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## In re Lipitor Antitrust Litigation: The Third Circuit's Prescription for Judicial Reviewability of Reverse Payment Settlements

John Miraglia

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*IN RE LIPITOR ANTITRUST LITIGATION: THE THIRD CIRCUIT'S  
PRESCRIPTION FOR JUDICIAL REVIEWABILITY OF  
REVERSE PAYMENT SETTLEMENTS*

JOHN MIRAGLIA\*

“My shareholders expect me to make the most profit . . .  
that’s the ugly, dirty truth.”<sup>1</sup>

I. DIAGNOSING THE REVERSE PAYMENT SETTLEMENT PHENOMENON

While delivering his first State of the Union address, President Donald J. Trump noted that “the FDA approved more new and generic drugs . . . than ever before in our history.”<sup>2</sup> President Trump cited this fact in support of his proposition that access to “affordable generic drugs” is apparently on the rise.<sup>3</sup> Unfortunately, when the FDA approves a generic drug, there is no guarantee that the drug will make it to the market in a timely fashion.<sup>4</sup> Often, when generic drugs are approved, a brand-name manufacturer will sue the generic manufacturer for patent infringement.<sup>5</sup> Put simply, these suits often result in the delayed entry of the generic drug because of a unique type of inter-party settlement, a “reverse payment” settlement.<sup>6</sup>

A reverse payment settlement occurs when a brand-name drug manufacturer essentially pays off a generic drug manufacturer that is challeng-

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\* J.D. Candidate, 2019, Villanova University Charles Widger School of Law; B.A., Philosophy, 2016, Haverford College.

1. Dan Diamond, *Martin Shkreli Admits He Messed Up: He Should've Raised Prices Even Higher*, FORBES (Dec. 3, 2015), <https://www.forbes.com/sites/dandiamond/2015/12/03/what-martin-shkreli-says-now-i-shouldve-raised-prices-higher/#2ccc4abf1362> [<https://perma.cc/6NHV-F7G2>]. This is a quote from Martin Shkreli, the man who was infamously behind a number of notorious pharmaceutical drug price increases; most notably, he was responsible for raising the price of the AIDS drug, Daraprim, over 5000%. See *id.* (discussing Shkreli’s notoriety).

2. State of the Union 2018: Read the full transcript, CNN POLITICS, available at <https://www.cnn.com/2018/01/30/politics/2018-state-of-the-union-transcript/index.html> [<https://perma.cc/28YH-RT6Q>] (last updated Jan. 31, 2018).

3. See *id.* (noting that approval was aimed at “speed[ing] access to breakthrough cures and affordable generic drugs”).

4. See *infra* notes 28–36 and accompanying text (outlining how FDA approval of generic drugs may ultimately lead to reverse payment settlements delaying generic drug’s entry into market).

5. See *infra* notes 28–33 and accompanying text (describing how paragraph IV approval leads to litigation).

6. See *F.T.C v. Actavis, Inc.*, 570 U.S. 136, 140–41 (2013) (describing “reverse payment” settlement agreements).

ing the validity of the brand-name manufacturer's patent(s).<sup>7</sup> This reverse payment is beneficial for both parties; the generic manufacturer gets a payday, and the brand-name manufacturer gets to maintain its monopoly.<sup>8</sup> Of course, the foregoing explanation is quite reductionist, but it gets at the problematic aspect of reverse payment settlements—they can be anticompetitive.<sup>9</sup> It is this potentially anticompetitive characteristic of reverse payment settlements that has spawned a great deal of litigation.<sup>10</sup>

A number of plaintiffs have contended that reverse payment settlements violate antitrust laws because they are anticompetitive.<sup>11</sup> Irrespective of whether a reverse payment settlement *actually violates* antitrust laws, a crucial issue is whether (and when) a reverse payment settlement is even *judicially reviewable* for an antitrust violation.<sup>12</sup> This issue—the reviewabil-

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7. See Joshua B. Fischman, *The Circular Logic of Actavis*, 68 AM. U. L. REV. 91, 95 (2016) (outlining the basic nature of reverse payment settlements). The Supreme Court has also provided a useful and concise summary of reverse payment settlements:

Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.

*Actavis*, 570 U.S. at 140–41; see also *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 256 (D. Mass. 2017) (citing *Actavis*, 570 U.S. at 140–41) ("An anticompetitive reverse payment occurs when a brand-name manufacturer . . . induces a potential generic rival to delay or abandon its challenges to the patent and its entry into the market by providing *some form of compensation*") (emphasis added).

8. See Fischman, *supra* note 7, at 94–95 ("This arrangement allows the patent owner to continue earning monopoly profits . . . [and] the patent holder shares its monopoly profits with the generic by making what is known as a 'reverse payment' to the generic firm."). Many commentators outside the legal field have similarly weighed in on the importance of discouraging monopolistic behavior in the pharmaceutical drug industry. See, e.g., Sydney Lupkin, *5 Reasons Prescription Drug Prices Are So High in the U.S.*, MONEY (August 23, 2016), <http://time.com/money/4462919/prescription-drug-prices-too-high/> [<https://perma.cc/A7DR-HJ4D>] (noting that regulatory system in U.S. confers legally protected monopolistic rights and allows brand-name manufacturers to set their own prices).

9. See *Actavis*, 570 U.S. at 148–49 (reasoning that settlement agreements can violate antitrust laws by being anticompetitive); see also *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 250–51 (3d Cir. 2017) (interpreting *Actavis* and outlining features of reverse payment settlements that may discourage competition), *cert. denied*, 200 L. Ed. 2d 300 (2018).

10. See *infra* notes 60–70 and accompanying text (discussing reverse payment settlement jurisprudence).

11. See, e.g., *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 239–40 (D. Mass. 2014) (summarizing procedural posture of class action challenging reverse payment settlement as anticompetitive under the Sherman Act); see also Jennifer E. Sturiale, *Hatch-Waxman Patent Litigation and Inter Parties Review: A New Sort of Competition*, 69 ALA. L. REV. 59, 62–63 (2017) (noting trend of "challeng[ing] . . . [reverse payment] settlements as anticompetitive").

12. See *infra* notes 40–42, 54–70 and accompanying text (discussing judicial reviewability).

ity of reverse payment settlements—is a hotbed of judicial disagreement, especially after the Third Circuit's recent decision: *In re Lipitor Antitrust Litigation*.<sup>13</sup>

*In re Lipitor Antitrust Litigation* is significant because it touches on the reviewability of reverse payment settlements as potential antitrust violations.<sup>14</sup> The ostensibly plaintiff-friendly stance adopted by the Third Circuit has tremendous consequences for practitioners, as it may promote judicial review of reverse payment settlements.<sup>15</sup> A closer look at this decision informs how settling parties may be able to structure these settlements to avoid such review.<sup>16</sup> Specifically, *Lipitor* is the latest in a series of decisions attempting to discourage brand-name manufacturers from delaying their generic competitors' entry, as part of complex reverse payment settlements.<sup>17</sup>

In order to unpack the merits and implications of the Third Circuit's decision, Part II of this Casebrief will examine the statutory framework that underlies and motivates reverse payment settlements.<sup>18</sup> Part III analyzes the relevant case law leading up to the Third Circuit's decision.<sup>19</sup> Part IV discusses the facts of the case, and Part V analyzes the court's reasoning.<sup>20</sup> Part VI provides some practical insights regarding how this decision will affect both pharmaceutical companies and lawyers.<sup>21</sup>

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13. 868 F.3d 231 (3d Cir. 2017). This Casebrief will focus exclusively on the *Lipitor* plaintiffs and defendants, and it will not discuss the claims stemming from Effexor XR, on which the Third Circuit also ruled. See *id.* at 239 (summarizing Third Circuit's holding as it applied to complaints in both *Lipitor* and Effexor litigation). The timeliness of this issue is also evinced by the recent explosion in the popularity of reverse payment settlements. See Raymond J. Prince, Note, *Pay-for-Delay: How Brand-Name and Generic Pharmaceutical Drug Companies Collude and Cost Consumers Billions*, 68 S.C. L. REV. 689, 691–92 (2017) (noting recent trend in reverse payment settlement popularity).

14. See generally *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017); see also *infra* notes 90–108 and accompanying text (providing narrative analysis of *Lipitor*).

15. See *infra* notes 109–19 and accompanying text (highlighting promotion of judicial reviewability).

16. See *infra* notes 108–09 and accompanying text (discussing how to avoid judicial review).

17. See *infra* notes 60–70 and accompanying text (detailing other cases discouraging reverse payment settlements).

18. See *infra* notes 22–33 and accompanying text (discussing Hatch-Waxman Act framework).

19. See *infra* notes 34–70 and accompanying text (highlighting relevant case law).

20. See *infra* notes 71–122 and accompanying text (providing narrative and critical analyses of *Lipitor*).

21. See *infra* notes 123–35 and accompanying text (forecasting potential impact of *Lipitor*).

## II. REGULATORY FRAMEWORK UNDER THE HATCH-WAXMAN ACT

Reverse payment settlements are a statutory creation, of sorts, because they are a byproduct of the procedures set out in the Hatch-Waxman Act, a complex nest of regulations setting out the approval processes for both brand-name and generic drugs.<sup>22</sup> Put simply, the act aims to ensure proper testing of pharmaceutical drugs as well as stimulate competition within the pharmaceutical marketplace.<sup>23</sup> To meet these legislative ends, the act establishes a framework that encourages generic manufacturers to challenge the validity of brand-name manufacturers' patents.<sup>24</sup>

The act also contains a mechanism encouraging reverse payment settlements that is important to consider before delving into the statutory approval processes; that mechanism is known as the exclusivity period.<sup>25</sup> When a generic manufacturer successfully challenges and defeats a brand-name patent, the generic and brand-name manufacturers enjoy an exclusive 180-day period during which no other manufacturer may compete; without this exclusivity period, other generic manufacturers could enter the market and sell generic versions of the brand-name drug because it no longer enjoys patent protection.<sup>26</sup> However, before any exclusivity period may be granted, a generic manufacturer must first obtain FDA approval for a brand-name equivalent.<sup>27</sup>

A generic manufacturer may obtain FDA approval for the generic equivalent of existing brand-name drugs, which have already been ap-

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22. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (outlining the procedures to which pharmaceutical companies must adhere to obtain FDA approval); see also Joseph Fielding, Note, *From Pay-for-Delay to Product Hopping: The Limited Utility of Antitrust Law in the Pharmaceutical Industry*, 38 CARDOZO L. REV. 1915, 1922–27 (2017) (outlining regulatory procedures set out by Hatch-Waxman Act).

23. See Sturiale, *supra* note 11, at 62–63 (outlining aims of the Hatch-Waxman Act); see also Fielding, *supra* note 22, at 1918 (regarding Hatch-Waxman Act as “attempt to balance” tension between too much and too little generic competition).

24. See *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 240–41 (3d Cir. 2017) (outlining framework established by Hatch-Waxman Act); see also *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142–44 (2013) (discussing approval process).

25. See 21 U.S.C. § 355 (j)(5)(B)(iv)(I) (2018) (granting 180-day exclusivity period to first applicant that successfully challenges patent of brand-name manufacturer).

26. See *id.* (granting 180-day exclusivity period); see also *Lipitor*, 868 F.3d at 241 (outlining benefits of obtaining exclusivity period); Sturiale, *supra* note 11, at 63 (“If the first filer is successful in securing a determination that the patent claims are invalid or not infringed, the first filer is entitled to 180 days of exclusive competition with the brand-name drug manufacturer . . . [and] no other generic drug manufacturer seeking FDA approval on similar grounds may enter the market.”).

27. See *Actavis*, 570 U.S. at 142 (“[O]nce the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through [the] use of abbreviated procedures.”).

proved through a lengthy testing process.<sup>28</sup> To do so, a generic manufacturer must submit an Abbreviated New Drug Application (ANDA); an ANDA allows the generic manufacturer to obtain approval by demonstrating the “generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug.”<sup>29</sup> A specific type of ANDA approval, known as “paragraph IV certification,” includes an assertion by the generic manufacturer that the drug either does not infringe a relevant patent, or, alternatively, that any infringed patent is invalid.<sup>30</sup> Because paragraph IV certification necessarily challenges the validity of a brand-name manufacturer’s patent(s), it often incites the litigation that leads to reverse payment settlements.<sup>31</sup> Thus, reverse payment settlements may be characterized as a byproduct of the statutory framework established by the Hatch-Waxman Act.<sup>32</sup> The act incentivizes generic manufacturers to challenge weak brand-name patents by granting successful challengers a lucrative exclusivity period, and the brand-name manufacturers evade successful challenges by entering into reverse payment settlements.<sup>33</sup>

### III. ANTITRUST SCRUTINY OF SETTLEMENT AGREEMENTS UNDER *F.T.C. v. ACTAVIS*

To resolve paragraph IV litigation, brand-name and generic manufacturers often enter into reverse payment settlements.<sup>34</sup> Whereas typical settlements involve a payment tendered to the plaintiff, *reverse* payment settlements involve a payment by the brand-name manufacturer, which is

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28. See *Lipitor*, 868 F.3d at 240 (discussing the process by which generic manufacturers may obtain FDA approval that is parasitic upon approval of brand-name drug).

29. *Id.* (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (outlining ANDA approval process)).

30. *Id.* at 241 (citing *Actavis*, 570 U.S. at 142–43) (holding that reverse payment settlement agreements are subject to antitrust scrutiny). This type of certification is named after a provision in the act, which specifies that a generic manufacturer can obtain ANDA certification on the grounds that the brand-name manufacturer’s “patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” *Id.* at 240–41 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)). This process is also facilitated by the publication of patent information in the Approved Drug Products with Therapeutic Equivalence Evaluations, which is commonly known as the “Orange Book.” *Id.* at 240 (citing *Caraco*, 566 U.S. at 405–06). After obtaining NDA approval, brand-name manufacturers must “list any patents issued relating to the drug’s composition or methods of use” for publication in the Orange Book. *Lipitor*, 855 F.3d at 135.

31. See *Lipitor*, 868 F.3d at 241 (noting that “paragraph IV certification often ‘means provoking litigation’ instituted by the brand manufacturer”) (quoting *Caraco*, 566 U.S. at 407).

32. Fielding, *supra* note 22, at 1922–27.

33. See *supra* notes 22–32 and accompanying text (discussing statutory approval process and profits associated with exclusivity period).

34. See *Actavis*, 570 U.S. at 140–41 (noting origin of reverse payment settlements).

alleging patent infringement, to the generic manufacturer(s).<sup>35</sup> In return for this payment, generics agree to both delay their entry into the market and render some ancillary services to the brand-name manufacturer.<sup>36</sup>

A number of class actions have alleged, to varying degrees of success, that reverse payment settlements are actually aimed at delaying the entry of generic competitors into the marketplace.<sup>37</sup> Under this view, these agreements are violative of Section I of the Sherman Act, which proscribes, *inter alia*, agreements that restrain interstate commerce.<sup>38</sup> Before the Supreme Court's landmark decision in *F.T.C. v. Actavis Inc.*, a number of courts eschewed judicial review of reverse payment settlements, reasoning that the brand-name manufacturer's patent conferred a bundle of rights, which were necessarily anticompetitive, at least to a certain extent.<sup>39</sup>

In *Actavis*, the Court announced that reverse payment settlements may be subject to judicial review when they are "large and unjustified."<sup>40</sup> Nevertheless, the lower courts remain divided as to exactly what characteristics make a reverse payment large and unjustified.<sup>41</sup> Despite this inter-

35. *See id.* at 152 ("In reverse payment settlements . . . a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market.").

36. *See, e.g., King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 397-98 (3d Cir. 2015) (describing terms of reverse payment settlement involving delayed market entry), *cert. denied*, 137 S. Ct. 446 (2016)).

37. *See infra* notes 60-70 and accompanying text (outlining relevant cases challenging reverse payment settlements as anticompetitive).

38. *See* 15 U.S.C. § 1 (2012) ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States . . . is hereby declared to be illegal."). Reverse payment settlements may also violate Section II of the Sherman Act because they tend to further monopolies held by brand-name manufacturers. *See supra* note 9 and accompanying text (noting potentially anticompetitive nature of reverse payment settlements).

39. *See In re Lipitor Antitrust Litig.*, 868 F.3d 231, 250 (3d Cir. 2018) (detailing jurisprudence). Settlement agreements were essentially "immune from antitrust scrutiny so long as the asserted anticompetitive effects fell within the scope of the patent." *Id.* (quoting *King Drug Co.*, 791 F.3d at 399 (discussing pre-*Actavis* approach to settlement agreements). Additionally, there is "a general legal policy favoring the settlement of disputes." *Actavis*, 570 U.S. at 154 (citing *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298, 1313-14 (11th Cir. 2012)); *see also* *United States v. General Electric Co.*, 272 U.S. 476, 485 (1926) ("[U]nder the patent law the patentee is given by statute a monopoly of making, using and selling the patented article.").

40. *See Actavis*, 570 U.S. at 158 (summarizing holding).

41. *See id.* (outlining scenario which leads to reverse payment settlements); *see also* Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 9 (2014) [hereinafter *Payment After Actavis*] ("There is no dispute that settlements in which a brand pays cash to a generic for delayed entry constitute payment. But beyond this scenario, opinions diverge."). Carrier's article is aimed at "articulating a framework for determining what constitutes an 'exclusion payment' that violates the antitrust laws." *Id.*; Michael A. Carrier, *How Not to Apply Actavis*, 109 NW. U. L. REV. ONLINE 113, 113 (2014) [hereinafter *How Not to Apply Actavis*] (regarding *Actavis* decision as "one of the most important business cases in the past generation").

pretive discord, *Actavis* remains the guidepost for courts determining the reviewability of reverse payment settlements for potential antitrust violations.<sup>42</sup>

A. F.T.C. v. *Actavis*: *The Supreme Court Subjects Large and Unjustified Reverse Payment Settlements to Judicial Review*

The facts and circumstances leading up to *Actavis* began when a brand-name manufacturer, Solvay Pharmaceuticals, received approval for its new pharmaceutical drug, Androgel.<sup>43</sup> In addition to obtaining FDA approval, Solvay also acquired and published patent protection for its product.<sup>44</sup> Thereafter, two generic manufacturers sought paragraph IV certification for generic drugs “modeled after AndroGel.”<sup>45</sup> In response to these ANDA applications, Solvay sued the generic manufacturers for patent infringement pursuant to the procedures laid out in the Hatch-Waxman Act.<sup>46</sup> Although *Actavis* ultimately obtained paragraph IV approval, the parties engaged in a settlement agreement.<sup>47</sup>

The settlement agreement included multi-million-dollar payments to each of the generic companies, purportedly in return “for other services the generics promised to perform.”<sup>48</sup> Nevertheless, the FTC contended

42. See Carrier, *Payment After Actavis*, *supra* note 41, at 8–9 (noting importance of *Actavis* and disagreement as to its application).

43. See *Actavis*, 570 U.S. at 136 (discussing facts).

44. See *id.* at 144 (citing F.T.C. v. Watson Pharms., Inc., 677 F.3d 1298, 1308 (11th Cir. 2012)) (noting that patent disclosure is mandated by Hatch-Waxman Act).

45. See *id.* (discussing facts). Specifically, *Actavis*, Inc. and Paddock Laboratories both filed ANDAs. See *id.* A third generic manufacturer, Par, was also a party to the litigation and subsequent settlement, but Par “did not file an application of its own but joined forces with Paddock, agreeing to share the patent litigation costs in return for a share of profits if Paddock obtained approval for its generic drug.” *Id.* at 144–45.

46. See *id.* at 145 (detailing inception of case). In addition to motivating competition by providing for a 180-day exclusivity period, the Hatch-Waxman Act provides a window in which the brand-name manufacturer can forestall approval of a generic equivalent by bringing suit for patent infringement. See 21 U.S.C. § 355 (j)(5)(B)(iii) (noting that FDA approval for ANDA is effective unless “a [ ] [timely] action is brought for infringement of the patent that is the subject of the certification”).

47. See *id.* (discussing facts).

48. *Actavis*, 570 U.S. at 145. These other services included *Actavis* “agree[ing] to promote AndroGel to urologists. The other generic manufacturers made roughly similar promises.” *Id.* Carrier provides a comprehensive list, including the abovementioned promotion, of “unrelated generic services” which might provide a legitimate justification for a large payment:

[T]he brand could pay for a generic (1) to market or co-promote its product; (2) to provide inventory or backup manufacturing services; (3) to supply the brand with raw material or with finished drug products; or (4) for development agreements in the form of up-front payments, milestones, sales percentages, or development fees for unrelated products.

Carrier, *Payment After Actavis*, *supra* note 41, at 21 (citing Fed. Trade Comm’n, Agreements Filed with the Federal Trade Commission Under the Medicare Pre-



that the settlement was anticompetitive in nature, and therefore violated the Sherman Act.<sup>49</sup> Unfortunately, neither the district court nor the Eleventh Circuit found that the FTC had sufficiently alleged an antitrust violation.<sup>50</sup>

The Supreme Court began its analysis by noting that the central antitrust inquiry was “whether . . . an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws.”<sup>51</sup> The mere fact that a settlement may be motivated or enabled by the bundle of rights conferred by a patent does not mean that a settlement cannot violate antitrust laws.<sup>52</sup> Accordingly, the Court looked to the specific terms of the settlement, as they are essential to determining its net effect on competition.<sup>53</sup>

Upon examining the settlement, the Court found that the reverse payment settlement *sub judice* was “large and unjustified,” and therefore judicially reviewable for an antitrust violation.<sup>54</sup> The Court provided five central justifications for its holding: (1) the settlement could have negatively impacted competition; (2) this negative impact could be unjustified; (3) the ability to make such a large payment indicates that the patentee might hold improper market power; (4) such an antitrust action is administratively feasible; and (5) the settlement could have been structured so as

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scription Drug, Improvement, and Modernizations Act of 2003: Summary of Agreements Filed in FY 2006, 4-5 (2007), available at [www.ftc.gov/reports/mmact/MMAreport2006.pdf](http://www.ftc.gov/reports/mmact/MMAreport2006.pdf) [<https://perma.cc/NMB9-NLXS>]; see C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 664 (2009) (summarizing different types of generic side deals).

49. See *Actavis*, 570 U.S. at 145 (“According to the FTC the true point of the payments was to compensate the generics for agreeing not to compete against AndroGel until 2015.”).

50. See *In re AndroGel Antitrust Litigation*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010) (dismissing FTC’s complaint), *aff’d*, *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

51. *Actavis*, 570 U.S. at 141 (first citing 15 U.S.C. § 1 (prohibiting arrangements “in restraint of trade or commerce among the several States”); then citing *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (*per curiam*)).

52. See *id.* at 147 (“The agreement’s ‘anticompetitive effects [may] fall within the scope of the exclusionary potential of the patent.’ But we do not agree that that fact . . . can immunize the agreement from antitrust attack.”). Because a patent is a necessary exclusionary instrument, there is an inherent tension, at least at some level, between its effects and the aims of antitrust laws. See *United States v. Line Material Co.*, 333 U.S. 287, 310 (1948) (“The monopoly granted by the patent laws is a statutory exception to this freedom for competition [called for by the Sherman Act] and consistently has been construed as limited to the patent grant.”); *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 401 (1948) (noting that “efforts to monopolize [may occur] through patents as well as in non-patent fields”).

53. See *Actavis*, 570 U.S. at 154 (noting that “payment in return for staying out of the market” is potentially problematic).

54. *Id.* at 158 (noting that “large and unjustified [reverse payment settlements] can bring with [them] the risk of significant anticompetitive effects”).

to avoid liability.<sup>55</sup> While all of these concerns are certainly valid, some commentators have refused to accept them as sufficient to disrupt the settlement process.<sup>56</sup>

*Actavis* did not articulate any criterion, other than the rule of reason, by which reverse payment settlements are to be examined to determine whether they actually constitute antitrust violations.<sup>57</sup> Instead, it explicitly left it up to the lower courts to determine antitrust violations on an *ad hoc* basis.<sup>58</sup> The only thing that is clear, is that not every reverse payment settlement will be *per se* judicially reviewable for an antitrust violation.<sup>59</sup>

#### B. *Post-Actavis Reverse Payment Settlement Jurisprudence*

In the wake of *Actavis*, courts remain uncertain as to what characteristics a reverse payment settlement must have to render it judicially reviewable for a potential antitrust violation.<sup>60</sup> Although some circuits have interpreted *Actavis* to reach non-cash settlements, there has been confusion among the lower courts regarding whether a cash payment is required, especially district courts lacking any binding precedent from their respective appellate courts.<sup>61</sup>

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55. See *id.* at 154–58 (outlining “five sets of considerations” that motivated Court’s holding). Another primary consideration is that “when . . . [reverse payment] settlements are made, the validity of [the brand-name manufacturer’s] patent is in question.” Fielding, *supra* note 22, at 1931 (discussing why *Actavis* Court refused to examine reverse payment settlements, which induced delayed market entry, under historical scope of patent approach).

56. See Fischman, *supra* note 7, at 115 (regarding the majority opinion in *Actavis* as the product of any “interdisciplinary misunderstanding”). Fischman is critical of *Actavis* for a number of sophisticated reasons, rooted in economic theory; among other things, he asserts that *Actavis* “ignores the interdependence between the litigants’ settlement and the court’s interference.” Fischman, *supra* note 7, at 97.

57. See *Actavis*, 570 U.S. at 159–60. Rather, the Court explicitly refused to enunciate any specific test (other than the rule of reason test, generally) by which to examine reverse payment settlements for purposes of antitrust liability stating, “[w]e therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.” *Id.* at 160.

58. See *supra* note 57 and accompanying text (delegating structuring to lower courts).

59. See *Actavis*, 570 U.S. at 159 (discussing complexities related to reverse payment settlements bringing about anticompetitive effects); see also Fielding, *supra* note 22, at 1933 (noting that “not all reverse [payment] settlements will trigger antitrust liability”).

60. See Fischman, *supra* note 7, at 138 n.216.

61. See, e.g., *In re Loestrin* 24 FE Antitrust Litig., 45 F. Supp. 3d 180, 192 (D.R.I. 2014) (reasoning that “*Actavis* fixates on the one form of consideration that was at issue in that case: cash”), *vacated* 814 F.3d 538 (1st Cir. 2016); *In re Opana Er* Antitrust Litig., 162 F. Supp. 3d 704, 718-20 (N.D. Ill. 2016) (finding that plaintiffs sufficiently pled a large and unjustified settlement). Fischman takes note of the *Loestrin* case, among others, in a footnote explaining that “district courts have struggled to apply *Actavis* . . . [specifically that] some courts have applied *Actavis* only to reverse payments involving cash, but no other forms of consideration.” Fischman, *supra* note 7, at 137–38 n.216 (citing *Loestrin*, 45 F. Supp. 3d at 192; *In re*

The First Circuit, for example, has interpreted *Actavis* to permit judicial review of non-monetary reverse payment settlements.<sup>62</sup> Such a non-monetary settlement might involve “significant forgiveness of debt” or the release of certain legal claims, rather than merely a large cash payment.<sup>63</sup> The Third Circuit has similarly found that non-cash settlements may be subject to antitrust scrutiny in *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*<sup>64</sup> There, a generic manufacturer and brand-name manufacturer entered into a settlement agreement following the invalidation of one of the brand-name manufacturer’s patent claims.<sup>65</sup> As part of the agreement, the brand-name manufacturer agreed not to manufacture an *authorized generic*, allegedly in exchange for the generic manufacturer delaying market entry.<sup>66</sup> Despite the defendants’ argument that “only cash

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Lamictal Direct Purchaser Antitrust Litig., 18 F. Supp. 3d 560, 570 (D.N.J. 2014) (refusing to review non-cash settlement), *vacated* 791 F.3d 388 (3d Cir. 2015); *c.f.* *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp.3d 734, 751 (E.D. Pa. 2015) (reasoning that “*Actavis* did outline a specific type of competitive harm”) (emphasis added). Although the Supreme Court left the lower courts the task of examining the factual circumstances surrounding each claimed violation, it was generally concerned with generic manufacturers “abandon[ing] [their] patent claim[s], eliminating the risk of patent invalidation or a finding of invalidity.” *Id.* (first citing *Actavis*, 570 U.S. at 156; then citing *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016)). Accordingly, *Actavis* was not meant to reach parties who, although they entered into certain settlement agreements, continued “the underlying patent litigation.” *Wellbutrin XL*, 133 F. Supp. at 750–51.

62. See *Am. Sales Co., LLC v. AstraZeneca LP (In re Nexium (Esomeprazole) Antitrust Litig.)*, 842 F.3d 34, 41–42 (1st Cir. 2016) (noting that settlement “in which a brand name manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny and militates against limiting the Supreme Court’s decision to pure cash payments” (quoting *In re Loestrin 24 Fe Antitrust Litigation*, 814 F.3d 538, 549 (1st Cir. 2016))).

63. See *Am. Sales Co.*, 842 F.3d at 45–46 (outlining terms of disputed settlement which, although it included a multi-million dollar payment, involved non-monetary benefits to the generics (citing *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 286 (D. Mass. 2014))); see also Michael A. Carrier, *Symposium Article: Eight Reasons Why “No Authorized-Generic” Promises Constitute Payment*, 67 RUTGERS U. L. REV. 697, 698 (2015) (asserting that non-monetary payments, specifically no-AG agreements, constitute payment under *Actavis*).

64. 791 F.3d 388, 409 (3d Cir 2015), *cert. denied*, 137 S. Ct. 446 (2016) (reasoning that “noncash nature” of agreement *sub judice* should not affect the inquiry); see also Meghan Fay, *The Role of Antitrust Principles in Patent Monopolies: The Third Circuit Applies Antitrust Scrutiny to No-AG Patent Settlements in SmithKline*, 58 B.C. L. REV. E. SUPP. 128, 143 (2017) (reasoning that Third Circuit “correctly ruled that no-AG agreements are subject to antitrust scrutiny under the rule of reason”).

65. See *King Drug Co.*, 791 F.3d at 397 (noting that judge found “that the patent’s main claim, for the invention of [the drug’s active ingredient], was invalid”).

66. See *id.* at 397 (noting that generic manufacturer would likely have launched generic drug without an official determination as to validity or non-infringement of brand-name manufacturer’s patent). An authorized generic “is a generic drug sold by the company [that] markets the brand name drug.” *Sanofi-Aventis v. Apotex, Inc.*, 659 F.3d 1171, 1174–75 (Fed. Cir. 2011) (outlining potential negative economic effects introduction of authorized generic may have on ge-

payments constitute actionable reverse payments,” the court found that non-monetary benefits, like the agreement not to market an authorized generic, could potentially constitute antitrust violations.<sup>67</sup>

Applying *Actavis* does not merely involve whether to distinguish cash and non-cash payments, but it also involves careful application of the federal pleading requirements.<sup>68</sup> Pursuant to the federal fact-pleading requirements, plaintiffs alleging that reverse payment settlements violate antitrust laws must, at the very least, show that the settlement is not readily justified by a legitimate explanation.<sup>69</sup> Although this requirement can be rigorously applied to dismiss complaints in the early stages, it ought not be

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neric during exclusivity period) (citing *Mylan Pharms, Inc. v. United States*, 454 F.3d 270, 273 (4th Cir. 2006)). A “no-AG agreement” constitutes valuable consideration for the generic manufacturer because authorized generics can compete with traditional generic drugs during the statutorily granted exclusivity period. *See id.* at 1175.

67. *King Drug Co.*, 791 F.3d at 398 (citing *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir. 2012) (noting that cash payment might indicate antitrust violation), *vacated* 570 U.S. 913 (2013), *abrogated by* *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013)). In *King Drug Co.*, the Third Circuit discussed the effect that *Actavis* had on its precedent, namely that it calls for a “full-fledged rule of reason standard.” *King Drug Co.*, 791 F.3d at 398 n.16 (citations omitted); *see also* Fay, *supra* note 64, at 144–46 (footnotes omitted) (citations omitted) (“[T]he *SmithKline* ruling effectuates the congressional intent to increase competition with the Hatch-Waxman Act. . . . [and] no-AG agreements represent a large transfer of value that should be evaluated under the rule of reason.”).

68. *See, e.g., In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 549 (1st Cir. 2016) (citing *Evergreen Partnering Grp. v. Pactiv Corp.*, 720 F.3d 33, 46–47 (1st Cir. 2013)) (noting that strict adherence to *Twombly* might unfairly prejudice plaintiffs in antitrust actions). *Compare In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 135–36 (2nd Cir. 2014) (“[T]he complaint does little more than attach antitrust ‘labels and conclusions’ to what is, at most, an ordinary contract dispute to which the plaintiffs are not even parties.” (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2008))), *with In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 261 (D. Mass. 2017) (noting that antitrust plaintiffs alleging existence of monopolistic scheme “should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each” (quoting *Cont’l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698–99 (1962))).

69. *See In re Cipro Cases I & II*, 348 P.3d 845, 871 (Cal. 2015) (“The prima facie case requires the plaintiff to eliminate the possibility that litigation costs or other products or services could explain the consideration paid the generic . . . . [and then] dispel each additional justification the defendants put forward[.]”); *see also supra* notes 37–39 and accompanying text (explaining history of reverse payment settlements and their connection to antitrust scrutiny). While the Second Circuit has not expressly held that only cash payments are reviewable under *Actavis*, it has applied a seemingly burdensome pleading standard to reverse payment settlements. *See Adderall*, 754 F.3d at 135–36 (affirming lower court’s dismissal of antitrust complaint stemming from settlement). There, the generic manufacturers, who had yet to obtain ANDA approval, delayed their entry into the market as part of a settlement agreement. *See id.* at 130–31 (describing events leading up to settlement agreement and outlining its terms).

used to require unequivocal proof from antitrust plaintiffs at the pleading stage.<sup>70</sup>

IV. *IN RE LIPITOR* ANTITRUST LITIGATION: THE THIRD CIRCUIT'S  
FOLLOW-UP APPOINTMENT WITH NON-CASH  
REVERSE PAYMENT SETTLEMENTS

The Third Circuit has, once again, weighed in on the judicial reviewability of reverse payment settlements in litigation stemming from a generic equivalent for Lipitor.<sup>71</sup> The settlement agreement at issue in *Lipitor* was subject to review for a potential antitrust violation, and it primarily concerned non-monetary terms.<sup>72</sup> Before discussing the merits and implications of the Third Circuit's opinion, the facts and procedure of *Lipitor* will be briefly summarized.<sup>73</sup>

A. *Rising Blood Pressure: Facts and Procedure of In re Lipitor*

Lipitor is a "brand-name drug" manufactured by Pfizer, and the drug is "designed to reduce the level of LDL cholesterol in the bloodstream."<sup>74</sup> Pfizer obtained initial patent protection for the active ingredient of Lipitor, and this patent protection was subsequently extended until March 24, 2010.<sup>75</sup> Pfizer further tried to protect the drug from competition by claiming additional patent protection for a specific form of its active ingredient.<sup>76</sup> While a comprehensive understanding of the exact nature and scope of these patents may not be necessary to an understanding of the

70. See *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014) (citing *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 341 n.42 (3d Cir. 2010) ("While it is possible that defendants will be able to supply evidence to rebut plaintiffs' allegations regarding the true value of the [disputed] services . . . [federal precedent] does not require an antitrust plaintiff to plead facts that, if true, definitively rule out all possible innocent explanations."). In *Niaspan*, the Pennsylvania Eastern District Court considered a number of factual allegations in holding that plaintiffs had sufficiently pled their complaints. See *Niaspan*, 42 F. Supp. 3d at 754–56. These allegations included, *inter alia*, the size of the reverse payment, research regarding the likelihood that the generic would have prevailed in the underlying litigation, and the generic's "willingness to launch at risk" before entering into the agreement. *Id.*

71. See generally *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 239 (3d Cir. 2018) (applying *Actavis* and subjecting settlement to judicial review despite lack of substantial cash payment).

72. See *infra* notes 83–84, 97–100 and accompanying text. (noting terms of disputed settlement agreement).

73. See *infra* notes 74–89 (summarizing facts and procedure of case)

74. *Lipitor*, 868 F.3d at 242. The active ingredient in Lipitor is atorvastatin. See *id.* (describing Lipitor's active ingredient).

75. See *id.* (summarizing process by which Pfizer sought and obtained patent protection).

76. See *id.* (describing additional measures Pfizer undertook to patent specific ingredient components of Lipitor). Specifically, Pfizer "claimed protection for atorvastatin calcium, the specific salt form of the active atorvastatin molecule in Lipitor." *Id.*; U.S. Patent No. 5,273,995 (filed Feb. 26, 1991).

case, these aggressive patent strategies evince how Pfizer, like many industry pharmaceutical companies, has tried to maximize its market share.<sup>77</sup>

In 2002, a generic manufacturer (Ranbaxy) obtained ANDA approval from the FDA.<sup>78</sup> Ranbaxy sought paragraph IV certification, pursuant to the Hatch-Waxman Act, and that triggered the series of events leading to the antitrust litigation before the Third Circuit.<sup>79</sup> Before Ranbaxy began distributing its generic, Pfizer sued Ranbaxy for patent infringement within the statutory window prescribed by the Hatch-Waxman Act.<sup>80</sup> The ensuing litigation yielded a number of different results at different levels, including the invalidation of certain claims from Lipitor-related patents held by Pfizer.<sup>81</sup> Eventually, in 2008, Pfizer brought suit against Ranbaxy once again.<sup>82</sup>

Shortly after the 2008 litigation commenced, Pfizer and Ranbaxy entered into a settlement agreement, which the “plaintiffs allege[d] constituted an unlawful reverse payment.”<sup>83</sup> A key aspect of this settlement was non-monetary, and involved the release of patent infringement claims that Pfizer had previously made against Ranbaxy for another pharmaceutical drug, Accupril.<sup>84</sup>

The Lipitor direct purchasers and end payors subsequently brought suit.<sup>85</sup> Their separate complaints were consolidated into two “substantively identical claims.”<sup>86</sup> First, the plaintiffs claimed that Pfizer violated Section II of the Sherman Act because the reverse payment settlement tended to create a monopoly.<sup>87</sup> Second, the plaintiffs alleged that the

77. See Sturiale, *supra* note 11, at 63 (noting practice of preserving weak patents to maintain market share).

78. See Lipitor, 868 F.3d at 243 (In August 2002, Ranbaxy obtained ANDA first-filler status for a generic version of Lipitor.”).

79. See *id.* (noting that paragraph IV certification asserts “that Ranbaxy’s sale, marketing, or use of generic Lipitor would not infringe any valid Pfizer patent”).

80. See *id.* (explaining initial steps Pfizer took to block ANDA approval of generic version of Lipitor).

81. See *id.* at 243–45 (outlining the various holdings from the Delaware District Court and Federal Circuit).

82. See *id.* at 244 (“[Pfizer] again sued Ranbaxy . . . claim[ing] that Ranbaxy’s generic Lipitor would infringe Pfizer’s two Lipitor-related process patents.”). The plaintiffs asserted that the 2008 litigation was “a sham because no imminent threat of harm to Pfizer existed and because Pfizer knew Ranbaxy’s generic would not violate those patents.” *Id.*

83. *Id.* (noting terms of disputed settlement)

84. See *id.* at 253 (“Pfizer agreed to release the Accupril claims against Ranbaxy, which were likely to succeed and worth hundreds of millions of dollars, in exchange for Ranbaxy’s delay in the release of its generic version of Lipitor.”).

85. See *id.* at 245 (outlining the procedural posture of the case). The direct purchasers bought Lipitor directly from the manufacturer, whereas the end payors acquired Lipitor through intermediaries. See *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 561–62 (E.D. Tenn. 2014) (noting that end payors are “final consumers who absorbed the overcharge passed along the distribution chain”).

86. *Lipitor*, 868 F.3d at 245 (noting consolidation of claims).

87. See *id.* (explaining first claim asserted by Plaintiffs); see also 15 U.S.C. § 2 (2018) (“Every person who shall monopolize, or attempt to monopolize, or com-

agreement unlawfully restrained trade and therefore violated Section I of the Sherman Act.<sup>88</sup> The district court dismissed both of these claims.<sup>89</sup>

B. *Non-Monetary Advantages Can't Buy Antitrust Immunity:  
Narrative Analysis*

In reviewing the district court's dismissal of the plaintiff's complaints, the Third Circuit began its analysis by outlining how a reverse payment settlement ought to be examined in light of the Supreme Court's decision in *Actavis*.<sup>90</sup> Accordingly, the court noted that reverse payment settlements may give rise to antitrust liability "when the payments are both 'large and unjustified.'"<sup>91</sup> This potentiality for antitrust liability, as established by *Actavis*, departs from the historical "scope of the patent" approach that generally allowed patent holders broad power to exclude others from the market.<sup>92</sup>

Instead, the modern *Actavis* approach calls for a balancing of rights granted by a patent against pro-competition policies underlying, and em-

bine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony.").

88. See *Lipitor*, 868 F.3d at 245 (noting that plaintiffs "challeng[ed] the settlement agreement as an unlawful restraint of trade."); see also 15 U.S.C. § 1 (2018) (providing that, "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal").

89. See *Lipitor*, 868 F.3d at 245–46 (citing *In re Lipitor Antitrust Litig.*, No. 2:12-cv-2389, 2013 U.S. Dist. LEXIS 126468, at \*96–97 (D.N.J. Sept. 5, 2013) (describing district court's ruling on Pfizer's motions to dismiss Lipitor-plaintiffs' complaints)).

90. See *id.* at 251–52 (citing *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 158–59 (2013)).

91. *Id.* at 251 (quoting *Actavis*, 570 U.S. at 158). The Third Circuit noted that the *Actavis* Court sought to "exempt[ ] 'commonplace forms' of settlement from scrutiny." *Id.* at 250 (quoting *Actavis*, 570 U.S. at 152).

92. *Id.* at 250 (citing *Actavis*, 570 U.S. at 146) (noting the prior "categorical rule . . . [which] relied on the premise that, because a patentee possesses a lawful right to keep others out of its market, the patentee may also enter into settlement agreements excluding potential patent challengers from entering that market"); see Fielding, *supra* note 22, at 1929 (noting that historical scope of patent approach "originally developed as a device to restrict patentee behavior"). Fielding notes that the scope of patent approach originated in the context of "patent tying arrangements, in which the sale of a patented good was conditioned on the concordant sale of an unpatented good." Fielding, *supra* note 22, at 1929; see also *Int'l Salt Co. v. United States*, 332 U.S. 392, 396 (1947) (invoking scope of patent approach to prevent machine manufacturer from restricting trade of unpatented goods). The approach has since been used to insulate manufacturer from antitrust liability, as noted above, by providing a shield for manufacturers that engage in anticompetitive behavior limited to the disputed product. See Fielding, *supra* note 23, at 1930 ("[T]he scope of the patent analysis has also been used defensively to immunize facially anticompetitive agreements from antitrust scrutiny, provided that the agreements are within the rights conferred by the patent.").

bodied by, the Sherman Act.<sup>93</sup> After establishing that reverse payment settlements may lead to antitrust violations, the Third Circuit noted that the plaintiffs could survive dismissal if they have sufficiently pled an improper reverse payment.<sup>94</sup> The Third Circuit, having already addressed the pleading requirements for allegedly improper reverse payment settlements in *King Drug Co.*, noted that non-cash settlements may be improper under *Actavis*.<sup>95</sup> Simply because a payment is not in cash does not mean that it cannot be disproportionate.<sup>96</sup>

Although the agreement did not include an unusually large cash payment, the Third Circuit found that the agreement was judicially reviewable as a potential antitrust violation.<sup>97</sup> The Third Circuit reasoned that Pfizer's release of its Accupril claims, which might be worth in excess of \$100 million dollars, were unusually large.<sup>98</sup> While such a non-monetary benefit might be properly justified by a legitimate explanation, this benefit was disproportionate to any cognizable benefit in the present case; as such, it was reasonable to conclude that this considerable non-monetary payment

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93. See *Lipitor*, 868 F.3d at 250 (reasoning that patent rights must be “measure[ed] . . . against procompetitive antitrust policies” (quoting *Actavis*, 570 U.S. at 148)). The tension between patent rights and antitrust laws, which motivated the adoption of the Hatch-Waxman Act, constantly bubbles beneath the surface of decisions determining the judicial reviewability of reverse payment settlements. See Fielding, *supra* note 22, at 1918 (footnote omitted) (“Considering that antitrust laws are designed to protect competition from monopolistic market power, while patent law holds out monopolistic power as an incentive to innovate, Hatch-Waxman’s balancing of incentives to innovate with opportunities to compete provides an analytically fertile backdrop against which to evaluate recent antitrust scrutiny of patent use in the pharmaceutical industry.”).

94. See *Lipitor*, 868 F.3d at 251–52 (“Therefore, to survive a motion to dismiss when raising an antitrust violation under *Actavis*, plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large an unjustified reverse payment under *Actavis*.” (quoting *In re Loestrin*, 814 F.3d 538, 552 (1st Cir. 2016))).

95. See *id.* at 252 (noting that reverse payment settlements may potentially violate antitrust laws regardless of whether settlement was “in cash form” (citing *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403–09 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016))); *MacDermid Printing Solutions LLC v. Cortron Corp.*, 833 F.3d 172, 185 (2nd Cir. 2016) (reasoning that “settlement of patent litigation is not immune from possible antitrust liability, [but] neither is it inherently anticompetitive” (citing *F.T.C. v. Actavis Inc.*, 570 U.S. 136, 158–59 (2013))).

96. See *Lipitor*, 868 F.3d at 252–53 (noting that an “early-entry provision” failed to account for non-monetary consideration agreed to by patentee (citing *King Drug Co.*, 791 F.3d at 410)). An unusually large non-cash payment may, just like a large cash payment, indicate that the brand-name manufacturer either holds some improper market power or is concerned about the validity of its patent. See *id.* at 251 (citing *Actavis*, 570 U.S. 136 at 157 (articulating why magnitude of payment is relevant to determining lawfulness of settlement)).

97. See *id.* at 253 (noting that plaintiffs “plausibly pled an unlawful reverse payment settlement agreement”).

98. See *id.* at 255 (noting that Accupril claims could have succeeded against Ranbaxy and had tremendous value).



may have been intended to defer Ranbaxy's entry into the market.<sup>99</sup> As the plaintiffs argued, there was simply no way that the services the generic manufacturer would provide, in addition to any saved litigation costs, were commensurate with the release of the Accupril claims.<sup>100</sup>

Moreover, the Third Circuit went on to criticize the district court's dismissal of the complaints for applying an improper, and unduly onerous, pleading standard.<sup>101</sup> According to the Third Circuit, the federal pleading requirements do not require an antitrust plaintiff to engage in a rigorous and holistic economic analysis of the reverse payment settlement.<sup>102</sup> Although plaintiffs must point to specific facts as opposed to merely reciting legal conclusions, they need not "set out *in detail* the facts" that entitle the plaintiff to relief.<sup>103</sup> Under this standard, the *Lipitor* plaintiffs sufficiently pled a potential antitrust violation.<sup>104</sup> The Third Circuit

99. *See id.* at 256 (noting that settlement may properly be justified by "avoiding litigation costs, providing payment for services, or other consideration" (citing *Actavis*, 570 U.S. at 156)).

100. *See Lipitor*, 868 F.3d at 253–54 ("Despite the large expected damages arising from the Accupril suit and the high likelihood of its success, Pfizer subsequently released its *Accupril* claims as part of a settlement agreement with Ranbaxy . . . *Lipitor* plaintiffs allege that the release of the *Accupril* claims was unjustified, as the release of the potential liability in *Accupril* 'far exceeded' any of Pfizer's saved litigation costs or any services provided by Ranbaxy.") (internal citations omitted). Because there was no reasonable (or legitimate) explanation for this disparity, the Court was sympathetic to the plaintiffs' argument that this massive compensation was meant to induce a delayed entry into the market by Ranbaxy. *See id.* (describing Court's reaction to plaintiffs' argument); Carrier, *Payment After Actavis*, *supra* note 41, at 19 (reasoning that "*Actavis* recognized two categories for which the settling parties could offer justifications . . . the payment (1) is no larger than litigations costs; or (2) is for unrelated generic services rather than delayed entry."). Carrier similarly notes that it is incumbent upon the "settling parties . . . [to] show that their payment is in fact for unrelated services." Carrier, *Payment After Actavis*, *supra* note 41, at 25.

101. *See Lipitor*, 868 F.3d at 254 (reasoning that district court applied "a heightened pleading standard contrary to *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 [2007] . . . and *Ashcroft v. Iqbal*, 556 U.S. 662 [2009]"). ". . . The Court in *Twombly* required that plaintiffs plead "only enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Similarly, the Court in *Iqbal* reasoned that plaintiffs must support legal conclusions with specific facts to avoid dismissal. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009).

102. *See Lipitor*, 868 F.3d at 255 (refusing to apply any "special valuation requirement" to antitrust plaintiffs).

103. *Lipitor*, 868 F.3d at 254 (first quoting *Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013) (interpreting federal pleading requirements); then quoting *Twombly*, 550 U.S. at 555 n.3).

104. *See id.* at 255 (noting that "the Supreme Court in *Actavis* was deliberately opaque about the parameters of reverse payment antitrust claims"). The Third Circuit went on to criticize the onerous pleading standard applied by the lower court (and argued for by the defendants): "The Supreme Court [in *Actavis*] did not require the advanced valuations asked for by *Lipitor* defendants and required by the District Court." *Id.*; *see also In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 541 (1st Cir. 2016) ("Consistent with *Twombly*, which declined to 'require heightened fact pleading of specifics' [in an antitrust suit], we do not require that the

refused to require any “special valuation requirement,” and instead reasoned that the non-monetary payment was sufficiently disproportionate “to permit a plausible inference” that Pfizer was improperly wielding its patents to monopolize the market.<sup>105</sup>

In summary, the Third Circuit found that the plaintiffs’ allegations were sufficient to survive a motion to dismiss.<sup>106</sup> The complaints detailed a reverse payment settlement that was unusually large and evidently unjustified by any legitimate explanation.<sup>107</sup> Put otherwise, the plaintiffs could not point to any legitimate explanation for the settlement, and, in response, the defendants failed to explain away this apparent lack of justification.<sup>108</sup>

#### V. CRITICAL ANALYSIS: A TOUGH PILL TO SWALLOW FOR BRAND-NAME MANUFACTURERS

The Third Circuit’s decision seemingly increases the scope of judicial scrutiny of reverse payment settlements for two reasons.<sup>109</sup> First, the

plaintiffs provide precise figures and calculations at the pleading stage.” (first quoting *Twombly*, 550 U.S. at 570; then quoting *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 WL 5610752, at \*13 (S.D.N.Y. Sept. 22, 2015) (explaining why defendants’ arguments were rejected)).

105. *Lipitor*, 868 F.3d at 255 (reasoning that “Pfizer [might have] possessed the power to bring about an unjustified anticompetitive harm through its patents and had serious doubts about the ability of those patents to lawfully prevent competition” (citing *Actavis*, 570 U.S. 136 at 156-57)).

106. *See id.* at 256 (reasoning that plaintiffs’ allegations were sufficient “at this juncture”).

107. *See id.* (“To plausibly allege an unjustified reverse payment, an antitrust payment need only allege the absence of a ‘convincing justification’ for the payment.” (quoting *Actavis*, 570 U.S. at 159)).

108. *See id.* at 257 (“An *antitrust defendant* may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.” (quoting *Actavis*, 570 U.S. at 156)). Under this view, there is an aspect of burden-shifting; once the plaintiffs suggest that a reverse payment settlement is suspect, it becomes the defendants’ burden to justify this apparent impropriety. *See id.* (“The Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*.”). The *Lipitor* defendants attempted to justify the magnitude of the reverse payment settlement, “contend[ing] that the reverse payment . . . was no more than a commonplace settlement.” *Id.* at 257. The Third Circuit, however, found the “argument [to be] unpersuasive.” *Id.* The opinion went on to delineate between actual “‘commonplace forms’ of settlement, such as tender by an infringer of less than the patentee’s full demand” and settlements like the one *sub judice*, which the Court viewed as “a token payment by the purportedly infringing generic manufacturer.” *Id.* at 257–58 (first quoting *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 402 (3d Cir. 2014); then quoting *Actavis*, 570 U.S. at 152). In rejecting the defendants’ arguments, the Court reemphasized that plaintiffs are entitled to all “reasonable inferences arising [from their plausible allegations].” *Id.* at 258.

109. *See Rich Samp, Third Circuit Antitrust Decision Makes Pharmaceutical Patent Disputes Nearly Impossible to Settle*, FORBES (Oct. 23, 2017 11:22 AM), <https://www.forbes.com/sites/wf/2017/10/23/third-circuit-antitrust-decision-makes-pharmaceutical-patent-disputes-nearly-impossible-to-settle/4/#4c4b17bd1038> [https://per

Third Circuit has reaffirmed its prior determination that non-cash payments are reviewable under *Actavis*.<sup>110</sup> Second, the court advocated a seemingly plaintiff-friendly pleading standard for such antitrust actions, because its approach explicitly shifts the burden to antitrust defendants to provide justifications for the reverse payment settlement.<sup>111</sup>

Placing non-cash settlements within the purview of *Actavis* is ostensibly emerging as the norm among federal courts that have ruled on the issue.<sup>112</sup> Although some district courts have refused to extend *Actavis* to non-cash payments, appellate courts have overturned these decisions.<sup>113</sup> Additionally, commentators have provided strong justifications as to why all reverse payment settlements, even those where no cash is exchanged, can still violate antitrust laws; as one commentator has observed, “[i]t does not make economic sense to preclude antitrust scrutiny when a brand, instead of paying with cash, pays with another form of consideration.”<sup>114</sup> If *Actavis* is meant to protect consumers from potentially monopolistic be-

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ma.cc/P2DA-JX3F] (arguing that *Lipitor* wrongly extended *Actavis* to apply to non-monetary disputes). Samp is sharply critical of the Third Circuit’s decision: “The Third Circuit’s advocacy of antitrust criteria that would halt virtually all future drug-patent litigation cannot be squared with *Actavis*, given that decision’s stated intent to create a standard under which settlements could still flourish.” *Id.*

110. See *Lipitor*, 868 F.3d at 252–53 (noting that “reverse payment underlying an *Actavis* claim need not be in cash form” (citing *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 403-09 (3d Cir. 2015)); see also *supra* notes 64–67 and accompanying text (explaining facts and holding of *King Drug Co.*).

111. See *Lipitor*, 868 F.3d at 256–57 (noting antitrust defendants’ burden of explaining ostensibly unjustified settlements); see also *supra* notes 106–08 and accompanying text (summarizing *Lipitor*’s holding).

112. See *supra* notes 61–67 (summarizing relevant judicial standards applied to reverse settlement payment analyses and outlining decisions of other courts ruling on same issue); see also Fay, *supra* note 64, at 145-46 (reasoning that interpreting *Actavis* as limited to cash payments “would disservice *Actavis* and allow pharmaceutical drug manufacturers to creatively avoid antitrust scrutiny by disguising valuable compensation through non-cash means”).

113. See, e.g., *In re Loestrin* 24 FE Antitrust Litig., 45 F. Supp. 180, 192 (D.R.I. 2014), vacated 814 F.3d 538 (1st Cir. 2016); see also *supra* notes 59–64 and accompanying text (listing *Loestrin* and other district court decisions that have been vacated by their appellate courts).

114. Carrier, *supra* note 63, at 716. Carrier provides eight interrelated justifications as to why a no-AG agreement, specifically, constitutes payment under *Actavis*. See *id.* at 706–19. These eight justifications are as follows: (1) the text of *Actavis* focused on overpayment and proportionality, rather than explicitly mentioning cash; (2) the facts of *Actavis* involved disproportionate payments for “generic services;” (3) a no-AG clause can have tremendous cash-value; (4) a no-AG clause is disproportionate to legal costs; (5) no-AG clauses have “brand” value; (6) refusing to incorporate non-cash payments would be overly formalistic; (7) the “threat[ ] to introduce an AG” is coercive; and (8) “no-AG pledges present a form of market division.” *Id.* at 706–09 (citations and footnotes omitted). Although Carrier’s analysis is anchored in a specific form of non-monetary consideration, non-AG agreements, his reasoning is similarly applicable to other non-cash forms of consideration. See *id.* For a further discussion of non-cash forms of consideration, see *supra* note 39.

havior, then its applicability should not hinge on the “formalistic” distinction between cash and non-cash.<sup>115</sup>

The Third Circuit may, however, extend some of the *Actavis* Court’s plaintiff-friendly language a bit too far.<sup>116</sup> A key aspect of the Third Circuit’s decision was its reasoning that “an antitrust plaintiff need only allege the absence of a ‘convincing justification’ for the payment.”<sup>117</sup> While the Third Circuit correctly noted that the absence of a convincing justification is a factor in determining the judicial reviewability of reverse payment settlements, it is merely one factor.<sup>118</sup> By appreciating the burden that antitrust plaintiffs must satisfy in order to survive a motion for summary judgment, the Third Circuit may have, either inadvertently or intentionally, tipped the scales in favor of the plaintiffs’ bar; this may result in an increased number of settlements that satisfy, at least at the early stages of litigation, the large and unjustified standard enunciated by the Supreme Court in *Actavis*.<sup>119</sup>

Nevertheless, the Third Circuit may be rightly attempting to shine a light on surreptitious practices by large pharmaceutical companies that suppress competition.<sup>120</sup> The simple fact remains that many of these agreements may have been intentionally aimed at maintaining a monop-

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115. Carrier, *supra* note 63, at 715–16 (reasoning that antitrust holding should depend on “demonstrable economic effect rather than . . . formalistic line drawing” (quoting *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58–59 (1977))).

116. Compare *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 256–57 (3d Cir. 2017) (reasoning that *Actavis* clearly places burden on defendants to justify payment by proffering legitimate justifications), with *F.T.C. v. Actavis*, 570 U.S. 136, 156 (2013) (noting that “possibility” of traditional or fair settlement “does not justify dismiss[al]”). The Third Circuit’s opinion follows logically from *Actavis*, but the opinion also uses more explicit and plaintiff-friendly language than *Actavis*. See *Lipitor*, 868 F.3d at 256–57.

117. *Lipitor*, 868 F.3d at 256 (quoting *Actavis*, 570 U.S. at 159).

118. See *Actavis*, 570 U.S. at 159 (noting that absence of a convincing justification is one of many factors that should be considered). The excerpted language used by the Court in *Actavis* comes from a paragraph detailing the multi-layered nature of the analysis: “[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” *Id.* (emphasis added).

119. See *In re Cipro Cases I & II*, 348 P.3d 845, 871 (Cal. 2015) (discussing parties’ respective burdens throughout litigation process). Regardless of whether the Third Circuit’s standard actually constitutes a lower, or less computationally intensive pleading standard, the plaintiff will always have the ultimate burden of proof. See *id.* at 871 (“The ultimate burden throughout [the litigation] rests with the plaintiff to show that a challenged settlement agreement is anticompetitive.” (citing *Bert G. Gianelli Distributing Co. v. Beck & Co.*, 172 Cal.App.3d 1020, 1048 (Cal. App. 1985))).

120. See *Prince*, *supra* note 13, at 693 (regarding reverse payment settlements as tool “to keep . . . weak patents intact and stifle generic competition by paying competitors to delay entry of their lower-cost alternatives”); see also *supra* notes 97–98 and accompanying text.

oly over a certain aspect of the pharmaceutical market so as to enable monopoly pricing.<sup>121</sup> As commentators have pointed out, brand-name manufacturers often charge outrageous prices for their brand-name drugs when they have an exclusive market share.<sup>122</sup>

#### VI. POTENTIAL SIDE EFFECTS: CONCLUSION

The *Lipitor* decision has undoubtedly increased the scope of judicial review of reverse payment settlements for antitrust violations, at least in the Third Circuit.<sup>123</sup> As a direct result, both brand-name manufacturers and generic manufacturers must take care that they craft fair settlements, regardless of whether a large sum of cash is being exchanged.<sup>124</sup> Put otherwise, there must be some valuable consideration contributed by the generic manufacturers rather than some sham or token consideration in addition to delayed entry into the market.<sup>125</sup>

Moreover, there is an emerging consensus that any valuable consideration can constitute an antitrust violation, regardless of whether the settlement involves the exchange of massive amounts of cash.<sup>126</sup> From a policy perspective, this might be a step in the right direction of promoting further competition among brand-name and generic manufacturers; when

121. See *Carrier*, *supra* note 60, at 719 (“Like all anticompetitive market-allocation agreements, the reciprocal pledges [involved in reverse payment settlements] increase the parties’ joint profits at the expense of consumers, who pay higher prices than they otherwise would . . . .”); see also *Prince*, *supra* note 13, at 694 (reasoning that reverse payment settlements have a “staggering” impact on consumers).

122. See *Prince*, *supra* note 13, at 694 (noting that “price of a generic drug . . . can drop more than 90% below what the brand-name drug company was able to initially charge with full market exclusivity”). Although *Prince* roots his analysis in South Carolina state law, he points out a number of valid concerns that support a liberal construction of *Actavis* so as to protect consumers from monopolistic pricing. See *id.* (discussing costs associated with limited access to generic drugs).

123. See *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 255–58 (3d Cir. 2017) (applying federal pleading requirements and reasoning that plaintiffs sufficiently alleged an unjustified settlement under *Actavis*); see also *supra* notes 116–19 and accompanying text (describing Third Circuit’s scope of review of reverse settlement payments based on its interpretation of Supreme Court precedent).

124. See *Lipitor*, 868 F.3d at 257–58 (distinguishing settlement *sub judice* from “commonplace settlement” that ought not be subjected to judicial review); see also *supra* notes 92–95 and accompanying text (explaining Third Circuit’s reasoning for subjecting settlement agreement in *Lipitor* to judicial review even though it did not include a substantial amount of cash).

125. See *Lipitor*, 868 F.3d at 258 (noting insignificant value of services generic manufacturer agreed to supply as part of settlement); see also *supra* notes 92–95 and accompanying text (noting that Third Circuit focused on “disproportionate” settlement agreement between generic manufacturer and Pfizer).

126. See, e.g., *Am. Sales Co., LLC v. AstraZeneca LP (In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 41–42 (1st Cir. 2016) (refusing to limit *Actavis* to cash payments); see also *supra* notes 44–49 and accompanying text (dissenting post-*Actavis* jurisprudence interpreting what makes settlement large and unjustified).

reverse payment settlements are increasingly likely to result in expensive antitrust litigation, they become decreasingly attractive to brand-name manufacturers.<sup>127</sup> If one considers that the real goal of antitrust legislation and antitrust common law is to promote competition, then non-cash settlements with potentially anticompetitive effects ought to be within the reach of *Actavis*.<sup>128</sup>

Nevertheless, reverse payment settlements are often attractive options for all parties to the patent litigation.<sup>129</sup> As such, a pro-pharmaceutical stance might chastise the Third Circuit for chilling companies from engaging in amicable settlements that make pragmatic sense for each involved party.<sup>130</sup> Parties must, however, ensure that these settlements are mutually advantageous and proportional, and that they are not merely obfuscating anticompetitive intentions.<sup>131</sup> If, however, parties refuse to engage in permissible settlements, it is unclear how and whether courts could force litigation among parties that have otherwise resolved their dispute.<sup>132</sup>

A great deal of uncertainty continues to surround the scope of *Actavis* and its application to non-cash settlements.<sup>133</sup> Questions continue to persist as to how rigorous a pleading standard ought to apply to antitrust plaintiffs complaining of improper reverse payment settlements.<sup>134</sup> One

127. See Fay, *supra* note 64, at 146 (noting that increased scrutiny of settlements may ultimately benefit consumers); see also *supra* notes 60–64, 109 and accompanying text (noting expanded scope of judicial review of reverse settlement payments in context of antitrust violations and justifications in support of this expanded scope).

128. See Fay, *supra* note 64, at 144–46 (reasoning that subjecting non-cash settlement to antitrust scrutiny is consistent with aims of Hatch-Waxman Act and antitrust principles); see also *supra* note 36 and accompanying text (quoting Section I of Sherman Act, which prohibits business activities that restrain trade).

129. Amy C. Waltz, Note, *Closing the Deal: Making the Right Congressional Decision About Patent Settlement Agreements*, 5 IND. HEALTH L. REV. 155, 157 (2008) (explaining advantages afforded to both brand-name and generic manufacturer when they engage in settlement agreement).

130. See *id.* at 168–73 (advancing arguments in support of litigants' right to engage in efficient settlements to avoid costly and uncertain litigation); see also note 8 and accompanying text (noting pragmatic benefits of settlement parties involved in patent litigation).

131. See *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 257–58 (3d Cir. 2017) (noting disparity between anticipated litigation costs and value of released claims); see also *supra* note 108 and accompanying text (noting that Third Circuit denied defendants' argument, finding reverse settlement agreement to be "token payment").

132. See Fischman, *supra* note 7, at 105 (noting that extensive judicial review will discourage settlements).

133. For a further discussion of uncertainties surrounding the scope of *Actavis*, see *supra* notes 127–28 and accompanying text.

134. See *supra* notes 65–67 and accompanying text (outlining various courts' views on required pleading standards).

thing is, however, certain; pursuant to the mandates of the *Actavis* Courts, the common law must continue to interpret and define the bounds of *Actavis* and its progeny.<sup>135</sup>

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135. See *F.T.C. v. Actavis*, 570 U.S. 136, 160 (2013) (leaving interpretation of rule of reason as to reverse payment settlements to lower courts).