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The Problem of Reverse Payments in the Pharmaceutical Industry Following Actavis

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Notes

The Problem of Reverse Payments in the Pharmaceutical Industry Following *Actavis*

TRACI AOKI*

Reverse payments are payments that are made as a component of a patent infringement settlement, between a brand-name pharmaceutical company to a competitor who is attempting to market a generic version of the patented brand-name drug. The patentee not only drops its patent infringement suit against the generic manufacturer, but also compensates this alleged infringer. Reverse payment settlements raise antitrust concerns because they suggest that the generic manufacturer could have proved the brand-name's patent either invalid or non-infringed, and thus entered the marketplace to provide consumers with lower priced generic drugs, if they had continued with the litigation. This also insinuates that the motive behind the payment was to persuade the generic manufacturer to delay marketing its lower priced drug, and therefore prolong the brand-name company's monopoly. By settling with the generic manufacturer, the brand-name company is able to continue selling its pharmaceutical at a monopoly-set price, at the expense of consumers who are forced to pay higher costs for their medications.

In FTC v. Actavis, Inc., the Supreme Court held that reverse payment settlements sometimes violate antitrust laws, and that each settlement should be reviewed on a case-by-case basis, under the antitrust rule of reason standard, to determine if it is illegal. Under the rule of reason, courts must weigh the procompetitive and anticompetitive effects of the settlement to determine whether the payment is reasonable. The Supreme Court, however, declined to provide a framework for the rule of reason analysis of reverse payment settlements, leaving it to the lower courts to establish.

Following this decision, district courts have diverged greatly in their application of Actavis to the reverse payment settlements before them. Some courts believe Actavis

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directs antitrust scrutiny only to settlements involving monetary payment, while others believe the holding also applies to noncash settlements. This Note argues that Actavis antitrust scrutiny should be applied not only to monetary settlements, but also to nonmonetary settlements, because reverse payments can bring a risk of significant anticompetitive effects regardless of the particular form of the transfer of value. Additionally, this Note proposes a model of analysis to apply when determining whether the terms of a nonmonetary settlement violate antitrust law.

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INTRODUCTION: THE PROBLEM OF REVERSE PAYMENTS
IN THE PHARMACEUTICAL INDUSTRY

One of the most significant economic problems facing Americans today is rising healthcare costs.¹ A large part of this expenditure stems from pharmaceutical purchases. Pharmaceutical spending in 2014 reached \$373.9 billion, a 13.1% increase from 2013.² Generic versions of brand-name pharmaceuticals produce tremendous cost benefits, saving consumers, taxpayers, businesses, and federal and state programs \$239 billion in 2013 alone.³ However, these lower priced options are eliminated when pharmaceutical companies engage in reverse payment settlements and conspire to keep generics off the market, leaving the brand-name drug as consumers' only option.

“Reverse payment” or “pay-for-delay” settlements occur when a brand-name pharmaceutical company that is suing a generic manufacturer for patent infringement drops its lawsuit and instead pays the generic company to delay marketing its generic drug until a specified date.⁴ This flow of consideration from the patentee, brand-name pharmaceutical company to the generic manufacturer contrasts with that of traditional patent infringement settlements, where infringing parties pay patentees to drop the lawsuits against them. These reverse payment settlements delay both the availability of generic drugs to consumers and competition among pharmaceutical companies, raising strong antitrust concerns. As reverse payment settlements become increasingly popular in the pharmaceutical industry, steps must be taken to combat their anticompetitive effects.⁵

The main problem with reverse settlements is that the benefits they provide for the brand-name pharmaceutical company and the generic drug manufacturer are often at the expense of consumers, who are forced to pay higher prices for their medications. According to a recent Federal Trade Commission (“FTC”) statement, “eliminating these pay-for-delay settlements would still save consumers \$35 billion over ten years—or about \$3.5 billion per year.”⁶ This is because, on average, generic drugs

1. See HARRIET KOMISAR, THE EFFECTS OF RISING HEALTH CARE COSTS ON MIDDLE-CLASS ECONOMIC SECURITY 1 (2013), http://www.aarp.org/content/dam/aarp/research/public_policy_institute/security/2013/impact-of-rising-healthcare-costs-AARP-ppi-sec.pdf.

2. IMS INST. FOR HEALTHCARE INFORMATICS, MEDICINES USE AND SPENDING SHIFTS: A REVIEW OF THE USE OF MEDICINES IN THE U.S. IN 2014, at 3 (2015).

3. See GENERIC PHARM. ASS'NS, GENERIC DRUG SAVINGS IN THE U.S. 1 (6th ed. 2014), http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf.

4. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 740 (E.D. Pa. 2014).

5. FTC, FTC AUTHORIZED GENERIC DRUGS STUDY 145–46 (2011), <http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>.

6. Jon Leibowitz, Chairman, FTC, “Pay-for-Delay” Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay for

cost ten times less than their brand-name counterparts.⁷ However, these savings are lost when the brand-name pharmaceutical company settles with the generic manufacturer in order to eliminate the risk of expensive litigation that could ultimately invalidate its patent and open the door to competition from generic drugs. By delaying the manufacture and sale of a version of its drug, the brand-name company is able to maintain its monopoly-set price and thus, make more than it and the generic challenger would have made combined if they were to compete with each other on the market. In an anticompetitive reverse payment settlement, the generic company agrees to drop its application to produce a low-cost generic version of the drug in exchange for a share of the monopolized profits. In such a scenario, where the brand-name and generic drug companies conspire to intentionally block competition, their actions constitute an antitrust violation. Until *FTC v. Actavis, Inc.*, it was unclear whether *all* reverse payment settlements raised antitrust concerns.

For years, the federal circuit courts were split on whether reverse payment settlements were illegal under antitrust law.⁸ This conflict was finally resolved in *Actavis*, where the Supreme Court held that, although reverse settlements in pharmaceutical patent infringement lawsuits should not automatically be deemed illegal, some do violate antitrust laws.⁹ The Court decided that reverse settlements should be reviewed on a case-by-case basis, under the antitrust “rule of reason” standard, to determine whether they violate antitrust law.¹⁰ However, following this decision, a sub-issue has caused a divide in lower courts’ application of *Actavis*. Specifically, district courts have come to inconsistent conclusions

Health Care Reform (The \$35 Billion Solution), Address Before the Center for American Progress 8 (June 23, 2009) (transcript available at http://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements-pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf).

7. See FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), <http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

8. See *infra* Part II; see, e.g., *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 U.S. Dist. LEXIS 142206, at *60 (D.N.J. Oct. 6, 2014) (holding that reverse payment settlements were presumptively illegal); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *abrogated by* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (holding that reverse payment settlements only violated antitrust law if they exceeded the exclusionary “scope of the patent,” unlawfully extending the patent monopoly); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006), *abrogated by Actavis*, 133 S. Ct. 2223 (advocating the “scope of the patent” test when reviewing reverse payment settlements for unlawful anticompetitive effect); *In re Cardizem, CD Antitrust Litig.*, 332 F.3d 896, 904 (6th Cir. 2003) (holding that reverse payments were per se illegal).

9. *Actavis*, 133 S. Ct. at 2237.

10. *Id.* The rule of reason standard requires courts to weigh a settlement’s anticompetitive effects against its procompetitive effects to determine if it violates antitrust law. See *infra* Part II.C for a discussion of the rule of reason standard. This standard was first developed in *Addyston Pipe & Steel Co. v. United States* as a legal doctrine used to interpret the Sherman Act, the core of U.S. antitrust policy. 175 U.S. 211 (1899).

as to whether *Actavis* applies to reverse payments with nonmonetary settlement terms, or if it is limited only to monetary exchanges.¹¹ While many courts have held that the term “reverse payment” is not limited to monetary payment,¹² other courts have dismissed cases because they interpret *Actavis* to require cash consideration in order to trigger rule of reason antitrust scrutiny.¹³

This Note explains why reverse payment settlements should not be limited to monetary terms and proposes a model for courts to apply when determining whether the terms of a nonmonetary settlement violate antitrust law. First, Part I summarizes the Hatch-Waxman Act and its role in allowing reverse payment settlements and their anticompetitive effects to exist. Next, Part II describes the pre-*Actavis* circuit split over the proper antitrust analysis of reverse payment settlements. Part III examines the facts and holding of *Actavis*, as well as the rule of reason antitrust standard set forth by the Court. Part IV then examines lower courts’ contrasting interpretations of whether *Actavis* and its rule of reason antitrust scrutiny are limited to reverse payment settlements involving an exchange of cash. Part V provides support for the argument that *Actavis*’s rule of reason antitrust scrutiny should not be limited to monetary settlements. Finally, Part VI proposes a formula for applying the *Actavis* rule of reason analysis to determine whether a particular nonmonetary settlement violates antitrust law.

I. THE HATCH-WAXMAN ACT AND ITS ROLE IN ANTICOMPETITIVE REVERSE PAYMENT SETTLEMENTS

In response to rising healthcare and pharmaceutical costs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”) to expedite the approval process of generic drugs. This allows generics to quickly enter the market and reach consumers once the patent on the brand-name drug expires.¹⁴ However, since its passage, the Hatch-Waxman Act has unintentionally enabled

11. See *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1064 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206, at *60; *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 550 (D.N.J. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735 (E.D. Pa. 2014); *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180 (D.R.I. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231 (D. Mass. 2014).

12. See *United Food*, 74 F. Supp. 3d at 1069; *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 751; *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

13. *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180; *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560 (D.N.J. 2014).

14. JON LEIBOWITZ, FTC, SECOND ANNUAL IN-HOUSE COUNSEL OF FORUM ON PHARMACEUTICAL ANTITRUST: EXCLUSION PAYMENTS TO SETTLE PHARMACEUTICAL PATENT CASES; THEY’RE B-A-A-A-CK! (2006); Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.) [hereinafter Hatch-Waxman Act].

pharmaceutical companies to enter into anticompetitive reverse settlements.¹⁵ This negative consequence and the aspects of the Hatch-Waxman Act that contribute to it will be discussed after the following summary of the approval process for generic drugs.

To begin the expedited approval process for their drug, potential generic manufacturers file an Abbreviated New Drug Application (“ANDA”) in which they assert that their generic drug is “bioequivalent” to a brand-name drug that the U.S. Food and Drug Administration (“FDA”) has already approved.¹⁶ This means that the generic drug contains the same active ingredients as the brand-name drug.¹⁷ Because the drugs are “bioequivalent,” the FDA can simply refer to the safety and efficacy findings it previously made during the testing and approval process of the brand-name drug when examining the ANDA-filer’s drug.¹⁸ By allowing generics to bypass expensive and time-consuming drug trials, the ANDA’s procedure accelerates the availability of low-cost generic drugs to consumers.

To submit an ANDA, applicants must make one of four “paragraph certifications” that their generic product will not infringe the brand-name’s patents.¹⁹ The fourth option, the “paragraph IV certification,” is the one involved in reverse settlement cases.²⁰ Under a paragraph IV certification, the ANDA applicant either asserts that the brand-name’s patent is invalid or that the “manufacture, use, or sale” of the generic drug will not infringe the patent.²¹ Once the generic manufacturer files an ANDA with a paragraph IV certification, the brand-name patentee has forty-five days to attempt to stop the generic from receiving FDA approval by filing a patent infringement suit against the generic company.²² This patent infringement suit triggers a thirty-month stay during which the FDA will not approve the generic drug, and the two parties litigate the validity or infringement of the patent.²³

To incentivize generic manufacturers to file paragraph IV ANDA applications despite the risk of being sued for patent infringement, the Hatch-Waxman Act grants 180-days of marketing exclusivity to the first generic drug manufacturer to file a paragraph IV ANDA application (the generic “first-filer”).²⁴ During this period, the FDA will not approve generic drug applications from any other company that would compete

15. FTC, *supra* note 5, at 139.

16. 21 U.S.C. § 355(j) (2012).

17. *Id.* § 355(j)(2)(A)(i)-(iv).

18. *Id.* § 355(j)(2)(A).

19. *Id.* § 355(j)(2)(A)(vii).

20. *Id.* § 355(j)(2)(A)(vii)(IV).

21. *Id.*

22. 35 U.S.C. § 271(e)(2)(A) (2012).

23. 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

24. *Id.* § 355(j)(5)(B)(iv).

with the first generic manufacturer.²⁵ Through this provision, the Hatch-Waxman Act benefits consumers by encouraging challenges to invalid patents and the marketing of noninfringing generics, increasing the availability of generic drugs and price competition among pharmaceutical manufacturers.²⁶

However, in reverse payment settlements, the brand-name pharmaceutical company “pays” the generic first-filer to stay off the market until a specified date. In this scenario, the patentee essentially pays the generic company to postpone its 180-day marketing exclusivity period, allowing the brand-name manufacturer to stretch out its monopoly period. Such arrangements are possible because of the Medicare Modernization Amendments Act of 2003, under which the generic first-filer’s exclusivity period is not triggered until the generic product actually enters the market.²⁷ In exchange for settling, the brand-name company often agrees not to launch its own generic drug, which would otherwise have competed with the generic first-filer’s product during its marketing exclusivity period.²⁸ This type of settlement provision is called a “no-AG” agreement.²⁹

An “AG,” or “authorized generic,” is the brand-name manufacturer’s own generic version of the patented drug. Although the Hatch-Waxman Act prevents other generic companies from entering the market during the first-filer’s 180-day exclusivity period, it does not exclude the original patentee from doing so.³⁰ By releasing its own generic version of the drug, the brand-name patentee is able to “recover some of the sales and profits it would otherwise lose when a [generic first-filer] begins to market and sell its generic.”³¹ For this reason, a no-AG agreement with the brand-name company is a powerful incentive for a generic first-filer to delay release of its generic drug. Studies have shown that competition from the patentee’s AG generally reduces the generic company’s revenues during its 180-day exclusivity period by about fifty percent.³² Through their reverse payment settlement, the brand-name patentee and the generic first-filer are both able to enhance their profits while extending the period in which other generics are excluded from the market.

25. *Id.*

26. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 741–42 (E.D. Pa. 2014).

27. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21, 26, and 42 U.S.C.).

28. *See* FTC, *supra* note 5, at 145–46.

29. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 567 (D.N.J. 2014).

30. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 741.

31. *Id.*

32. FTC, *supra* note 5, at 139.

At this stage, the Hatch-Waxman Act plays a key role in the parties' ability to engage in anticompetitive reverse payment settlements. Because the generic first-filer's 180-day exclusivity period creates a duopoly, the two parties can conspire together to set monopoly-level prices without outside competition to hold them in check.³³ Additionally, because only the first generic company to file an ANDA is entitled to an exclusivity period, other generic companies are less motivated to attempt to enter the drug market before the patent's expiration date.³⁴ Although they may believe that either the patent is invalid or their product does not infringe the patent, other generic companies are unwilling to risk the expense of litigation with the patentee without the incentive of the 180-day exclusivity period.³⁵ Therefore, the reverse payment settlement essentially prevents not only the generic first-filer from entering the market, but also all other generic companies from doing so, thus preserving the brand-name company's monopoly.

When the patentee and the generic challenger agree to a reverse payment settlement, the brand-name manufacturer's patent remains intact, and the public does not get the benefit of price competition.³⁶ This harms consumers by slowing both generic entry into the marketplace and the additional competition the AG could have provided during the generic competitor's 180-day exclusivity period.³⁷ In order to prevent pharmaceutical companies from taking advantage of the inadvertent loophole in the Hatch-Waxman Act and attempting to unlawfully hinder competition, it is imperative that suspicious reverse payment settlements be examined for violations of antitrust law.

II. *FTC v. ACTAVIS, INC.*

In 2013, following years of debate and contrasting holdings in regard to the legality of reverse payment settlements, the Supreme Court in *FTC v. Actavis, Inc.* ruled that such settlements *sometimes* violate antitrust law, and that they should be examined for unlawful anticompetitive effect under the antitrust "rule of reason" standard of analysis.³⁸ However, *Actavis* failed to provide a framework for lower courts to use when applying the rule of reason to evaluate reverse payments for possible antitrust violations. As a result, lower courts have

33. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21, 26, and 42 U.S.C.).

34. 21 U.S.C. § 355(j)(5)(D).

35. Henry N. Butler & Jeffrey P. Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 65 (2010).

36. *FTC*, *supra* note 5, at 139.

37. *Id.*

38. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

diverged greatly in their interpretations and applications of the *Actavis* holding.

A. PRE-*ACTAVIS* CIRCUIT SPLIT ON WHETHER REVERSE PAYMENT SETTLEMENTS VIOLATED ANTITRUST LAW

Prior to *Actavis*, there was a federal circuit split regarding the legality of reverse payment settlements. On one side of split, the Sixth Circuit held that reverse payments were “per se illegal,”³⁹ and the Third Circuit decided that such settlements were “prima facie evidence of an unreasonable restraint on trade.”⁴⁰ The Third Circuit held that the defendant has the burden of proving that the patentee’s “payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”⁴¹ On the other side, the Second and Eleventh Circuits, along with the Federal Circuit, adopted a “scope of the patent” test.⁴² Under this test, reverse payment settlements only violate antitrust law if they exceed the exclusionary “scope of the patent,”⁴³ by extending the patent monopoly.⁴⁴ This split was finally resolved in *Actavis*, where the Court held that reverse payment settlements are not automatically unlawful and should be examined under the antitrust “rule of reason test.”⁴⁵

B. *FTC v. ACTAVIS, INC.*

In *Actavis*, the FTC brought suit against four pharmaceutical companies, alleging that they had “violated the antitrust laws” by conspiring in restraint of trade to maintain monopoly-set drug prices and share the profits at the expense of consumers.⁴⁶ Specifically, the FTC challenged a reverse payment settlement where the patentee pharmaceutical company, Solvay, paid several hundred million dollars to three generic companies—Paddock, Par, and Actavis—to delay marketing

39. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 905–06 (6th Cir. 2003).

40. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

41. *In re K-Dur Antitrust Litig.*, 686 F.3d at 218.

42. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F. 3d 1323 (Fed. Cir. 2008), *abrogated by Actavis*, 133 S. Ct. 2223 (rejecting the scope-of-the-patent test); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006), *abrogated by Actavis*, 133 S. Ct. 2223; *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *rev’d, Actavis*, 133 S. Ct. 2223.

43. Under the “scope of the patent” test, there is no anticompetitive effect in violation of antitrust law as long as competition is restrained only within the scope of the patent. *In re K-Dur Antitrust Litig.*, 686 F.3d at 212. In other words, the agreements only violate antitrust law if they “restrict competition beyond the exclusionary zone of the patent.” *Id.* at 214 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F. 3d at 1336).

44. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 212–13, *abrogated by Actavis*, 133 S. Ct. 2223.

45. *See infra* Part II.B.

46. *Actavis*, 133 S. Ct. at 2227. The FTC is the government entity in charge of protecting consumers from anticompetitive business practices in the marketplace.

their generic versions of Solvay's drug AndroGel for approximately nine years.⁴⁷ The FTC argued that by "unlawfully agreeing 'to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years,'" the settling parties had violated § 5 of the Federal Trade Commission Act.⁴⁸

Under its settlement with Solvay, Actavis agreed not to release its generic until sixty-five months prior to Solvay's patent expiration date, unless another party marketed a generic before that date.⁴⁹ Additionally, Actavis would promote Solvay's AndroGel to physicians.⁵⁰ In return, Solvay, the patentee, paid \$12 million to Paddock, \$60 million to Par, and \$19 million to \$30 million to Actavis for the next nine years.⁵¹

Applying the "scope of the patent" test, the Eleventh Circuit dismissed the complaint.⁵² It concluded that the settlement was "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."⁵³ On appeal, the Supreme Court reversed and remanded the Eleventh Circuit's decision, establishing the "rule of reason" as the standard to be used when determining if a reverse payment settlement restricts competition in violation of antitrust law.⁵⁴ In doing so, the Court held that "there is reason for concern that settlements taking this form tend to have significant adverse effects on competition."⁵⁵ However, the Court also noted that reverse, or "pay-for-delay," settlements in pharmaceutical patent infringement litigation cannot automatically be deemed anticompetitive and illegal.⁵⁶ Rather, reverse settlements must be reviewed on a case-by-case basis and under the antitrust "rule of reason" standard.⁵⁷ Under the rule of reason standard, courts should evaluate

47. *Id.* at 2229.

48. *Id.* at 2229–30.

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.* at 2224 (citing *FTC v. Watson Pharms., Inc.*, 677 F.3d 1289, 1312 (2012)).

53. *Id.* at 2230 (quoting *Watson Pharms., Inc.*, 677 F.3d at 1312).

54. *See, e.g., id.* at 2231 (reversing Eleventh Circuit's dismissal of FTC's complaint). The Eleventh Circuit had initially reviewed the complaint under the scope-of-the-patent test. *Watson Pharms., Inc.*, 677 F.3d at 1312. However, following the Supreme Court's ruling, the Eleventh Circuit will reexamine the case under the rule of reason test. *See Actavis*, 133 S. Ct. at 2238.

55. *Actavis*, 133 S. Ct. at 2238.

56. *Id.* at 2237.

57. *Id.* at 2237–38. The rule of reason is a judge-made doctrine that was first developed in *Addyston Pipe & Steel Co. v. United States* and used to interpret the Sherman Antitrust Act that was first developed. 175 U.S. 211 (1899). However, since *Standard Oil of New Jersey v. United States*, it has been deemed the customary standard by which courts ascertain whether conduct violates the Sherman Act. 221 U.S. 1, 62 (1911).

both the procompetitive and anticompetitive effects of these settlements in a balancing test to determine if it violates antitrust law.⁵⁸

C. RULE OF REASON ANALYSIS

According to the Court in *Actavis*, district courts should administer a three-part test when examining a reverse payment settlement for anticompetitive effect: (1) determine if there was a reverse payment; (2) determine if that payment was “large and unjustified;” and (3) apply the rule of reason.⁵⁹ Not all reverse payments require scrutiny for antitrust violations under the rule of reason. Rather, “the 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.”⁶⁰ In other words, only settlements that are both “reverse” and “large and unjustified” need to be examined under the rule of reason. Then, if the settlement’s anticompetitive effects outweigh its procompetitive ones, the settlement likely violated antitrust law, and the FTC is allowed to pursue an antitrust claim against the settling parties.⁶¹

The *Actavis* Court laid out five factors to guide lower courts’ analyses when applying the rule of reason and weighing a settlement’s anticompetitive and procompetitive effects: (1) whether the consideration at issue has the “potential for genuine adverse effects on competition;” (2) whether these anticompetitive consequences will “at least sometimes” be “unjustified;” (3) whether the reverse payment “threat[ens] to work unjustified anticompetitive harm;” (4) whether an antitrust action is administratively feasible; and (5) the parties’ reasons for preferring “settlements that include reverse payments.”⁶² Courts should consider each of these factors carefully when determining whether a settlement has an overall anticompetitive impact or a procompetitive one. The following is a detailed explanation of each of the five factors, including examples of the analysis that should go into each of them.

I. Whether the Consideration at Issue Has the “Potential for Genuine Adverse Effects on Competition”

First, a district court examining a reverse settlement should determine whether the settlement terms have the “potential for genuine

58. *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977).

59. *See Actavis*, 133 S. Ct. at 2237–38.

60. *Id.*

61. *Id.* at 2234.

62. *Id.* at 2234–37.

adverse effects on competition.”⁶³ For example, reverse payments that encourage generic challengers to drop viable claims of patent invalidity or non-infringement, and thus delay launching their generic products, have “a genuine adverse effect on competition.”⁶⁴ This is because settlements with reverse payments postpone consumer access to lower priced generic drugs by an average of seventeen months longer than patent infringement settlements without such payments.⁶⁵ These reverse payments allow the patentee to maintain the same high price for its pharmaceutical by keeping generic competitors off the market. The patentee is essentially dividing its monopoly profits with the generic challenger. As a result, both settling parties earn more than they would have made competing with each other on the market. All of this is ultimately at the expense of consumers, raising the cost of life-saving medication and preventing a diversity of options.

2. *Whether Anticompetitive Consequences Will “at Least Sometimes” Prove Unjustified*

Second, district courts should ask whether there are justifications for the anticompetitive consequences of the agreement. For example, a payment may be justified if it equals the approximate litigation costs avoided by settlement, along with “compensation for other services the generic has promised to perform.”⁶⁶ Other possible justifications, which will be further examined in Part IV of this Note, include demonstrating that the settlement increased product output, decreased product price, or increased consumer choice.⁶⁷ The settlement may also be justified if the generic manufacturer was financially unable to produce and market its generic drug without the reverse payment it received from the patentee.⁶⁸

3. *Whether the Reverse Payment Threatens to Bring About “Unjustified Anticompetitive Harm”*

Third, district courts should examine whether the patentee has the market power to bring about the anticompetitive harm. Paying large settlements to convince others to stay out of the market strongly suggests that the brand-name drug manufacturer has the market power to create anticompetitive harm by “charg[ing] prices higher than the competitive level.”⁶⁹ The likelihood of the reverse settlement causing anticompetitive harm depends on “its size, its scale in relation to the [settling patentee’s]

63. *Id.* at 2234 (quoting *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447, 460–61 (1986)).

64. *Id.*

65. *FTC*, *supra* note 7, at 4.

66. *Actavis*, 133 S. Ct. at 2235–36.

67. *See infra* Part IV.

68. *Actavis*, 133 S. Ct. at 2234.

69. *Id.* at 2236.

anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”⁷⁰

4. *Whether an Antitrust Action Is Administratively Feasible*

Fourth, the district court should examine whether the settlement is so large that it implies the patent is weak.⁷¹ “Unexplained large reverse payments” might indicate that the patentee has “serious doubts” that the patent is strong enough to survive litigation and an examination of its validity.⁷² This in turn suggests that the patentee’s motive for settling with the generic company was purely to eliminate the risk of losing its patent-created monopoly and encountering generic competition, thereby preserving its ability to “maintain supracompetitive prices.”⁷³ These are unjustified motives for setting that raise antitrust concerns.

5. *The Parties’ Reasons for Preferring “Settlements That Include Reverse Payments”*

The fifth factor involves the district courts’ examination of whether the parties could have settled in a way that did not involve the use of a reverse payment, as well as why they preferred a reverse settlement.⁷⁴ If their motive in choosing such a settlement was to “maintain and to share patent-generated monopoly profits, then, in the absence of some other justification,” their settlement raises antitrust concerns.⁷⁵

Essentially, reverse payment settlements must be reviewed on a case-by-case basis, under the antitrust rule of reason standard.⁷⁶ Under a rule of reason analysis, courts must evaluate both the procompetitive and anticompetitive effects of these settlements.⁷⁷ Although the *Actavis* Court provided five factors to consider when examining reverse payment settlements, it declined to create a specific framework for the rule of reason analysis. Instead, the Court left it to the lower courts to establish.⁷⁸ Since *Actavis*, courts have largely varied in their application of

70. *Id.*

71. *Id.*; see also *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 U.S. Dist. LEXIS 142206, at *60 (D.N.J. 2014).

72. *Actavis*, 133 S. Ct. at 2236.

73. *Id.*

74. *Id.*; see also *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206, at *60.

75. *Actavis*, 133 S. Ct. at 2237.

76. *Id.* at 2237–38.

77. See Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 62–63 (2010).

78. See *Actavis*, 133 S. Ct. at 2238 (holding that “the structuring of the present rule-of-reason antitrust litigation” would be left “to the lower courts”).

the holding to the reverse payment settlements before them. For instance, some district courts have held that reverse payment scrutiny is limited to exchanges of monetary consideration, whereas others have disagreed.⁷⁹ Furthermore, while many courts do agree that nonmonetary settlements are not exempt from antitrust scrutiny under *Actavis*, they diverge in their application of the rule of reason test. This Note's proposal seeks to address these remaining post-*Actavis* uncertainties.

III. POST-*ACTAVIS* CIRCUIT SPLIT

District courts have come to varying conclusions about whether *Actavis* extends antitrust scrutiny to noncash reverse payment settlements, or if the holding only applies to monetary settlement terms.⁸⁰ Most courts have held that *Actavis* should be applied broadly to include nonmonetary settlements.⁸¹ However, other courts have dismissed antitrust lawsuits against pharmaceutical companies on the grounds that reverse payment settlements devoid of a monetary exchange are not reverse payments.⁸² This discrepancy in the interpretation and application of *Actavis* is evident in the following cases.

In *In re Loestrin 24 FE Antitrust Litigation*, the District of Rhode Island dismissed an antitrust lawsuit because it determined that *Actavis* only applied to monetary settlements.⁸³ The settlement at issue in this case involved the generic manufacturer's agreement to delay launching its generic drug until six months before the patent expiration date, in exchange for the brand-name manufacturer's agreement to: (1) not launch its AG within the generic manufacturer's 180 days of exclusivity; (2) not license other generics during that exclusivity period; (3) grant the generic company a license to market the generic worldwide, starting during that period; (4) pay the generic manufacturer annual fees and a

79. Cf. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 569 (D.N.J. 2014) ("It is good jurisprudence that the result flows from the factual source; this Court will not extend the holding of *Actavis* to the non-monetary facts before it."); cf. *In re Nexium Esomeprazole Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone. Adopting a broader interpretation of the word 'payment,' on the other hand, serves the purpose of aligning the law with modern-day realities.").

80. See Table 1 *infra* for a summary of the circuit split that has occurred following the *Actavis* decision.

81. See, e.g., *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-MD-02409, 2014 U.S. Dist. LEXIS 17718, at *17 (D. Mass. Feb. 12, 2014) (declining to limit the principles in *Actavis* to monetary based arrangements); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 741 (E.D. Pa. 2014) (holding that term "reverse payment" is not limited to cash payment).

82. See, e.g., *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180, 182 (D.R.I. 2014) (holding that *Actavis* requires cash consideration in order to trigger rule of reason scrutiny); *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 Supp. 3d at 569–70 (holding that the Supreme Court in *Actavis* considered reverse payment to be limited to an exchange of money).

83. See *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d at 192–93.

percentage of net sales in connection with the co-promotion of a separate drug produced by the patentee; and (5) give the generic manufacturer the exclusive right to earn brand sales of a separate drug.⁸⁴ In granting the defendant settling parties' motion to dismiss, the court interpreted *Actavis* to require actual "cash payment" in order for a reverse payment settlement to trigger rule of reason scrutiny and potentially violate antitrust law.⁸⁵ The court held that because the plaintiffs failed to "adequately allege[] payment in the form of cash, . . . [they] failed to state a claim upon which relief may be granted."⁸⁶ Further explaining its reasoning, the court stated that if the Supreme Court had intended for *Actavis* to apply to nonmonetary settlements, "it could simply have said so," but instead the Court consciously chose to focus solely on cash settlements, with "cash-focused guidance for applying the rule of reason."⁸⁷

In contrast, in *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, the Eastern District of Pennsylvania held that *Actavis* does apply to nonmonetary reverse settlement terms.⁸⁸ The *United Food* court did not find the District of Rhode Island's reasoning persuasive, especially with regard to that court's conclusion that *Actavis* does not apply to nonmonetary settlements because they are "almost impossible to measure."⁸⁹ Challenging this assertion, the court explained that the monetary value of no-AG agreements could be estimated as the difference between the generic's "projected revenues with the agreement" and their "projected revenues had they competed with the pioneer's authorized generic" (that is, without the no-AG agreement).⁹⁰ Therefore, the court reasoned that these complaints should not be dismissed merely because the reverse payment settlements involved nonmonetary terms, and denied the defendants' motion to dismiss.⁹¹

Many courts argue that restricting the application of *Actavis* to only cash settlements will allow pharmaceutical patentees to shield payments for delayed generic entry from antitrust scrutiny simply by settling in nonmonetary terms.⁹² The Eastern District of Pennsylvania in *In re Niaspan Antitrust Litigation* noted that such limitations on *Actavis* would

84. *Id.* at 186.

85. *Id.* at 192–93.

86. *Id.* at 195.

87. *Id.* at 192.

88. *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069–70 (N.D. Cal. 2014).

89. *Id.* at 1069.

90. *Id.* at 1071.

91. *Id.* at 1071–72. See *infra* Part VII for further discussion on the conversion of noncash settlements to monetary values.

92. See *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014).

permit settling parties to “cloak reverse payments . . . under the guise of compensating” for such terms as co-promotion and manufacturing agreements, to ensure the challenger does not market a generic version of their drug or challenge the validity of their patents.⁹³ This would allow the patentee to surreptitiously, yet unlawfully, maintain its monopoly-set prices at the expense of consumers—the very scenario *Actavis* was trying to prevent.

Meanwhile, reaching a compromise between the two views, other courts have held that plaintiffs alleging anticompetitive conduct by the two settling parties must convert the noncash terms into a monetary value before examining the settlement for anticompetitive effect.⁹⁴ For example, the District of New Jersey dismissed the suit in *In re Lipitor Antitrust Litigation* because the plaintiffs had failed to provide a reliable estimate of the values of the nonmonetary settlement terms.⁹⁵ Although *Actavis* never explicitly stated that reverse payments were limited to cash, the Court did emphasize monetary payments in its holding.⁹⁶ Therefore, some courts assert that when applying *Actavis* to analyze a settlement, the nonmonetary payment should be converted to a “reliable estimate of its monetary value,” so that courts can analyze it using the *Actavis* factors.⁹⁷

Despite its apparent focus on monetary settlements in its decision, it seems unlikely that the *Actavis* Court intended its holding to only apply to monetary reverse payments to the exclusion of nonmonetary settlement terms. Restricting antitrust scrutiny to solely monetary settlements would hinder *Actavis* from fully achieving the Court’s goal of protecting consumers from the higher drug prices that result from these anticompetitive business practices. If the holding of *Actavis* does not apply to nonmonetary reverse payment settlements, then pharmaceutical companies can escape liability for antitrust violations simply by structuring their settlements to avoid monetary terms. Therefore, it is important that the reverse payment scrutiny be extended to nonmonetary settlement terms as well as to monetary ones.

93. *Id.* at 752.

94. See *In re Effexor XR Antitrust Litig.*, No. 11-CV-5479, 2014 U.S. Dist. LEXIS 142206, at *62 (D.N.J. Oct. 6, 2014); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 550 (D.N.J. 2014).

95. *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d at 550.

96. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2235–36 (2013).

97. *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206, at *62.

TABLE I: SUMMARY OF POST-*ACTAVIS* CIRCUIT SPLIT

Case	District	Reverse Payment Settlement	Decision	Holding Regarding Nonmonetary Settlement Terms
<i>In re Effexor</i> ⁹⁸	D.N.J.	No-AG agreement	The case was dismissed in part.	Plaintiffs bringing the complaint must convert noncash terms into a monetary value.
<i>In re Lipitor</i> ⁹⁹	D.N.J.	Side deals ¹⁰⁰	The case was dismissed because the complaint must include reliable cash value of nonmonetary payment.	Plaintiffs bringing the complaint must convert noncash terms into a monetary value.
<i>In re Lamictal</i> ¹⁰¹	D.N.J.	No-AG agreement	The case was dismissed but is now on appeal in the Third Circuit.	<i>Actavis</i> is limited to monetary-based settlements.
<i>In re Nexium</i> ¹⁰²	D. Mass.	No-AG agreement and side deals ¹⁰³	The defendants' motions for summary judgment were granted in part and denied in part.	<i>Actavis</i> applies to nonmonetary settlements.
<i>In re Loestrin</i> ¹⁰⁴	D.R.I.	No-AG agreement, side deals, ¹⁰⁵ and licenses to the generic manufacturer	The case was dismissed but is now on appeal in the First Circuit.	<i>Actavis</i> is limited to monetary-based settlements.
<i>In re Aggrenox Antitrust Litig.</i> ¹⁰⁶	D. Conn.	No-AG agreement, co-promotion, and side deals	The defendants' motions to dismiss were partially denied.	<i>Actavis</i> applies to nonmonetary settlements.
<i>United Food</i> ¹⁰⁷	N.D. Cal.	No-AG agreement and \$96 million in free product	The defendants' motion to dismiss was denied.	<i>Actavis</i> applies to nonmonetary settlements.
<i>In re Niaspan</i> ¹⁰⁸	E.D. Pa.	Cash payment, no-AG agreement, Supply and co-promotion agreements	The defendants' motion to dismiss on grounds that term "reverse payment" is limited to cash payments was denied.	<i>Actavis</i> applies to nonmonetary settlements.

98. *Id.*

99. *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523.

100. The side deals in *Lipitor* included overseas licensing rights and settlement of overseas litigation, as well as litigation concerning a separate product unrelated to the underlying patent. *Id.* at 541–42.

101. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560 (D.N.J. 2014).

102. *In re Nexium Esomeprazole Antitrust Litig.*, 42 F. Supp. 3d 231 (2014).

103. The side deals in *In re Nexium* included: (1) "Distribution Agreements," under which the generic company would distribute authorized generic versions of other drugs owned by the patentee; (2) an agreement under which the generic company would store some of the patentee's products; (3) a "Supply Agreement," under which the generic company would provide the patentee with supplies of the "active pharmaceutical ingredient" in the patented drug; and (4) an agreement by the generic to supply the patentee with quantities of the patented pharmaceutical drug. *Id.* at 261–62.

104. *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180 (D.R.I. 2014).

105. The side deals in *In re Loestrin* included a promise not to license other generics for a certain period and licenses and co-promotion agreements involving other drugs owned by the brand-name company that were not related to the underlying patent. *Id.* at 186.

106. *In re Aggrenox Antitrust Litig.*, No. 14-MD-2516, 2015 U.S. Dist. LEXIS 35634 (D. Conn. Mar. 23, 2015).

107. *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052 (N.D. Cal. 2014).

108. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735 (E.D. Pa. 2014).

IV. REVERSE SETTLEMENT SCRUTINY SHOULD NOT BE LIMITED TO MONETARY SETTLEMENTS

Since *Actavis* the question of whether the Court intended its holding to apply solely to monetary reverse payments, or to all forms of reverse payment settlements, including nonmonetary ones, has been strongly debated. This Part argues that the holding of *Actavis* should also apply to nonmonetary settlement terms, since such terms are just as capable of producing anticompetitive effects as monetary ones by persuading generic companies to drop their patent challenges and keep their lower priced drugs off the market.

Another reason antitrust scrutiny should extend to nonmonetary agreements is that pharmaceutical companies are increasingly incorporating noncash terms into their settlements.¹⁰⁹ The FTC has reported that the frequency of nonmonetary terms, such as no-authorized-generic (“No-AG”) provisions,¹¹⁰ in reverse payment settlements is growing. Illustrating this point, in 2012, nineteen out of forty potential reverse payment settlements included a no-AG agreement.¹¹¹ This means that nearly half of all reverse payment settlements in 2012 incorporated the most popular nonmonetary term. If *Actavis* is only applied to monetary reverse payment settlements, at least half of all pharmaceutical reverse settlements will escape antitrust scrutiny.

In response to the rising settlement trend involving nonmonetary terms, many district courts have held that reverse payment scrutiny should not be limited to monetary exchanges.¹¹² Rather, it should be broadly applied to include “anything of value to the generic that can induce it to ‘give up the patent fight’” and delay launching its product.¹¹³ Following this perspective, settlement provisions such as no-AG agreements should qualify as “reverse payments” because they have “tremendous value to the generic manufacturer.”¹¹⁴ The generic’s 180-day marketplace exclusivity that no-AG agreements protect can be worth “several hundred million dollars” to the generic company.¹¹⁵

109. *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d at 193–94.

110. FTC, *supra* note 5, at 2.

111. BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2012, at 1 (2013), <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf>.

112. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) (quoting *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2235–36 (2013)).

113. *Id.*; *see also Payments*, BLACK’S LAW DICTIONARY (10th ed. 2014) (defining “payments” as “performance of an obligation by the delivery of money or some other valuable thing accepted in partial or full discharge of the obligation”).

114. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 750.

115. *Actavis*, 133 S. Ct. at 2229.

Meanwhile, brand-name manufacturers could enhance their own profits by six percent to twenty-one percent during the 180-day exclusivity period by marketing their own AG—that is, if they do not enter a no-AG agreement with the generic company.¹¹⁶ Indeed, many of these settlement terms work “exactly as would a payment of cash.”¹¹⁷ Similarly to other anticompetitive strategies, no-AG provisions lead generic manufacturers to “agree to a later entry date than [they] would otherwise agree to in order to settle a patent-infringement case.”¹¹⁸ Therefore, it seems logical to extend antitrust scrutiny to these types of nonmonetary terms.

In considering whether *Actavis* applies to nonmonetary payments or is restricted to only cash settlements, it is important to note that the Supreme Court’s main concern when deciding the case was whether there were “genuine adverse effects on competition.”¹¹⁹ As explained earlier, nonmonetary terms often perform the same function as monetary terms, incentivizing generic companies to drop their patent validity challenges and agree to delay launching their generic drugs. If *Actavis* is only applied to monetary settlements, pharmaceutical companies can engage in anticompetitive activity yet escape antitrust liability simply by disguising their conduct under the shield of nonmonetary settlements.¹²⁰ It is especially important to expand antitrust scrutiny to nonmonetary agreements because pharmaceutical patent settlements are increasingly taking on “unconventional, noncash forms,” in a surreptitious attempt to escape antitrust scrutiny.¹²¹ Therefore, both monetary and nonmonetary reverse payment settlements should be reviewed under *Actavis* for unlawful restraints on competition.

V. DETERMINING WHETHER NONMONETARY SETTLEMENT TERMS VIOLATE ANTITRUST LAW

To provide guidance for how courts should determine whether a nonmonetary reverse payment settlement’s terms violate antitrust law, this Note proposes the following four-step model of analysis.¹²² First, the plaintiffs alleging anticompetitive activity (generally, the FTC, consumers of the involved pharmaceutical drug, or other interested parties) must

116. FTC, *supra* note 5, at 62.

117. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 752.

118. *Id.*

119. *Actavis*, 133 S. Ct. at 2234.

120. *See, e.g., In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180, 193 (D.R.I. 2014) (holding that in limiting *Actavis* to cash payments, pharmaceutical companies “are likely to evade Sherman Act scrutiny so long as [they] take the obvious care to structure their settlements in ways that avoid cash payments”).

121. *Id.* at 193–94; *see also* FTC, *supra* note 5, at 145–46 (concluding that no-AG agreements are increasingly common as “compensation to generics for restrictions on entry”).

122. *See supra* Figure I.

calculate the monetary value of all noncash settlement terms.¹²³ Second, the plaintiffs must approximate the litigation costs the patentee and generic challenger avoided by settling.¹²⁴ Under this Note's proposed standard, if the reverse payment value is less than or equal to the avoided litigation costs, then the reverse settlement would escape further antitrust scrutiny and the complaint should be dismissed. However, if the settlement value exceeds the avoided litigation costs, then the burden shifts to the settling parties—that is, the brand-name patentee and the generic ANDA filer—to prove that the large payment is justified, either by “other services”¹²⁵ provided to the patentee by the generic manufacturer or other “valid, reasonable justifications.”¹²⁶

If the settlement included payment for other services conferred by the generic challenger, such as supplying the patentee with raw materials to manufacture its drugs, or serving as a back-up supplier for the brand-name company's products, then the defendants must show that the value of these services makes up for the discrepancy between the reverse payment and the avoided litigation costs. This is the third step of this Note's proposed model of analysis. In rebuttal, the plaintiffs may provide evidence that the generic services in the agreement were not actually rendered, or that the payment exceeded the market value of those services, thus suggesting that these settlement terms were made merely as a cover for unlawful reverse payments in an attempt to restrict competition.

If the monetary value of the reverse payment is approximately equal to the sum of the avoided litigation costs and the market value of services actually provided by the generic manufacturer, the settlement should escape further examination and the complaint should be dismissed. However, if the payment greatly exceeds the market value of what the brand-name company truly received, the two settling parties have the burden of either: (1) proving that their settlement terms are justified; or (2) demonstrating that the patentee pharmaceutical company had a high likelihood of prevailing in the underlying infringement lawsuit. This is the fourth and final step of this Note's proposed model of analysis. If the settling defendants are unable to meet their burden on either alternative, their settlement will be deemed anticompetitive and therefore, in violation of antitrust law.¹²⁷

123. *See infra* Part V.A.

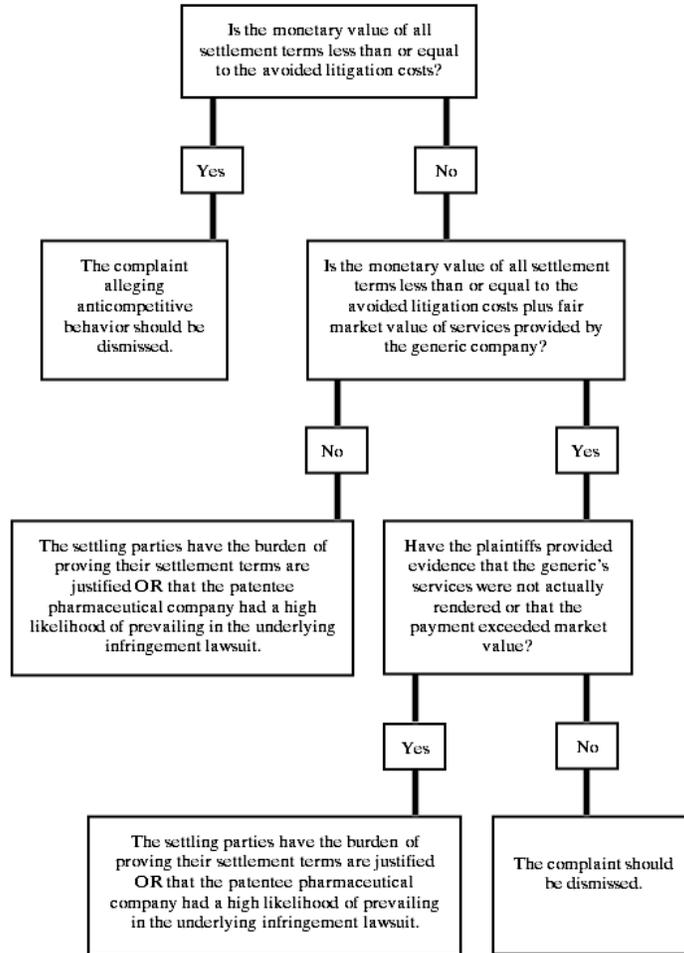
124. *See infra* Part V.B.

125. *See infra* Part V.C.

126. *See infra* Part V.D.

127. *See infra* Figure 1.

FIGURE 1: PROPOSED MODEL FOR APPLYING *ACTAVIS* TO NONMONETARY REVERSE PAYMENTS



A. STEP I: THE PLAINTIFFS MUST CALCULATE THE MONETARY VALUE OF ALL NONCASH SETTLEMENT TERMS.

Under this proposed model, the plaintiffs, that is, the parties alleging the anticompetitive behavior between the settling patentee and generic manufacturer have the burden of first determining the value of each nonmonetary settlement term in the agreement at issue. This step is crucial because it will allow the court to later decide if the reverse payment was “large and unjustified,” and thus carried “the risk of

significant anticompetitive effects.”¹²⁸ The plaintiffs must include these settlement term values, as well as a reliable foundation that supports these particular values, in the complaint. If the plaintiffs are unable to fulfill their burden, the suit cannot move forward. The reason for this is that without reliable values, the court is unable to determine whether the settlement truly was “large and unjustified,” as well as whether it was “reverse.” Indeed, many post-*Actavis* courts have agreed that all noncash terms must be converted to a monetary value in order to enable proper analysis of reverse payment settlements.¹²⁹

When bringing their complaint, plaintiffs must calculate the value of all consideration the alleged generic infringer received as part of the settlement. This consideration may include such nonmonetary terms as forgiving a debt (such as damages from a separate patent infringement case for a different patent involving the same two parties), no-AG agreements (the most common noncash settlement term), granting rights in foreign markets, early entry (that is, delaying marketing of the generic while still allowing marketplace entry prior to the patent expiration date), and payment for unrelated services supposedly provided by the generic company.

When estimating the value of a nonmonetary agreement term, the plaintiffs must produce a “reliable foundation supporting that value,” including an explanation of how they had calculated the payment value.¹³⁰ One example of a case dismissed because the plaintiffs failed to fulfill this burden is *In re Effexor XR Antitrust Litigation*.¹³¹ In this case, the plaintiffs calculated the settlement as the sum of the values of an eleven-month no-AG agreement and an allowed generic entry date prior to the patent expiration date, minus the sum of the avoided litigation costs and the royalties the generic challenger would pay the brand-name manufacturer during its eleven months of exclusivity—in other words, the duration of the eleven-month no-AG agreement.¹³² However, the court dismissed the antitrust violation claim because the plaintiffs had not adequately established a reliable foundation that supported the settlement values that their complaint relied on.¹³³ Without reliable values, the court could not determine the direction of the payment,

128. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

129. *See, e.g., United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1068 (N.D. Cal. 2014) (holding that in order to decide whether a term is a “large and unjustified payment,” courts “must be able to calculate its value”); *see also In re Effexor XR Antitrust Litig.*, No. 11-5479 2014, U.S. Dist. LEXIS 142206, at *66 (D.N.J. Oct. 6, 2014) (holding that “when an alleged reverse payment involves” nonmonetary terms, it “must be valued in terms of a monetary amount in order to determine if it is ‘large’ within the meaning of *Actavis*”).

130. *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206, at *69.

131. *Id.*

132. *Id.* at *71.

133. *Id.* at *71–73.

meaning whether the net value was directed in “reverse,” toward the generic manufacturer, or whether the settlement value was “large” and “unexplained.”¹³⁴

In another example, the settlement in *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.* involved the brand-name company giving the generic manufacturer \$96 million in brand product, as well as agreeing to not launch its own authorized generic drug during the generic company’s 180-day exclusivity period.¹³⁵ Because the agreement “plausibly incentivized [the generic challenger] to accept an entry date later than it otherwise would have—which is precisely the harm that *Actavis* sought to prevent,” the court held that the no-AG agreement had value.¹³⁶ Indeed, a no-AG agreement is very valuable to generic manufacturers because the “vast majority of [their] potential profits . . . materialize during the 180-day exclusivity period.”¹³⁷

The value of a no-AG agreement, the most common noncash settlement term, should be estimated as the difference between the generics’ “projected revenues with the no-AG agreement” and their “projected revenues had they competed with the pioneer’s authorized generic” (that is, without the no-AG agreement).¹³⁸ To calculate this latter value, the plaintiffs must determine both the market share percentage that the brand-name company would lose to the generic company upon generic entry and the “retail price of generic drugs during 180-day exclusivity periods, with and without the presence of an AG on the market.”¹³⁹ According to a recent FDA study, the first generic to hit the market can “capture [eighty percent] of the brand-name’s market share” and sell at ninety percent of the brand-name’s price.¹⁴⁰ However, the availability of a second generic, such as an AG, results in the first generic only capturing around forty percent of the market, and lowers the [generic] drug’s price to fifty-two percent of the brand-name’s.”¹⁴¹ Using such data, plaintiffs can calculate a reliable estimate of the value of the no-AG agreement at issue, as well as that of any other nonmonetary settlement terms. Once the plaintiff determines the monetary value of

134. *Id.*

135. *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1068 (N.D. Cal. 2014).

136. *Id.* at 1074.

137. Letter from Kathleen Jaegar, President & CEO, Generic Pharm. Ass’n, to Donald S. Clark, Sec’y of the Comm’n of FTC 2 (June 27, 2006), https://www.ftc.gov/system/files/documents/public_comments/2006/06/062806gpha.pdf.

138. *United Food*, 74 F. Supp. 3d at 1074.

139. *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206, at *71.

140. *Id.* at *12.

141. FTC, *supra* note 5, at 58; *see also* Carl W. Hittinger & M. Mitchell Oates, ‘Actavis’ *Still Raising More Questions Than It Answers*, LEGAL INTELLIGENCER, May 4, 2015, at 3.

each settlement term and presents a reliable foundation for these values, they must then determine the avoided litigation costs.

B. STEP 2: THE PLAINTIFFS MUST DETERMINE THE AVOIDED LITIGATION COSTS.

Litigation costs avoided by the settlement must be factored into this analysis because they provide a justifiable motive for the reverse payment. These expenses include fees of outside and local counsel, exhibit preparation, analytical testing, expert witnesses, paralegal services, fees for court reporters, and jury advisors.¹⁴² According to a recent survey of intellectual property litigation costs, patent litigation costs an average of \$2.8 million when there is \$1 million to \$25 million in controversy and \$6 million where there is more than \$25 million at issue.¹⁴³ While the median cost of patent litigation is \$4.5 million,¹⁴⁴ patentees often spend more than this median amount when trying to uphold their patents.¹⁴⁵ Additionally, patent infringement litigation can cost generic companies “as much as \$10 million per suit.”¹⁴⁶

Upon receiving the complaint, the court should compare the estimated avoided litigation costs against the total value of the reverse payment, both of which will be acquired from reliable sources and included in the complaint by the plaintiffs. Under this proposed test, if the reverse payment value is less than or equal to the avoided litigation costs, the settlement will escape further judicial scrutiny and the complaint will be dismissed. The reason for this is that an attempt to avoid incurring additional legal fees associated with ongoing litigation is a well-founded reason for settling a lawsuit. However, if the settlement value exceeds the avoided litigation costs, this suggests that the parties’ motives for settling were not legitimate, but instead a bribe by the brand-name company to the generic manufacturer, to delay marketing its generic drug. Therefore, the burden then shifts to the settling parties (that is, the patentee pharmaceutical company and the generic manufacturer) to prove that the large payment is justified by “other services” provided to the patentee by the generic manufacturer.

142. AM. INTELLECTUAL PROP. LAW ASS’N, REPORT OF THE ECONOMIC SURVEY 34 (2013).

143. *Id.*

144. *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d, 523, 546 (D.N.J. 2014) (citing C. Scott Hamphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, N.Y.U. L. REV. 1553, 1623 n.89 (2006)).

145. *Id.*

146. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2243–44 (2013) (Roberts, J., dissenting).

C. STEP 3: THE DEFENDANTS MUST ASCERTAIN THE VALUE OF “OTHER SERVICES” PROVIDED BY THE ALLEGED GENERIC INFRINGER TO THE PATENTEE.

The *Actavis* Court held that payments are “justified” when they reflect “traditional settlement considerations,” such as “avoided litigation costs or *fair value for services*” provided to the brand-name company by the generic challenger.¹⁴⁷ Thus, the next step is to calculate the market value of services rendered by the generic company and to compare that amount to any discrepancy between the total value of the reverse payment settlement and the avoided litigation costs. The settling parties have the burden of calculating this amount and showing that the value of the “other services” provided by the generic company makes up for the difference between the values of the reverse payment and avoided litigation costs. Examples of other services that generic companies might provide include: supplying the patentee with raw materials or finished pharmaceuticals, helping to promote the brand-name manufacturer’s products (to doctors), and serving as a ready backup supplier for the brand-name company’s products.¹⁴⁸ Other payments may also include development fees for unrelated products that the generic will produce for the patentee.¹⁴⁹

However, when determining the value of “other services” included in the settlement, only the market values of those services that were *actually* provided, versus merely promised but not performed, should be considered. Additionally, this appraisal should be based on the fair market value of the services rendered. These distinctions are important because the FTC has reported settlements where some of the services agreed upon were not actually provided, or the amount paid to the generic company far exceeded the market value of the products and services it had supplied to the brand-name company.¹⁵⁰ This implies that the payments were not truly for those listed products and services, but rather for the generic company’s agreement to stay out of the marketplace. The settling parties included the generic services in their agreement merely as an attempt to shield their unlawful anticompetitive behavior.

Yet, even when the defendants do produce evidence that the fair market value of the generic company’s “other services” make up for the price discrepancy, the plaintiffs may submit evidence of their own to

147. *Id.* at 2237.

148. BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006, at 4–5 (2007).

149. *Id.*

150. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1060–61 (2003).

rebut it, attacking the necessity of those services. Considering the necessity of the generic's services will help the court determine whether the settlements are legitimate agreements or were entered into merely to keep competing generic products off the market and maintain the patentee's monopoly.¹⁵¹ Evidence indicating a lack of necessity may include the patentee's failure to request sales projections or reports from the generic, or the patentee's lack of concern when the generic suspends work on the project.¹⁵² Side deals that are "expressly contingent" on the generic staying off the market also raise suspicions of anticompetitive intent.¹⁵³ However, evidence that the brand-name company had already been "seeking this type of business opportunity" prior to the settlement suggests that the side deal was necessary, and thus weighs in favor of the settling parties.¹⁵⁴ Such evidence might include internal documents from before the settlement date, in which the brand-name company discussed pursuing similar services.¹⁵⁵ The court should take all evidence related to the side deals' necessities into consideration when determining if the services make up for the difference between the value of the reverse payment and the avoided litigation costs.

In re Niaspan Antitrust Litigation presents an example of a reverse payment settlement that involved suspicious side deals. In the settlement, the brand-name manufacturer paid the generic challenger to co-promote two drugs to women's health doctors and serve as a ready back-up supplier.¹⁵⁶ However, the settlement also required the generic to delay marketing its drug until a specified date.¹⁵⁷ The *In re Niaspan* court agreed with the plaintiff's assertion that the settlement was unlawful given three critical findings.¹⁵⁸ First, the brand-name manufacturer did not need the standby services of the generic manufacturer.¹⁵⁹ Second, the Co-Promotion Agreement required the patentee to pay royalties based on a percentage of *all* sales of Niaspan and Advicor, even though the generic company was only promoting the products to women's health doctors.¹⁶⁰ Finally, the standby payment far exceeded the value the generic company was providing as a ready-to-manufacture supplier.¹⁶¹ Even more indicative of anticompetitive behavior, each term in the

151. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014).

152. *In re Schering-Plough Corp.*, 136 F.T.C. at 1051.

153. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 753; *see also* Hittinger & Oates, *supra* note 141, at 2-3.

154. Hittinger & Oates, *supra* note 141, at 2.

155. *Id.*

156. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 744.

157. *Id.* at 745.

158. *Id.* at 752.

159. *Id.* at 752-53.

160. *Id.* at 753.

161. *Id.*

agreement was “expressly contingent on the generic manufacturer’s promise to delay generic entry.”¹⁶² For all these reasons, the *In re Niaspan* court held that the plaintiffs had “plausibly alleged the existence of a reverse payment for delayed entry with no legitimate procompetitive justification,” and that “but for the anticompetitive settlement agreements, the generic manufacturer would have prevailed in the underlying patent litigation against the patentee.”¹⁶³ In other words, the settling parties in *In re Niaspan* had failed to meet their burden of showing that the market value of “other services” provided by the generic company made up for the discrepancy between the values of the reverse payment and avoided litigation costs. Therefore, their motion to dismiss the plaintiffs’ complaint against them was denied.¹⁶⁴

However, if the settling parties are able to fulfill their burden of proving that the value of “other services” provided by the generic makes up for the discrepancy between the reverse payment and avoided litigation costs, unlike the defendants in *In re Niaspan*, the burden shifts to the plaintiffs. The plaintiffs must then demonstrate that the generic services were not actually provided, were not truly needed by the patentee, or were overpaid for based on their market value. If the plaintiffs satisfy this burden, the defendants must then prove “valid justifications” for their settlement terms.

D. STEP 4: DEFENDANTS’ BURDEN OF PROVING “VALID, CONVINCING JUSTIFICATIONS” FOR THEIR SETTLEMENT TERMS

If the value of the reverse payment exceeds the combined value of avoided litigation costs and services provided by the generic company, the settling parties have one last chance to prove that their settlement terms are justified. Alternatively, they could justify their settlement by showing that the patentee had a high likelihood of prevailing in the underlying patent infringement lawsuit, which suggests the settlement actually had an overall procompetitive effect. This proposition is supported by *Actavis*.

Consistent with the Court’s analysis in *Actavis*, the defendants will have the burden of demonstrating a “legitimate justification” for the settlement terms.¹⁶⁵ “Valid justifications” for reverse settlements include “avoided cost of litigation, payments for other services provided by the generic challenger to the patentee company, and “any other convincing justifications.”¹⁶⁶ However, the *Actavis* Court left the interpretation of

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013).

¹⁶⁶ *Id.* at 2237.

what “other convincing justifications” may include to the lower courts to decide.

One justification the defendants could attempt to use to validate their settlement is the early generic entry date their agreement provided. The earlier the generic entry date, the greater the settlement’s procompetitive effect, because it brings lower priced generic drugs to consumers before the patent’s expiration date. During settlement, the brand-name patentee and the generic company negotiate a date of generic entry that will fall somewhere between immediate entry and the patent’s expiration date. This date is based on each party’s assessment of its relative strengths in the infringement litigation and “their judgments of the likely outcome of the suit.”¹⁶⁷ For instance, if the patent is strong and the brand-name pharmaceutical company has a high likelihood of winning the litigation, the generic entry date will be later than if the patent is weak and it seems the generic company will prevail.

However, the problem with reverse payment settlements is that they compel generic companies to accept a later entry date than they would have agreed to based “solely on the estimated strength of [their] litigation position.”¹⁶⁸ Therefore, plaintiffs may rebut the settling parties’ defense that their settlement was procompetitive by submitting evidence that the generic challenger would have entered the market even earlier if it were not for the reverse payments it received from the brand-name manufacturer.

Illustrating such a rebuttal, the plaintiffs in *United Food* successfully presented evidence that the generic manufacturer would have launched its generic product at an earlier date “at-risk”—that is, as soon as it obtained FDA approval—had it not been for the reverse payment it received from the brand-name patentee.¹⁶⁹ First, the generic company had “increased production capacity” and purchased the raw materials necessary to start marketing its product, in anticipation of the launch.¹⁷⁰ Second, the large settlement the generic manufacturer was able to procure suggested the patentee’s fear that it would launch the generic drug at-risk.¹⁷¹ Based on this evidence, the court held that the settling parties had “not demonstrated procompetitive effects sufficient to offset the alleged injury to competition under the rule of reason analysis.”¹⁷² Rather, the settlement had an anticompetitive effect because the generic

167. *Id.* at 2233–34.

168. *Id.*

169. *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1068 (N.D. Cal. 2014).

170. *Id.* at 1074.

171. *Id.*

172. *Id.* at 1075.

company would have released its generic product but for the payment of \$96 million in brand product.¹⁷³

Courts have suggested a number of possible justifications by settling parties for their reverse payments, including a demonstration that the settlement value was less than the profits the generic would have earned upon winning the paragraph IV litigation and marketing its generic drug, or that the settlement increased product output, decreased product price, or increased consumer choice.¹⁷⁴ Additionally, various scholars have also suggested possible justifications for seemingly large reverse payments, such as the generic manufacturer's financial inability to produce and market its drug without a reverse payment from the patentee.¹⁷⁵ Other proposed justifications are risk aversion and the settling parties' differing views about their chances of prevailing in litigation.¹⁷⁶

As an alternative to justifying their settlement terms, the defendant parties can fulfill their burden by proving that the patentee drug manufacturer would have likely prevailed in the underlying patent infringement lawsuit. Courts have commented that large, unexplained reverse payments are a strong indicator of a patent's weakness and that the generic challenger would have succeeded in invalidating that patent had they continued litigation instead of settling and accepting the patentee's reverse payment.¹⁷⁷ By showing that the patentee would have likely prevailed, the settling parties eliminate this presumption. This proves that the reverse payments did not prolong a monopoly the patentee would have lost through continued litigation, and suggests that the settlement's procompetitive effects outweigh its negative effects.

Any settlement that allows a generic to enter the market prior to a valid patent's expiration date, even if that entry date is still far into the future, has an overall procompetitive effect that benefits consumers.¹⁷⁸ This is because without the agreement, the generic drug would not be released until the patent's expiration.¹⁷⁹ For this reason, settling parties should be given the opportunity to justify their choice to enter into a

173. *Id.* at 1068.

174. *Id.* at 1067.

175. Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 114 (2010).

176. Barry C. Harris et al., *Activating Actavis: A More Complete Story*, 28 ANTITRUST 83 (2014).

177. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236–37 (2013); *see, e.g., United Food*, 74 F. Supp. 3d at 1072 (holding that unexplained, large payments may suggest that generic challenger would have prevailed had they continued litigation, proving either that patent was invalid or not infringed by its generic product).

178. *See* Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 376–77 (2010).

179. *Id.*

settlement, even when it appears on first glance that the payment to the generic is unduly large. As mentioned by courts and scholars discussing this issue, antitrust scrutiny cannot be applied too strictly to reverse payments settlements. Strict antitrust scrutiny would prevent an “easy way out” of litigation for companies who attempt to legitimately market a generic drug but are sued by a patentee brand-name company for patent infringement.¹⁸⁰ If strict antitrust scrutiny were applied, the generic company would be forced to either proceed with expensive litigation or drop its pursuit of marketing a generic entirely.¹⁸¹ This result would reduce the Hatch-Waxman Act’s effectiveness at promoting generic challenges to invalid patents and increasing the availability of lower priced generic drugs to consumers.

Therefore, if the settling defendants are able to fulfill this burden and provide a valid justification for their settlement terms or prove the patentee likely would have prevailed in the underlying patent infringement suit, the complaint alleging unlawful anticompetitive conduct will be dismissed. However, if the settling defendants are unable to meet their burden, their settlement will be deemed anticompetitive and in violation of antitrust law.

CONCLUSION

In conclusion, *Actavis* did not intend to limit antitrust scrutiny to reverse payment settlements with monetary terms. Courts that interpret *Actavis* in this way are creating a loophole for pharmaceutical companies, allowing them to engage in anticompetitive behavior by simply structuring their settlements to avoid cash payments. There is already an increasing trend of unconventional, nonmonetary terms in settlements between brand-name patentees and generic manufacturers. To prevent these pharmaceutical companies from engaging in anticompetitive behavior, the *Actavis* rule of reason antitrust test cannot be applied solely to cash settlements. Intentionally anticompetitive agreements that prolong monopolies and hinder competition, with no significant procompetitive effect, are the exact type of behavior the *Actavis* Court sought to eliminate. To fulfill the intent of the Court, the holding of *Actavis* should be applied to both monetary *and nonmonetary* settlements.

However, until the Supreme Court decides to reexamine the issue of pharmaceutical reverse payment settlements and provide further guidance to its antitrust rule of reason analysis, the uncertainties,

180. See *FTC v. Abbvie Inc.*, No. 14-5151, 2015 LEXIS 59115, at *16 (E.D. Pa. May 6, 2015); Allison A. Schmidt, *Competition Ahead? The Legal Landscape for Reverse Payment Settlements After Federal Trade Commission v. Actavis, Inc.*, 29 *BERKELEY TECH. L.J.* 493, 515–16 (2014).

181. See *Abbvie Inc.*, 2015 LEXIS 59115, at *16; Schmidt, *supra* note 180, at 515–16.

debates, and divergent holdings will only continue. This Note's proposed model provides guidance for applying *Actavis* to reverse payment settlements, including those with nonmonetary provisions, and analyzing the settlement terms for antitrust law violations. Adopting this framework would create more consistent holdings while also addressing the larger anticompetitive problems at issue.

APPENDIX A: DEFINED TERMS

Brand-name company/manufacturer = The owner of the patent (“patentee”). This pharmaceutical company produces and sells the brand-name drug.

The brand-name company is the party that made the “reverse payment” at issue, to a generic drug company, presumably to incentivize the generic company to delay sale of its generic version of the brand-name drug.

Brand-name drug = The pharmaceutical drug produced and sold by the brand-name pharmaceutical company.

Brand-name drugs tend to be fairly expensive during the patent’s term because there are no competing drugs in the marketplace.

Complaint = In this Note, “the complaint” refers to the suit brought by the FTC or other interested parties (“plaintiffs”) against the “settling parties” (i.e., the brand-name and generic drug companies). In the complaint, the plaintiffs allege that the settling parties engaged in anticompetitive behavior (via their reverse payment settlement) that violates antitrust law.

Exclusivity period / marketing exclusivity period = The 180-days of marketing exclusivity that the Hatch-Waxman Act grants to the first generic company to successfully apply to market a generic version of a brand-name drug, through the FDA’s Abbreviated New Drug Application (“ANDA”) process.

It is this 180-day exclusivity period that allows the brand-name and generic drug companies to enter into reverse payment settlements that restrain competition and preserve the brand-name manufacturer’s monopoly.

First-filer = The first generic company to file an application with the FDA to produce a generic version of an existing brand-name drug.

Reverse payment settlements are generally between a generic first-filer and brand-name pharmaceutical company, with the generic first-filer accepting payment to delay release of their generic drug.

Generic challenger/company = The “first-filer.” The generic company initially filed with the FDA to market a generic version of the brand-name drug, but then settled with the brand-name company and agreed to delay release of its generic drug in exchange for payment.

Hatch-Waxman Act = Enacted in response to rising pharmaceutical costs, the Hatch-Waxman Act aims to speed up the FDA approval process of generic drugs.

However, certain provisions of the Hatch-Waxman, specifically the 180-day marketing exclusivity period granted to the generic first-filer, create a scenario that allows the settling parties’ to enter into reverse payment settlements that delay competition.

Patent infringement lawsuit = The initial lawsuit, between the brand-name drug company and generic company, that triggered the reverse payment settlement at issue in the antitrust lawsuit.

In this initial lawsuit, the brand-name drug company sued the generic company for patent infringement. These two “settling parties” then agreed to a “reverse payment settlement,” in which the brand-name company paid the generic company, presumably to delay release of its generic drug.

Patentee = the brand-name pharmaceutical company who owns the patent on the drug at issue

Plaintiffs = The parties bringing the complaint against the settling parties for engaging in unlawful anticompetitive behavior through their reverse payment settlement. This may be the FTC or other interested parties.

Reverse payment settlements / Pay for delay settlements = An agreement in which a brand-name pharmaceutical company makes a payment to a competing company that was attempting to market a generic version of the brand-name drug, in the course of a patent infringement settlement.

Reverse payment settlements raise antitrust concerns because they delay the availability of low-cost, generic drugs to consumers. The concern is that the payment was an incentive to the generic company to keep its competing drug off the market until a specified, delayed date.

Settling parties = the brand-name pharmaceutical company (the patentee) and the generic company (the first-filer) involved in the reverse payment settlement at issue.

The two settling parties are both defendants in the antitrust lawsuit, which alleges that their reverse payment settlement violates antitrust law.