

2-5-2020

## THREE CHALLENGES FOR PHARMACEUTICAL ANTITRUST

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## THREE CHALLENGES FOR PHARMACEUTICAL ANTITRUST

Michael A. Carrier\*

*Pharmaceutical antitrust law is hard. When drug companies delay generic entry, is that beneficial “life-cycle management”? Or is it unjustified anti-competitive behavior? The question arises in multiple settings, including patent settlements by which brand firms pay generics to delay entering the market, product reformulations made to prevent generic adoption, citizen petitions filed with the U.S. Food and Drug Administration (FDA), and the denial of samples that generics need to enter the market.*

*Courts confront challenges when addressing these complex questions. And sometimes, they veer astray. Why? This essay seeks to answer that question, cataloging three mistakes courts have made in this setting, which are based on (1) complexity, (2) simplicity, and (3) Sisyphus.*

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\* Distinguished Professor, Rutgers Law School. I would like to thank participants in the *Antitrust and Silicon Valley* conference held at Santa Clara University Law School. Copyright © 2020 Michael A. Carrier. Parts of this essay are adapted from previous work.

Pharmaceutical antitrust law is hard. When drug companies delay generic entry, is that beneficial “life-cycle management”? Or is it unjustified anti-competitive behavior? The question arises in multiple settings, including patent settlements by which brand firms pay generics to delay entering the market, product reformulations made to prevent generic adoption, citizen petitions filed with the U.S. Food and Drug Administration (FDA), and the denial of samples generics need to enter the market.

Courts confront challenges when addressing these complex questions. And sometimes, they veer astray. Why? This essay seeks to answer that question, cataloging three mistakes courts have made in this setting, which are based on (1) complexity, (2) simplicity, and (3) Sisyphus.

## I. COMPLEXITY

First, the pharmaceutical industry is unique in its complexity, with nuanced markets and multiple regulatory regimes.

### A. Markets

Pharmaceutical markets are complex. Unlike other markets, “the consumer who pays does not choose, and the physician who chooses does not pay.”<sup>1</sup> This disconnect has created a gap that can be exploited. Brand firms can convince doctors to prescribe expensive drugs even if equally effective cheaper drugs are available. In fact, brands have done so through an array of activity that includes samples, mailings, detailing (sales calls to doctor’s offices), sponsored continuing medical education programs, and advertising in media and medical journals.<sup>2</sup>

This range of activity entails significant expenditures, with brands often spending more on marketing than on research and development (R&D).<sup>3</sup> And it has been effective. Just to give one example, nearly half the doctors in one study considered information provided by sales representatives important and almost one-third changed their prescribing behavior as a result.<sup>4</sup> At the same time, adding another layer of complexity, drug firms have increased direct-to-consumer advertising,

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1. BUREAU OF CONSUMER PROTECTION, DRUG PRODUCT SELECTION: STAFF REPORT TO THE F.T.C. 2 (Jan. 1979).

2. STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 87-93 (2d ed. 2007).

3. *E.g.*, *id.* at 82; Ana Swanson, *Big Pharmaceutical Companies are Spending Far More on Marketing than Research*, WASH. POST, Feb. 11, 2015.

4. SCHWEITZER, *supra* note 2, at 85.

which has resulted in doctors acceding to patients' wishes and writing more prescriptions.<sup>5</sup>

### B. Regulatory regime

In addition to complex markets, the pharmaceutical industry is characterized by a complicated regulatory regime consisting of patent law, the Hatch-Waxman Act, and state drug product selection laws.

First is the patent system. The pharmaceutical industry and its advocates famously trumpeted the costs of bringing a drug to market and its need for patents.<sup>6</sup> In "product-hopping" cases (in which the brand firm switches from one version of a drug to another just to stifle generic entry), brands highlight the benefits of their (often patented) reformulated drugs.<sup>7</sup> And in cases in which brands settle patent infringement litigation by paying generics to delay entering the market, the brands seek to highlight the strength of their patents.<sup>8</sup>

The second aspect of the regulatory regime is the Hatch-Waxman Act, Congress's calibration of the patent and antitrust laws in the pharmaceutical industry.<sup>9</sup> The Act fostered innovation through patent term extensions, periods of market exclusivity not based on patents, and an automatic 30-month stay of generic approval.<sup>10</sup> The Act also increased generic competition by allowing experimentation on a drug during the patent term, letting generics rely on brands' safety and effectiveness studies, and providing 180 days of marketing exclusivity to the first generic (known as a "Paragraph IV filer") to challenge a brand firm's patent.<sup>11</sup>

Third are state drug product selection laws, which are in effect in all 50 states and are designed to lower prices to consumers.<sup>12</sup> Absent a doctor's contrary instructions, these laws allow (and in some cases

5. *Id.* at 98-99; *see also* Chloe Reichel, *Direct-to-Consumer Drug Advertising Spikes Demand*, BUSINESS ETHICS, May 8, 2018, <https://www.business-ethics.com/2018/05/08/direct-to-consumer-drug-advertising-spikes-demand/>.

6. *See, e.g.*, Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 J. HEALTH ECON. 20, 31 (2016) (\$2.6 billion to bring drug to market in 2013).

7. *See, e.g.*, *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 674 (E.D. Pa. 2014).

8. *E.g.*, *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1797, 2015 WL 6750899, at \*6 (E.D. Pa. Nov. 5, 2015) (finding that evidence relating to patent could be considered when the alleged purpose was "to demonstrate that a reasonable litigant could have believed the patent to be valid at the time of the reverse-payment settlements.").

9. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355).

10. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 43-45 (2009).

11. 21 U.S.C. § 355(j)(5)(B)(iv).

12. Norman V. Carroll et al., *The Effects of Differences in State Drug Product Selection Laws on Pharmacists' Substitution Behavior*, 25 MED. CARE 1069, 1069-70 (1987).

require) pharmacists to substitute generic versions of brand drugs.<sup>13</sup> The laws address the disconnect between prescribing doctors who are not responsive to price and paying insurers and consumers who do not select the drug.<sup>14</sup> In particular, they carve out a role for pharmacies, which vigorously compete on price with other pharmacies and which enjoy higher margins on generic drugs.<sup>15</sup>

## II. SIMPLICITY

One way courts have dealt with complex markets and regulatory regimes is by applying simple frameworks. Courts have full dockets, pharmaceutical antitrust cases are complicated, and rather than engage in what could lead to the outcome most consistent with the regulatory regime's goals, courts sometimes resort to approaches that lead to quick resolutions. Four such approaches focus on an encouragement of settlement, a patent's presumptive validity, the number of products on the market, and the size of the generic firm. The first two approaches were prevalent in the decade before the Supreme Court rejected them in 2013 in *FTC v. Actavis*.<sup>16</sup> The latter two have not been overturned.

### A. Settlement

The first simple framework courts adopted, in the context of settlements of patent litigation, was based on a general policy in favor of settlement. Courts before *Actavis* recognized that settlements conserve resources, provide certainty that encourages investment, and result in licenses increasing competition.<sup>17</sup> These courts also noted that settlements were particularly beneficial for patent litigation, which is lengthy, complex, and costly.<sup>18</sup> For these reasons, the court in *In re Tamoxifen Citrate Antitrust Litigation* explained that “‘ courts are bound to encourage’ . . . settlement[s].”<sup>19</sup> The court in *Schering-Plough Corp. v. FTC* found that “[t]he general policy of the law is to favor the settlement of litigation” and that “the policy extends to the settlement of

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13. Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010).

14. BUREAU OF CONSUMER PROTECTION, *supra* note 1.

15. Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 13-15 (2009).

16. 570 U.S. 136 (2013).

17. See *In re Schering-Plough Corp.*, 36 F.T.C. 956, 999-1003 (2003), *vacated*, *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1058 (11th Cir. 2005); U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 5 (1995).

18. In 2017, patent litigation in which there was more than \$25 million at risk cost on average \$3 million. AM. INTELLECTUAL PROP. LAW ASS'N, REPORT OF THE ECONOMIC SURVEY 41 (2017).

19. *In re Tamoxifen*, 466 F.3d 187, 202 (2d Cir. 2006).

patent infringement suits.”<sup>20</sup> And the court in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* highlighted the “long-standing policy in the law in favor of settlements, [which] extends to patent infringement litigation.”<sup>21</sup>

In the crucial *Actavis* decision, the Supreme Court appropriately did not immunize settlements from antitrust scrutiny. In particular, it provided five reasons why the “general legal policy favoring the settlement of disputes” did not displace ordinary antitrust analysis.<sup>22</sup>

First, the Court emphasized that settlements have the “potential for genuine adverse effects on competition,” explaining that “[t]he payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.”<sup>23</sup> Second, the Court noted that the “anticompetitive consequences” of reverse-payment<sup>24</sup> settlements would “sometimes prove unjustified.”<sup>25</sup> Third, the Court linked the size of the payment to market power: “where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.”<sup>26</sup> Fourth, the Court explained that “an antitrust action is likely to prove more feasible administratively than the [court below] believed.”<sup>27</sup> And fifth, the Court noted that its rule “does not prevent litigating parties from settling their lawsuit,” as “[t]hey may, as in other industries, settle in other ways, for example by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”<sup>28</sup>

In conclusion, the Court synthesized, five considerations, “taken together, outweigh the single strong consideration—the desirability of settlements—that led the [court below] to provide near-automatic antitrust immunity to reverse payment settlements.”<sup>29</sup>

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20. 402 F.3d 1056, 1072 (11th Cir. 2005).

21. *In re Ciprofloxacin*, 544 F.3d 1323, 1333 (Fed. Cir. 2008).

22. *Actavis*, 570 U.S. at 153-58.

23. *Id.* at 153-54.

24. These are called “reverse payments” because the consideration flows from patentee to alleged infringer (unlike typical settlements in which alleged infringers pay patentees).

25. *Actavis*, 570 U.S. at 156.

26. *Id.* at 157.

27. *Id.*

28. *Id.* at 158.

29. *Id.*

### B. Presumptive validity

The second simplistic framework that courts before *Actavis* applied upheld settlements based on a presumption of patent validity. Section 282 of the Patent Act states that patents “shall be presumed valid.”<sup>30</sup> Courts relied on this presumption as a starting point in ascertaining the validity crucial to determining the appropriate antitrust treatment.<sup>31</sup> A settlement that allows generic entry before the end of the term of a valid patent promises to accelerate competition. In contrast, if the patent were invalid, a settlement delaying entry beyond the date the generic could have entered could allow the firms to divide the market, with the brand obtaining the assurance that generic entry will be delayed and the generic getting the certainty of knowing it will receive payment.<sup>32</sup>

For reasons similar to the rejection of the scope-of-the-patent test articulated below, the Court in *Actavis* appropriately recognized that “[t]he patent . . . may or may not be valid, and may or may not be infringed” and that “an *invalidated* patent carries with it no . . . right . . . [to] permit the patent owner to charge a higher than competitive price for the patented product.”<sup>33</sup> In other words, a patent cannot conclusively be presumed to be valid. It must be shown to be so. That makes sense since the Patent Act’s presumption of validity (1) is only a procedural evidentiary presumption; (2) should be entitled to the least amount of deference in situations in which the parties enter agreements that prevent validity from even being challenged; (3) is undermined by the Hatch-Waxman Act’s encouragement of invalidity challenges; and (4) is questioned by empirical studies that have shown that a significant percentage of granted patents are invalid.<sup>34</sup>

### C. Number of products

The third example of a simplistic approach is based on courts’ assessment of the number of products involved. The case of *Walgreen v. AstraZeneca Pharmaceuticals*, which involved AstraZeneca’s conversion from heartburn drug Prilosec to Nexium, is instructive.<sup>35</sup> The plaintiffs alleged that there was “almost no difference” between the drugs and there was “no pharmacodynamic reason” the two forms would have different effects in the body.<sup>36</sup> The plaintiffs also alleged that AstraZeneca “aggressively promoted and ‘detailed’ Nexium to doctors”

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30. 35 U.S.C. § 282(a).

31. See Carrier, *supra* note 10, at 62.

32. *Id.*

33. *Actavis*, 570 U.S. at 147 (emphasis in original).

34. Carrier, *supra* note 10, at 64-65.

35. 534 F. Supp. 2d 146 (D.D.C. 2008).

36. *Id.* at 149.

while stopping its promotion and detailing of Prilosec.<sup>37</sup> And they claimed that AstraZeneca was able to switch the market (to a barely different reformulation receiving patent protection for an additional 13 years) only through “distortion and misdirection in marketing, promoting and detailing Nexium.”<sup>38</sup>

The court ignored the plaintiffs’ detailed allegations of the price disconnect (by which the doctor who prescribes the product does not pay for it, and the consumer [or her insurer] who pays for it, does not choose it). The court granted AstraZeneca’s motion to dismiss, concluding that “there is no allegation that AstraZeneca eliminated any consumer choices.”<sup>39</sup> But that conclusion rested on three factual assertions, all of which required the court to ignore the price disconnect. The court asserted that:

- (1) AstraZeneca added choices . . . [by] introduc[ing] a new drug to compete with already-established drugs . . . [;]
- (2) [D]etermin[at]ions of] which product among several is superior . . . are left to the marketplace[; and]
- (3) New products are not capable of affecting competitors’ market share unless consumers prefer the new product.<sup>40</sup>

Each of those factual assertions contradicted plaintiffs’ allegations regarding the price disconnect and its effects.<sup>41</sup> In a price-disconnected market, doctors’ switching prescriptions from an original branded product (facing impending generic competition) to a reformulated product (not facing generic competition)—what the court called “add[ing] choices”<sup>42</sup>—significantly impairs consumers’ ability to choose a generic product. The “added choice” of the reformulated product is actually the means by which consumers’ real choice is eliminated. In addition, the question should not be which product among several is superior, but rather which product offers the consumer the *best trade-off between price and quality*, a determination that “the marketplace” cannot make in a price-disconnected market. In fact, when brands switch the market from the original to the reformulated version, they are capable of affecting competitors’ market shares despite consumers’ preferences because of the effects of significant promotion

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37. *Id.* (footnote omitted).

38. *Id.* at 148-49.

39. *Id.* at 151.

40. *Id.*

41. First Amended Complaint and Demand for Jury Trial for Walgreen Co. at 8, *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008).

42. *Walgreens*, 534 F. Supp. 2d at 151.



and marketing.<sup>43</sup> The court's contrary assertion ignored not only the plaintiffs' detailed allegations, but also the economic rationale of state substitution statutes and the Hatch-Waxman Act. None of those statutes would be necessary if consumers in fact revealed their preferences through price/quality choices.

*D. Size of generic*

A final approach based on simplicity focuses on the size of the generic company. One example is presented by the Third Circuit's decision in *Mylan Pharmaceuticals v. Warner Chilcott (Doryx)*.<sup>44</sup> In that case, Warner Chilcott engaged in an array of concerning behaviors: it stopped selling capsule versions of acne-treating Doryx to wholesalers; removed Doryx capsules from its website; worked with retailers to "auto-reference" the Doryx tablet whenever a doctor filed a Doryx prescription; informed wholesalers, retailers, and dealers that "Doryx Capsules have been replaced by Doryx Tablets"; and bought back and destroyed capsule inventory.<sup>45</sup> The Third Circuit nonetheless rejected Mylan's claims of anticompetitive conduct, finding that "Mylan was not foreclosed from the market."<sup>46</sup> Even though it found, "viewing the facts in the light most favorable to Mylan, that defendants had indeed made the Doryx 'hops' primarily to 'delay generic market entry,'" it affirmed summary judgment for the defendants.<sup>47</sup>

After concluding that the plaintiff—the competitor generic manufacturer—failed to adduce evidence of monopoly power, the court indicated that it would have affirmed summary judgment on the alternative ground that the plaintiff failed to satisfy its initial burden of introducing evidence of an anticompetitive effect under the Rule of Reason.<sup>48</sup> The court, however, never explained what it considered to be an anticompetitive effect. Nor did it consider whether a substantial reduction in the prescription base available for automatic generic substitution would count. Instead, in direct opposition to the Supreme Court's instruction that the relevant effect is on consumers, not

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43. *E.g.*, STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 87-93 (2d ed. 2007) (doctors are subject to "a vast array of drug promotion, which includes detailing (sales calls to doctor's offices), direct mailings, free drug samples, medical journal advertising, sponsored continuing medical education programs, and media advertising").

44. 838 F.3d 421 (3d Cir. 2016).

45. *Id.* at 429.

46. *Id.* at 438.

47. *Id.* at 431 (quotation omitted).

48. *Id.* at 438.

competitors,<sup>49</sup> the court focused exclusively on the effect of Warner Chilcott's conduct on Mylan, the generic *competitor*, never even mentioning the effect on *consumers*.<sup>50</sup>

Regarding the product hops' effects on Mylan (and assuming this were an appropriate inquiry), the court offered only a series of non-sequiturs, asserting that Warner Chilcott's conduct was not anticompetitive because:

(1) Mylan received a 180-day exclusivity period under the Hatch-Waxman Act (although Mylan's sales at relatively high generic prices are irrelevant to whether Warner Chilcott substantially reduced the number of sales and profits that Mylan would have made absent the product hop)<sup>51</sup>;

(2) Mylan set its generic price higher than the brand price for a period of time (although the court failed to explain the relevance of this fact and did not consider whether the product hop caused Mylan's pricing strategy, as a generic unable to distribute its product through automatic substitution could increase the price for the sales it can make)<sup>52</sup>; and

(3) Mylan made profits of \$146.9 million on the sales of generic Doryx (although that number does not mean much unless compared to the profits that Mylan would have made absent the product hops).<sup>53</sup>

In short, the court focused on Mylan's status as a "Goliath" competitor, taking its eye off the ball of what should have been the goal: the consumer.

### III. SISYPHUS

Quick. Don't think of a patented blue elephant. What do you think of? Well, a patented blue elephant, of course. (Assuming you're not wondering how a blue elephant could be patented.) Brand firms have an array of patented blue elephants they can parade before courts. In other words, brand firms defend their behavior by offering plausible-sounding arguments that sometimes are difficult for courts to dislodge from their analysis.

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49. *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 385 (3d Cir. 2005) (noting that Supreme Court in *Brunswick v. Pueblo Bowl-O-Mat*, 429 U.S. 477, 488-89 (1977), held that "antitrust laws protect consumers, not competitors").

50. *Doryx*, 838 F.3d at 439.

51. *Id.*

52. *Id.*

53. *Id.*

Brand firms offer not only arguments that sound legitimate on their face but also frameworks that create enough uncertainty that they are significantly more likely to win. The mythological figure Sisyphus labored to push a boulder uphill. But the progress he achieved in inching the boulder uphill was quickly followed by the boulder rolling back downhill.<sup>54</sup> So too do courts feel the pressure to let the boulder roll downhill when they are confronted with arguments difficult for plaintiffs to disprove. This section discusses eight of these hurdles, focusing on arguments based on safety, product liability, immunity, innovation, the scope of the patent, risk aversion, patent validity, and assisting rivals.

#### A. REMS: Safety

The first challenge stems from brands' claims that they should not be forced to share samples of their drugs with generics because of safety concerns. The context in which this has most frequently arisen involves Risk Evaluation and Mitigation Strategies (REMS) programs.<sup>55</sup> Pursuant to legislation enacted in 2007, the FDA requires REMS when a drug's risks (such as death or injury) outweigh its rewards.<sup>56</sup> Brands have used this regime, intended to bring drugs to the market, to block generic competition.

Brands have claimed that they should not be compelled to share their samples with generics because of safety concerns. For example, Celgene contended that the sale of samples imposed safety concerns as the "ingestion of . . . two teratogenic drugs [which produce birth defects] by unknown, healthy subjects entails risk of fetal exposure, which is why Mylan discusses its safety measures at length" and Celgene "need not accept others' conclusions that . . . these measures are adequate."<sup>57</sup> In a different case, Celgene "question[ed] the efficacy" of the generic's "study protocol's safety."<sup>58</sup> And Actelion explained that it "has an obvious and legitimate commercial interest to make sure that its liability,

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54. *Sisyphus*, ENCYCLOPAEDIA BRITANNICA, <https://www.britannica.com/topic/Sisyphus> (last visited May 26, 2019).

55. *Risk Evaluation and Mitigation Strategies (REMS)*, F.D.A., <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems> (last visited May 26, 2019).

56. U.S. Food and Drug Administration Amendments Act of 2007 (FDAAA), 21 U.S.C. § 355-1(a)(1).

57. Brief in Support of Defendant Celgene Corporation's Motion to Dismiss at 4, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH, 2014 U.S. Dist. LEXIS 182222, at \*17 (D.N.J. May 25, 2014).

58. *Lannett Co. v. Celgene Corp.*, No. 08-3920, 2011 WL 1193912, at \*2 (E.D. Pa. Mar. 29, 2011).

reputational issues, and concerns are taken into account and are dealt with.”<sup>59</sup>

The problem is that brands’ concerns that a generic’s use of samples *automatically* poses a heightened risk for which they would be responsible are misplaced. Use does not occur in a vacuum. The FDA ensures the safety of not only brand drugs but also generics. The agency tightly regulates the use of samples, including through clinical trials.<sup>60</sup> As a generic official has explained, “merely having a sample doesn’t mean a company has unfettered discretion to use it improperly, to have poor clinical trials, [or] to expose their employees to risk” since the FDA “continues to monitor what happens to that sample.”<sup>61</sup> An attorney for generic company Roxane explained that generics “have been buying samples and using them for years and years and years, of both REMS-covered and non-REMS-covered drugs, and there has never been some parade of horrors in terms of a brand being forced to come in and monitor what we’re doing.”<sup>62</sup> Finally, safety concerns are significantly reduced when the samples are used for lab testing rather than on humans<sup>63</sup> or (showing the illusory nature of such concerns) when brands provide samples to noncompeting research organizations.<sup>64</sup>

#### B. REMS: Product liability

Brand firms also have defended their refusal to provide samples to generics on the grounds of product liability. Celgene, for example, has contended that its sale of samples would impose heightened risks, stating that it “would face increased exposure to products liability suits for sales to generic . . . filers,” as “[s]ome courts have accepted the notion that a branded drug manufacturer may be liable for injuries caused by the generic drug it did not sell.”<sup>65</sup> Celgene also worried that “Mylan makes lengthy allegations regarding its willingness to indemnify Celgene” while noting that “Celgene is not required to accept these risks even with indemnification.”<sup>66</sup> In a separate case, Celgene complained that a

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59. Transcript of Motions Hearing at 100, *Actelion Pharm. Ltd. v. Apotex, Inc.*, Civil Action No. 1:12-cv-05743 (D.N.J. Oct. 17, 2013), ECF No. 93.

60. *CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition: Hearing Before the Subcomm. on Antitrust, Competition, Policy & Consumer Rights, S. Judiciary Comm.*, 114th Cong., at 1:49:11 (testimony of Beth Zelnick Kaufman), <https://www.c-span.org/video/?411609-1/creates-act-ending-regulatory-abuse-protecting-consumers-ensuring-drug-price-competition>.

61. *Id.*

62. *Actelion Transcript*, *supra* note 59, at 65.

63. *Id.* at 58.

64. *Id.* at 110.

65. Celgene Brief, *supra* note 57, at 17.

66. *Id.*

proposed generic insurance policy “has inadequate limits of liability and does not cover human clinical trials.”<sup>67</sup>

Most fundamentally, such claims are not consistent with the Hatch-Waxman Act, the relevant regulatory regime that the Supreme Court made clear in *Verizon Communications v. Trinko* that antitrust must be “attuned to” and take “careful account” of.<sup>68</sup> Generic access to samples during the patent term was an essential aspect of the regime, allowing generics to avoid replicating clinical studies.<sup>69</sup> Allowing brands to deny samples based on product-liability (or safety) justifications would undermine the carefully balanced tradeoff between competition and innovation at the heart of the Hatch-Waxman Act.

If there were any question remaining as to brands’ concerns with product liability, it would be dispelled by brands’ *refusals to accept generics’ proposals to indemnify them* for product liability claims. Similar to insurance and self-insurance, generic indemnification can serve a vital role in managing brand risk. But the cases reveal brands’ lack of interest in such risk management.

In *Mylan v. Celgene*, for example, Mylan agreed, over the course of a five-year negotiation for the sale of Thalomid, to indemnify Celgene for liability resulting from Mylan’s studies.<sup>70</sup> Even at the time of this essay, eleven years after the parties signed an indemnification agreement in April 2009, the sale has not yet occurred. And for the sale of Revlimid, Mylan offered Celgene an executed indemnification agreement and alleged that it “requested the purchase of limited Revlimid samples for bioequivalence testing, offering to pay market value,” to which Celgene responded with a “voluminous information request” and rejection of “Mylan’s offer to enter into an indemnification agreement, which included nearly every concession to terms Celgene requested” during earlier negotiations on Thalomid.<sup>71</sup>

### C. Citizen petitions: Immunity

A third argument brand firms have advanced stems from claims that the citizen petitions they file are immune as a type of petitioning conduct. Under the *Noerr-Pennington* doctrine, “[t]hose who petition [the]

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67. *Lannett*, 2011 WL 1193912, at \*2.

68. 540 U.S. 398, 411 (2004).

69. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 42-43 (2009).

70. Transcript of Oral Opinion at 6, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 14-2094-ES (D.N.J. Dec. 22, 2014), ECF No. 54.

71. Plaintiff Mylan Pharms.’ Brief in Opposition to Celgene’s Motion to Dismiss at \*10, *Mylan Pharms. Inc. v. Celgene Corp.*, Civ. Action No. 2:14-cv-02094-ES-MAH, 2014 U.S. Dist. Ct. Briefs LEXIS 1435 (D.N.J. June 16, 2014).

government for redress are generally immune from antitrust liability.<sup>72</sup> This doctrine, however, contains a well-established exception for sham conduct. Even in *Noerr* itself, the Supreme Court cautioned that petitioning behavior could lose its protection if it were a “sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor[.]”<sup>73</sup> Since the *Noerr* decision, the Supreme Court has applied the exception to misrepresentations made to courts and administrative agencies,<sup>74</sup> including patent-infringement suits based on a patent obtained through fraud.<sup>75</sup>

Many citizen petitions are questionable. Even though they are meant to raise legitimate safety concerns with the FDA, my empirical research found that the FDA has denied nearly all of the petitions. In particular, I found that the FDA denied 92% of petitions targeting generic entry, with that figure rising to 98% for petitions filed at the “last minute,” within six months of the expiration of a patent or FDA exclusivity period.<sup>76</sup>

In addition to these general findings, particular examples demonstrate concern in the form of:

- Multiple petitions (such as Teva’s 8 petitions on MS-treating Copaxone and Shire Viropharma’s 24 petitions on a life-threatening gastrointestinal infection)<sup>77</sup>;
- Late-filed petitions (such as Bayer Healthcare filing a petition one day before the expiration of the patent on Mirena, a long-acting intrauterine device (IUD))<sup>78</sup>;
- The combination of citizen petitions and product hopping (as shown by acne-treating Doryx)<sup>79</sup>; and

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72. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 56 (1993); see *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136, 140-41 (1961).

73. *Noerr*, 365 U.S. at 144.

74. *E.g.*, *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 512 (1972).

75. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-77 (1965).

76. Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and at-Last Denied*, 66 AM. U. L. REV. 305, 308, 323 (2016).

77. *Id.* at 344-46; see generally Complaint for Injunctive and Other Equitable Relief, *FTC v. Shire ViroPharma Inc.*, (D. Del. Feb. 7, 2017); *FTC v. Shire ViroPharma Inc.*, 917 F.3d 147 (3d Cir. 2019).

78. Carrier & Minniti, *supra* note 76, at 346-47.

79. *Id.* at 347-49.

- The combination of petitions and entry-delaying settlements (as shown by Mylan’s allergic-emergency-treating EpiPen).<sup>80</sup>

The FDA has also voiced unease with this conduct. In seeking to invigorate its ability to summarily deny petitions submitted “with the primary purpose of delaying” generic approval, the agency introduced a draft guidance articulating relevant factors, which included long-delayed petitions, repetitive petitions, submissions immediately before generic approval, petitions without support, and a history of concerning petitions.<sup>81</sup>

In short, any attempted defense based on petitioning immunity runs headlong into the sham nature of petitions that are almost always denied and that often raise significant concerns of delayed generic competition, which directly harms consumers by increasing price.

#### *D. Product hopping: Innovation*

The fourth argument is based on innovation. Innovation is a core American value, like baseball and apple pie. So, when brand firms (and commentators supporting them) claim that their behavior is needed for innovation, it is difficult for courts to resist the spell. One setting in which the issue arises involves “product hopping.”

Two respected commentators, Joshua Wright, a former Commissioner on the Federal Trade Commission (FTC), and Judge Douglas Ginsburg, a Senior Judge on the U.S. Court of Appeals for the D.C. Circuit, have offered the most thorough argument for why innovation should receive deference and antitrust liability is not appropriate for product hopping.<sup>82</sup> The authors worry that “applying a standard competition law analysis is likely to deter innovation that would have benefitted consumers.”<sup>83</sup> They contend that “innovations,

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80. *Id.* at 350-51; Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53, 64-66 (2017).

81. U.S. Dept. of Health and Human Servs., FDA, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*, at 16, Oct. 2018, <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM622235.pdf>.

82. Joshua D. Wright & Douglas H. Ginsburg, *Comment on the Canadian Competition Bureau’s Draft Updated Intellectual Property Enforcement Guidelines 2* (Aug. 10, 2015), [https://www.ftc.gov/system/files/documents/public\\_statements/734661/150810canadacomm ent.pdf](https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomm ent.pdf).

83. *Id.*

including even small changes in product design, can generate significant consumer benefits.”<sup>84</sup>

The authors claim that “[c]ompetition law is not a suitable instrument for micromanaging product design and innovation” as it “requires competition agencies and courts to weigh the benefits to consumers from the innovation against any costs to consumers arising from the diminution of competition.”<sup>85</sup> The agencies and courts are “ill-equipped” to make these determinations, and it is “unclear” whether such a balancing “can be done at all.”<sup>86</sup>

The authors trust not the antitrust agencies but the “judgment [of] the value of product design changes levied by consumers in the market.”<sup>87</sup> The apparent problem of applying antitrust law is that agencies and courts would be “substituting their judgment for the judgment made by consumers.”<sup>88</sup> The authors claim that subjecting drug reformulations to antitrust scrutiny “most remarkably assumes that pharmaceutical markets are somehow so different from other product markets that producers are free to ignore consumer judgments about the value of product innovations.”<sup>89</sup>

In contrast to these assertions, however, no empirical or other evidence suggests that a well-structured antitrust analysis would deter innovation in this setting.<sup>90</sup> For the subset of potentially anticompetitive reformulations, antitrust scrutiny is likely not to deter innovation, but to spur it. Brand firms often *withhold incremental innovations from the market* to use them later as part of a product hop.<sup>91</sup> For example, manufacturers in one case sought approval for a new treatment in connection with a reformulation even though “[t]he data necessary to get the new indication was available much earlier.”<sup>92</sup> Similarly, in a second case involving criminal liability for promoting off-label uses of a

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84. *Id.* at 2. See also *Mylan Pharms. v. Warner Chilcott*, 838 F.3d 421, 440 (3d Cir. 2016) (worrying about courts “balanc[ing] the important public interest in encouraging innovation in the pharmaceutical industry with [its] obligations to protect consumers and to ensure fair competition under the antitrust laws” while at the same time being “wary both of second-guessing Congress’s legislative judgment and of turning courts into tribunals over innovation sufficiency”).

85. Wright & Ginsburg, *supra* note 82, at 2.

86. *Id.*

87. *Id.* at 3.

88. *Id.* at 4.

89. *Id.*

90. For a more detailed critique, see Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 201–05 (2016).

91. Maribel Rios, *The Outsourcing Advantages in Formulation Development* (Jan. 2005), [https://files.pharmtech.com/alfresco\\_images/pharma/2014/08/22/c5f902d1-917e-4f63-83fa-48e96af5c645/article-141797.pdf](https://files.pharmtech.com/alfresco_images/pharma/2014/08/22/c5f902d1-917e-4f63-83fa-48e96af5c645/article-141797.pdf)

92. Steve Shadowen et al., *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 41 INT’L REV. OF INTEL. PROP. & COMP. LAW 698, 710 (2011).



seizure-treating drug, the brand firm conceded that a “principal reason for not seeking FDA approval for those uses was that it wanted to reserve them for a later promotional campaign for its reformulated product.”<sup>93</sup> And in the last case, the brand firm waited until generic competition for the twice-daily drug was imminent before introducing the once-daily version, even though “[a]ll other . . . disease treatments are administered once a day.”<sup>94</sup> It is telling that in this case, the brand firm had obtained FDA approval to market the once-daily version three years earlier but had withheld it from the market until entry of the twice-daily generics was looming.<sup>95</sup>

Limiting antitrust scrutiny of product hopping to “sham innovations” is a recipe for anticompetitive behavior in complex markets that would have dramatic effects on consumers. At the same time, the talisman of “innovation” is difficult for courts to resist. As a result, courts could apply an excessively deferential approach that allows product hops that make no sense other than delaying generic entry.

#### *E. Scope of patent*

In the settlement context, the first—and perhaps most fundamental—boulder running downhill involves the “scope” of the patent. Between 2005 and 2012, courts upheld reverse-payment settlements that allowed generic entry (even with payment) at or before the end of the patent term. The *Ciprofloxacin* court found that “[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.”<sup>96</sup> The *Schering-Plough* court similarly concluded that reverse payments were “within the patent’s exclusionary power.”<sup>97</sup> The *Tamoxifen* court found that the settlement did not “unlawfully extend the reach” of the patent.<sup>98</sup> And the court in *Valley Drug v. Geneva Pharmaceuticals* sought to achieve “[a] suitable accommodation between antitrust law’s free competition requirement and the patent regime’s incentive system” by immunizing activity within the patent’s scope.<sup>99</sup>

The Court in *Actavis* correctly rejected the scope test, understanding that “[t]he patent . . . may or may not be valid, and may or may not be infringed” but that “an *invalidated* patent carries with it

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93. *Id.*

94. *New York v. Actavis PLC*, 787 F.3d 638, 647 (2d Cir. 2015).

95. *Id.* at 647-48.

96. *Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.)*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).

97. *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1072 (11th Cir. 2005).

98. *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 213 (2d Cir. 2006).

99. *Valley Drug Co. v. Geneva Pharm.*, 344 F.3d 1294, 1307 (11th Cir. 2003).

no . . . right . . . [to] permit the patent owner to charge a higher than competitive price for the patented product.”<sup>100</sup> Importantly, the Court made it clear that the relevant question was not merely what rights patent law would have conferred. It concluded that “[i]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent policy, rather than by measuring them against procompetitive antitrust policies as well.”<sup>101</sup> Rather, both antitrust and patent policies were relevant to determining the proper “scope of the patent monopoly—and consequently antitrust immunity—that is conferred by a patent,” as “[w]hether a particular restraint lies beyond the limits of the patent monopoly is a *conclusion* that flows from [traditional antitrust] analysis and not . . . its starting point.”<sup>102</sup>

It thus would have appeared clear after *Actavis* that the scope-of-the-patent argument was no longer an effective justification that the settling parties could rely on. But the difficulties of finally burying this argument are revealed by the lure of the claim that generic entry before patent expiration is procompetitive. On its face, and with *Actavis* receding ever further into the rearview mirror, courts are tempted to find that pre-expiration entry provides “extra” competition that is good for the consumer. As discussed immediately below, an FTC Administrative Law Judge (ALJ) and a district court took this bait.

In *In the Matter of Impax Laboratories*, the ALJ concluded that it was “procompetitive” for a settlement to permit a generic “to enter the market eight months before the original patents expired.”<sup>103</sup> Such entry allowed “consumers [to] benefit[] . . . by having uninterrupted and continuous access” to the generic, with this “product on the market and available to consumers today” because the generic “had the foresight to negotiate licenses to future patents.”<sup>104</sup> The ALJ stated that entry before the end of the patent term “can be considered in assessing the [settlement’s] competitive consequences.”<sup>105</sup> And the ALJ even downplayed the anticompetitive harm at the heart of *Actavis* by claiming that “the magnitude or extent of such harm is largely theoretical, based on an inference” that the generic’s entry date would have been earlier without the reverse payment, and that this theoretical harm was

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100. *Actavis*, 570 U.S. at 147 (emphasis in original).

101. *Id.* at 148.

102. *Id.* at 148-49 (emphasis in original).

103. Dkt. No. 9373, at 144, 146 (FTC ALJ Chappell May 18, 2018).

104. *Id.* at 146.

105. *Id.*

outweighed by “the . . . substantial . . . real world procompetitive benefits” of the settlement.<sup>106</sup>

A similar ruling occurred in the context of a generic’s underpayment for products provided by the brand firm. In that case, the FTC claimed that Abbott (AbbVie’s parent company) paid Teva to delay entering the market with a generic version of testosterone gel AndroGel by providing Teva with an authorized generic version of cholesterol drug TriCor at “a price that is well below what is customary in such situations.”<sup>107</sup> In granting defendants’ motion to dismiss, however, the court failed to recognize a potential payment, formalistically finding that “the AbbVie Defendants are not making any payments to Teva,” but “[i]t is Teva which is paying Abbott for the supply of TriCor.”<sup>108</sup> The court recognized that “the FTC correctly alleges that something of large value passed from Abbott to Teva,” but erred in concluding that “it was not a reverse payment under *Actavis*.”<sup>109</sup>

The court then compounded its error in insufficiently recognizing payment by linking it to the scope-of-the-patent test. Not recognizing that the patent could have been invalid or not infringed, the court praised the agreement’s “allow[ing] Teva to enter the AndroGel market almost six years prior to the expiration of the ‘894 Patent.’”<sup>110</sup> The court viewed this as “an early entry date into the AndroGel market.”<sup>111</sup> And the court considered the separate agreement involving TriCor as “procompetitive” since it “allows Teva to enter the cholesterol drug market with a generic product to compete with Abbott’s product and thus advantage the purchasers of cholesterol drugs.”<sup>112</sup>

In short, the *Impax* and *TriCor* rulings are examples of courts applying the scope-of-the-patent test unequivocally rejected in *Actavis*. Generic entry before the end of the patent term is procompetitive only if the patent is valid and infringed. But whether there is a valid, infringed patent is *precisely* the inquiry short-circuited when a brand pays a generic to drop its patent challenge. And given that 89% of patents in settled litigation cover not the active ingredient but only ancillary aspects (with the majority of these patents ultimately overturned<sup>113</sup>), the revival of the scope test threatens significant harms.

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106. *Id.* at 156-57.

107. *F.T.C. v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015).

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.* at 438.

112. *Id.* at 436.

113. C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 *SCIENCE* 1386, 1387 (2013) (finding that companies are less likely to win on secondary patents (32%) than on active ingredient patents (92%)).

*F. Settlements: Risk aversion*

Another boulder in the settlement context involves brands' justifications for settlement based on an aversion to risk, in other words, an attempt to avoid the chance that the patent would be declared invalid or not infringed. Such an argument, however, can only be considered in the context of the *Actavis* decision, in particular its emphasis on the instructive role played by payment. The Court in *Actavis* found that the settlement at issue had the "potential for genuine adverse effects on competition" since "payment in return for staying out of the market . . . keeps prices at patentee-set levels."<sup>114</sup> In addition, the Court highlighted the harms from a payment to a generic, which "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product."<sup>115</sup>

The Court revealed its strong preference for determining patent strength by examining the payment rather than the patent. The "size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."<sup>116</sup> Even strong patents (*i.e.*, those covering the active ingredient) are not immune from the concern with payments, as an unexplained payment on a "particularly valuable patent . . . likely seeks to prevent the risk of competition," with this consequence "constitut[ing] the relevant anticompetitive harm."<sup>117</sup> In other words, the Court made clear that risk aversion was not an acceptable justification for a reverse-payment settlement.

In identifying the avoidance of the risk of competition as an antitrust violation, the Court dispensed with the "risk aversion" defense long advocated by settling parties (and economists), including in *Actavis* itself. For example, in *Actavis*, a group of economists filed an amicus brief that asserted that reverse payments "may . . . be necessary for brand companies to overcome bargaining disadvantages caused by risk aversion."<sup>118</sup> The brief also stated that "[b]rand companies are likely to be more risk averse than their generic challengers because they usually have significantly more to lose from a negative trial outcome."<sup>119</sup> And it contended that "the size of a reverse payment generally does not

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114. *Actavis*, 570 U.S. at 153-54.

115. *Id.*

116. *Id.* at 158.

117. *Id.* at 157.

118. Brief of Antitrust Economists as Amici Curiae in Support of Respondents at 3, F.T.C. v. *Actavis*, 570 U.S. 136 (2013) (No. 12-416).

119. *Id.* at 20.

provide a reliable benchmark to determine whether the payment is anticompetitive.”<sup>120</sup> Faced squarely with these justifications, the Court refused to accept them.<sup>121</sup>

But the power of the risk aversion argument is that the argument keeps rolling down the mountain to the case law. This is remarkable given that the *Supreme Court* pushed that boulder uphill, correctly recognizing that reverse-payment settlements prevent the risk that a patent will be invalidated or found to be not infringed.

In direct contravention of *Actavis*, the Third Circuit in *In re Wellbutrin XL Antitrust Litigation* was “persuaded” by an economists’ amicus brief that “explains why risk aversion makes it difficult to use the size of a settlement as a proxy for the brand-name’s likelihood of success in litigation.”<sup>122</sup> The court even found that this reasoning (which the Supreme Court rejected in calling the “prevent[ion of] the risk of competition” the “relevant anticompetitive harm”<sup>123</sup>) “serves as an effective rebuttal to the [plaintiffs’] claim that the size of the reverse payment is a ‘surrogate’ for patent weakness.”<sup>124</sup> The Third Circuit seemed not to understand that a risk-aversion defense could be raised in literally every case to justify a payment of any amount, no matter how weak the patent, which would essentially immunize reverse-payment settlements.

### G. Settlements: Patent invalidity

A final challenge in the settlement context involves patent invalidity in the determination of causation. The plaintiff in *Actavis* was the Federal Trade Commission. As a government agency, the FTC does not need to demonstrate causation because it automatically has standing.<sup>125</sup> In contrast, private plaintiffs need to make such a showing.<sup>126</sup> And some courts have required plaintiffs to “prove precisely how, absent the illegal settlement agreement, generic entry would have

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120. *Id.* at 21.

121. See HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE & MICHAEL A. CARRIER, *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 16.01[D], at 16-27 (3d ed. 2017) (“[T]he Court did not accept as a justification risk aversion or the patentee’s desire to convert an uncertain patent right into a certain one without litigation.”).

122. 868 F.3d 132, 168 (3d Cir. 2017).

123. *Actavis*, 570 U.S. at 157.

124. *Wellbutrin*, 868 F.3d at 168-69.

125. See, e.g., *Cal. v. Am. Stores Co.*, 495 U.S. 271, 295-96 (1990).

126. See, e.g., Brief of Amicus Curiae Federal Trade Comm’n in Support of No Party, *In re Nexium (Esomeprazole) Antitrust Litig.* at 12-16, 842 F.3d 34 (1st Cir. 2016) (Nos. 15-2005, 15-2006, 15-2007).

happened earlier.”<sup>127</sup> Plaintiffs have pursued three paths to showing this: patent litigation resulting in a finding of invalidity or noninfringement, generic entry “at risk” (before a court has issued a finding that the patent is invalid or not infringed) during the patent litigation, and a settlement without payment allowing earlier entry.<sup>128</sup> Courts applying a rigid approach to causation require plaintiffs to select among these paths and “prove specifically how entry would have occurred in the absence of the illegal settlement agreement.”<sup>129</sup>

One example was provided by the only trial on a reverse-payment settlement since *Actavis*, in which the jury issued a verdict for the defendants. The jury found that AstraZeneca had exercised market power, that the settlement included a “large and unjustified payment,” and that it was “unreasonably anticompetitive.”<sup>130</sup> But despite all of this, the jury found that “[h]ad it not been for” the settlement, AstraZeneca would not have “agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014.”<sup>131</sup> The court had earlier raised concerns related to the plaintiffs’ ability to show causation, given the failure to offer “direct evidence that the FDA was likely to grant final approval to Ranbaxy’s generic Nexium product within the proposed timeline,” as well as evidence that Ranbaxy would “never” have launched generic Nexium at risk.<sup>132</sup> In upholding the verdict, the First Circuit found that “the district court saw no evidence that would allow the plaintiffs to overcome the likelihood that [the brand firm’s] patents, not its reverse payment . . . , were the bar to a generic launch.”<sup>133</sup> The court concluded that the district court “did not err by requiring some evidence of the patents’ invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory.”<sup>134</sup>

Similarly, in *In re Wellbutrin XL Antitrust Litigation*, the Third Circuit rejected the plaintiffs’ argument that the generic would have launched at risk since this did not “take into account [a] blocking patent.”<sup>135</sup> The court stated that the plaintiffs were required to “show that the launch would have been legal” because “if the launch were

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127. Kevin B. Soter, Note, *Causation in Reverse Payment Antitrust Claims*, 70 STAN. L. REV. 1295, 1314 (2018) (emphasis omitted).

128. *Id.*

129. *Id.*

130. Jury Verdict in Favor of Defendants Against Plaintiffs Returned, *In re Nexium Antitrust Litig.* (D. Mass. Dec. 8, 2014) (No. 12-md-02409), ECF No. 1374.

131. *Id.*

132. *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 272 (D. Mass. 2014).

133. *In re Nexium*, 842 F.3d 34, 63 (1st Cir. 2016).

134. *Id.*

135. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017).

stopped because it was illegal,” then the plaintiffs’ injury “would be caused not by the settlement but by the patent laws prohibiting the launch.”<sup>136</sup>

The Third Circuit also rejected plaintiffs’ “litigation-based scenario” by which the generic would have prevailed in patent litigation. Downplaying *Actavis* and drawing curious distinctions, the court asserted that “[w]hile the size of the reverse payment may have some relevance in determining how confident a litigant is in the strength of its case,” it “is far from dispositive,” especially where “the settlement is complex and multi-faceted” and “there are multiple plausible ways to interpret the reverse payment.”<sup>137</sup>

In short, some courts have imposed causation as a Sisyphean hurdle for plaintiffs, one that (in requiring plaintiffs to prove that the patent definitively would have been ruled invalid) is nearly impossible to prove and that flies in the face of the Court’s direction in *Actavis* that patent validity need not be litigated.

#### H. Duties to deal

The final issue involves duties to deal. In the setting of denying samples generics need to enter the market pursuant to REMS programs, brand firms have claimed they have no duty to deal with rivals. For example, Actelion contended that it “is under no duty to deal with or assist its would-be generic competitors,” as the “well-settled rule of law is subject to narrow and rare exceptions, none of which applies” to the denial of samples.<sup>138</sup> Speaking even more broadly, Actelion asserted that “[t]his right to choose with whom to do business—and to choose not to do business with a rival—is a cornerstone of America’s free enterprise system, and is consistent with basic free market principles.”<sup>139</sup> Continuing the theme of hyperbole, Celgene asserted that even if its “insistence on appropriate procedures and guarantees were not motivated by the safety of fetuses and the survival of its business, antitrust law still would not require it to deal with its potential rivals.”<sup>140</sup>

To be sure, the Court in *Trinko* was skeptical of refusal-to-deal cases, stating that “as a general matter, the Sherman Act ‘does not restrict the long recognized right of [a] trader or manufacturer engaged in an

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136. *Id.*

137. *Id.* at 168.

138. Memorandum of Law in Support of Plaintiffs’ Motion for Judgment on the Pleadings and to Dismiss Counterclaims at 2, *Actelion Pharms. Ltd. v. Apotex, Inc.* (D.N.J. Jan. 16, 2012) (Civ. 1:12-cv-05743), ECF No. 44-1.

139. *Id.* at 12.

140. Brief in Support of Defendant Celgene Corporation’s Motion to Dismiss, *supra* note 57, at 4.

entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal.’”<sup>141</sup> On the other hand, the “high value” that the Court “placed on the right to refuse to deal with other firms does not mean that the right is unqualified.”<sup>142</sup> The Court explained that “[u]nder certain circumstances, a refusal to cooperate with rivals can constitute anticompetitive conduct and violate [Section] 2.”<sup>143</sup> While there might not be a general duty to deal in many contexts, several factors presented by the combination of the unique pharmaceutical regulatory setting and conduct that makes no sense other than by harming a rival suggest an exception for REMS behavior.

First, the facts of REMS sample denials, with readily-available samples, resemble those cases in which the Supreme Court has found liability. The Court in *Trinko* found that the defendants in the cases of *Aspen Skiing v. Aspen Highlands Skiing*<sup>144</sup> and *Otter Tail Power v. United States*,<sup>145</sup> should have offered ski lift tickets and power transmission, respectively, which were already available to the public.<sup>146</sup> For REMS programs that the FDA requires after the drug is already on the market, by definition the product is available. And even when a sample is requested before approval, the brand is in the business of producing drugs and the provision of a sample after the drug is manufactured does not require additional effort.

Second, the REMS-related conduct makes no economic sense absent the impairment of generic competition. Generics have been willing to pay a high price for samples, with one even stating that it pays “ridiculous amounts of money” for “a commercially immaterial quantity of drug.”<sup>147</sup> The caselaw provides examples of generics’ willingness to purchase samples at a rate that would be profitable to the brand.<sup>148</sup>

The Court in *Aspen Skiing* found exclusionary conduct where a defendant was “willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival.”<sup>149</sup> In contrast, the *Trinko* Court denied liability where Verizon

141. *Trinko*, 540 U.S. at 408.

142. *Id.* (quotation omitted).

143. *Id.*

144. 472 U.S. 585 (1985).

145. 410 U.S. 366 (1973).

146. *Trinko*, 540 U.S. at 409-10.

147. *The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition: Hearing Before the Subcomm. on Antitrust, Competition, Policy & Consumer Rights, S. Judiciary Comm.*, 114th Cong., at 2:10:38-47 (testimony of Beth Zelnick Kaufman), <https://www.cspan.org/video/?411609-1/creates-act-ending-regulatory-abuse-protecting-consumers-ensuring-drug-price-competition>.

148. Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL L. REV. 1, 38-39 (2017).

149. *Aspen*, 472 U.S. at 611.



could obtain only a “cost-based rate of compensation”<sup>150</sup> from sharing its network with rivals. Brands refusing to sell samples lose the opportunity to obtain at least a market (and sometimes significantly higher) price for samples.

Third is the ineffectiveness of the regulatory regime. The *Trinko* Court underscored the importance of regulation (and lack of a need for antitrust enforcement) in the setting of the Telecommunications Act, which was effectively enforced through financial penalties, daily or weekly reporting requirements, and the suspension or revocation of long-distance approval.<sup>151</sup> In contrast, antitrust regulation is needed in this setting given that the REMS regime is not working as intended, with the FDA unable to fix the problem and eager to punt competition issues to the FTC.<sup>152</sup>

To date, this is one area where courts have appropriately appreciated the role of antitrust liability. In distinguishing the sample-denial setting from *Trinko*, the court in *Actelion v. Apotex* explained that the Supreme Court’s refusal-to-deal decisions were “fact-specific” and “industry-specific” and made clear that the FDA “d[id] not have the regulatory power to compel samples” and that “there [was] no other potential remedy to a defendant suffering anticompetitive conduct in that regulatory scheme.”<sup>153</sup> As a result, the court correctly found that antitrust regulation was appropriate. In addition, the *Mylan v. Celgene* court found that Third Circuit cases had found prior dealing between the parties to be “relevant but not dispositive” in determining whether a duty to deal applies.<sup>154</sup>

#### IV. CONCLUSION

Courts confronting pharmaceutical antitrust law issues face significant challenges. The issues are complex. The courts yearn for simplicity. And the defendants erect Sisyphean hurdles in the form of facially reasonable arguments related to safety, innovation, and patents that plaintiffs must rebut. As issues of drug pricing become more

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150. *Trinko*, 540 U.S. at 409.

151. *See Trinko*, 540 U.S. at 412-14.

152. *See, e.g., F.D.A., Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition*, May 17, 2018, <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm> (“making public a list of companies that have potentially been blocking access to . . . samples of their branded products”).

153. Transcript of Motions Hearing at 115-16, *Actelion Pharm. Ltd. v. Apotex, Inc.*, Civ. 12-5743(NLH/AMD) (D.N.J. Oct. 17, 2013), 2013 WL 5524078.

154. Transcript of Oral Opinion at 12-13, *Mylan Pharms. Inc. v. Celgene Corp.*, Civ. 14-2094 (ES)(MAH) (D.N.J. 2015), 2015 WL 409655.

prominent and the conduct described in this essay shows no signs of abating, it is worth remembering the challenges confronting courts.