

2017

## Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game is Rigged

Mark S. Levy

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### Recommended Citation

Levy, Mark S. (2017) "Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game is Rigged," *American University Law Review*: Vol. 66 : Iss. 1 , Article 6.  
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# Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game is Rigged

## **Keywords**

FTC v. Actavis, antitrust, Risk Evaluation & Mitigation Strategies, REMS, "legitimate business" defense

# BIG PHARMA MONOPOLY: WHY CONSUMERS KEEP LANDING ON “PARK PLACE” AND HOW THE GAME IS RIGGED

MARK S. LEVY\*

*Now, more than ever before, pharmacologists are contributing medical advances to confront ravaging disease. They are developing drugs to mitigate the effects of Alzheimer’s, HIV, multiple sclerosis, and various forms of cancer. To capitalize on the opportunity, brand-name pharmaceutical firms are patenting these drugs, consequently guarding formulas and, with it, profits. Patents grant brand-name firms market exclusivity, which essentially allows them to set their own prices.*

*Even though brand-name firms are investing some of their capital to cultivate new drugs, they also are enjoying gigantic revenue streams, absurd profit margins, and seemingly unfettered control of their respective markets. Consequently, sick patients are unable to afford their medication; high prices are bankrupting consumers in the absence of reasonably-priced generic alternatives. Despite the fact that generic drugs contain identical ingredients, cure the same symptoms, and cost 70% less, brand-name drugs persistently dominate their generic counterparts.*

*Indeed, brand-name firms are improperly preventing generic market entry. Without generic competition, no watchdog exists to curb big pharma’s prohibitive prices. Despite the Supreme Court’s fleeting fix in *FTC v. Actavis*, which condemned reverse payment settlements that precluded competition,*

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\* Note & Comment Editor, *American University Law Review*, Volume 66; J.D. Candidate, May 2017, *American University Washington College of Law*, B.A. Psychology, *James Madison University*. I would like to offer a profound thank you to my family, friends, professors, and colleagues, who all continue to inspire and encourage me every day. I also would like to extend a special thanks to the ever-hard-working staff of the *American University Law Review* for their efforts throughout the publication process.

*brand-name firms are employing other tactics predatorily to extend their market exclusivity and charge consumers unaffordable prices.*

*To prevent brand-name abuse and help infirm patients afford their medication, this Comment proposes that courts apply federal antitrust law to brand-name firms that attempt to monopolize a pharmaceutical market through anticompetitive means, particularly by abusing Risk Evaluation & Mitigation Strategies (REMS) and by “product hopping.” To combat exclusionary conduct, courts should mirror the “rule of reason” framework set forth in *Actavis* and apply an “enhanced” version specifically tailored to the pharmaceutical industry, giving stronger credence to generic challengers. In addition to finding brand-name tactics exclusionary, this Comment also proposes that courts adopt a bright-line rule prohibiting brand-name firms from exploiting the “legitimate business” defense to immunize their destructive conduct.*

*The current framework perpetuates abuse and grants brand-name firms ostensibly indefinite monopolies. Analyzing brand-name defensive tactics under federal antitrust law would facilitate generic market entry and consequently moderate drug prices. Even after sacrificing their entire financial portfolios, patients are still unable to afford their medication. This Comment interprets *Actavis* as prohibiting the “legitimate business” defense and provides a remedy to deserving consumers by preventing REMS abuse and product hopping, fostering generic competition, and tempering excessive drug prices.*

#### TABLE OF CONTENTS

Starting at “Mediterranean Avenue” .....	250
I. The Rules of the Game .....	256
A. Hatch-Waxman Seeks to Keep an Eye on the “Banker” .....	258
1. Expanding brand-name patent exclusivity .....	259
2. Mandating REMS and mitigating consumer risk .....	260
3. Reducing generic market entry expenses.....	261
4. Requiring pharmacists to substitute generic drugs....	262
B. Consumers Win “Free Parking” in <i>Actavis</i> .....	263
1. The decline of patent law's “scope of the patent” test.....	264
2. Antitrust law's rule of reason applied to reverse- payment settlements .....	265
II. How Brand-Names Are Still Collecting Too Much When They “Pass Go” .....	269
A. REMS Exploitation .....	270
1. The “profit sacrifice” test and the “no economic sense” test.....	272
2. The essential facilities doctrine.....	274

2016]	BIG PHARMA MONOPOLY	249
	B. Product Hopping.....	276
III.	No “Chance Card” Can Make This Game Fair.....	279
	A. Examining Pharma’s Unique Characteristics Is No Smooth Ride on the “B. & O.” .....	280
	B. Mirroring an “Enhanced” Rule of Reason Framework from <i>Actavis</i> .....	283
	C. Brand-Names Should “Go Straight to Jail Without Passing Go” for Exclusionary Conduct .....	285
	1. REMS manipulation constitutes exclusionary conduct.....	285
	a. Refusing to sell makes “no economic sense” .....	286
	b. Refusing to sell denies generic firms an “essential facility” .....	288
	2. Product hopping constitutes exclusionary conduct...	291
	a. Coercing consumers is exclusionary.....	291
	b. Avoiding an examination of a product’s superiority .....	294
	D. The “Legitimate Business” Defense Is No “Get Out of Jail Free” Card .....	295
	1. Honoring the Sherman Act.....	296
	2. Upholding the purpose of the Hatch-Waxman Act.....	297
	a. Allowing the defense facilitates REMS manipulation.....	298
	b. Allowing the defense facilitates product hopping.....	299
	3. Preventing brand-names from being pharma’s gatekeepers.....	299
	Landing on “Park Place” .....	301

*“The chess-board is the world;  
the pieces are the phenomena of the universe;  
the rules of the game are what we call the laws of Nature.  
The player on the other side is hidden from us.”*<sup>1</sup>

#### STARTING AT “MEDITERRANEAN AVENUE”

How much money would you spend to save a loved one’s life? An individual contemplating such a quandary might consider many options: dipping into a child’s college fund, taking out a second mortgage, or possibly even declaring bankruptcy. How do you begin to weigh the ultimate effect that exorbitant healthcare costs will have on your family? People say you cannot put a price tag on a life, but with the ever-rising prices of pharmaceutical drugs, this choice is one millions of Americans face every day.

Consider the following scenario: doctors diagnosed Jacqueline Racener, a seventy-six-year-old secretary, with leukemia.<sup>2</sup> The good news? A new drug, Imbruvica, reduces the risk of Racener’s disease progressing by seventy-eight percent and her risk of death by fifty-seven percent.<sup>3</sup> The bad news? The life-saving medication is outrageously expensive; even after Medicare covered a majority of the cost, she would still pay nearly \$8000.<sup>4</sup> Racener chose not to fill her prescription.<sup>5</sup> Although she could not afford her medication,

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1. Richard Mills, *Food Inflation Harsh Times—A New Normal*, MKT. ORACLE (Apr. 9, 2011, 1:31 AM), <http://www.marketoracle.co.uk/Article27446.html> (quoting Thomas Henry Huxley). The theme of this Comment is developed from the board game, “Monopoly.” The game is based on economic principles; players move around the board with the objective of “becom[ing] the wealthiest player,” or the monopolist, by buying and selling property. See *Monopoly*, PARKER BROTHERS, <http://www.hasbro.com/common/instruct/00009.pdf> (last visited Oct. 19, 2016) (explaining the rules of the game). “Park Place” is one of the worst properties to land on: its owner is usually the strongest competitor, the rent is exceptionally pricey, and it usually causes the trespasser to fear imminent bankruptcy.

2. Joseph Walker, *Patients Struggle with High Drug Prices*, WALL ST. J. (Dec. 31, 2015, 10:38 AM), <http://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981>.

3. *FDA Expands Approved Use of Imbruvica for Chronic Lymphocytic Leukemia*, FDA (July 28, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm406916.htm>.

4. Walker, *supra* note 2. Before insurance, the drug costs between \$116,000 and \$155,400. *Id.* Paradoxically, it was not until her salary was cut by forty percent that she qualified for aid and was subsequently able to afford her prescription. *Id.*

5. *Id.*

Imbruvica was not concerned with losing her as a customer—its global sales were roughly \$1 billion in 2015.<sup>6</sup>

Similarly, Stuart Chapin, a fifty-five-year-old teacher, was diagnosed with colorectal cancer.<sup>7</sup> Doctors gave Chapin just six months to live, straining his finances and troubling his wife, who began to suffer from an anxiety disorder.<sup>8</sup> After spending \$60,000 on medication and exhausting his eighteen-year-old son's college fund, Chapin could no longer afford treatment.<sup>9</sup> As a result, Chapin and his wife discussed the possibility of removing his nephrostomy tube, which would kill him in a matter of days or weeks.<sup>10</sup>

Stories like Racener's and Chapin's permeate our daily news cycle and elicit mixed reactions.<sup>11</sup> Faced with surging pharmaceutical

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6. *See id.* (adding that AbbVie Inc., the company that owns Imbruvica, projected sales at around \$5 billion in 2020).

7. Rich McHugh & Tracy Connor, *Cancer Patients Sick with Worry over High Cost of Drugs*, NBC NEWS (July 23, 2015, 10:02 PM), <http://www.nbcnews.com/health/cancer/cancer-n397281>.

8. *Id.*

9. *Id.*

10. *Id.* Chapin's thirteen-year-old daughter even co-wrote a novel, attempting to raise enough money to pay for her dad's treatment. *Id.* Chapin explained his family's predicament, stating, "[O]ur choices are lose the house or lose my life. There's no third choice." *Id.*

11. Compare Maggie Fox, *Can We Get Cheaper Cancer Drugs? More than 100 Experts Weigh in*, NBC NEWS (July 23, 2015, 5:43 PM), <http://www.nbcnews.com/health/cancer/experts-weigh-how-make-cancer-drugs-affordable-n397336> (reporting that patients pay \$25,000 to \$30,000 in annual, out-of-pocket costs for some cancer-treating drugs), and Olga Khazan, *The True Cost of an Expensive Medication*, ATLANTIC (Sept. 25, 2015), <http://www.theatlantic.com/health/archive/2015/09/an-expensive-medication-human-cost/407299> (discussing the high cost of prescription drugs), with Katie Thomas, *Brand-Name Drug Prices Rise Sharply, Report Says*, N.Y. TIMES (Nov. 28, 2012), [http://www.nytimes.com/2012/11/29/business/cost-of-brand-name-prescription-medicines-soaring.html?\\_r=0](http://www.nytimes.com/2012/11/29/business/cost-of-brand-name-prescription-medicines-soaring.html?_r=0) (noting that brand-name pharmaceutical trade groups attribute high drug costs to the high costs of developing those drugs, particularly specialty drugs used for multiple sclerosis and cancer—a pharmaceutical executive stated that "[w]ithout the development of new medicines by innovator companies, there would be neither the new treatments essential to progress against diseases nor generic copies"). In another related story, doctors diagnosed Karen Winkler, mother of three, with multiple sclerosis (MS). *Are Generic Drugs Being Delayed to Market?*, PBS NEWSHOUR (June 28, 2014, 1:31 PM), <http://www.pbs.org/newshour/bb/generic-drugs-delayed-market>. Doctors prescribed Winkler with Provigil, costing \$700 for a six-month supply. *Id.* (observing that the cost of one pill jumped from about seven dollars to around sixteen dollars). Unfortunately, Winkler's medication is not the only MS drug whose price has skyrocketed. Daniel M. Hartung et al., *The Cost of Multiple Sclerosis Drugs in the US and the Pharmaceutical Industry*, NEUROLOGY (Apr. 24, 2015), <http://www.neurology.org/content/84/21/2185>

costs, patients are often forced to choose between their medication and their mortgage.<sup>12</sup> In contrast, pharmaceutical companies increasingly profit from the same bills that choke patients.<sup>13</sup> For example, Martin Shkreli, former CEO of Turing Pharmaceuticals, recently raised the price of Daraprim, a drug used to treat toxoplasmosis, a life-threatening disease seen in patients with HIV/AIDS.<sup>14</sup> Overnight, Shkreli skyrocketed the cost of one tablet from \$13.50 to \$750, equating to a 5000% markup.<sup>15</sup> Consequently, he strong-armed thousands of Americans to pay somewhere between \$336,000 and \$634,500 for one year of medication.<sup>16</sup>

Shkreli has been called a “morally bankrupt sociopath,” a “garbage monster,” and “everything that is wrong with capitalism.”<sup>17</sup> But are we carelessly focusing on one man’s transgressions and ignoring a deeper, underlying issue? Indeed, pharmaceutical price gouging, rendering patients insolvent from unaffordable drugs, is not unusual.<sup>18</sup> Manufacturers elevate prices of life-saving drugs used to

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(finding that during the past two decades, MS drug prices have “increased annually at rates [five] to [seven] times higher than prescription drug inflation”).

12. See Lesley Stahl, *The Cost of Cancer Drugs*, CBS NEWS (Oct. 5, 2014), <http://www.cbsnews.com/news/the-cost-of-cancer-drugs/> (maintaining that most patients are ineligible for financial aid, and that many patients must therefore either forgo their medicine or take “half-doses” to spread out the cost).

13. See Paul Barrett, *Shkreli Wasn’t the First to Hike Drug Prices—And He Won’t Be the Last*, BLOOMBERGBUSINESSWEEK (Dec. 23, 2015, 7:00 AM), <http://www.bloomberg.com/news/articles/2015-12-23/shkreli-wasn-t-the-first-to-hike-drug-prices-and-he-won-t-be-the-last> (discussing various drugs and their price increases).

14. Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

15. Julie Beck, *The Drug with a 5,000 Percent Markup*, ATLANTIC (Sept. 22, 2015), <http://www.theatlantic.com/health/archive/2015/09/daraprim-turing-pharmaceuticals-martin-shkreli/406546>.

16. Anna Almendrala, *What the Daraprim Price Hike Actually Does to Health Care*, HUFFINGTON POST (Sept. 22, 2015, 10:38 AM), [http://www.huffingtonpost.com/entry/daraprim-price-turing-shkreli\\_560063cee4b00310edf82060](http://www.huffingtonpost.com/entry/daraprim-price-turing-shkreli_560063cee4b00310edf82060).

17. Zoe Thomas & Tim Swift, *Who Is Martin Shkreli?—‘The Most Hated Man in America’?*, BBC NEWS (Sept. 23, 2015), <http://www.bbc.com/news/world-us-canada-34331761>.

18. See Barrett, *supra* note 13. Additionally, Valeant increased the cost of its heart drug by 525%, Rodelis raised its tuberculosis drug price from \$20 to \$360 per pill, and Questcor ballooned its MS drug from \$1235 to more than \$29,000 per vial. *Id.*; see also Tammy Worth, *The Rising Cost of Generic Prescriptions*, MED. ECON. (Feb. 25, 2015), <http://medicaleconomics.modernmedicine.com/medical-economics/news/rising-cost-generic-prescriptions?page=full> (highlighting drug prices that rose from \$20 to \$1829 for 500 tablets and \$916 to \$4489 for twenty-five vials).

treat cancer, diabetes, and multiple sclerosis by more than ten percent annually, a rate much higher than that of inflation.<sup>19</sup>

Brand-name pharmaceutical firms enjoy gigantic revenue streams,<sup>20</sup> absurd profit margins,<sup>21</sup> and unfettered control of their own markets<sup>22</sup> even though generic drugs contain identical ingredients, cure the same symptoms, and cost twenty percent to seventy percent less than their brand-name counterparts.<sup>23</sup> Admittedly, brand-name firms shoulder high research and development costs,<sup>24</sup> but, even after recouping their investments and then some, they are still unearthing ways to circumvent federal law and preclude competition.<sup>25</sup> A simple statistic illustrates the blatant

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19. See Barrett, *supra* note 13; Worth, *supra* note 18 (positing that some drug prices, including those used to treat muscle pain and inflammation, rose more than thirty percent).

20. The top five U.S.-headquartered pharmaceutical companies and their corresponding sales in 2014 were as follows: (1) Johnson & Johnson, \$74.3 billion; (2) Pfizer, \$49.6 billion; (3) Merck, \$42.2 billion; (4) AbbVie (Abbot Labs), \$20 billion; and (5) Eli Lilly, \$19.6 billion. *Big Pharma*, DRUGWATCH, <http://www.drugwatch.com/manufacture> (last visited Oct. 19, 2016).

21. Elyse Tanouye, *Price Markups on Generics Can Top Brand-Name Drugs*, WALL ST. J. (Dec. 31, 1998, 12:01 AM), <http://www.wsj.com/articles/SB915062993167849000> (asserting that “branded pills can have a margin of 90% or higher”).

22. See Charles W. Schmidt, *Drugs as Intellectual Property*, 4 AM. CHEMICAL SOC'Y: MOD. DRUG DISCOVERY 25 (June 2001), <http://pubs.acs.org/subscribe/archive/mdd/v04/i06/html/06rules.html> (“Patents provide the manufacturer market exclusivity over the formulation and the right to set its own price.”).

23. See *Generic Drugs and Low-Cost Prescriptions*, FTC (July 2012), <http://www.consumer.ftc.gov/articles/0063-generic-drugs-and-low-cost-prescriptions>; *Facts About Generic Drugs*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> (last visited Oct. 19, 2016) (“Generic manufacturers are able to sell their products for lower prices because they are not required to repeat the costly clinical trials of new drugs and generally do not pay for costly advertising, marketing, and promotion.”).

24. See Robert Weisman, *Cost of Bringing Drug to Market Tops \$2.5b, Research Finds*, BOS. GLOBE (Nov. 18, 2014), <https://www.bostonglobe.com/business/2014/11/18/cost-bringing-prescription-drug-market-tops-billion-tufts-research-center-estimates/6mPph8maRxcvftWjr7HUN/story.html> (providing one research center’s estimate that bringing a brand-name drug to market costs \$2.558 billion, marginalizing “the \$802 million figure in its last major study, done in 2003”); *Billion Dollar Pills*, ECONOMIST (Jan. 25, 2007), <http://www.economist.com/node/8585891> (assessing that initial research and development, marketing, and manufacturing for each new drug costs somewhere between \$500 million and \$2 billion).

25. See generally Editorial Board, *Sneaky Ways to Raise Drug Profits*, N.Y. TIMES (June 8, 2015) [hereinafter *Sneaky Ways to Raise Drug Profits*], [http://www.nytimes.com/2015/06/08/opinion/sneaky-ways-to-raise-drug-profits.html?\\_r=0](http://www.nytimes.com/2015/06/08/opinion/sneaky-ways-to-raise-drug-profits.html?_r=0) (denouncing “devious tactics by manufacturers of brand-name drugs to delay competition from cheaper generic drugs”).

abuse: generic drugs account for eighty percent of filled prescriptions but only comprise twenty-seven percent of overall prescription costs.<sup>26</sup> Unsurprisingly, brand-name pharmaceutical firms are manipulating their market share to preserve their disproportionate profits.<sup>27</sup>

Although private monitors exist, the pharmaceutical industry needs a stronger, more effective watchdog: federal antitrust law. For instance, in the recent landmark case *FTC v. Actavis, Inc.*,<sup>28</sup> the United States Supreme Court alleviated consumer coercion by holding that, under some circumstances, antitrust law can apply to pharmaceutical patent holders.<sup>29</sup> Despite the Court's momentary effectiveness in tempering abuse, brand-name firms are utilizing other strategies to delay or prevent generic drugs from entering their markets, consequently allowing them to enjoy market exclusivity long past their patents' expiration dates and thereby harming consumers.<sup>30</sup>

Brand-name firms preclude generic competition in two main ways: by manipulating Risk Evaluation & Mitigation Strategies (REMS) and "product hopping."<sup>31</sup> The FDA requires a brand-name firm to implement REMS to mitigate patient risk if it believes a drug is particularly risky.<sup>32</sup> Sometimes the FDA merely prescribes an extra warning label, but, for a more dangerous drug, the FDA may restrict its availability.<sup>33</sup> Brand-name firms exploit this constraint by alleging that the restriction prohibits them from selling drug samples to firms wishing to engineer a generic competitor, which effectively precludes

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26. Lynne Taylor, *US FDA Plans Generics 'Super Office'*, PHARMATIMES (Sept. 12, 2012), [http://www.pharmatimes.com/article/12-09-12/US\\_FDA\\_plans\\_generics\\_Super\\_Office.aspx](http://www.pharmatimes.com/article/12-09-12/US_FDA_plans_generics_Super_Office.aspx).

27. See *Sneaky Ways to Raise Drug Profits*, *supra* note 25 (describing "buying off the competition" and "product hopping" as two tactics used to increase brand-name profitability).

28. 133 S. Ct. 2223 (2013).

29. *Id.* at 2227.

30. See *infra* Sections II.A–B (condemning gambits, specifically REMS manipulation and product hopping, that brand-name firms employ to preclude generic competition).

31. *Id.*; see also *infra* note 121 and accompanying text (condemning brand-name firms for purposely limiting market access for generic brands by making it difficult for generic brands to obtain product samples, also known as REMS exploitation); *infra* note 167 and accompanying text (noting that brand-name firms engage in "product hopping" to preserve high prices by exploiting gaps in the Hatch-Waxman Act).

32. See MARY WILLY, FDA, OVERVIEW OF RISK EVALUATION & MITIGATION STRATEGIES (REMS) 2–7 (2012), <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM307704.pdf>.

33. See *id.*

generic market entry.<sup>34</sup> Brand-name firms also engage in product hopping.<sup>35</sup> Product hopping refers to the practice in which brand-name firms “hop” to a “new” drug to preclude generic firms from entering the market. Specifically, as a brand-name patent approaches its expiration date, generic firms anticipatorily prepare to enter the market by developing an imitation, or “generic,” version. Right before its expiration, however, the brand-name firm withdraws its drug, slightly modifies it, and remarkets it as a “new” drug.<sup>36</sup> This maneuver forces generic firms to abandon their development and start all over again in an attempt to manufacture a generic version of the most recent brand-name drug.<sup>37</sup> Brand-name firms may “hop” several times, each time delaying generic competitors.<sup>38</sup> Both REMS manipulation and product hopping hinder generic market entry and, as a result, prevent any savings from trickling down to consumers. Because of the lack of generic competition, pharmaceutical consumers are overpaying for their medication by millions of dollars each year.

To address these issues, this Comment proceeds in three parts. Part I sheds light on the natural tension between antitrust and patent law in the pharmaceutical industry. Section I.A describes the salient provisions of the Hatch-Waxman Act,<sup>39</sup> Congress’s tool that sought to repair the pharmaceutical industry. Next, Section I.B summarizes reverse-payment settlements, a common brand-name ploy to delay generic market entry, and the U.S. Supreme Court’s treatment of them in *Actavis*. Notwithstanding the win for consumer welfare in *Actavis*, Part II explains how brand-name pharmaceutical firms are exploiting Hatch-Waxman’s gaps through REMS manipulation and product hopping. Part III argues that antitrust law can consistently ameliorate big pharma’s pernicious practices. More specifically, this Comment proposes that courts should mirror the test set forth in *Actavis*, the rule of reason, and apply an “enhanced” version specifically tailored to the pharmaceutical industry. Utilizing this

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34. See, e.g., *Natco Pharma Ltd. v. Gilead Scis., Inc.*, No. CV 14-3247 (DFW/JSM), 2015 WL 5718398, at \*5 (D. Minn. Sept. 29, 2015) (alleging that a brand-name firm’s “REMS program [was] a scheme designed to preclude access”).

35. See *infra* Section II.B (outlining the ways that brand-name firms product hop).

36. See *infra* notes 174–78 and accompanying text.

37. Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1472 (2008) (contending that brand-name firms slightly alter their drugs to “shift consumers from the older version to the new” to “stave off competition from generic manufacturers”).

38. See *id.*

39. 21 U.S.C. § 355 (2012).

“enhanced” rule of reason, Sections III.B and III.C examine how REMS manipulation and product hopping each delay generic market entry and thus constitute exclusionary conduct, violating section 2 of the Sherman Act.<sup>40</sup> Finally, Section III.C rejects the “legitimate business purpose” defense, recommending that courts adopt a bright-line prohibition of the defense when brand-name firms use it to shield antitrust liability.

### I. THE RULES OF THE GAME

Over the past 120 years, great tension has amassed between the pillars of antitrust and patent law. The natural dividing line between the two is blurred at best, but, in many respects, the principles of antitrust law stand in stark contrast to those of patent law.<sup>41</sup> On the one hand, antitrust law “condemns exclusionary conduct” by criminalizing monopolization; on the other hand, patent law “grants exclusionary [conduct]” by facilitating monopolization.<sup>42</sup>

Passed in 1890, the Sherman Act sought to encumber powerful tycoons with overzealous business tactics from wielding excessive influence over the United States economy.<sup>43</sup> The Sherman Act does

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40. 15 U.S.C. § 2 (2012).

41. See Christopher R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34 J. CORP. L. 1259, 1259 (2009) (addressing the natural tension between antitrust and patent law and contrasting them as “anti-monopoly” and “monopoly,” respectively); see also, e.g., *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001) (per curiam) (rejecting the idea that companies have an “absolute and unfettered right to use its intellectual property as it wishes”).

42. Leslie, *supra* note 41, at 1260 (emphasis added) (maintaining that antitrust law “stimulat[es] competition” while patent law “temporarily suppress[es] it”); see also Joel S. Sprout, Note, *Presumptively Illegal: The Supreme Court’s Missed Opportunity in FTC v. Actavis, Inc.*, 42 CAP. U. L. REV. 763, 766 (2014) (describing the tension between patent and antitrust law in terms of their “conflicting goals” because “patent law grants . . . the new patent holder . . . exclusive rights to profit from the patented product, while antitrust law combats monopolistic practices”). The Framers specifically mentioned patent law and its salience, recognizing that despite their anticompetitive nature, patents produce a net benefit to society. See U.S. CONST. art. I, § 8, cl. 8 (“[Patents] promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . .”).

43. See 15 U.S.C. §§ 1–2. Although pharmaceutical patent issues commonly overlap with section 1 violations, this Comment primarily focuses on section 2. Compare 15 U.S.C. § 1 (prohibiting contracts and combinations that restrain trade or commerce), with 15 U.S.C. § 2 (prohibiting attempted or actual monopolization that restrains trade or commerce).

not criminalize superior business acumen;<sup>44</sup> it does, however, prohibit monopolization that restrains competition.<sup>45</sup> More specifically, section 2 promotes competition by proscribing individuals and business associations from possessing or attempting to possess monopoly power while engaging in anticompetitive conduct.<sup>46</sup>

In contrast, patent law is designed to promote innovation, protect ingenuity, and earn profits for investors.<sup>47</sup> Patents essentially restrain competition, but their anticompetitive effects are permissible because the “exclusivity period encourages and finances ongoing new product development,” ultimately benefitting consumer welfare.<sup>48</sup> Simplistically, patent law “reimburses” the patentee for its research and development costs by allowing it alone to profit from its fruits.<sup>49</sup> Theoretically, that advantage is then passed on to consumers in the form of a price-cut or the general benefit of a new product.<sup>50</sup>

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44. See *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 390–91 n.15 (1956) (reinforcing that antitrust law does not penalize those “who merely by superior skill and intelligence” outperform competitors); see also *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966) (admitting that courts tend to avoid assigning antitrust liability to monopolists who own substantial market share through “a superior product, business acumen, or historic accident”).

45. *Charles A. Ramsay Co. v. Associated Bill Posters*, 260 U.S. 501, 512 (1923) (“The fundamental purpose of the Sherman Act was to secure equality of opportunity and to protect the public against . . . destruction of competition through monopolies . . .”); see also *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (directing that the “purpose of the Sherman Act is to prohibit monopolies” from “unduly interfer[ing]” with competitors).

46. To prevail under section 2, a plaintiff must demonstrate that the monopolist (1) “engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.” *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). The antitrust issues analyzed in this Comment concentrate on the first element: exclusionary or anticompetitive conduct.

47. *Pactiv Corp. v. Perk-Up, Inc.*, No. 08-05072 (DMC), 2009 WL 2568105, at \*8 (D.N.J. Aug. 18, 2009) (reasoning that patent law “provide[s] an incentive to invent” and discloses inventions to promote further ingenuity); Roberta Schugmann & Leslie Shaw, Comment, *The Application of Trade Secret Protection to Safety and Effectiveness Data of Patented Drugs*, 16 U.C. DAVIS L. REV. 463, 477–78 (1983) (deducing that patent law encourages invention by facilitating both public disclosure and exclusivity protection).

48. Sprout, *supra* note 42, at 778 (providing that the tension between antitrust and patent law does not necessarily arise from a patent’s enforced exclusivity but from the restriction of competition).

49. See *id.* (opining that exclusivity from patents is “an incentive to induce investment in innovation” (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003))).

50. See *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015) [hereinafter *Namenda*] (recognizing that “[p]roduct innovation generally

In addition to the inherent conflict between antitrust and patent law, pharmaceutical patents in particular effectuate a breeding ground for abuse and constitute an added concern for consumers.<sup>51</sup> High research and development costs, coupled with the potential for astronomical profits, often attract fervent investors willing to circumvent soft regulation.<sup>52</sup> Unfortunately, unlike consumers in various other markets, consumers in pharmaceutical markets are particularly vulnerable, frequently purchasing products out of necessity rather than convenience or luxury.<sup>53</sup> Without adequate oversight, brand-name pharmaceutical firms seemingly regulate their own markets; rather than let the market play its course, they preclude competition, harming consumers lacking the wherewithal to alleviate their symptoms.<sup>54</sup>

A. *Hatch-Waxman Seeks to Keep an Eye on the “Banker”*

In response to brand-name firms dominating the pharmaceutical industry and charging steep prices, Congress sought to alleviate the tension building between antitrust and patent law.<sup>55</sup> As a result,

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benefits consumers”), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

51. See generally Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 632 (2007) (“The intersection of patent and antitrust law has rarely been witness to a more protracted tension than that which currently resides in the pharmaceutical industry.”).

52. See Weisman, *supra* note 24 (estimating that initial research and development, marketing, and manufacturing costs are over \$2.5 billion to bring new brand-name drugs to market). From 2013–2014, the top ten largest pharmaceutical companies generated \$429.4 billion of revenue, spent nearly \$2.9 billion on lobbying expenses (more than any other industry), and expended more than \$15 million in campaign contributions. *Big Pharma*, *supra* note 20.

53. See generally McHugh & Connor, *supra* note 7 (highlighting consumer vulnerability when faced with life-threatening illnesses and colossal drug prices).

54. See *infra* Section IIIA (analyzing the pharmaceutical industry’s unique characteristics); see also Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y L. & ETHICS 293, 297–301 (2015) (chronicling the history before Hatch-Waxman’s enactment).

55. 21 U.S.C. § 355 (2012); Kesselheim & Darrow, *supra* note 54, at 295. Prior to Hatch-Waxman’s enactment, the 1962 Kefauver-Harris Amendment to the FDCA was the only tool utilized to curb big pharma. Kesselheim & Darrow, *supra* note 54, at 297. However, that regulatory scheme compelled the FDA to be a “gatekeeper,” consuming significant agency time and resources. See *id.* at 298. Its shortcomings soon became obvious: most brand-name drugs lacked a generic counterpart. See *id.* at 300; see also Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 302 (2001) (noting that the 1962 Kefauver-Harris Amendments failed because they required an inefficient “pre-market approval system”).

Congress enacted the Hatch-Waxman Act (“the Act”) in 1984. The Act was the federal government’s attempt to bolster both brand-name and generic pharmaceuticals by incentivizing drug pioneers to innovate while also subsidizing market entry costs for generic firms in an attempt to lower overall consumer costs.<sup>56</sup> To do so, Hatch-Waxman expanded patent exclusivity for brand-name firms, yet it also created an abbreviated process for generic firms to bring their products to market at a relatively low cost.<sup>57</sup>

The Act had three major objectives: expanding brand-name exclusivity, mandating REMS and mitigating consumer risk, and reducing generic market entry costs.<sup>58</sup> To better understand the issues that have arisen since Hatch-Waxman’s enactment, it is imperative to recognize these goals and, in some cases, the way they interact with some state substitution laws.<sup>59</sup>

### *1. Expanding brand-name patent exclusivity*

First, Hatch-Waxman requires a generic firm wishing to enter a market to investigate and “certify” whether its drug would infringe on a brand-name patent.<sup>60</sup> Once the generic firm has certified that its

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56. See *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 95–96 (2003) (statement of Daniel E. Troy, Chief Counsel, FDA) (asserting that the Act intended to (1) “ensure that brand-name [firms] . . . have meaningful patent protection and a period of market exclusivity to enable them to recoup their investments in the development of valuable new drugs” and (2) “ensure that . . . consumers would benefit from the rapid availability of lower priced generic versions of innovator drugs”); Alex Galvan, Note, *A Second Opinion on Pharmaceutical Reverse Payment Settlements: Why Actavis Missed the Mark*, 30 GA. ST. U. L. REV. 561, 567 (2014) (explaining that Congress sought to remedy the problem of skyrocketing drug prices by “removing many of the hoops a generic manufacturer would have to jump through to break into the pharmaceutical market with its significantly cheaper product”).

57. See *supra* note 56; see also Cheng, *supra* note 37, at 1478 (“Congress enacted [the Act] . . . (1) to increase the availability of low-cost generic drugs and (2) to create new incentives for brand name drug manufacturers to make greater investments in research and development of new drugs.”).

58. See § 355(j)(2)(A)(vii)(I)–(IV) (listing the steps generic brands must take so as not to impede on brand-name exclusivity); § 355(p) (outlining risk mitigation strategies); *infra* note 72 and accompanying text (noting that generic firms enjoy a less costly and laborious application process than brand-name firms).

59. See, e.g., NEV. REV. STAT. § 639.2583 (West 2015) (requiring that, absent instructions otherwise, a pharmacist must fill a brand-name prescription with a less expensive generic substitution).

60. § 355(j)(2)(A)(vii)(I)–(IV). Generic firms must “certify” one of the following: (I) no relevant patents exist, (II) any patent that is relevant has since expired, (III) the generic firm will wait until a relevant patent expires, or (IV) the

drug will not do so,<sup>61</sup> the brand-name firm may initiate a patent infringement suit, which, as a result, confers upon the brand-name firm an automatic thirty-month period of exclusivity.<sup>62</sup> During this period, the brand-name, regardless of whether it possesses a valid patent or not, retains exclusive control over the market because the FDA will not approve the generic drug until either the thirty-month period expires or the patent infringement suit concludes.<sup>63</sup>

## 2. *Mandating REMS and mitigating consumer risk*

Second, although the Hatch-Waxman Act<sup>64</sup> mandated REMS to protect consumers from particularly harmful drugs, it unintentionally created more opportunities for brand-name firms to abuse the patent and antitrust regulatory schemes.<sup>65</sup> REMS permit the FDA to require companies to conduct a deliberative analysis of a drug's potential safety risks and propose strategies to mitigate those risks.<sup>66</sup> The FDA mandates REMS when they are "necessary to ensure" that a drug's benefits outweigh its risks—notably, the riskier the drug, the more likely it will require a stronger mitigation strategy.<sup>67</sup> Sometimes the

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generic firm's drug does not infringe on a relevant patent. *Id.*; see also Kesselheim & Darrow, *supra* note 54, at 303.

61. § 355(j)(5)(B)(iii); Kesselheim & Darrow, *supra* note 54, at 303. To assist in identifying potential infringement issues, brand-name firms are required to list their patented drugs in the "Orange Book." See *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA, <http://www.accessdata.fda.gov/scripts/cder/ob> (last updated Sept. 2016). To be listed in the Orange Book, the patent claim must (1) constitute an approved drug and (2) be reasonably defensible in patent infringement litigation. 21 C.F.R. § 314.53(b) (2014).

62. § 355(j)(5)(B)(iii).

63. See *id.*

64. Food & Drug Administration Amendments Act (FDAAA) of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007). Although REMS were not part of the original Hatch-Waxman Act, the Act has since been amended to include it.

65. See § 355(p)(1)(B) (requiring a risk analysis before certain drugs can be sold); see also Darren S. Tucker et al., *REMS: The Next Pharmaceutical Enforcement Priority?*, ANTITRUST, Summer 2014, at 74 (estimating that REMS restrictions apply to nearly forty percent of new drugs). Unlike before, the FDCA amendment now requires "drug companies to prove both safety and efficacy of new drugs." Shashank Upadhye & Braden Lang, *The FDA and Patent, Antitrust, and Property Takings Laws: Strange Bedfellows Useful to Unblock Access to Blocked Drugs*, 20 B.U.J. SCI. & TECH. L. 84, 91-92 (2014).

66. See Upadhye & Lang, *supra* note 65, at 92-94 (comparing "low-level REMS" with "high-level REMS," the latter being the most restrictive and reserved for riskier drugs).

67. Pub. L. No. 110-85, 121 Stat. 823, 926 (2007). The FDA may require REMS, either before or after approval, when obliged to mitigate a drug's risks against its potential benefits. *Id.* at 926-27. The FDA considers several variables for requiring REMS: (1) "size of the population likely to use the drug," (2) "seriousness of the disease," (3) "expected benefit of the drug," (4) "duration of [the] treatment," (5)

FDA merely prescribes an extra warning label on the drug, but, for more dangerous drugs, the FDA can limit the drug's availability for certain classes of patients.<sup>68</sup> One such REMS, titled Elements to Assure Safe Use (ETASU),<sup>69</sup> may restrict drug dispensation; for instance, an ETASU may limit a drug's distribution to only hospital-like settings.<sup>70</sup> By placing distribution restrictions on risky drugs, REMS seek to improve consumer safety.

### 3. *Reducing generic market entry expenses*

Third, to reduce consumer costs, Hatch-Waxman created an abbreviated pathway for generic market entry.<sup>71</sup> Rather than file a New Drug Application (NDA), a generic firm need only file an Abbreviated New Drug Application (ANDA), thereby avoiding the costly and laborious approval process, including clinical trials, which brand-name firms must endure.<sup>72</sup> Furthermore, a successful ANDA grants firms 180 days of generic exclusivity.<sup>73</sup> Although an approved generic drug still competes with the brand-name drug, the exclusivity period creates a "bottleneck" for other generic drugs.<sup>74</sup> Because the market lacks other generic competitors, the first generic filer may

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"seriousness of any known or potential adverse events," and (6) "[w]hether the drug is . . . new." *Id.* at 926.

68. WILLY, *supra* note 32, at 5, 7. Among other things, REMS may require medication guides, patient package inserts, or communication plans. Tucker et al., *supra* note 65, at 74.

69. Tucker et al., *supra* note 65, at 74.

70. WILLY, *supra* note 32, at 7–8.

71. Kyle Virtue, Note, *FTC v. Actavis: Analysis of the Court's Decision and How It Affects Drug Prices for Those Who Need Them the Most*, 21 WASH. & LEE J.C.R. & SOC. JUST. 121, 128–29 (2014) ("The Hatch-Waxman Act increased competition by streamlining the process for generic drug approval, consequently creating an incentive for generic[s] . . . to enter the market.").

72. See RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY, CONG. BUDGET OFFICE 20 (Oct. 2006), <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf> (assessing that drug companies devote around twelve years and more than \$800 million to bring a single new drug to market); Kenneth Glazer & Jenée Desmond-Harris, *Reverse Payments: Hard Cases Even Under Good Law*, ANTI-TRUST, Spring 2010, at 15 (expounding that ANDAs merely "reference" a brand-name firm's safety and efficacy data, so generic firms "need only supplement [their ANDA] with studies showing that [their] drugs are the 'bioequivalent' of already-approved brand-name drugs"); *Facts About Generic Drugs*, *supra* note 23 (noting that generic firms can sell their products for lower prices because they are not required to repeat costly clinical trials).

73. 21 U.S.C. § 355(j)(5)(B)(iv) (2012).

74. Virtue, *supra* note 71, at 129.

charge a higher price than the market would otherwise tolerate, incentivizing speedy generic market entry.<sup>75</sup>

Generally, firms need only demonstrate that their proposed generic drug is the “bioequivalent” of the brand-name it wishes to imitate.<sup>76</sup> Specifically, bioequivalence requires that a generic drug contain the same route of administration, dosage, and strength as the mimicked brand-name drug.<sup>77</sup> By merely demonstrating that their drug is the bioequivalent of the respective brand-name drug, generic firms avoid the expensive and time-consuming clinical trials that brand-name firms complete and can therefore allow the savings to trickle down to consumers in the form of a discounted price.<sup>78</sup> Accordingly, abbreviated generic market entry reduces entry expenses in order to reduce overall consumer costs.

#### 4. *Requiring pharmacists to substitute generic drugs*

Finally, state “drug product substitution” laws complement the Hatch-Waxman Act to round out the pharmaceutical regulatory framework. In the past, prescribing physicians were often unfamiliar with most lower-priced generic equivalents, and, because of direct-to-consumer advertising by brand-name firms, patients typically did not ask their physicians about generic alternatives.<sup>79</sup> As a result,

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75. See *id.* at 129 n.44 (explaining that the exclusivity period gives an anticompetitive advantage to the generic manufacturer).

76. § 355(j)(2)(A)(iv); see also 21 C.F.R. § 320.1(e) (2015) (defining “bioequivalence” as the “absence of a significant difference in the rate and extent to which the active ingredient . . . becomes available at the site of drug action when administered at the same molar dose under similar conditions”).

77. § 355(j)(2)(A)(iii).

78. See Kesselheim & Darrow, *supra* note 54, at 301–02; see also *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 896 (9th Cir. 2008) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)) (noting that “benefits . . . flow to consumers from discounted prices”).

79. See Steinman et al., *What’s in a Name? Use of Brand Versus Generic Drug Names in United States Outpatient Practice*, 22 J. GEN. INTERNAL MED. 645, 646–47 (2007) (finding that physicians used a drug’s brand-name significantly more than its generic and suggesting unfamiliarity as a possible reason). Brand-name firms exploit unfamiliarity by advertising directly to consumers. Additionally, some argue that “Direct-to-Consumer” pharmaceutical advertising causes consumers to ask for particular brand names. See April L. Foreman, *Web of Manipulation: The Learned Intermediary Doctrine and Direct-to-Consumer Advertising on the World Wide Web*, 35 J. MARSHALL L. REV. 97, 99–101, 108–10 (2001) (recognizing the danger of “Direct-to-Consumer” pharmaceutical advertising and observing that the FDA has previously set moratoriums on “product specific” advertising); Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 675–76

physicians prescribed brand-name drugs almost exclusively, and patients rarely purchased generic drugs, unaware that generics were a viable and equally effective alternative to their brand-name equivalents.<sup>80</sup> Further compounding the problem, pharmacists lacked the lawful authority to deviate from written prescriptions to dispense cost-effective alternates.<sup>81</sup> Today, however, nearly every state either requires or allows pharmacists to exercise their discretion in substituting a lower-priced generic drug.<sup>82</sup> In essence, federal and state law function in tandem to increase generic drug sales and temper pharmaceutical costs.

### B. Consumers Win “Free Parking” in Actavis

Notwithstanding Hatch-Waxman’s moderate success,<sup>83</sup> brand-name firms, burdened with prohibitive regulatory hurdles, began using anticompetitive tactics to recapture some of the market share that Hatch-Waxman allotted to generic firms. For example, brand-name firms kept generic firms out of their markets by proposing “reverse settlements,” whereby a generic manufacturer would agree to stay out

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(2007) (highlighting that from 1996 to 2005, promotional spending “grew from \$11.4 billion to \$29.9 billion . . . at an average annual rate of 10.6%”).

80. See Cheng, *supra* note 37, at 1479–83 (arguing that direct-to-consumer advertising can often skew consumer perceptions about brand-name drugs and negatively influence their interactions with their physicians).

81. See *id.* at 1479–80 (chronicling that most state laws prior to the 1970s prohibited pharmacists from substituting brand-name drugs for generic drugs when the physician prescribed a brand name).

82. Vikrama Chandrashekar, Comment, *Getting Even Less than What They Paid for: The Plight of Generic Drug Consumers Under the Levine-Mensing Dichotomy*, 86 U. COLO. L. REV. 259, 271 (2015); see also Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835, 1847 (2013) (observing that state substitution laws either “require the pharmacist to [notify] the patient” or “[obtain] the patient’s consent when making a substitution”). Thirty-two states allow a discretionary generic substitution for brand-name drugs, fifteen states require the substitution, and the remaining three states are unclear on the topic. Chandrashekar, *supra*, at 271 & n.62. Accordingly, consumers significantly benefit from lower-priced generic alternatives. *Id.* at 273 (highlighting that, on average, patients pay \$17.90 for generic drugs compared to \$44.50 for brand-name drugs, and insurers pay \$26.67 for generic drugs compared to \$135.26 for brand-name drugs).

83. See HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, CONG. BUDGET OFF. ix (July 1998), <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf> (explaining that before Hatch-Waxman’s enactment, generics comprised nineteen percent of the pharmaceutical market and rose to forty-three percent by 1996).

of the market in exchange for annual payments.<sup>84</sup> Although brand-name firms would initiate the litigation alleging patent infringement, they happily compensated these generic firms to eliminate generic competition, thereby sustaining market exclusivity.<sup>85</sup>

Not uncommonly, courts dismissed antitrust challenges to reverse settlements, consequently preserving high prices for consumers.<sup>86</sup> In response to the contrasting pulls of antitrust and patent law, however, they applied analyses from both areas of law, which unsurprisingly yielded inconsistent results.<sup>87</sup>

### 1. *The decline of patent law's "scope of the patent" test*

Prior to *Actavis*, courts employed the "scope of the patent" test to determine whether pharmaceutical patent lawsuits that alleged brand-name misconduct should be dismissed.<sup>88</sup> Specifically, a court would ask whether "the challenged [conduct] restrict[ed] competition beyond the exclusionary effects of the . . . patent."<sup>89</sup> Provided that the brand-name firm operated under a valid patent and

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84. See *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1301 (11th Cir. 2012), *rev'd sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013) (noting that the FTC alleged that these arrangements allowed all respective companies to share in monopoly profits, ultimately hurting consumers).

85. See, e.g., *id.* at 1304–05 (elucidating that Watson pharmaceuticals attacked the validity of Solvay's patent for a brand-name drug, putting Watson in a position to drive Solvay into reverse settlement). The Supreme Court later reversed the Eleventh Circuit's decision allowing reverse settlements, holding that such agreements could have unlawfully restrained trade and violated federal antitrust laws. See *Actavis*, 133 S. Ct. at 2230–32 (emphasizing that these settlements should be scrutinized for their "anticompetitive effects . . . against procompetitive antitrust policies," regardless of patent validity).

86. See, e.g., *Watson Pharm.*, 677 F.3d at 1312–15 (dismissing the FTC's antitrust claims because exclusivity "fall[s] within the scope . . . of the patent" and a simple likelihood of a patent being invalid is insufficient to void a settlement); see also William J. Newsom, Note, *Exceeding the Scope of the Patent: Solving the Reverse Payment Settlement Problem Through Antitrust Enforcement and Regulatory Reform*, 1 HASTINGS SCI. & TECH. L.J. 201, 207–09 (2009) (noting that most circuits before *Actavis* held that as long as the reverse settlement was within the exclusivity granted by the patent, there was no antitrust issue).

87. See generally Newsom, *supra* note 86, at 209–26 (2009) (outlining the circuit split regarding reverse-payment settlements).

88. See, e.g., *Watson Pharm.*, 677 F.3d at 1312 (holding that, "absent sham litigation or fraud in obtaining the patent," a business tactic "is immune from antitrust attack so long as . . . it[] . . . fall[s] within the scope of the exclusionary potential of the patent"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005) (holding that a business tactic is immune from attack "as long as competition is restrained only within the scope of the patent").

89. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005).

the alleged conduct fell within the scope of that patent, the firm was not liable under such test, even if the firm intentionally restrained competition.<sup>90</sup> The courts justified the “scope of the patent” test by contending that patents should be presumed valid, and that even if a patent was weak, it would be subject to subsequent attacks from other generic manufacturers.<sup>91</sup> However, a minority of courts questioned this reasoning, arguing instead that (1) by presuming the patent’s validity, the courts have literally “assum[ed] away” the underlying lawsuit; (2) brand-name firms’ substantial profits allowed them to settle repeatedly and eliminate even more generic competitors; and (3) ultimately, the consumer would suffer from higher pharmaceutical prices.<sup>92</sup>

## 2. *Antitrust law’s rule of reason applied to reverse-payment settlements*

The “scope of the patent” test created a void that allowed brand-name firms to drive up their pharmaceutical prices and leave consumers aching for generic alternatives.<sup>93</sup> Fortunately, the ultimate resolution came to fruition in 2013 when the Supreme Court

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90. See *In re Ciprofloxacin*, 363 F. Supp. 2d at 535 (rationalizing that a market sustains no injury unless a “patent is shown to have been procured by fraud, or a suit . . . is shown to be objectively baseless”); see also Jessica Hudson Bechtel, Note, *A Framework to Evaluate Pharmaceutical Pay-for-Delays: A Balancing Test Based upon Reasonableness*, 102 Ky. L.J. 501, 502, 510–14 (2014) (examining adversarial arguments about using the “scope of the patent” test).

91. See, e.g., *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d. Cir. 2012), *vacated sub nom.* *Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013) (discussing the rationale of the “scope of the patent” test).

92. See *In re K-Dur*, 686 F.3d at 214–15 (challenging the Second Circuit’s rationale for the “scope of the patent” test and arguing that a policy favoring weak patent elimination is within the public’s interest and consistent with the application of antitrust law); see also Bechtel, *supra* note 90, at 513–14 (contending that the “scope of the patent” analysis protects the brand-name’s “wallet” rather than the “strength of [its] patent”); David Ernest Balajthy, Note, *A Pharmaceutical Park Place: Why the Supreme Court Should Modify the Scope of the Patent Test for Reverse Payment Deals*, 20 J. INTELL. PROP. L. 315, 341 (2013) (arguing that the test incentivizes monopolies and encourages manufactures to raise drug prices). *But see Watson Pharm.*, 677 F.3d at 1312 (pointing out that “[i]f the patent actually is vulnerable, then presumably other generic companies . . . will attempt to enter the market and make their own challenges to the patent”).

93. See Susan Schipper, Note, *Bad Medicine: FTC v. Actavis, Inc. and the Missed Opportunity to Resolve the Pay-for-Delay Problem*, 73 MD. L. REV. 1240, 1267 (2014) (arguing that the “scope of the patent” test “ignores the reality” that many generic manufacturers may have successful challenges to a patent’s validity).

analyzed a pharmaceutical patent issue through an antitrust lens.<sup>94</sup> In the landmark case *FTC v. Actavis, Inc.*, a generic firm filed an ANDA and certified that its generic drug did not infringe on any brand-name patents.<sup>95</sup> In response, a brand-name firm initiated paragraph IV patent litigation, triggering the automatic thirty-month moratorium on any generic entry.<sup>96</sup> Notwithstanding both parties' monetary incentive to litigate,<sup>97</sup> the parties settled.<sup>98</sup> Ordinarily in settlements, the plaintiff accepts cash from the defendant in exchange for abandoning its suit; however, unique to the situation in *Actavis*, the brand-name firm (the plaintiff) paid the generic firms (the defendants) over \$200 million to abandon their ANDAs and recuse themselves from the market for nine years.<sup>99</sup> Due to the settlement's unusual nature, commentators coined this practice a "reverse-payment settlement."<sup>100</sup> In response, the FTC filed a lawsuit alleging that the parties violated antitrust laws by agreeing to share the brand-name's monopoly profits; ultimately, the Court agreed.<sup>101</sup>

The Court in *Actavis* suggested that reverse payments artificially extended exclusivity, effectively eliminating competition and allowing

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94. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013) (rejecting the rationale behind the scope of the patent test as irreconcilable with antitrust principles).

95. *Id.* at 2229.

96. *Id.* Under ANDA rules, a generic drug manufacturer can make a paragraph IV certification that its drug does not infringe on any patents or that any patents its drug infringes on are invalid. 21 U.S.C. § 355(j)(2)(A)(IV) (2012). However, any challenges to an ANDA certifying under paragraph IV triggers a mandatory thirty-month hold on the application's approval. § 355(j)(5)(B)(iii); see also *supra* notes 60–63 and accompanying text (detailing paragraph IV patent litigation).

97. See Joshua B. Fischman, *The Circular Logic of Actavis*, 66 AM. U. L. REV. 91, 100–04 (2016) (laying out the economic incentives of both brand-name and generic firms to engage in reverse-payment settlements).

98. See *Actavis*, 133 S. Ct. at 2229 (describing the settlement terms); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006) (demonstrating that a successful challenge to a major brand-name patent could be worth several hundred million to the first generic to file).

99. See *Actavis*, 133 S. Ct. at 2229 (conveying that Solvay, the brand-name firm, described the \$200 million as payment for promised services by the generic firms).

100. See *supra* note 84 (describing reverse settlements as a way for brand-name firms to defend weak patents by paying off a generic firm).

101. See *id.* at 2227, 2229–30 (explaining that reverse settlements can violate antitrust law); Schipper, *supra* note 93, at 1240–41 (summarizing *Actavis* and noting that the Court held that such settlements must be evaluated against a "traditional antitrust framework").

brand-name firms to maintain high prices.<sup>102</sup> Compared to the riskier alternative of trial, settling in this fashion was a more attractive option due to its low risk and high returns.<sup>103</sup> This profitability incentivized reverse payments, inhibited innovation, and ultimately harmed consumer welfare.<sup>104</sup>

Instead of applying patent law's "scope of the patent test," the Court sought to repair the broken system by analyzing this novel issue with an antitrust tool: the rule of reason.<sup>105</sup> The rule of reason test balances the alleged conduct's anticompetitive effects with its procompetitive justifications.<sup>106</sup> Under this burden-shifting framework, the plaintiff must first establish a prima facie case by demonstrating that the defendant's conduct yields anticompetitive effects.<sup>107</sup> If the plaintiff is successful, the burden shifts to the defendant, permitting it to offer procompetitive justifications for its conduct.<sup>108</sup> Here, the fact-finder considers all relevant factors to

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102. See *Actavis*, 133 S. Ct. at 2234–35 (denouncing reverse payments because they keep prices at high, "patentee-set levels" such that "[t]he patentee and the challenger gain" and "the consumer loses").

103. Michael Owens, Comment, *A Cure for Collusive Settlements: The Case for a Per Se Prohibition on Pay-for-Delay Agreements in Pharmaceutical Patent Litigation*, 78 MO. L. REV. 1353, 1388–89 (2013) (arguing that the "net reward for pseudo-innovation" is greater than "genuine innovation," which is "harder, more costly, or less certain than pseudo-innovation"); see also Hemphill, *supra* note 98, at 1580–81 (contending that "[e]conomic modeling" demonstrates that reverse payments "provide consumers with less welfare, on average, than seeing the litigation to completion").

104. See Owens, *supra* note 103, at 1388 (contending that reverse payments "can cause a reduction in the rate of true innovation").

105. See *Actavis*, 133 S. Ct. at 2236; see also *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 691 (1978) (characterizing the rule of reason as a balancing inquiry into whether conduct "promotes" or "suppresses" competition). In establishing whether conduct violates section 2, courts generally "apply one of three antitrust standards: (1) per se rule, (2) quick-look analysis, or (3) rule of reason analysis." Virtue, *supra* note 71, at 137. On the one extreme, the per se rule is appropriate when the conduct is "so inherently anticompetitive" that it should be foreclosed without any understanding of its market impacts or justifications. See *id.* (cautioning that the per se rule is used only in "rare circumstances"). At the other extreme, the rule of reason permits defendants to offer procompetitive justifications for their exclusionary conduct. See *infra* notes 106–10 and accompanying text. Somewhere in between, the "quick-look" is an "abbreviated" version of the rule of reason analysis, dodging "an intense, lengthy process." Sprout, *supra* note 42, at 773. An abbreviated "quick look" analysis applies where an agreement's anticompetitive nature is obvious to anyone with "a rudimentary understanding of economics." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 759, 770 (1999).

106. See *United States v. Visa USA, Inc.*, 344 F.3d 229, 238 (2d Cir. 2003).

107. *United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir. 2001) (per curiam).

108. *Id.*

assess the conduct's potential economic impact, including (1) "specific information about the relevant business"; (2) "the restraint's history, nature, and effect"; (3) the relevant market's structure and "the [defendant's] market power"; (4) the "reasonable necessity of the restraint"; and (5) "the presence of less restrictive alternatives."<sup>109</sup>

At this point, defendants often proffer a "legitimate business purpose" defense, highlighting economic efforts to maximize profits.<sup>110</sup> In other words, defendants may proffer a market-related excuse for their conduct, contending that the anticompetitive effects are merely incidental to an underlying business decision that benefits the company.<sup>111</sup> Pharmaceutical patent holders often claim that their anticompetitive conduct serves a legitimate business purpose to immunize themselves from antitrust liability; for instance, they argue that reverse payment settlements reflect a purely *economic* desire to avoid excessive litigation costs.<sup>112</sup> Successfully invoked, the defense shifts the burden back for the final time, and "the plaintiff must demonstrate that the anticompetitive harm of the conduct outweighs the procompetitive benefit."<sup>113</sup>

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109. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885–86 (2007) (quoting *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997)); Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 BYU L. REV. 1265, 1270, 1321–22 (1999); Jason A. Casey, Note, *The Rule of Reason After Leegin: Reconsidering the Use of Economic Analysis in the Antitrust Arena*, 42 SUFFOLK U. L. REV. 919, 919 n.4 (2009).

110. *See, e.g., Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 483 (1992) (explaining that the monopolist "took exclusionary action to maintain its parts monopoly and used its control over parts to strengthen its monopoly share," so "[i]ability turn[ed] on whether 'valid business reasons' [could] explain" its conduct); *Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2015 WL 1736957, at \*5 (E.D. Pa. Apr. 16, 2015) (analyzing whether the brand-name firm's product changes were justified by "legitimate business reasons"), *aff'd*, No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016); *see also* Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841, 852 (1989) (pronouncing that a "denial of access is never per se unlawful," so that a valid "business purpose can save[] the defendant").

111. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 596–97, 600, 602 (1985) (distinguishing between anticompetitive behavior and legitimate purposes); Areeda, *supra* note 110, at 852 (arguing that there are two types of legitimate purposes, the first being context-specific and the second being more generalized as policies advancing procompetitive behavior).

112. *See* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) (clarifying that the size of reverse payments can provide insights into patent validity, with "unexplained large" payments being more likely to advance anticompetitive practices). Nevertheless, the Court emphasized that patent holders can offer "legitimate justifications . . . under the rule of reason." *Id.* at 2236.

113. *Microsoft*, 253 F.3d at 59.

Antitrust law's rule of reason, unlike patent law's "scope of the patent" test, facilitates a fact-intensive review that protects consumers by providing generic firms a fair opportunity to prevent brand-name abuse. Lower courts have successfully applied the rule of reason in other reverse payment cases. In *King Drug Co. v. Smithkline Beecham Corp.*<sup>114</sup> and *In re Cipro Cases I & II*,<sup>115</sup> the U.S. Court of Appeals for the Third Circuit and the Supreme Court of California, respectively, expanded *Actavis*'s foothold.<sup>116</sup> However, even after the decision in *Actavis*, brand-name firms have developed other tactics to maintain premium prices and thwart generic entry.<sup>117</sup> To provide sufficient safeguards against manipulation, courts should apply the rule of reason to other pharmaceutical patent issues that thwart generic market entry.

## II. HOW BRAND-NAMES ARE STILL COLLECTING TOO MUCH WHEN THEY "PASS GO"

Notwithstanding reverse payments falling out of vogue thanks to *Actavis* and its progeny, brand-name firms have gradually resorted to precluding generic competition by exploiting REMS and product hopping.<sup>118</sup> Seeing that generic drugs appropriate \$254 billion dollars annually from brand-name revenue, it is understandable why brand-name firms persistently bend the rules to recoup lost profits.<sup>119</sup>

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114. 791 F.3d 388 (3d Cir. 2015), *petition for cert. filed*, 84 U.S.L.W. 3482 (Feb. 19, 2016) (No. 15-1055).

115. 348 P.3d 845 (Cal. 2015).

116. *See id.* at 863–64 (holding that the exclusionary period for patent holders should be based on the "expected life" of a patent and not the "full life"); *see also King Drug Co.*, 791 F.3d at 403–04 (applying the *Actavis* rule of reason analysis to a similar reverse payment including cash).

117. After the Court examined reverse payment settlements in *Actavis*, brand-name firms seamlessly focused their attention on other tactics to preclude generic competition. *See infra* Section III.C.1 (condemning REMS manipulation); *infra* Section III.C.2 (denouncing product hopping).

118. *See, e.g., In re Thalomid & Revlimid Antitrust Litig.*, No.: 14-6697 (KSH) (CLW), 2015 WL 9589217, at \*2 (D.N.J. Oct. 29, 2015) (noting the plaintiffs' assertion that a brand-name firm "manipulated the FDA regulatory scheme and Hatch-Waxman Act to prevent or delay generic manufacturers" from entering the market by "withh[olding] samples"); *see also* Kellie Lerner, *Early Lessons from the REMS Battlefield*, LAW360 (Mar. 9, 2015, 10:22 AM), [www.law360.com/articles/627220/early-lessons-from-the-rems-battlefield](http://www.law360.com/articles/627220/early-lessons-from-the-rems-battlefield) ("In their latest ploy to evade competition, brand name [firms] are increasingly invoking their [REMS] to delay or preclude competition from [generics].").

119. GENERIC PHARM. ASS'N, *GENERIC DRUG SAVINGS IN THE U.S.* 1 (2015), [http://www.gphaonline.org/media/wysiwyg/PDF/GPhA\\_Savings\\_Report\\_2015.pdf](http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf) (reporting a total savings of \$1.68 trillion over the past ten years).

However, their anticompetitive ploys—guzzling \$5.4 billion annually in lost savings that would have otherwise been passed on to consumers—are a tough pill to swallow for those who cannot afford vital medications.<sup>120</sup> By artificially extending a patent's life and precluding competition, each turn around the board enables brand-name firms to pocket more than their lawful share of profits.

#### A. REMS Exploitation

Brand-name firms hide behind the claim that FDA-mandated REMS prohibit them from selling their drug samples to generic firms.<sup>121</sup> Of course, if the FDA finds a drug particularly risky, it will require a firm to implement an ETASU;<sup>122</sup> sometimes, an ETASU limits to whom a firm may distribute its drug.<sup>123</sup> Troubles develop, however, when brand-name firms, saddled with a mandated ETASU, refuse to sell their drug samples to generic firms wishing to enter the market.<sup>124</sup> Unfortunately, firms need those samples to obtain FDA approval.<sup>125</sup> It is virtually impossible for a generic firm to prove its drug's bioequivalence without a brand-name sample; thus, refusing to

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120. ALEX BRILL, MATRIX GLOBAL ADVISORS, LOST PRESCRIPTION DRUG SAVINGS FROM USE OF REMS PROGRAMS TO DELAY GENERIC MARKET ENTRY 1 (2014), [http://www.gphaonline.org/media/cms/REMS\\_Studyfinal\\_July2014.pdf](http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf) (documenting that “[n]early 40 percent of new FDA approvals are subject to REMS”). See generally *Approved Risk Evaluation and Mitigation Strategies (REMS)*, FDA, <http://www.accessdata.fda.gov/scripts/cder/remis/> (last visited Oct. 19, 2016) (listing various prescription drugs and their corresponding mandated REMS).

121. See Tucker et al., *supra* note 65, at 74 (rebuking brand-name firms for “inappropriately limit[ing] access to product samples” that generic firms “need for bioequivalence testing, a predicate for FDA approval of generic drugs”).

122. See *supra* Section I.A.2 (discussing REMS as a federally-mandated approach for managing drugs that are at risk of abuse); see also Tucker et al., *supra* note 65, at 74 (noting that ETASUs are risk controls for particularly dangerous drugs that go further than simple notification and often restrict distribution); Upadhye & Lang, *supra* note 65, at 92–94 (describing different approaches to low-risk and high-risk drugs under REMS).

123. WILLY, *supra* note 32, at 7. ETASUs may require that doctors who prescribe the drug, and the facilities that handle the drug, have specialized training or that drug patients are monitored. *Id.* For example, Caprelsa, a drug used to treat thyroid cancer, requires prescribers to educate their patients about “the drug’s risk of abnormal heart rhythms” and be “specially certified” to handle it. *A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS)*, FDA 14, <http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf>.

124. See Upadhye & Lang, *supra* note 65, at 94–95.

125. See *supra* notes 71–78 and accompanying text (explaining that generic firms must prove that their generic drug is the “bioequivalent” of a corresponding brand-name drug).

sell such samples effectively thwarts any chance for competitors to enter the same market.<sup>126</sup>

While Congress is silent on many pharmaceutical patent issues,<sup>127</sup> it addressed REMS abuse in Hatch-Waxman with the following language: “No holder of an approved covered application shall use any required [ETASU] . . . to block or delay approval of . . . a drug that is the subject of an [ANDA].”<sup>128</sup> Although the statute’s plain language seemingly prohibits a firm from abusing REMS, the statute neither specifies enforcement procedures nor addresses noncompliance sanctions.<sup>129</sup> However, because reverse-payment settlements and REMS abuse similarly prevent generic market entry, courts should employ the plain language to function as a dagger to the heart of brand-name efforts to monopolize, consequently curbing abuse and protecting consumers.<sup>130</sup>

At this point, courts have resolved relatively few REMS abuse cases.<sup>131</sup> As was the case in *Actavis*, generic firms can challenge a brand-name’s refusal to sell by demonstrating the anticompetitive effects of that refusal under the rule of reason.<sup>132</sup> Because this issue has not yet reached a federal appeals court, however, lower courts remain divided about whether generic firms should be permitted to

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126. See Upadhye & Lang, *supra* note 65, at 94–95. If no REMS exist, generic firms typically purchase brand-name samples through “wholesalers or distributors.” *Id.* Theoretically, a firm could simply pay a patient to feign symptoms and visit a physician to obtain samples; however, this strategy would not produce “enough samples for reverse engineering.” *Id.*

127. See, e.g., *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2242 (2013) (observing that “Congress has repeatedly declined to enact legislation addressing” reverse payments).

128. See 21 U.S.C. § 355-1(f)(8) (2012).

129. Upadhye & Lang, *supra* note 65, at 95–96 (citing § 355-1(f)(8)) (noting the absence of any administrative procedures).

130. See Tucker et al., *supra* note 65, at 74 (recognizing the similarity between REMS abuse and reverse payments); see also *infra* Section III.C.1 (arguing that REMS abuse constitutes exclusionary conduct).

131. See Lerner, *supra* note 118 (observing that there are “limited rulings to date”). In fact, few cases have produced a motion to dismiss opinion. See, e.g., *Lannett Co. v. Celgene Corp.*, No. 08-3920, 2011 WL 1193912, at \*3 (E.D. Pa. Mar. 29, 2011) (denying a brand-name firm’s motion to dismiss). Even fewer cases have produced a summary judgment opinion. Kat Greene, *Actelion Settles Row over Giving Drugs to Generics Makers*, LAW360 (Feb. 28, 2014, 7:07 PM), <http://www.law360.com/articles/514434/actelion-settles-row-over-giving-drugs-to-generics-makers> (noting that the “judge offered little explanation for [his] refusal[] to dismiss the matter, which ended . . . in a confidential settlement”).

132. See, e.g., *Natco Pharma Ltd. v. Gilead Scis., Inc.*, No. 14-3247 (DWF/JSM), 2015 WL 5718398, at \*6 (D. Minn. Sept. 29, 2015) (alleging that a brand-name firm “unreasonably restrained trade under . . . a rule of reason analysis”).

challenge such a refusal.<sup>133</sup> Assuming the brand-name firm possesses monopoly power,<sup>134</sup> a court's primary inquiry focuses on whether a "refusal to supply product samples for certain REMS-restricted drugs . . . constitute[s] exclusionary conduct."<sup>135</sup> In this context, courts may infer a firm's exclusionary intent by one of two means: (1) demonstrating that a brand-name firm sacrificed profits or (2) employing the "essential facilities" doctrine.

1. *The "profit sacrifice" test and the "no economic sense" test*

Firms generally retain the right to refuse unilaterally to deal with competitors;<sup>136</sup> however, antitrust jurisprudence also establishes that this right is not absolute.<sup>137</sup> For instance, a firm's conduct may be exclusionary when, in refusing to deal with competitors, it sacrifices profits.<sup>138</sup> Firms enjoying a substantial market share of their

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133. Compare *id.* at \*9 (granting a motion to dismiss a generic firm's complaint challenging a brand-name firm's refusal to sell samples), with *In re Thalomid & Revlimid Antitrust Litig.*, No. CV 14-6997, 2015 WL 9589217, at \*17 (D.N.J. Oct. 29, 2015) (denying a motion to dismiss).

134. Indeed, this Comment assumes that brand-name firms possess monopoly power. Although monopoly power is sometimes at issue in pharmaceutical patent litigation—see, for example, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2015 WL 1736957, at \*11 (E.D. Pa. Apr. 16, 2015) (holding that a generic firm "failed to produce economically plausible evidence" demonstrating that the brand-name firm wielded monopolistic power over "the relevant market"), *aff'd*, No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016)—a brand-name patent, for the most part, creates an artificial monopoly, so the firm's market share is rarely disputed. See, e.g., *Namenda*, 787 F.3d 638, 646–47 (2d Cir. 2015) (conceding that the relevant market was "undisputed" and that brand-name drugs were "the only [like] therapies in their class . . . currently on the market"), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

135. Tucker et al., *supra* note 65, at 75.

136. *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984) (acknowledging that a firm "generally has a right to deal, or refuse to deal, with whomever it likes, as long as it does so independently"); *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (ensuring that the Sherman Act "does not restrict" a private firm's right to engage and "freely . . . exercise his own independent discretion as to parties with whom he will deal").

137. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985) (conceding that a firm's right to refuse to deal with others is not "unqualified").

138. *Id.* at 608 (holding that a firm violates section 2 when it "elect[s] to forgo . . . short-run benefits because it was more interested in reducing competition"); *Otter Tail Power Co. v. United States*, 410 U.S. 366, 377 (1973) (ruling that a firm violates section 2 when it "use[s] its monopoly power . . . to foreclose competition or gain a competitive advantage, or to destroy a competitor").

respective market may not use their market power to intentionally drain smaller competitors of their resources.<sup>139</sup>

The “profit sacrifice” test is one mechanism litigants employ to demonstrate anticompetitive conduct.<sup>140</sup> Courts may infer exclusionary intent when a firm jettisons a sale that would have earned immediate profit.<sup>141</sup> In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*,<sup>142</sup> for example, a monopolist and a smaller competitor operated two separate ski resorts, together controlling all of the recreational skiing in the area.<sup>143</sup> The smaller competitor sought to buy lift tickets from the monopolist to create a convenient bundle package for visitors to pay one price to access both resorts.<sup>144</sup> Nevertheless, the monopolist refused to sell its lift tickets to the smaller competitor.<sup>145</sup> The Supreme Court condemned the monopolist’s apparent willingness to “forgo daily ticket sales,” consequently sacrificing short-term profits.<sup>146</sup> Accordingly, the Court found “an inference that the monopolist made a deliberate effort to discourage its customers from doing business with its smaller rival,” and its refusal, primarily motivated by an interest in curtailing competition, violated section 2 of the Sherman Act.<sup>147</sup>

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139. See, e.g., *Lorain Journal Co. v. United States*, 342 U.S. 143, 154 (1951) (explaining that a firm may not “use[] its monopoly to destroy threatened competition”).

140. The Supreme Court recently clarified the profit sacrifice test in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004). The Court rejected the profit sacrifice test because the monopolist was statutorily compelled to deal with its competitor. See *id.* at 409–10. By concluding that the monopolist had no duty to deal with its competitors, the Court narrowed—but by no means extinguished—the profit sacrifice test to require “anticompetitive malice.” *Id.* at 409 (deducing that a firm violates section 2 when its conduct is motivated by “anticompetitive malice” rather than “competitive zeal”). Therefore, antitrust scrutiny is appropriate when a firm refuses to sell a publicly available product, but not when a statute compels the sale and provides a form of relief for the neglected competitors.

141. See *supra* note 138 and accompanying text.

142. 472 U.S. 585 (1985).

143. *Id.* at 588–91 & nn.3–9.

144. *Id.* at 593.

145. *Id.* at 593–94.

146. *Id.* at 608.

147. *Id.* Some critics believe that the profit sacrifice test requires that plaintiff have a preexisting agreement with the defendant to prevail. See *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1074 (10th Cir. 2013) (“[T]here must be a preexisting voluntary and presumably profitable course of dealing between the monopolist and rival.”). They highlight the importance of a prior course of dealing to distinguish cases from *Aspen Skiing*. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 410 (2004) (contrasting *Aspen Skiing*, in which a “defendant refused to provide to its competitor . . . a product that it already sold at

The “no economic sense” test is another tool competitors use to challenge a monopolist’s anticompetitive conduct.<sup>148</sup> Although similar to the “profit sacrifice” test, the “no economic sense” test reaches one step further: conduct is exclusionary if “it would make no economic sense . . . but for the tendency to eliminate or lessen competition.”<sup>149</sup> Instead of examining whether short-term profits were possible, this test is designed for scenarios in which a particular event offers a “but for” analysis.<sup>150</sup> For instance, in *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*,<sup>151</sup> Japanese companies engaged in a conspiracy to set television prices below the feasible manufacturing costs for American companies in order to drive the U.S. companies out of the market.<sup>152</sup> Because the Japanese companies maintained such low prices, they also sustained substantial losses.<sup>153</sup> The Court concluded that the Japanese companies had “every incentive *not* to engage in [this] conduct,” so the companies must have been striving to preclude competition.<sup>154</sup> Thus, sacrificing earnings to eliminate competition sufficiently establishes a firm’s exclusionary intent.<sup>155</sup>

## 2. *The essential facilities doctrine*

Litigants also use the “essential facilities” doctrine to determine whether a firm’s refusal to sell its goods or services to competitors

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retail”). However, cases since *Trinko* demonstrate that the doctrine is alive and well. See, e.g., *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 895 (N.D. Cal. 2011) (holding that the challengers “offer[ed] sufficient evidence . . . with respect to whether Abbott’s conduct constituted a violation of its antitrust duty to deal”).

148. See, e.g., *Spirit Airlines, Inc. v. Nw. Airlines, Inc.*, 431 F.3d 917, 950–51 (6th Cir. 2005) (challenging a monopolist-airliner that dropped its prices to a predatory level and operated at a loss to drive out a competitor, then raised its prices shortly after the competitor’s exit); *Novell*, 731 F.3d at 1075 (concluding that a section 2 violation requires “that the monopolist’s refusal to deal was part of a larger anticompetitive enterprise, such as . . . seeking to drive a rival from the market or discipline it for daring to compete on price”).

149. Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The “No Economic Sense” Test*, 73 ANTITRUST L.J. 413, 413 (2006).

150. Vikram Iyengar, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?*, 97 J. PAT. & TRADEMARK OFF. SOC’Y 663, 680 (2015) (contrasting the “profit sacrifice” test with the “no economic sense” test, which “looks at the conduct as a whole, over time”); Werden, *supra* note 149, at 420.

151. 475 U.S. 574 (1986).

152. *Id.* at 597.

153. *Id.*

154. *Id.* at 595.

155. See *supra* notes 148–50 and accompanying text.

constitutes exclusionary conduct.<sup>156</sup> The Court first considered the doctrine in *Otter Tail Power Co. v. United States*,<sup>157</sup> in which a single utility company owned the sole means to distribute electric power in a given service area.<sup>158</sup> After time, some municipalities sought to replace the private company with a public utility system.<sup>159</sup> To begin operating, the municipal system required access to the monopolist's power; refusing to grant such access eliminated the municipality's "threatened competition" and forced consumers to continuously employ the monopolist.<sup>160</sup> The Court determined that the monopolist's refusal constituted exclusionary conduct, explaining that a firm may not refuse to deal with competitors who require a facility to function.<sup>161</sup> In other words, antitrust laws protect competitors that wish to enter a market but that are unable to "practically or reasonably duplicate" an essential product or facility without the monopolist.<sup>162</sup> The doctrine is commonly used in "(1) transportation systems, such as highway and road systems, bridges, railways, airline systems, and ports; (2) communication systems, such as telephone networks and postal services; (3) governance systems, such as court systems; and (4) basic public services and facilities, such as schools, sewers, and water systems."<sup>163</sup> To prevail, a firm must demonstrate that the product or facility is either impossible or "economically infeasible" to duplicate.<sup>164</sup> Notwithstanding its recent

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156. See, e.g., *MCI Commc'ns Corp. v. AT&T Co.*, 708 F.2d 1081, 1132 (7th Cir. 1983) (cautioning that by controlling an essential facility, a monopolist can exploit their monopoly power in one market to extend their control in another market).

157. 410 U.S. 366 (1973).

158. *Id.* at 368.

159. *Id.* at 368–69.

160. See *id.* at 377 (noting explicitly that the monopolist was in violation of antitrust laws).

161. See *id.* at 378 (accepting the lower court's argument that the monopolist's reasoning for refusing to sell was solely based on its fear that the competitor might erode its position).

162. See *MCI Commc'ns Corp. v. AT&T Co.*, 708 F.2d 1081, 1132–33 (7th Cir. 1983) (providing that there are four elements in the essential facilities doctrine: (1) the monopolist must control the essential facility, (2) the competitor must be unable to duplicate the essential facility, (3) the monopolist must deny the competitor the use of the facility, and (4) the situation must be one where the facility could feasibly be provided).

163. Spencer Weber Waller, *Areeda, Epithets, and Essential Facilities*, 2008 WIS. L. REV. 359, 371–72 (2008).

164. See *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 546 (9th Cir. 1991) (maintaining that the essential facilities doctrine requires that a firm's "facility gives [it] the power to eliminate competition"); *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 992 (D.C. Cir. 1977) ("To be 'essential' a facility need not be indispensable; it is

criticism and reconsideration in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*,<sup>165</sup> the essential facilities doctrine still has a pulse and can be used in other contexts.<sup>166</sup>

### B. Product Hopping

In addition to reverse-payment settlements and REMS manipulation, firms exploit the gaps in Hatch-Waxman to preserve high prices through product hopping.<sup>167</sup> In the pharmaceutical patent realm, state drug substitution laws complement overarching federal law.<sup>168</sup> Generic firms benefit from the interplay between federal and state law: federal law abbreviates their market entry while state law compels pharmacists to substitute brand-name drugs with their generic counterparts.<sup>169</sup> To profit from these advantages, generic firms need only prove that their drug is the “bioequivalent” of a corresponding brand-name drug.<sup>170</sup>

To avoid losing market exclusivity from generic competition, however, brand-name firms “hop” from product to product, precluding generic market entry in the process. As a brand-name patent approaches its expiration date—or draws near the “patent cliff”—the prospect of losing market share becomes imminent.<sup>171</sup>

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sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants.”).

165. 540 U.S. 398 (2004); see Upadhye & Lang, *supra* note 65, at 106 (commenting that pundits have cited *Trinko* “as a death knell for the essential facilities doctrine”).

166. See *Trinko*, 540 U.S. at 411 (considering the essential facilities doctrine and “find[ing] no need either to recognize it or to repudiate,” but rather noting “the indispensable requirement for invoking the doctrine is the unavailability of access”); *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1076 (10th Cir. 2013) (analyzing and applying the essential facilities doctrine); see also Abbott B. Lipsky, Jr. & J. Gregory Sidak, *Essential Facilities*, 51 STAN. L. REV. 1187, 1193 (1999) (“Although the essential facilities doctrine has been the target of some distinguished critics, the [doctrine] has enjoyed persistent, even growing, popularity . . . .” (footnote omitted)). But see Waller, *supra* note 163, at 365 (scrutinizing that “all subsequent essential facilities doctrine cases [after *Trinko*] have been unsuccessful”).

167. Product hopping can be defined as “a strategy in which a firm manages the lifecycle of a product by transitioning consumers to a new version or design.” Richard J. Gilbert, *Not Another Drug! Antitrust for Drug and Other Innovations*, ANTITRUST, Fall 2015, at 38.

168. See *supra* Section I.A.4 (detailing state drug product substitution laws, which either require or permit pharmacists to distribute generic alternatives).

169. See *supra* Section I.A.4.

170. See *supra* Section I.A.4.

171. See Rizwan Ahmed, *The Patent Cliff: Implications for the Pharmaceutical Industry*, TRIPLE HELIX ONLINE (July 10, 2014), <http://triplehelixblog.com/2014/07/the-pate>

Meanwhile, generic firms anticipate the opportunity and start their ANDAs, preparing to enter the market upon the patent's expiration.<sup>172</sup> After a patent expires and generic firms start competing, a brand-name firm will generally lose up to ninety percent of its market share, equating to billions of dollars in lost profits.<sup>173</sup> To avoid this outcome, immediately before its patent expires, a brand-name firm withdraws its drug from the market and introduces a slightly new version of the same drug. Needing to mimic precisely the corresponding brand-name drug to enter the market, producing this "new" brand-name drug forces generic firms to start their ANDAs all over again, effectively delaying their market entry.<sup>174</sup> Brand-name firms utilize one or more of the following strategies to "hop" from one product to the next: (1) switching from once-daily to twice-daily medication,<sup>175</sup> (2) altering the drug's dosage,<sup>176</sup> (3) replacing a single score tablet with a dual score tablet,<sup>177</sup> or (4) changing the route of its administration.<sup>178</sup>

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nt-cliff-implications-for-the-pharmaceutical-industry ("[T]he pharmaceutical industry will lose upwards to \$127 billion in brand spending by 2016 due to patent expiration and cheaper generics in the market." (citation omitted)).

172. *See id.*

173. Robert Williams, *Patent Deaths Spell Danger for These Firms*, WALL ST. DAILY (Nov. 3, 2014), <http://www.wallstreetdaily.com/2014/11/03/patent-expiration> ("[O]nce a drug has lost its hallowed patent protection and lower-priced generic brands enter the market, the original developer can see sales crash by up to 90%. Hardly surprising, given that generic drugs average about 30% of the cost of the brand name."); *see also id.* (positing that when Celebrex's patent expires, the brand-name firm will lose \$3 billion in annual sales).

174. *See* Lars Noah, *Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents*, 19 MARQ. INTELL. PROP. L. REV. 161, 165 (2015) (censuring brand-name firms that "routinely introduce new and improved versions of successful drugs as their patents on older products wind down and generic rivals prepare to enter the market"); *see also* Cheng, *supra* note 37, at 1472 (contending that brand-name firms "stave off competition from generic manufacturers" by making a "slight alternation to their prescription drug . . . to shift consumers from the older version to the [newer one]").

175. *See, e.g., Namenda*, 787 F.3d 638, 648 (2d Cir. 2015), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

176. *See, e.g., Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2015 WL 1736957, at \*5 (E.D. Pa. Apr. 16, 2015), *aff'd*, No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016).

177. *See, e.g., id.*

178. *See, e.g., In re Suboxone* (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 673-74 (E.D. Pa. 2014) (switching from film to tablets); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 422-23 (D. Del. 2006) (switching from capsules to tablets).

To prevail in an antitrust suit that alleges product hopping, a generic firm must establish that the brand-name product hop constituted exclusionary conduct.<sup>179</sup> Currently, the leading case in this area is *New York ex rel. Schneiderman v. Actavis PLC* (“*Namenda*”),<sup>180</sup> in which a brand-name firm manufactured a twice-daily drug for individuals suffering from Alzheimer’s disease.<sup>181</sup> As the brand-name patent approached its expiration date, generic firms began the abbreviated, albeit still demanding, ANDA process to prepare to enter the market.<sup>182</sup> To avoid the looming patent cliff, the brand-name firm introduced a new once-daily version of the drug and withdrew its twice-daily drug from the market.<sup>183</sup> Though the two drugs had the “same active ingredient and the same therapeutic effect,”<sup>184</sup> the generic firm could not bring its drug to market because its *twice*-daily generic drug, developed to mimic a *twice*-daily brand-name drug, was not the “bioequivalent” of the now *once*-daily brand-name drug.<sup>185</sup> Because state drug substitution laws only benefit generic drugs that are the exact “bioequivalent” of a corresponding brand-name drug, the generic firm was forced to start another ANDA for the once-daily medication.<sup>186</sup> The Second Circuit affirmed the district court’s preliminary injunction against the hard-switch because it prevented consumers from purchasing a generic version of the twice-daily medication: by “hopping” from a twice-daily tablet to a once-daily tablet, the brand-name firm was able to effectively thwart generic competition, pocketing, for itself, consumer savings.<sup>187</sup>

In reaching its conclusion in *Namenda*, the Second Circuit relied in part on *Berkey Photo, Inc. v. Eastman Kodak Co.*<sup>188</sup> In that case, Kodak introduced a new camera, which could only be operated with a new type of film.<sup>189</sup> A competitor alleged that Kodak inappropriately used its monopoly power in the *film* market to monopolize the *camera*

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179. See *supra* note 46 and accompanying text (discussing the elements of section 2).

180. 787 F.3d 638 (2d Cir. 2015), *cert. dismissed sub nom.* Allergan PLC v. *New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

181. *Id.* at 642. The brand-name drug generated approximately \$1.5 billion in annual sales in 2012 and 2013. *Id.* at 647.

182. *Id.* at 642.

183. *Id.*

184. *Id.* at 647.

185. *Id.* at 643.

186. *Id.*

187. *Id.*

188. 603 F.2d 263 (2d Cir. 1979).

189. *Id.* at 267–68.

market, consequently precluding competition.<sup>190</sup> However, the court explained that the concurrent introduction of a new film and a new camera “did not coerce camera purchasers” because Kodak did not remove its old films from the market, so customers still had choices.<sup>191</sup> Thus, the *Namenda* court concluded, a monopolist that introduces a slightly new product, but keeps its old product on the market, does not necessarily violate section 2 of the Sherman Act; however, a monopolist that withdraws its old product, forcing consumers to switch to its new product, may violate section 2.<sup>192</sup>

Although Hatch-Waxman sought to benefit pharmaceutical consumers, brand-name firms relentlessly exploit the regulatory framework by virtue of reverse payment settlements, REMS manipulation, and product hopping. In *Actavis*, the Supreme Court marginally tempered brand-name gambits, but abuse persists nonetheless. Without a generic antidote, no cure exists for consumers unable to afford ravenous brand-name prices.

### III. NO “CHANCE CARD” CAN MAKE THIS GAME FAIR

Despite Hatch-Waxman’s attempt to shield consumers from brand-name firms’ insatiable hunger for profit, Congress overlooked gaps in the Act that actually facilitate excessive pharmaceutical prices.<sup>193</sup> Brand-name firms employ exclusionary strategies—specifically, REMS manipulation and product hopping—to preclude generic market entry.<sup>194</sup> Although it seems natural to view pharmaceutical patent issues through a patent law lens, patent law alone cannot rectify a brand-name firm’s manipulation of the existing rules, allowing brand-name firms to continue thriving at the expense of the pharmaceutical consumer.<sup>195</sup> Accordingly, courts should turn to antitrust scrutiny to make the game fair again. When confronted with novel, preclusive brand-name tactics, courts should use *Actavis* as a model to protect

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190. *Id.* at 267–68, 278.

191. *Id.* at 287.

192. *See id.* at 288 (dismissing a competitor’s antitrust suit because it failed to demonstrate that the monopolist “dissuaded” consumers from purchasing its old camera because its new film was only compatible with its new camera).

193. *See supra* Part II (delineating patent issues that have surfaced since *Actavis*).

194. *See infra* Sections III.A–B (highlighting that manufacturers are able to manipulate their markets because the pharmaceutical system is prone to monopolization).

195. *See, e.g.*, *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1308–09, 1311 (11th Cir. 2012), *rev’d sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (applying the scope of the patent test and explaining that “any new exclusionary rights the holder buys to add to that bundle do not fall within the scope of the patent grant”).

consumers. Further, not only should courts find that such tactics constitute exclusionary conduct, but they also should apply a bright-line rule that prohibits those firms from exploiting the “legitimate business purpose” defense.

A. *Examining Pharma’s Unique Characteristics Is No Smooth Ride on the “B. & O.”*

Pharmaceutical commerce is comprised of many moving parts, rendering a need—and hope—that no one part breaks.<sup>196</sup> But the industry is no well-oiled machine: parts frequently break and require repair.<sup>197</sup> Understanding the industry’s salient characteristics—namely, its vulnerability to monopolization and price-detached consumers—is necessary to appreciate its need for special antitrust treatment.

Industries driven by monopolies generally benefit from additional oversight.<sup>198</sup> Telephony, for instance, is an industry fraught with regulation.<sup>199</sup> Because (1) its consumers highly value products like telephones and (2) market entry barriers like constructing phone lines are exceptionally expensive, competition is unlikely to thrive naturally.<sup>200</sup> The pharmaceutical industry, similarly, necessitates an added layer of protection for consumers: drugs have an extremely high demand, often meaning the difference between life and death, and have exceptionally high fixed costs, all of which tempt manufacturers to monopolize their markets.<sup>201</sup> Regardless of whether

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196. See ALISON MASSON & ROBERT L. STEINER, FTC, *GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS* 5 (1985) (“The institutions of the prescription drug market are markedly different from those in most other product markets.”).

197. See *Namenda*, 787 F.3d 638, 645–46 (2d Cir. 2015) (illustrating that “the pharmaceutical market is not a well-functioning market” because physicians, as prescribers, are disconnected from a drug’s pricing, and patients, as payers, have little ability to choose), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015); see also Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 185, 234 (1999) (maintaining that “consumer welfare suffers” when pharmaceutical companies employ tactics to “maximize profits”).

198. See JERRY KANG, *COMMUNICATIONS LAW AND POLICY* 73 (4th ed. 2012) (noting that in natural monopolies, “[e]ven robust competition . . . eventually lead[s] to a single firm prevailing over all others”).

199. See *id.* at 73–75 (providing an overview of the monopoly issues within telephony).

200. See *id.* at 75 (explaining that “only one firm will prevail in such a natural monopoly market” and that “potential competitors will result in wasteful duplication of infrastructure because competition will be short-lived”).

201. See *supra* notes 24–25 and accompanying text.

it ultimately serves one patient or one-thousand patients, pharmaceutical firms must expend the initial time and money on research and development.<sup>202</sup> This extremely risky “sink-or-swim” reward system deters market entry and decreases overall competition.<sup>203</sup> As a result of the unique features associated with industries like telephony and pharmaceuticals, such industries may require additional scrutiny not explicitly prescribed by Congress.

Additionally, in contrast to consumers in most other industries,<sup>204</sup> the pharmaceutical consumer retains no opportunity to actively “shop” around in the market.<sup>205</sup> In fact, the consumer cannot even purchase a “product” without first obtaining a prescribing physician’s permission.<sup>206</sup> By ceding all decision-making to prescribing physicians, consumers surrender their “bargaining power.”<sup>207</sup> Not only does the physician choose which drug to prescribe, but insurers often pay most of the bill, thus effectively eliminating any incentive to consider the price.<sup>208</sup> Furthermore, when consumers do ask their

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202. See *supra* Sections I.A.2–3 (elaborating on the FDA-approval process that pharmaceutical firms endure).

203. Cf. KANG, *supra* note 198, at 73–74 (examining “natural monopolies” and characterizing telephony as an industry that has “expensive prerequisites”—namely, “phone lines and building infrastructure”—to market entry).

204. See, e.g., *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979) (analyzing the photographic industry, noting that “[u]nless consumers desired to use the [new] camera for its own attractive qualities, they were not compelled to purchase [the new film]”).

205. See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 374 (2007) (discussing that “doctors who prescribe drugs,” not their patients, are the “principal targets” of pharmaceutical firms). Brand-name firms advertise directly to patients who then may request certain drugs to their prescribing physician; the physician “may find it more expeditious” to prescribe the patient’s requested product rather than “exercise their own independent professional judgment.” *Id.*

206. See MASSON & STEINER, *supra* note 196, at 5 (explicating that the physician, rather than the consumer, “[makes] the choice among brands” because “[a] physician’s prescription is a necessary precondition for the purchase of a prescription drug”).

207. See David Wolman, *Drug Prices Are Too Damn High. Here’s How to Fix Them*, WIRED (Dec. 1, 2015, 6:40 AM), <http://www.wired.com/2015/12/rising-drug-costs> (contrasting “typical” markets, where “forces like competition and regulation help keep prices down,” with the pharmaceutical industry, where consumers lack “bargaining power”).

208. See *Namenda*, 787 F.3d 638, 646 (2d Cir. 2015) (yielding that the prescribing physician “may not know or even care about the price and generally has no incentive to take the price into account”), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015); Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363, 369 (2014) (“Physicians themselves do not pay for

physicians about specific drug options, they usually suggest brand-name drugs.<sup>209</sup> Pharmaceutical companies burn outrageous amounts of money on advertising to influence consumers, spending over \$27 billion on drug promotion in 2012 alone.<sup>210</sup> Although generic pharmaceuticals cost almost seventy percent less than their brand-name counterparts, the continual proclivity for prescribing brand-name drugs supports a system that is prone to abuse.<sup>211</sup> Consequently, because of the pharmaceutical industry's vulnerability to monopolization and the disconnect between consumers and the prices they pay for drugs, brand-name firms enjoy unique opportunities to manipulate their markets, often going unnoticed.<sup>212</sup>

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their patients' drugs, so there is no direct financial disincentive to prescribe any given medicine."); MASSON & STEINER, *supra* note 196, at 6 (examining the price disconnect in the pharmaceutical industry, noting that "physicians' incentives to choose the most cost-effective drug seem weak").

209. See Ranit Mishori, *Some Doctors Insist on Brand-name Drugs Even When Cheaper Generics Are Available*, WASH. POST (July 11, 2011), [https://www.washingtonpost.com/national/some-doctors-insist-on-brand-name-drug-s-even-when-cheaper-generics-are-available/2011/06/13/gIQAmC0L9H\\_story.html](https://www.washingtonpost.com/national/some-doctors-insist-on-brand-name-drug-s-even-when-cheaper-generics-are-available/2011/06/13/gIQAmC0L9H_story.html) (detailing that some physicians write on prescriptions "Dispense as Written" to avoid a generic substitution, ensuring that the patient receives a brand-name drug).

210. See *Persuading the Prescribers: Pharmaceutical Industry Marketing and Its Influence on Physicians and Patients*, PEW CHARITABLE TR. (Nov. 11, 2012), <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients> (highlighting that \$24 billion was expended on marketing towards physicians and that the remaining \$3 billion was spent on direct consumer marketing).

211. *Generic Drugs and Low-Cost Prescriptions*, *supra* note 23.

212. See Bureau of Consumer Protection, *Drug Product Selection: Staff Report to the FTC*, 2-3 (Jan. 1979) (conceding that the normal "forces of competition do not work well" in the pharmaceutical market because "the consumer who pays does not choose, and the physician who chooses does not pay," eliminating a patient's "influence in determining which products they will buy and what prices they [will] pay"). Although many times health insurance companies carry the burden of expensive pharmaceuticals, the insurer ultimately recoups those high costs through high healthcare premiums. See *Healthcare Is Killing Us*, GALLUP BUS. J. (Apr. 17, 2012), <http://www.gallup.com/businessjournal/151862/healthcare-killing.aspx> (characterizing the costs of the "wars in Afghanistan and Iraq" as "tiny compared to healthcare costs"). Indeed, healthcare insurance is one of the most lucrative industries in the United States. See Thomas A. Bass, *The Double Game of the U.S. Health Insurance Companies*, HUFFINGTON POST (Aug. 1, 2012), [http://www.huffingtonpost.com/thomas-a-bass/the-double-game-of-the-us\\_b\\_1558794.html](http://www.huffingtonpost.com/thomas-a-bass/the-double-game-of-the-us_b_1558794.html) (remarking that U.S. health insurers hiked their premiums by 9% and "just finished banking their third year of record-breaking profits"). For example, in 2011, UnitedHealthcare netted over \$4.6 billion in profits. *Id.*

*B. Mirroring an “Enhanced” Rule of Reason Framework from Actavis*

Bearing in mind that the pharmaceutical industry is susceptible to abuse, its corresponding antitrust test should reflect its unique characteristics. The rule of reason is a sensible legal test that provides adversaries the opportunity to rebut each other’s allegations, effectively preventing brand-name firms from gaming the system.<sup>213</sup> Not only should courts mirror *Actavis* by applying federal antitrust law to REMS manipulation and product hopping, but they also should apply an “enhanced” rule of reason that is specifically tailored to the pharmaceutical patent context, methodically scrutinizing a brand-name firm’s anticompetitive conduct.<sup>214</sup> Recognizing that a “per se illegal” determination for REMS manipulation and product hopping may be too extreme, courts should alternatively apply an “enhanced” rule of reason that gives stronger credence to generic firms that demonstrate a brand-name firm’s anticompetitive conduct.<sup>215</sup> Such an “enhanced” rule of reason still provides brand-name firms the opportunity to rebut their conduct’s illegality and proffer procompetitive justifications. However, courts should apportion more weight to the anticompetitive effects of brand-name conduct, rendering it more difficult for the procompetitive justifications to outweigh the anticompetitive effects and, consequently, more difficult for brand-name firms to take advantage of consumers.

Anticompetitive conduct in the pharmaceutical industry carries the potential for particularly devastating results.<sup>216</sup> For instance, a suffering cancer patient who cannot afford his or her medication evokes a very different response than a consumer who is forced to pay

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213. See *supra* notes 106–13 and accompanying text (explaining that the initial burden is on the generic firm to establish that the brand-name firm’s conduct was exclusionary, which then shifts the burden to the brand-name firm to offer procompetitive justifications for its conduct).

214. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2238 (2013) (adopting the rule of reason and noting that “trial courts can structure antitrust litigation so as to avoid the use of antitrust theories too abbreviated to permit proper analysis and consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question”).

215. Compare Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 255 (2009) (arguing for reverse payments to be per se illegal), with *Actavis*, 133 S. Ct. at 2238 (recognizing that, in some instances, reverse payments could be legal).

216. See *supra* Section III.A (examining the unique pharmaceutical industry and its characteristics).

more for a Budweiser beer.<sup>217</sup> By pressing their thumb on the scale and favoring generic market entry, courts would allow brand-name firms to justify their conduct, but they also would compensate for the pharmaceutical industry's susceptibility to abuse.<sup>218</sup> Accordingly, courts should limit the application of the "enhanced" rule of reason to vulnerable industries such as pharmaceuticals.

Indeed, courts have already shown a willingness to apply an "enhanced" rule of reason in other pharmaceutical patent litigation. For example, the Supreme Court arguably applied it in *Actavis*.<sup>219</sup> Despite the Court's strong preference for settlements, generally presuming their legality, it nonetheless held that a brand-name firm's settlement may have violated federal antitrust law.<sup>220</sup> Moreover, in applying *Actavis*, lower courts have effectively discouraged brand-name firms from wielding their monopoly power to coerce consumers.<sup>221</sup> In *King Drug*, for instance, the Third Circuit expanded *Actavis*'s foothold, holding that brand-name settlements that offer the alleged-infringer premature market entry, rather than a cash-payment like in *Actavis*, may likewise have violated the Sherman Act.<sup>222</sup> Additionally, in *In re Cipro Cases I & II*, the Supreme Court of California applied *Actavis* to the Cartwright Act,<sup>223</sup> a California state analog of the Sherman Act.<sup>224</sup>

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217. Compare *supra* notes 2–6 and accompanying text (identifying specific patients who cannot afford their medication), with Chad Bray & Michael J. de la Merced, *Anheuser-Busch InBev Approaches SABMiller on Possible Takeover*, N.Y. TIMES (Sept. 16, 2015), <http://www.nytimes.com/2015/09/17/business/dealbook/anheuser-busch-inbev-takeover-sabmiller.html> (elucidating the potential dangers from two beer companies merging).

218. See *supra* Section III.A (examining the pharmaceutical industry's susceptibility to monopolization and price-detached consumers).

219. See *Actavis*, 133 S. Ct. at 2234 (appreciating "the value of settlements," but concluding nonetheless "that this patent-related factor should not determine the result").

220. See *id.*; see also *United States v. Glens Falls Newspapers, Inc.*, 160 F.3d 853, 855–56 (2d Cir. 1998) (indicating the "strong public policy which encourages" settlements); *Hubb v. State Farm Mut. Auto. Ins. Co.*, 85 A.3d 836, 844 (D.C. 2014) (averring that courts "encourage[] settlements and . . . presume that a settled amount is fair and arrived at in good faith").

221. See, e.g., *King Drug Co. v. Smithkline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015) (finding that the holding in *Actavis* could not be narrowed only to the "reverse payments of cash"), *petition for cert. filed*, 84 U.S.L.W. 3482 (Feb. 19, 2016) (No. 15-1055); *In re Cipro Cases I & II*, 348 P.3d 845, 863–65 (Cal. 2015) (using *Actavis* to emphasize the antitrust issues involved in the case).

222. See *King Drug Co.*, 791 F.3d at 403 (equating the value of cash payments with the value of early market entry).

223. CAL. BUS. & PROF. CODE §§ 16720–16728 (West 2016).

As these cases demonstrate, the rule of reason is an ideal intermediary to repudiate anticompetitive conduct and accurately determine whether brand-name conduct is injurious to consumer welfare. Given a brand-name firm's predisposition to engage in anticompetitive manipulation, courts should mirror *Actavis* and impute a stronger presumption against brand-name firms that preclude generic competition through REMS manipulation and product hopping.

*C. Brand-Names Should "Go Straight to Jail Without Passing Go" for Exclusionary Conduct*

With little opposition to their ploys, brand-name firms are seemingly free to exploit the rules of the game. Indeed, brand-name firms possess the monopoly power to delay or avert generic market entry and consequently harm consumers.<sup>225</sup> Applying the same rule of reason analysis that the Supreme Court used in *Actavis*, courts can hold pharmaceutical companies accountable for injuring consumer welfare, sustaining unaffordable prices, and effectively hindering feeble patients from a successful recovery. Not only do REMS manipulation and product hopping constitute exclusionary conduct, but such gambits frustrate an underlying purpose of Hatch-Waxman.<sup>226</sup> Antitrust scrutiny would adequately shield anguished consumers from brand-name firms manipulating the rules.

*1. REMS manipulation constitutes exclusionary conduct*

Employing an "enhanced" rule of reason, a generic firm or consumer first needs to demonstrate a brand-name ploy's

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224. See *In re Cipro Cases I & II*, 348 P.3d at 863 (employing the rule of reason by extending *Actavis*'s principles "into the patent arena to prohibit a patentee's purchase of a potential competitor's consent to stay out of the market").

225. See Seth Silber et al., "Good Luck" Post-Actavis: Current State of Play on "Pay-for-Delay" Settlements, CPI ANTITRUST CHRON. 7, 9 (Nov. 2014), <https://www.wsg.com/publications/PDFSearch/silber-1114.pdf> (recognizing that reverse payments are attracting attention around the world, and arguing that "[o]ther [c]ountries [are] [l]ikely to [f]ollow" the U.S. courts due to their successes moderating abuse). But see Joshua D. Wright, *Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers*, FTC (Oct. 10, 2014), [https://www.ftc.gov/system/files/documents/public\\_statements/591131/141010actavisspeech.pdf](https://www.ftc.gov/system/files/documents/public_statements/591131/141010actavisspeech.pdf) (contending that "months after the Supreme Court's decision, the post-Actavis landscape remains unsettled").

226. See *supra* Section IA (describing Hatch-Waxman as a mechanism for bolstering brand-name pharmaceuticals by providing incentives for innovation and, at the same time, a mechanism for decreasing the market entry costs of generic pharmaceuticals).

anticompetitive effects and deem such conduct “exclusionary.”<sup>227</sup> Firms generally do not have a duty to deal with one another, but brand-name firms should be required to do so when they refuse to sell their samples to generic firms.<sup>228</sup> When they refuse to deal, brand-name firms forsake potential profits and deny generic firms a “facility” that is “essential” for market entry. Brand-name firms disguise their refusal as REMS compliance, but their conduct is intentionally predatory and severely impairs consumer welfare. Accordingly, their anticompetitive effects outweigh their procompetitive justifications, so courts should determine that such conduct violates section 2 of the Sherman Act.

*a. Refusing to sell makes “no economic sense”*

First, the refusal to sell samples satisfies both the profit sacrifice test and the “no economic sense” test, constituting exclusionary conduct.<sup>229</sup> Although a section 2 violation requires exclusionary conduct, conduct that demonstrates a firm’s exclusionary intent is also sufficient.<sup>230</sup> Courts can infer exclusionary intent from the mere fact that a for-profit firm rejected an otherwise profitable transaction.<sup>231</sup>

When firms restrain commerce by refusing to sell to competitors, firms should enjoy little-to-no-defense to justify their conduct.<sup>232</sup> In *Aspen Skiing*, for example, a ski resort refused to sell its lift tickets to a competitor that wished to create its own bundle package.<sup>233</sup> Because the resort’s lift tickets were publicly available and it would have

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227. See *supra* Section III.B (articulating an “enhanced” rule of reason).

228. *Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc.*, 555 U.S. 438, 448 (2009) (asserting that the general rule tolerates a firm’s discretion “to choose the parties with whom they will deal [and] the prices, terms, and conditions of that dealing”).

229. See *supra* Section II.A.1 (outlining the profit sacrifice and “no economic sense” tests).

230. See 15 U.S.C. § 2 (2012) (prohibiting attempted monopolization); *Tucker v. Apple Comput., Inc.*, 493 F. Supp. 2d 1090, 1101 (N.D. Cal. 2006) (inferring that forgoing “sales to prospective customers” is indicative of “anticompetitive malice rather than ‘competitive zeal’”).

231. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004) (maintaining that the “unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggest[s] a willingness to forsake short-term profits to achieve an anticompetitive end”).

232. See *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1077 (10th Cir. 2013) (“The point of the profit sacrifice test is to isolate conduct that has *no* possible efficiency justification.”).

233. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 593 (1985).

instantly profited from the transaction, the Court held that the refusal supported an inference of a deliberate, anticompetitive purpose.<sup>234</sup>

Similarly, brand-name firms operating lawful monopolies through their patents should not be able to exploit their market share to impede generic competition.<sup>235</sup> Just as the monopolist in *Aspen Skiing* abandoned revenue by refusing to sell its lift tickets, brand-name firms abandon potential revenue by refusing to sell their samples to generic firms.<sup>236</sup> Indeed, a brand-name firm can lose up to ninety percent of its market share when a generic product enters its market, which corresponds to billions of dollars in lost profits.<sup>237</sup> Recognizing that refusing to sell samples to generic firms will delay or even prevent generic market entry, brand-name firms have nothing to lose and everything to gain.

Brand-name firms clearly sacrifice short-term profits by refusing to sell their samples, and their refusal also satisfies the “no economic sense” test. This test applies a “but for” analysis, condemning conduct that “would make no economic sense . . . but for the tendency” to eliminate competition.<sup>238</sup> Firms that satisfy the test often operate at a loss to push out competitors who cannot sustain comparable deficits without folding.<sup>239</sup> Likewise, by refusing to sell their samples, brand-name firms forego substantial revenue in order to eliminate generic competition.<sup>240</sup>

Notwithstanding the sacrificed profits from a discounted wholesale price or an ordinary retail price, brand-name firms also forsake a

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234. *Id.* at 610–11.

235. *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 284 (2d Cir. 1979) (reproaching a firm “with monopoly power in one market to gain a competitive advantage in another by refusing to sell a rival the monopolized goods or services he needs to compete effectively in the second market”).

236. *See Aspen Skiing*, 472 U.S. at 610.

237. *See supra* note 173 and accompanying text.

238. *See supra* notes 148–49 and accompanying text.

239. *See Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1075 (10th Cir. 2013) (worrying that “a dominant firm may be able to forgo short-term profits longer than smaller rivals” to “drive rivals from the market”); *supra* notes 148–49 and accompanying text.

240. *See Novell*, 731 F.3d at 1075 (agonizing that “[g]iving up short-term profits . . . may risk doing less to enhance competition and consumer interests . . . and enable [the brand-name firm] to extract monopoly rents once the competitor is killed off or beaten down”); *infra* notes 254–60 and accompanying text (rationalizing that generic firms cannot economically survive by enduring the same challenges for approval that brand-name firms endure).

high-yield, premium sales price by refusing to sell their samples.<sup>241</sup> Indeed, brand-name firms still comply with the Sherman Act even if they choose to sell their samples to generic firms at a premium, generating a high profit margin. When manipulating REMS, however, brand-name firms offer *no* sales price for their samples. In other words, “but for” a brand-name firm’s “tendency” to eliminate generic competition so it can prevent potentially enormous losses looming from generic market entry and reduced prices, it would have sold its samples.<sup>242</sup> For example, the firm in *Matsushita* expelled competition by operating at a loss and forfeiting revenue; likewise, brand-name firms expel generic competition and avoid losing market share by refusing premium sales and forfeiting substantial revenue.<sup>243</sup> A for-profit firm operating at less-than-full capacity epitomizes exclusionary conduct.<sup>244</sup> Thus, the willingness to sacrifice not only a sale, but a high-yield premium sale, suggests that a brand-name’s refusal was motivated by “anticompetitive malice” rather than “competitive zeal,” which establishes exclusionary intent.<sup>245</sup>

*b. Refusing to sell denies generic firms an “essential facility”*

Above all, brand-name firms possess an “essential facility” to which generic firms need access in order to offer a product and lower prices

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241. See *Novell*, 731 F.3d at 1073 (arguing that if courts were required to “pick and choose” the appropriate price, it would only “risk judicial complicity in collusion and dampen[] price competition”); *VBR Tours, LLC v. Nat’l R.R. Passenger Corp.*, No. 14-cv-00804, 2015 WL 5693735, at \*7 (N.D. Ill. Sept. 28, 2015) (failing to state an antitrust claim even though the defendant removed its “discount, raising the cost of [its] tickets from wholesale to retail price[]”). Notwithstanding the discretion to charge a premium, brand-name firms do not enjoy an unfettered choice of price. See, e.g., *Safeway Inc. v. Abbott Labs.*, Nos. C 07-05470 CW, C 07-5985 CW, C 07-6120 CW, C 07-5702 CW, 2010 WL 147988, at \*7 (N.D. Cal. Jan. 12, 2010) (stating that “imposing a 400 percent increase in price” was sufficient “to show that this pricing conduct could have been motivated by anticompetitive malice”).

242. Compare *Spirit Airlines, Inc. v. Nw. Airlines, Inc.*, 431 F.3d 917, 950–51 (6th Cir. 2005) (holding that dropping prices and operating at a loss to eliminate competition satisfies the “no economic sense” test), with *Novell*, 731 F.3d at 1080 (accepting the monopolist’s “rationales” and rejecting the “no economic sense” test).

243. See *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 595–97 (1986); *supra* note 173 (rationalizing the need for such a method by noting that, on average, generic drugs cost seventy percent less than their brand-name equivalents).

244. See *Matsushita*, 475 U.S. at 580–81 (satisfying the “no economic sense” test because the defendant was operating at less-than-full capacity and needed to “operate at something approaching full capacity in order to make a profit”).

245. See, e.g., *Tucker v. Apple Comput., Inc.*, 493 F. Supp. 2d 1090, 1101 (N.D. Cal. 2006). But see *supra* note 147 (addressing the criticisms of the modern profit sacrifice test).

for consumers.<sup>246</sup> Inventing, manufacturing, and marketing a pharmaceutical drug is extremely expensive.<sup>247</sup> Despite the astronomical research and development costs that brand-name firms must endure to pioneer a new drug, they recoup their investment costs by charging correspondingly high sales prices.<sup>248</sup> Generic market entry, therefore, is of the utmost importance because it creates competition, consequently cutting consumer costs.<sup>249</sup> By functioning as the sole gatekeeper to vital, life-saving drugs, brand-name firms single-handedly preclude generic competition, preserve excessive prices, and risk patient health by setting a hurdle sometimes too high to climb.

Firms may not deny competitors an “essentially facility” that they require to function. In *Otter Tail*, for example, a single company owned the sole means of distribution of electric power in a service area and refused to provide access to competitors attempting to enter the market.<sup>250</sup> Since then, courts have determined that if a product or facility is under a monopolist’s exclusive control, the monopolist may not, under some circumstances, refuse to sell access to competitors.<sup>251</sup> In other words, monopolists may not deny a competitor a product or facility that a competitor requires to function and is unable to “practically or reasonably . . . duplicate” itself.<sup>252</sup>

Refusing access to these facilities is more than a deterrent; it realistically precludes most competition. Consumer welfare welcomes more players in the market because competition drives down prices, but, practically, firms cannot invest in costly capital expenditures *and* maintain low prices.<sup>253</sup> Capital expenditures,

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246. See generally Waller, *supra* note 163, at 359 (discussing the current framework for the essential facilities doctrine).

247. See *supra* note 24 (estimating that initial research and development, marketing, and manufacturing costs are over \$2.5 billion to bring a new brand-name drug to market).

248. See *supra* notes 119, 212 and accompanying text.

249. Devon M. Herrick, *What Is Increasing the Cost of Generic Drugs? (Part II: Regulatory and Legal Reasons)*, NAT’L CTR. FOR POL’Y ANALYSIS (Oct. 7, 2015), <http://www.ncpa.org/pub/what-is-increasing-the-cost-of-generic-drugs-part-ii-regulatory-and-legal-reasons> (articulating that the “FDA needs to clear the backlog of applications and allow [generic] competition to flourish” because this “would alleviate some of the price hikes caused by market consolidation”).

250. *Otter Tail Power Co. v. United States*, 410 U.S. 366, 368 (1973).

251. *Upadhye & Lang*, *supra* note 65, at 100.

252. *MCI Commc’ns Corp. v. AT&T Co.*, 708 F.2d 1081, 1132–33 (7th Cir. 1983).

253. Cf. Richard M. Lipton, *Economic Substance—Two District Courts Reach Differing Conclusions in Very Different Contexts*, 110 J. TAX’N 170, 177 (2009) (discussing an oil company that, because of its “capital expenditures toward acquiring and aggressively

though in many cases worthwhile in the end, require an enormous amount of capital—usually from debt, equity, or surplus.<sup>254</sup> Notwithstanding the unlikelihood that firms possess enough capital surplus, investors are similarly unlikely to finance these projects because it is not economically feasible for a firm wishing to enter a new market to take such a risk. A new cellphone provider, for example, cannot profit and remain viable by constructing its own cell tower; instead, it needs access to an already-existing cell tower.<sup>255</sup> Without such access, the cellphone provider chooses one of two options: it either purchases access from a competitor's cell tower or abandons its market entry.<sup>256</sup>

Generic pharmaceutical firms are trapped in a similar dichotomy. A brand-name sample is the functional equivalent of a cell tower, telephonic network, bridge, or similar utility system: without access to a brand-name sample, producing a generic drug is economically infeasible. Recall that generic firms must demonstrate that their drug is the “bioequivalent” of a corresponding brand-name drug to obtain abbreviated market entry.<sup>257</sup> Logistically, establishing bioequivalence is grueling, if not impossible, without a brand-name sample.<sup>258</sup> Without one, the only other way to bring a generic drug to market is to complete the same laborious and expensive laboratory testing that the brand-name firm undertakes.<sup>259</sup> Unlike brand-name firms, however, generic firms lack the ability to recoup their research and development costs because they share the market with competitors.<sup>260</sup> Like the new cellphone provider without the capacity

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developing properties it believed to have tremendous potential,” could not feasibly produce low oil prices).

254. See 42 U.S.C. § 1320a-1(g) (2012) (defining a capital expenditure “as [a costly] expense of operation and maintenance,” which “substantially changes the services of the facility”); Kee H. Chung et al., *Investment Opportunities and Market Reaction to Capital Expenditure Decisions*, 22 J. BANKING & FIN. 41, 42 (1998) (asserting that capital expenditures for “public utility firms” are not as profitable as other industries).

255. See KANG, *supra* note 198, at 74 (discussing the “high up-front, fixed costs” of the telephony industry, which require a “[h]igh initial investment”).

256. See *id.*

257. See *supra* Section I.A.3 (describing the process in which a generic drug is approved).

258. See *supra* Section I.A.3.

259. See *supra* note 72 and accompanying text.

260. See KANG, *supra* note 198, at 74 (contending that a new firm, “to attract customers,” will not survive if it matches an incumbent price, so it must set its “price below its own cost of production and therefore operate at a loss”). Moreover, brand-name drugs do not “compete” in the same sense because they possess patent exclusivity, furnishing them the liberty to charge higher prices.

to invest in a costly capital expenditure, generic firms lack the same economic opportunity. As a result, a brand-name firm's refusal to sell samples denies generic firms an "essential facility" and indicates exclusionary intent because it practically precludes generic market entry, which preserves elevated prices and misappropriates millions of dollars in savings from consumers.

## 2. *Product hopping constitutes exclusionary conduct*

Following the analysis put forth in *Actavis*, courts should similarly examine product hopping under an "enhanced" rule of reason, demonstrating a brand-name firm's anticompetitive conduct.<sup>261</sup> Here, the central inquiry is whether slightly altering a product and re-marketing it is exclusionary conduct.<sup>262</sup> Brand-name firms that possess monopoly power by means of their patent's exclusivity should not be allowed to wield that power perpetually to preclude generic market entry.<sup>263</sup> To do so would eliminate consumer choice, epitomizing exclusionary conduct.<sup>264</sup>

### a. *Coercing consumers is exclusionary*

Eliminating consumer choice effectively precludes competition and is indicative of unlawful exclusion. To prevail, generic firms need not establish a brand-name's actual intent to exclude competition; rather, generics need only demonstrate a firm's slight alteration eliminated consumer choice.<sup>265</sup> The inference itself supplants the need to show

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261. See *supra* note 167 and accompanying text (defining product hopping).

262. See *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014) (examining product hopping by asking "whether the defendant combined the introduction of a new product . . . such that the comprehensive effect is likely to stymie competition, prevent consumer choice[,] and reduce the market's ambit").

263. See *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.3d 263, 274 (2d Cir. 1979) (disputing that a "monopolist may not wield [its power] to prevent or impede competition," even if its "power [was] legitimately acquired").

264. See *Namenda*, 787 F.3d 638, 652 (2d Cir. 2015) (maintaining that "[w]ell-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition"), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015); *supra* notes 167–78 and accompanying text (explaining the facts behind product hopping).

265. *In re Suboxone*, 64 F. Supp. 3d at 682 ("[S]imply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the [monopolist] combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice[,] and reduce the market's ambit."); see also *Cal. Comput. Prods., Inc. v. Int'l Bus. Machs.*

actual intent, focusing more on the alteration's effect rather than its cause.<sup>266</sup> By discarding potential competitors and eliminating consumer autonomy, monopolists artificially extend their exclusivity and force consumers to choose between either paying a steep premium for the product or forgoing the consumption. In the pharmaceutical industry, however, the alternative to paying is a uniquely perilous choice for consumers: they must forgo their medication and put their health at risk. Thus, focusing on consumer choice appropriately tempers vehement brand-name preclusion.

Pharmaceutical commerce is not the only industry in which consumer coercion appears. For instance, in the textbook market, preclusion ploys and predatory pricing regularly ravage consumers.<sup>267</sup> While Hatch-Waxman strives to be a champion for pharmaceutical consumers, federal copyright laws attempt the same for textbook consumers.<sup>268</sup> Despite that effort, students continue to pay excessive prices for textbooks, which often account for over one-third of their total cost of attendance.<sup>269</sup> Like brand-name firms hopping from drug to drug, authors frequently publish new textbook editions, forcing students to pay a premium for their newest version.<sup>270</sup> The elevated

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Corp., 613 F.2d 727, 735–36 (9th Cir. 1979) (concluding that “the test is whether the [monopolist’s] acts, otherwise lawful, were *unreasonably* restrictive of competition”).

266. See *Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946) (maintaining that acquiring “the power to exclude competitors from any part of the trade or commerce” is unlawful “provided that they have the intent and purpose to exercise that power”).

267. See, e.g., *Sunshine Books, Ltd. v. Temple Univ.*, 697 F.2d 90, 91–92, 96 (3d Cir. 1982) (withstanding summary judgment when students alleged a university attempted to monopolize the sale of undergraduate textbooks).

268. See 17 U.S.C. §§ 101–122 (2012); Gary Minda, *Monopoly Pricing on Campus: New York’s Textbook Access Act*, 29 PACE L. REV. 523, 538 (2009) (comparing the textbook market to the drug industry and recommending that textbooks adopt a “generic textbook alternative”).

269. Allie Bidwell, *Report: High Textbook Prices Have Students Struggling*, U.S. NEWS & WORLD REP. (Jan. 28, 2014, 9:28 AM), <http://www.usnews.com/news/articles/2014/01/28/report-high-textbook-prices-have-college-students-struggling> (finding that, on average, students spend \$1200 each year on textbooks, accounting for, on average, fourteen percent of tuition at four-year universities and thirty-nine percent of tuition at community colleges).

270. See Minda, *supra* note 268, at 534 (contending that “faculty should be subject to disclosure requirements, explaining why a higher cost, newer edition textbook is necessary”).

prices vexing consumers are a direct result of the lack of competition caused by brand-name firms and publishing companies.<sup>271</sup>

Pharmaceutical firms undeniably control the ability to modify their products,<sup>272</sup> but the Sherman Act's proscription against precluding competition supersedes any economically advantageous modification that also harms consumer welfare.<sup>273</sup> In *Berkey Photo*, a competing firm accused Kodak of using its monopoly power in the camera market to preclude competition.<sup>274</sup> The court concluded that consumers maintained their free choice, despite the introduction of a new product, because the old product was still available on the market.<sup>275</sup> In contrast, in *Namenda*, the court upheld a preliminary injunction in favor of the generic firm, again paying particular attention to consumer choice: the brand-name firm withdrew its old drug, forcing renewing consumers to purchase its new drug.<sup>276</sup> Thus, introducing a new product while simultaneously removing an old product supports the inference that the brand-name firm sought to preclude competition.<sup>277</sup>

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271. *See id.* at 531 (“The key to maintaining low competitive prices is the availability of substitute products in the market.”); Bidwell, *supra* note 269 (asserting that “[t]he problem . . . comes from a lack of competition in the textbook market”).

272. *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, No. CV 05-06419 MRP (AJWx), 2008 WL 7346921, at \*9 (C.D. Cal. July 9, 2008) (conceding that the “introduction of new products cannot, in and of itself, violate Section 2”); *see also* *Cal. Comput. Prods., Inc. v. Int’l Bus. Machs. Corp.*, 613 F.2d 727, 744 (9th Cir. 1979) (maintaining that firms are under “no duty to help” one another).

273. *See Namenda*, 787 F.3d 638, 652 (2d Cir. 2015) (accepting that “case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition”), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

274. *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 267–68 (2d Cir. 1979).

275. *See id.* at 281–88.

276. *See Namenda*, 787 F.3d at 649, 658 (“In withdrawing [the once-daily drug] from the market, [the firm’s] explicit purpose was to impede generic competition and to avoid the patent cliff—which occurs at the end of a drug’s exclusivity period when generics gain market share through state substitution laws.”).

277. *See, e.g., Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, 12-3824, 2015 WL 1736957, at \*12, \*18 (E.D. Pa. Apr. 16, 2015) (ruling against the generic firm on summary judgment because “doctors remained free to prescribe” the generic version, “pharmacists remained free to substitute [it],” and “patients remained free to ask their doctors and pharmacists for [it]”), *aff’d*, No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 682, 684 (E.D. Pa. 2014) (denying the brand-name firm’s motion to dismiss because the “threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film”); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 152 (D.D.C. 2008) (ruling against the

*b. Avoiding an examination of a product's superiority*

Although it may seem natural to do so when analyzing alleged product hopping, courts should avoid an inquiry that contemplates whether a newly-modified product is “superior” compared to its older one because it is beyond their expertise.<sup>278</sup> Such an inquiry improperly compels courts to compare products, extensively investigate markets, and ultimately quantify a new drug’s value to society.<sup>279</sup> Lacking a comprehensive understanding of medicine and pharmaceutical engineering, the disadvantage of allowing such an inquiry is obvious: judges function better in a black robe than a white lab coat. However diligent a court may be, this misplaced argument reduces the inquiry to personal preference rather than superior ingenuity or societal value.<sup>280</sup> Consumer coercion, on the other hand, is a more effective litmus test that focuses on objective market behavior. Requiring a brand-name firm temporarily to maintain its older product on the market allows *consumers*, rather than courts, to evince a new product’s value by choosing whether to purchase it.<sup>281</sup> Therefore, a finding that product hopping constitutes exclusionary conduct deters brand-name firms from executing pernicious practices that effectively preclude generic market entry, which in turn protects vulnerable pharmaceutical consumers.<sup>282</sup>

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generic firm on a motion to dismiss because the older drug “remains available as a consumer choice”); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 422 (D. Del. 2006) (denying the brand-name firm’s motion to dismiss because “consumers were not presented with a choice” between formulations); *see also Berkey Photo*, 603 F.3d at 286 n.30 (reasoning that rather than “the production introduction itself,” an additional, anticompetitive motive is required to support a section 2 violation).

278. *See, e.g., Namenda*, 787 F.3d at 653–55.

279. *See Berkey Photo*, 603 F.2d at 287 (contending that the “only question that can be answered is whether there is sufficient demand for a particular product to make its production worthwhile”).

280. *See id.* (discarding a court’s ability to “determine with any reasonable assurance whether one product is ‘superior’ to another,” positing that such a query “is a matter of individual taste”).

281. *See id.* (positing that determining whether “sufficient demand for a particular product to make its production worthwhile . . . can only be inferred from the reaction of the market”).

282. *See id.* at 279 (alleging that “Kodak, a film and camera monopolist, was in [the unique] position to set industry standards”); *Minda*, *supra* note 268, at 524–25 (“[T]extbook publishers are in the same position as drug makers; they offer unique products protected by intellectual property rights (patent, copyright, and trademark protection) and benefit from the moral hazard of having doctors or professors require the drug or the book without regard to the cost ultimately paid by the consumer. The person who buys the product does not get to choose it, and hence

*D. The “Legitimate Business” Defense Is No “Get Out of Jail Free” Card*

Applying the rule of reason in the pharmaceutical patent context, brand-name firms often proffer procompetitive justifications, attempting to defend their conduct’s anticompetitive effects. They contend that their alleged REMS manipulation or product hopping exhibits a “legitimate business purpose” immune from suit.<sup>283</sup> However, neither apology nor excuse should inoculate conduct that ultimately prevents ailing consumers from attaining life-saving pharmaceuticals.

The “legitimate business” defense carries with it the potential for abuse. Executives, not judges, manage private companies, and firms irrefutably remain entitled to make business decisions that maximize profits.<sup>284</sup> Nonetheless, such a notion does not save the day for a brand-name firm. Although firms are free to choose with whom they deal, they are not granted unfettered discretion to preclude generic market entry.<sup>285</sup> Firms may not avoid antitrust scrutiny by merely asserting that their conduct serves an economic, self-interested purpose.<sup>286</sup> They often characterize their exclusionary conduct as such to shield liability, but the doctrine should not function as a vaccine for gluttonous firms, especially considering the industry’s general susceptibility to abuse.<sup>287</sup> Granting a brand-name firm

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the price of the product is something that becomes merely what one needs to pay if he or she wants either medical treatment or an education.”).

283. See *supra* note 110 and accompanying text (detailing examples of the “legitimate business” defense and its application).

284. *Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc.*, 555 U.S. 438, 448 (2009); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 597 (1985) (explaining that “[a monopolist that] refuses to deal with a competitor in some manner does not violate Section 2 if valid business reasons exist for that refusal”).

285. See *Aspen Skiing*, 472 U.S. at 601 (conceding that a firm’s right to refuse to deal with others is not “unqualified”).

286. See *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (asserting that a “business [may] freely” choose with whom to deal except where its motivation is to “obtain or maintain a monopoly”); *Smith v. Pro Football*, 593 F.2d 1173, 1183 (D.C. Cir. 1978) (enunciating that a business decision’s “‘anticompetitive evils’ . . . must be carefully balanced against its ‘procompetitive virtues’ to ascertain whether the former outweigh the latter” (quoting Milton Handler, *Changing Trends in Antitrust Doctrines: An Unprecedented Supreme Court Term—1977*, 77 COLUM. L. REV. 979, 983 (1977))). But see, e.g., *Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2015 WL 1736957, at \*5 (E.D. Pa. Apr. 16, 2015) (accepting a brand-name firm’s legitimate business purpose and consequently granting it summary judgment), *aff’d*, No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016).

287. See *In re Thalomid & Revlimid Antitrust Litig.*, No. CV 14-6997, 2015 WL 9589217, at \*15 (D.N.J. Oct. 29, 2015) (explaining that “being motivated by anti-competitive goals” is “sufficient to conclude that [a] refusal to deal violated the

immunity through this defense would not only frustrate an underlying purpose of Hatch-Waxman, but it would also render federal antitrust law superfluous.<sup>288</sup> Accordingly, courts should apply a bright-line rule prohibiting firms from asserting the “legitimate business” defense when they find that a firm’s REMS manipulation or product hopping is exclusionary.

1. *Honoring the Sherman Act*

While a business decision resulting in market exclusivity is clearly economically beneficial to that firm, it can be equally destructive to consumer welfare.<sup>289</sup> If mere profitability were the sole standard, firms would rarely—and possibly never—violate section 2, and pharmaceutical prices would become unaffordable.<sup>290</sup> Precluding competition permits the monopolist to set supracompetitive prices with no threat of losing market share to lower-priced alternatives. Judges, however, are not economists and should not balance a business decision’s economic standing with its market effects. If, after applying an “enhanced” rule of reason, a generic firm proves that a brand-name firm precluded generic competition by either manipulating REMS or product hopping, courts should bar brand-name firms from asserting the “legitimate business” defense.<sup>291</sup> Demonstrating a brand-name firm’s predatory ploy elucidates its anticompetitive intentions and should accordingly extinguish the “legitimate business” defense, thereby providing relief to consumers.

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Sherman Act”); *supra* Section III.A (illustrating the pharmaceutical industry’s vulnerability to abuse due to its high, upfront costs and consumer-price disconnect).

288. *See infra* Sections III.C.1–2.

289. *See* *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 375 (1967) (contending that a firm’s “self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct,” and only conduct that “is not unlawful in its impact in the marketplace” will survive antitrust attack), *overruled on other grounds by* *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 57–58 (1977) (overturning the decision to apply a bright line rule finding that vertical trade restrictions are always detrimental to consumers); *City of Chanute v. Williams Nat. Gas Co.*, 678 F. Supp. 1517, 1534 (D. Kan. 1988) (same).

290. *See* *United States v. Timken Roller Bearing Co.*, 83 F. Supp. 284, 312 (N.D. Ohio 1949) (condemning firms that “form[] for the purpose . . . to fix prices and to eliminate competition,” and warning that they cannot “circumvent the law by entering into agreements purportedly to protect [such motives]”), *modified by* 341 U.S. 593 (1951), *overruled by* *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752 (1984).

291. *See supra* Sections III.B–C (arguing for an “enhanced” rule of reason and finding that REMS manipulation and product hopping constitute exclusionary conduct).

## 2. *Upholding the purpose of the Hatch-Waxman Act*

Relatedly, courts should rebuff brand-name firms asserting the “legitimate business” defense when they preclude generic market entry because allowing such a defense would frustrate an underlying purpose of the Hatch-Waxman Act. In passing Hatch-Waxman, Congress’s aims were two-fold: (1) maintain brand-name exclusivity to develop new drugs and (2) expedite generic market entry to lower consumer costs.<sup>292</sup> With these goals in mind, forcing a sale of samples or prohibiting product hopping are unlikely to frustrate either purpose: neither action would diminish pharmaceutical innovation, nor would they impede generic market entry. First, by continuing to respect patent exclusivity terms, brand-name firms would still maintain the ability to charge steep prices initially to recoup capital, settle debts, and invest in new drugs.<sup>293</sup> Of course, brand-name firms already do this, commonly charging five times the price of corresponding generics.<sup>294</sup> And second, rather than impede generic competition, rejecting such a defense would expedite generic market entry upon the natural conclusion of a brand-name patent’s life. REMS manipulation and product hopping preclude generic competition;<sup>295</sup> when brand-name firms employ such tactics, courts should disallow the “legitimate business” defense because it would frustrate Hatch-Waxman and effectively grant brand-name firms market isolation. Such market isolation allows brand-name firms to charge consumers unaffordable prices, sometimes impeding their road to recovery.

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292. See *supra* notes 55–57 and accompanying text.

293. See, e.g., *Christy Sports, LLC v. Deer Valley Resort Co.*, 555 F.3d 1188, 1194 (10th Cir. 2009) (elucidating that ski resort financiers can “recoup” their investments by “increas[ing] the price of lift tickets, rais[ing] room rates, serv[ing] only high-priced food, or, as it seems to have chosen, delv[ing] more deeply into the rental ski market”).

294. Upadhye & Lang, *supra* note 65, at 86; see also *Facts About Generic Drugs*, *supra* note 23 (contending that, “[o]n average, the cost of a generic drug is 80 to 85 percent lower than the brand name product,” saving consumers “an average of \$3 billion every week”). Patients find that pharmaceutical prices vary wildly, even among generic drugs. See Sy Mukherjee, *Study: CVS, Rite Aid, And Other Chain Pharmacies Sell Generic Drugs at up to 18 Times Their Cost*, THINKPROGRESS (May 29, 2015, 5:50 PM), <http://thinkprogress.org/health/2013/03/29/1798061/chain-pharmacies-generic-drugs>; *Same Generic Drug, Many Prices*, CONSUMER REP. (May 2013), <http://www.consumerreports.org/cro/magazine/2013/05/same-generic-drug-many-prices/index.htm> (describing one study that found, on average, “blockbuster” generic drugs sold for 447% higher than other generics).

295. See *supra* Sections III.C.1–2 (explaining how REMS manipulation and product hopping constitute exclusionary conduct).

*a. Allowing the defense facilitates REMS manipulation*

First, courts should prohibit brand-name firms from asserting the “legitimate business” defense when they manipulate REMS.<sup>296</sup> Brand-name firms assert that mandatory dealing opens them up to product liability, damages their reputation, potentially triggers additional mandated REMS, and even instigates their drug’s removal from the market.<sup>297</sup> However, firms retain the option to contractually indemnify themselves or charge a premium to offset potential liability. Furthermore, brand-name firms’ pleas for a laissez-faire pharmaceutical regulatory scheme are further undermined by Congress’s intent, as evidenced by its plain language prohibiting firms from “block[ing] or delay[ing]” ANDAs and its bioequivalence requirement.<sup>298</sup> Congress did not intend for REMS to prevent generic firms from market entry, but rather it sought to protect consumers from risky drugs.<sup>299</sup> Regardless of whether a brand-name firm sacrifices profits or denies generic firms an “essential facility,” either theory infers an intent to preclude generic market entry and should bar brand-name firms from asserting the “legitimate business” defense.<sup>300</sup> Allowing such a defense would only permit brand-name firms to deny generic firms the samples they need to function, effectively undermining antitrust safeguards at the expense of consumers.

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296. See *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 599 (1985) (concluding that “no valid business reason [exists] for refusing” a transaction that would have otherwise been profitable). Although the Supreme Court has held that a firm “has no obligation” to grant others access to its patented product, see *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432 (1945) (explaining that a “patent owner . . . [has] no obligation either to use it or to grant its use to others”), the Court has never held that such a proposition applies to pharmaceutical patents. Indeed, the pharmaceutical industry operates under a unique regulatory framework and is thus entitled to similar accommodations in the “refusal to deal” context. See, e.g., *supra* Section III.A (discussing the pharmaceutical industry’s price disconnect and vulnerability to abuse).

297. Tucker et al., *supra* note 65, at 77.

298. See 21 U.S.C. § 355-1(f)(8) (2012) (“No holder of an approved covered application shall use any [ETASUs] required . . . to block or delay approval of . . . a drug that is the subject of an [ANDA].”); § 355(j)(2)(A)(i)–(viii).

299. See *supra* notes 122–23, 128 and accompanying text (describing various consumer protections and purporting that Congress contemplated abuse by brand-name firms).

300. See *supra* Section III.C.1 (establishing that a brand-name firm’s refusal to deal constitutes exclusionary conduct).

*b. Allowing the defense facilitates product hopping*

Second, courts should prohibit brand-name firms from asserting the “legitimate business” defense when they engage in product hopping.<sup>301</sup> A pharmaceutical firm should not be able to justify consumer coercion, as evident by the simultaneous introduction of a new product and withdrawal of an old one, merely by demonstrating its profit-earning potential. Such conduct certainly yields profits, but it also precludes generic market entry.<sup>302</sup> Because Hatch-Waxman requires a generic drug to be identical to its brand-name counterpart, any slight alteration causes generic firms to start their market entry all over again. Repeatedly forcing generic firms to restart their ANDA process exhausts capital, depletes resources, and causes manufacturing costs to exceed probable profit, rendering it economically infeasible for generic firms to pursue market entry and pass savings on to consumers. Product hopping consequently preserves high prices without providing consumers any practicable alternative; thus, courts should ban the immunity that brand-name firms seek from the “legitimate business” defense.

*3. Preventing brand-names from being pharma’s gatekeepers*

Lastly, courts should prohibit brand-name firms from asserting the “legitimate business” defense so those firms cannot act as the sole gatekeepers to the pharmaceutical industry.<sup>303</sup> For example, hospitals confront much of the same coercion seen in the pharmaceutical industry. To combat astronomical healthcare costs and avoid over-saturated markets, some state legislatures enacted certificate-of-need (CON) laws.<sup>304</sup> CON laws attempt to protect consumer welfare by

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301. See *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919); *supra* Section III.C.1.

302. See Ross D. Petty, *Predatory Promotion: A Theory of Antitrust Liability Whose Time Has Come?*, 27 AM. BUS. L.J. 215, 229 (1989) (“[A]ntitrust cases also have condemned product modifications that appear to be exclusionary and offer no genuine innovation to consumers.”).

303. Brand-name firms assert a variety of different business purposes for their timely modifications. See, e.g., *Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2015 WL 1736957, at \*5 (E.D. Pa. Apr. 16, 2015) (arguing that a product hop is justified because of (1) shelf-life stability, (2) risk of injury with capsules compared to tablets, (3) concerns from international regulators, (4) potential esophageal injury from capsules, and (5) dosing flexibility), *aff’d*, No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016).

304. See Patrick John McGinley, Comment, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a “Managed Competition” System*, 23 FLA. ST. U. L. REV. 141,

requiring a state agency to approve all “hospital expansions and major equipment purchases.”<sup>305</sup> CON laws, however, shortsightedly achieve just the opposite and effectively perpetuate high healthcare costs.<sup>306</sup> Because market entry depends upon agency approval, CON laws restrict market entry, insulate incumbents from competition, and ultimately preserve inflated costs.<sup>307</sup> As a result, many state legislatures have repudiated CON laws altogether.<sup>308</sup>

Resembling the framework in CON laws, the pharmaceutical industry can expect a similar prognosis if courts continue to grant brand-name firms *carte blanche*. Indeed, the hospital and pharmaceutical markets share many attributes: both operate in monopolistic markets where entry is laborious, expensive, and fraught with regulatory barriers.<sup>309</sup> Comparably, REMS manipulation and product hopping insulate monopolists from competition and

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143 (1995) (contending that such a model “encourage[s] price competition among health care providers” by “attempt[ing] to lower costs by managing demand”).

305. *See id.*

306. *See* Gerard R. Goulet, *Certificate-of-Need over Hospitals in Rhode Island: A Forty-Year Retrospective*, 15 ROGER WILLIAMS U. L. REV. 127, 128–29 (2010) (maintaining that “conclusive evidence” exists that CON laws “constrain costs”); Andrew Kitchenman, *Explainer: Certificate of Need Determines Fate of Healthcare Facilities in NJ*, NJ SPOTLIGHT (Dec. 15, 2015), <http://www.njspotlight.com/stories/15/12/14/explainer-certificate-of-need-determines-which-healthcare-facilities-open-close> (expounding the controversial nature of CON laws, citing major delays in projects); *see also, e.g.*, Owen S. Mudge, Jr. & Allan Gibofsky, *The Developing Application of Antitrust Laws to Hospital Mergers*, 15 J. LEGAL MED. 355, 367 (1994) (reasoning that Tennessee’s CON law “significantly impairs” competition and preserves high prices).

307. *See* Milton L. Cruz, *Product and Geographical Market Measurements in the Merger of Hospitals*, 91 DICK. L. REV. 497, 513 (1986) (conceptualizing that CON laws make market entry “difficult,” so “hospitals are in a position to raise prices without entering immediate competition”).

308. *Certificate of Need: State Health Law and Programs*, NAT’L CONF. OF ST. LEGISLATURES (Jan. 2016), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (asserting that, despite the controversial nature of CON laws, as of 2014, about thirty-six states retain the laws in some form); *see also* Dani Kass, *DOJ, FTC Back SC Bill to End Certificate-of-Need Laws*, LAW360 (Jan. 11, 2016, 9:11 PM), <http://www.law360.com/articles/745225/doj-ftc-back-sc-bill-to-end-certificate-of-need-laws> (recounting the DOJ’s and FTC’s efforts to eliminate the CON law in South Carolina).

309. *Compare supra* notes 253–59 and accompanying text (discussing the pharmaceutical industry and capital expenditures, emphasizing the expensive and time-consuming process that deters investors), *with* Cruz, *supra* note 307, at 502 (explicating that the hospital industry has “low cross-elasticity,” such that “[i]f a hospital increases the prices it charges for certain services, a group of investors cannot get together and build a hospital to compete with the existing hospital without obtaining a [CON]”).

generate the same price inflations as CON laws.<sup>310</sup> In enforcing CON laws, state agencies failed to be adequate gatekeepers for hospital market entry; so, why should brand-name firms dictate when—or if—generic drugs may enter their markets?<sup>311</sup> Allowing the “legitimate business” defense would permit brand-name firms to function as the pharmaceutical industry’s ultimate gatekeepers, essentially rendering both Hatch-Waxman and the Sherman Act superfluous.<sup>312</sup>

The FDA, however, is not equipped to handle the pharmaceutical industry’s enforcement matters, so courts should entrust antitrust law to fill the void.<sup>313</sup> Because brand-name firms are unlawfully extending their market exclusivity to escalate prices, they should not benefit from a defense designed to protect consumer welfare. Simply put, their procompetitive justification—their economic benefit—never outweighs their anticompetitive effects. Therefore, courts should refuse to immunize brand-name firms that misuse the “legitimate business” defense to preclude generic competition and raise prices to supra-competitive levels, thereby harming consumers.

#### LANDING ON “PARK PLACE”

The pharmaceutical industry is comprised of many moving parts. Market entry, for instance, requires unusually high research and development costs. Additionally, unlike consumers in other industries, the pharmaceutical consumer is essentially unable to “shop around,” yielding market influence to prescribing physicians and third party

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310. See *supra* notes 18–19 (discussing recent, perilous pharmaceutical price increases).

311. See, e.g., *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 882–83 (N.D. Cal. 2011) (lacking antitrust scrutiny, a brand-name firm “raised the price . . . of Norvir from \$1.71 to \$8.57, which amounted to a 400-percent increase . . . [when its] previous price increases averaged 3.45 percent”).

312. In addition, brand-name firms are perpetuating fraud, falsely claiming that they have a “new” product. See *In re Thalomid & Revlimid Antitrust Litig.*, No. CV 14-6697, 2015 WL 9589217, at \*10 (D.N.J. Oct. 29, 2015) (entertaining an argument that a brand-name firm “engaged in sham litigation . . . by committing fraud on [a federal agency], stripping it of any immunity”); cf. *FTC v. Winsted Hosiery Co.*, 258 U.S. 483, 493 (1922) (stressing that “misbrand[ing] goods” to attract consumers by fraud is not entitled to a defense).

313. See *Darrow*, *supra* note 208, at 403 (deeming the FDA inefficient gatekeepers of the pharmaceutical industry); cf. Sarah Butcher, Note, *Fraud-on-the-FDA and Genetically Modified Foods: Will the Action Stand?*, 22 REV. LITIG. 669, 705 (2003) (“The FDA seems rather unprepared for the possibility that a company might perpetuate a fraud by concealing important information about a [genetically modified] food.”).

insurers. With such a volatile system, one glitch can cause harmful side effects for those that need prescription drugs the most.

Indeed, the smallest fracture can cause the entire system to crumble. By enacting the Hatch-Waxman Act, Congress sought to expedite generic market entry, yet preserve pharmaceutical innovation. While Congress accommodated both brand-name and generic firms, one underlying goal motivated the legislation: the desire to protect consumer welfare. Nevertheless, unforeseen gaps in the statute have splintered consumer protections. In an unusually vulnerable industry, corporate avidity has turned those gaps into chasms. Specifically, brand-name firms' REMS manipulation and product hopping have prevented generic market entry and devastated consumers with unaffordable prices.

Without a watchdog in their corner, pharmaceutical companies possess seemingly unfettered control of the drug market. Antitrust scrutiny, however, effectively protects consumers, and the rule of reason prescribes a balancing test to determine whether a firm's conduct is exclusionary. Although meticulous at times, judicial review of such matters ultimately conserves resources and saves pharmaceutical consumers billions of dollars. Courts should use *Actavis* as a model, interpreting it as an "enhanced" rule of reason test specific to the pharmaceutical industry, and use it to examine REMS exploitation and product hopping. Moreover, because of the industry's limitations, courts should also prohibit a brand-name firm from asserting the "legitimate business" defense once they find that it precluded competition.

First, manipulating REMS constitutes exclusionary conduct. Brand-name firms refusing to sell their samples to generic firms, at any price, forsakes profits and makes "no economic sense," supporting an inference of anticompetitive malice. Furthermore, their refusal denies generic firms an essential facility. Lacking the ability to charge high prices and recoup their invested capital, it is not economically feasible for generic firms to compete without access to such a fundamental resource, effectively eliminating the possibility of market entry. Second, product hopping also represents exclusionary conduct. Hopping from product to product coerces consumers and prevents them from purchasing cheaper alternatives.

Lastly, courts should apply a bright-line rule prohibiting brand-name firms from asserting the "legitimate business" defense when precluding generic competition. Most exclusionary conduct is economically profitable; if mere profitability was the quintessential factor, courts' allowance of the defense would undermine both

Hatch-Waxman and the Sherman Act. Inherently, brand-name firms encounter a conflict of interest if they function as gatekeepers to the pharmaceutical marketplace.

To be clear, examining pharmaceutical patent litigation through an “enhanced” rule of reason in no way shortens the lives of otherwise valid patents. Exclusivity from patents is crucial because it allows brand-name firms to recoup their investments and devote more capital to pioneering new drugs. Forbidding brand-name firms from gaming the system merely prevents them from using their patents anticompetitively. By impeding generic competition, they essentially grant themselves market exclusivity and thereby misappropriate enormous profits at the consumer’s expense.

Rather than shield brand-name firms, courts should apply antitrust scrutiny to uphold the underlying purpose of the Hatch-Waxman Act, preserve competition, and, most importantly, defend consumers from the pharmaceutical industry’s voracious grip. Without generic competition, brand-name firms occupy an unregimented and indefinite monopoly, thus allowing them to charge unaffordable prices. Millions of Americans like Jacqueline Racener and Stuart Chapin, though suffering from illness, also ache for consumer relief. The Act’s purpose was to protect consumers; instead, the Act is perpetuating abuse. Consumers are consistently landing on “Park Place,” and brand-name firms are forcing them to pay supracompetitive prices for their prescriptions, bankrupting them in the process. Mirroring *Actavis* and applying an “enhanced” rule of reason to pharmaceutical patent litigation repairs the rules of the game and adequately protects consumers against predatory conduct like REMS manipulation and product hopping. Such a fix allocates a sufficient profit to brand-name firms pioneering new life-saving drugs, but it also enables consumers to afford those drugs and treat their illnesses. After all, if the market players price pharmaceuticals too high to afford, what is the purpose of playing the game?