what price is “fair and reasonable,” after all?—but courts are now dealing with this very issue.\(^\text{18}\)

\(^\text{17}\) Commissioner Rosch suggested this in his separate statement in the Ovation case, supra note 8, at 1.

\(^\text{18}\) See, e.g., Microsoft Corp. v. Motorola, Inc., 795 F.3d 1024 (9th Cir. 2015) (upholding district court’s determination of a specific “reasonable” rate, which was substantially below rate demanded by patent holder) (contract suit for breach of commitment to license SEP patent portfolios on RAND terms).
The bottom line, though, is that this type of case—a drug acquisition followed by an exploitative price increase—is a targeted category of price-raising cases with a harm that comes within one of the main concerns of the antitrust laws: rent extraction that produces deadweight welfare loss and harms consumer welfare. It is a limited category of cases, fit for the Commission to take on as an “unfair method of competition.”

III. THE FTC SECTION 5 STATEMENT

Calling for a standalone Section 5 inquiry raises the question of the state of the law in this area. The FTC’s theories in N-Data and Google/Motorola Mobility were never tested in the courts and were thinly explained by the Commission itself. Does the Commission’s recently issued “Statement of Enforcement Principles Regarding ‘Unfair Methods of Competition’ Under Section 5 of the FTC Act” help?¹⁹

Not really.

The Statement is brief, making four points. The first one is that Section 5 includes conduct that violates the “spirit” of the antitrust laws and conduct that “if allowed to mature or complete” could violate the Sherman or Clayton Acts. The acquisition of a pharmaceutical drug followed by a substantial and unjustified price rise is not one that will “mature” into an antitrust violation, but does it violate the spirit of the antitrust laws? Perhaps it does, at least where high prices are unconstrained by market forces.

The second is that the Commission will be guided by the “promotion of consumer welfare.” Sustained high prices for these acquired drugs arguably harms consumer welfare, so perhaps this conduct could be reached as “spirit” plus “consumer welfare harm.”

But the third point emphasizes the use of a framework “similar” to the rule of reason, and the Commission’s explanation cites the Areeda Hovenkamp treatise for the view that “[a] monopolist acting reasonably does not violate Sherman Act § 2.” Would this include the standard view that high prices, alone, are “reasonable”? Or is the Commission just telling us that it would use a rule of reason framework similar to the one I have described to assess the anticompetitive effects and pro-competitive justifications?

And the fourth point states that the Commission will continue to rely on the Sherman and Clayton Acts if they are “sufficient” to address the competitive harm. But what if they aren’t, as is likely for the cases I am looking at?

Commissioner Ohlhausen, in dissent, argues that the Statement “does little to constrain the Commission.” She argues that “every Section 5 theory pursued in the last 45 years, no matter how controversial or convoluted, can be and has been couched in terms of protecting competition and/or consumers.” As an example she cites N-Data. Does this mean that the Commission is telling us it would follow N-Data in a similar case in the future? Or is the Commission simply silent on the matter, leaving the issue for future decisions?

¹⁹ The Commission’s Enforcement Principles, the Commission’s statement explaining the Principles, and Commissioner Ohlhausen’s dissent can be found at 80 Fed. Reg. 57056-59 (Sept. 21, 2015).
My concern with the Statement is not that it will allow the Commission to bring whatever enforcement actions it wants but that it will allow the Commission not to bring whatever enforcement actions it doesn’t want. Of course, that’s exactly the position that it usually is in because the Commission does not have to justify its decision not to file a case. I have argued in the past that enforcement guidelines are unnecessary in this area.20 Perhaps the current document, with its somewhat vague generalities, both guides and binds only slightly, which may be a good second-best outcome from my point of view.

IV. CONCLUSION

I draw three points from my examination of the problem of drug acquisitions followed by extreme price hikes:

First, based on its past enforcement actions, the FTC could properly be concerned when pharmaceutical companies acquire a drug and subsequently raise prices in a way that extracts rents and exploits consumers. The analogue is the exploitation of standard-essential patents by patentees that had previously committed to only extracting reasonable prices, an area in which the Commission has been, and continues to be, active. From a policy point of view, the Commission is at least as justified in taking action in the drug acquisition area, where price-gouging is particularly harmful economically and socially.21

Second, using Section 5 in such a case is reasonably anchored to traditional antitrust concerns. The drug cases examined above involve asset acquisitions, a discrete type of conduct that is already reviewed under Section 7 of the Clayton Act for unilateral price increases. Section 5 may be helpful where the asset acquisition doesn’t quite fit into Section 7’s requirements relating to market definition or “lessening competition” and doesn’t quite fit into traditional Section 2 jurisprudence either.22

Third, the Commission’s Statement of Section 5 enforcement principles should not be viewed as taking this issue off the table. Indeed, the drug pricing example is a cautionary tale about the issuance of enforcement guidelines in an area in which Congress has given the Commission substantial discretion. When it’s difficult to know what issues might be on the table when you are setting it, leave some room for what might come later. If the Commission’s Statement is viewed in that context, then it should be interpreted liberally to allow the Commission to assess new problems in light of traditional competition concerns: maintaining

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21 For a description of South Africa’s efforts to deal with excessive pricing of antiretroviral drugs used for treating HIV, see OECD Document DAF/COMP/WD(2014)68, available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WD%282014%2968&docLanguage=En (describing issuance of complaint in Hazel Tau case, charging abuse of dominance under South African Competition Act, followed by settlement that reduced royalty rates).

22 For an earlier argument that Section 5 can reach mergers where Section 7 does not quite fit, see Peter C. Carstensen & Nina H. Questal, The Use of Section 5 of the Federal Trade Commission Act to Attack Large Conglomerate Mergers, 63 CORN. L. REV. 841 (1978).
the competitive process and preventing the exploitation of consumers through the extraction of monopoly rents.