

June 2014

A Second Opinion on Pharmaceutical Reverse Payment Settlements: Why Actavis Missed the Mark

Alex Galvan

Follow this and additional works at: <https://readingroom.law.gsu.edu/gsulr>

 Part of the [Law Commons](#)

Recommended Citation

Alex Galvan, *A Second Opinion on Pharmaceutical Reverse Payment Settlements: Why Actavis Missed the Mark*, 30 GA. ST. U. L. REV. (2014).

Available at: <https://readingroom.law.gsu.edu/gsulr/vol30/iss2/5>

This Article is brought to you for free and open access by the Publications at Reading Room. It has been accepted for inclusion in Georgia State University Law Review by an authorized editor of Reading Room. For more information, please contact mbutler@gsu.edu.

A SECOND OPINION ON PHARMACEUTICAL REVERSE PAYMENT SETTLEMENTS: WHY *ACTAVIS* MISSED THE MARK

Alex Galvan¹

INTRODUCTION

On December 7, 2012, the Federal Trade Commission (FTC) sported a grin from ear-to-ear.² For years, the FTC unabashedly shopped and hopped federal circuits in hopes of creating a split regarding the application of antitrust law to reverse payment settlements between brand-name drug manufacturers and generic drug manufacturers.³ Over the years, the FTC has been the recipient of numerous judicial gut checks as the independent agency sought to formally denigrate the use of reverse payment settlements.⁴ Undaunted by previous losses, the FTC directly challenged many reverse payment settlements, while filing amicus briefs in suits brought by private entities challenging the same types of

1. J.D. Candidate, 2014, Georgia State University College of Law. Thanks to Monica, Sergio, and Vanessa Galvan for their encouragement and support throughout the writing process. Special thanks to Professor Jessica Gabel, Meg Buice, and Martin Minschwaner for their hard work, dedication, and insight throughout this process.

2. *See* *FTC v. Watson Pharm., Inc.*, 133 S. Ct. 787, 787 (2012) (granting certiorari).

3. *See, e.g.*, *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 30 (D.D.C. 2008) (“[T]he Commission is rather openly shopping for a circuit split on the issue of reverse-payment Hatch-Waxman settlements”) (footnote omitted). In a statement before the Senate Judiciary Committee, then-FTC Commissioner Jon Leibowitz stated that “[i]t is a matter of public knowledge that [the FTC is] looking to bring a case that will create a clearer split in the circuits and encourage the Supreme Court to resolve this issue.” *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing Before the S. Judiciary Comm.*, 110th Cong. 8 (2007) [hereinafter *Leibowitz*] (statement of Hon. Jon Leibowitz, Commissioner, Federal Trade Commission).

4. *E.g.*, *Cephalon, Inc.*, 551 F. Supp. 2d at 30; Edward Wyatt, *For Big Drug Companies, a Headache Looms*, N.Y. TIMES, July 26, 2012, at B1 (noting that the FTC unsuccessfully waged war against reverse payment settlements for more than a decade until the Eleventh Circuit’s decision in *Schering-Plough*). A reverse payment settlement, for the purpose of this Note, is the result of a patent infringement suit filed by a brand-name pharmaceutical manufacturer against a would-be generic competitor. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012). A sizeable payment is made to the alleged infringer (the generic manufacturer) and, in return, the alleged infringer agrees to stay out of the market for a specified period of time. *Id.* For a detailed discussion of reverse payment settlements, see *infra* Part I.A.

settlements.⁵ The FTC, alongside various members of the pharmaceutical industry, fought ardently to curtail this “new way of doing business.”⁶ According to FTC Commissioner Jon Leibowitz, if left unfettered, these reverse payment settlements will delay the entry of generic pharmaceuticals into the market and drive up the cost of prescription drugs, unhinging the results of legislation like the Hatch-Waxman Act, which successfully decreased the cost of many prescription drugs.⁷

On July 16, 2012, the Third Circuit granted the FTC’s wish.⁸ In a startling decision, the court held the existence of reverse payment settlements was *prima facie* evidence of an unreasonable restraint of trade.⁹ The Third Circuit created a split between itself and at least three other federal circuits.¹⁰ As a result of the Third Circuit’s

5. Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); *Cephalon, Inc.*, 551 F. Supp. 2d at 30; Brief for Federal Trade Commission as Amici Curiae Supporting Appellants and Urging Reversal, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (Nos. 10-2078, 10-2077, 10-2079); Corrected Brief of Amicus Curiae Federal Trade Commission in Support of Appellants and Urging Reversal, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097); Brief of Amicus Curiae Federal Trade Commission in Support of Plaintiffs-Appellants’ Petition for Panel Rehearing and Rehearing En Banc, *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (2d Cir. 2005) (No. 03-7641); Brief Amicus Curiae of Federal Trade Commission in Support of Rehearing En Banc, *Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.)*, 604 F.3d 98 (2d Cir. 2010) (Nos. 05-2851 & 05-2852).

6. Leibowitz, *supra* note 3, at 8. Commissioner Leibowitz notes that “just before *Schering* and *Tamoxifen*, there were no such payments. Just after these decisions, it appears to be the new way of doing business.” *Id.* He goes on to say that it will not

be hard to predict what will happen if nothing changes. There will be more and more of these settlements with later and later entry dates. No longer will generic companies vie to be the first to bring a drug to market. Instead, they will vie to be the first to be paid *not* to compete.

Id. (emphasis added).

7. *Id.* at 7. (“If these decisions are allowed to stand, drug companies will enter into more and more of these agreements, and prescription drug costs, which slowed in 2005 after years of precipitous growth, will begin to rise again.”) See Hatch-Waxman Act, 21 U.S.C. § 355(j) (2012); *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution: Hearing Before the S. Judiciary Comm.*, 110th Cong. 1–2 (2007) [hereinafter *Anticompetitive Patent Settlements*] (prepared statement of the Federal Trade Commission) (“Generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically-identical alternatives to brand-name drugs at a significantly reduced cost. To speed market entry of generic drugs, and to ensure that the benefits of pharmaceutical innovation would continue, in 1984 Congress passed the Hatch-Waxman Act.”).

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

9. *Id.*; Saranac Hale Spencer, *AstraZeneca Faces Class Action Suit Over Nexium Drug*, LEGAL INTELLIGENCER, Aug. 28, 2012, at 1.

10. Compare *In re K-Dur Antitrust Litig.*, 686 F.3d at 218 (“[W]e reject the scope of the patent test.

opinion, parties to the reverse payment settlement filed a petition for certiorari to the Supreme Court.¹¹ The Court granted certiorari in three reverse payment settlement cases, but only published an opinion in *FTC v. Actavis*.¹² While it seems that the FTC won the day at the Supreme Court, the agency did not come out unscathed.¹³ Instead of adopting the stringent and necessary level of scrutiny proposed by the FTC and the Third Circuit, the Court reversed and remanded the cases to be reanalyzed under a watered-down antitrust framework.¹⁴

This Note examines both the split among federal circuit courts regarding which test courts should use to determine if a reverse payment settlement violates antitrust law and also examines the Supreme Court's recent opinion in *FTC v. Actavis*. Part I dissects applicable law and legislative history surrounding the current split.¹⁵ Part II discusses the seminal cases represented in the split and analyzes the various tests adopted by each of the courts.¹⁶ Part III presents the Supreme Court's decision in *FTC v. Actavis*.¹⁷ Finally, Part IV explains why the Supreme Court's *Actavis* decision missed the mark by failing to enable lower courts to review reverse payment

In its place we will direct the District Court to apply a quick look rule of reason analysis based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties.”), with *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (aligning itself with the Eleventh Circuit), *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005) (“[T]he proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”), *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 212 (2d Cir. 2005) (“[S]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law, unless the exclusionary effects of the agreement exceed the scope of the patent’s protection.”) (internal quotation marks omitted), and *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) (“When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion.”).

11. *Merck & Co. v. La. Wholesale Drug Co.*, 686 F.3d 197 (3d Cir. 2012), *petition for cert. filed*, 2012 WL 3645102 (U.S. Aug. 24, 2012). (No. 12-245).

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

13. *Id.* at 2237.

14. *Id.* at 2238.

15. *See infra* Part I.

16. *See infra* Part II.

17. *See infra* Part III.

settlements with the level of antitrust scrutiny necessary to combat these harmful settlement agreements.¹⁸

I. PATIENT HISTORY: A LEGISLATIVE AND JUDICIAL BACKGROUND OF REVERSE PAYMENT SETTLEMENTS

A. *The Symptoms: An Overview of Pharmaceutical Reverse Payment Settlements*

When the manufacturer of a generic drug wishes to debut that drug on the market, the manufacturer must notify the brand-name patent holder that a generic medication will soon be released.¹⁹ This notification is required if a generic manufacturer intends to expedite FDA approval under the Hatch-Waxman Act.²⁰ After receiving this notice, many brand-name patent holders file patent infringement claims against their would-be generic competition.²¹ Many of these claims are resolved through settlements.²² At this juncture, according to the FTC, some of these settlements begin to skirt, if not completely contravene, the Sherman Act and established antitrust principles.²³

Often, particularly in the most nefarious of these settlement agreements, the brand-name patent holder will pay the generic manufacturer—the alleged infringer—to withdraw its patent challenge and to keep their generic product out of the market for an extended period of time.²⁴ These agreements are often referred to as reverse payment settlements, “exclusion agreements,” or, more colloquially, pay-for-delay settlements.²⁵ As the FTC became aware of this new phenomenon, the agency grew wary of the ramifications these reverse payment settlements could have on the availability of

18. *See infra* Part IV.

19. Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(A)(viii)(B)(iii) (2012); *see infra* Part. I.C.

20. Hatch-Waxman Act § 355(j); *see infra* Part. I.C.

21. Leibowitz, *supra* note 3, at 8.

22. *Id.* (noting that between fiscal years 2004 and 2006 there were forty-eight patent infringement settlements stemming from the Hatch-Waxman Act).

23. *Anticompetitive Patent Settlements*, *supra* note 7, at 1–2; Leibowitz, *supra* note 3, at 2–3.

24. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012).

25. *Id.*; Leibowitz, *supra* note 3, at 7 (referring to pay-for-delay settlements as “pernicious”).

affordable generic pharmaceuticals.²⁶ In response to this problem, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which included amendments to the existing Hatch-Waxman Act.²⁷ The amendments required that parties wishing to enter into patent infringement settlements, as described above, notify and file the agreements with the FTC and the Department of Justice (DOJ) for review.²⁸

After the passage of the amendments to Hatch-Waxman, the FTC was ready to dole out tough medicine to those pharmaceutical companies seeking to avoid competition.²⁹ The pharmaceutical world would soon learn, however, that the FTC was playing with nothing more than placebos and, when it came to restricting reverse payment settlements, the agency was powerless.³⁰ That is, until, December 7, 2012.³¹

B. Antitrust Antibiotics: The Sherman Act

In passing the Sherman Act in 1890, Congress empowered itself to address two serious issues facing the country: monopolization and restraint of trade or commerce.³² The purpose of the Sherman Act is

26. See S. REP. NO. 107-167, at 4 (2002) (“The Federal Trade Commission reports that some firms are exploiting [the Paragraph IV certification] by entering into secret deals to allow a maker of the generic drug to claim the 180-day grace period in order to block other generic drugs from entering the market, while at the same time getting paid by the brand name manufacturer for withholding sales of the generic version.”).

27. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 26 U.S.C. §§ 139A, 223, 4980G; 42 U.S.C. §§ 299b-7, 1395b-8, 1395b-9, 1395w-3a, 1395w-3b, 1395w-27a, 1395w-29, 1395w-101 to -104, 1395w-111 to -116, 1395w-131 to -134, 1395w-141, 1395w-151, 1395w-152, 1395cc-3, 1395kk-1, 1395zz, 1395hhh, 1396u-5).

28. *In re K-Dur Antitrust Litig.*, 686 F.3d at 204. The FTC and DOJ share responsibility for civil enforcement of antitrust laws. Albert A. Foer, *United States of America*, in COMPETITION REGIMES IN THE WORLD—A CIVIL SOCIETY REPORT 622 (Pradeep S. Mehta ed., 2006).

29. Leibowitz, *supra* note 3, at 8 (“[F]or fiscal year 2004 and the early part of fiscal year 2005, none of the nearly 20 agreements reported between brands and generics contained both a payment from the brand and an agreement by the generic to defer entry. . . . But data from fiscal year 2006 [after two federal appellate courts ruled reverse payment settlements were not *prima facie* evidence of antitrust violations] is far more disturbing.”) (emphasis added).

30. After the courts in *Schering* and *Tamoxifen* ruled in favor of reverse payment settlements, “half of all settlements, 14 out of 28, involve[d] some form of compensation to the generic and an agreement by the generic not to market its product for a period of time.” *Id.*

31. See *supra* INTRODUCTION.

32. Sherman Act, 15 U.S.C. § 1(a) (2012) (“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign

to “preserv[e] free and unfettered competition as the rule of trade.”³³ Under the Act, there are two basic types of violations: per se violations and violations of the rule of reason.³⁴ Per se violations are, on their face, so injurious to competition that there is no need for significant inquiry into the facts of a particular contract or deal.³⁵ To grapple with agreements that cannot be so easily deemed per se violations, the rule of reason approach takes into account the restrictive nature of agreements and further analyzes the agreement’s effect on competition.³⁶ The Supreme Court noted that it is essential to determine whether the agreement merely regulates and benefits the industry, or whether the agreement is injurious to competition within the industry.³⁷ As a result, rule of reason violations are characterized as such only after an assessment of the totality of the circumstances surrounding the agreement.³⁸ Factors of the inquiry include: (1) the

nations, is declared to be illegal.”); EARL W. KINTNER, *FEDERAL ANTITRUST LAW* 125–26 (1980) (“The Act’s formal title, ‘An Act to Protect Trade and Commerce Against Unlawful Restraints and Monopolies,’ well summarizes Congress’ remedial objective.”); Foer, *supra* note 28, at 621–22 (stating that the FTC and the DOJ jointly enforce the Sherman Act in civil courts while the DOJ is solely responsible for criminal prosecutions). *See generally* Kenneth Ewing, *Private Anti-Trust Remedies Under U.S. Law*, 1 *CROSS-BORDER: COMPETITION* 87 (2007) (explaining that private rights of action are also available under the Sherman Act).

33. *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958) (“[The Sherman Act] rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions.”).

34. *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 457–58 (1986); KEITH N. HYLTON, *ANTITRUST LAW: ECONOMIC THEORY & COMMON LAW EVOLUTION* 113–16 (2003); THOMAS V. VAKERICS, *ANTITRUST BASICS* § 1.03 (2011).

35. Per se unlawful conduct is that which has been found to have a “pernicious effect on competition” and “lack[s] . . . any redeeming virtue.” *Cont’l T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 58 (1977) (quoting *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)). For examples of per se unlawful conduct, see *Transource Int’l, Inc. v. Trinity Indus., Inc.*, 725 F.2d 274, 280 (5th Cir. 1984) (finding agreements not to compete between future and current competitors per se unlawful) and *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 100 (1984) (noting horizontal price-fixing as per se unlawful).

36. *Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (1918) (“[T]he legality of an agreement . . . cannot be determined by so simple a test, as whether it restrains competition. Every agreement concerning trade, every regulation of trade, restrains. To bind, to restrain, is of their very essence.”).

37. *Id.* The regulatory effect of the restraint will be weighed against any negative effects it may have on competition. *Id.* A regulation, while it may appear to restrain competition, may actually create efficiency within the particular industry. *See id.*

38. *Id.*

facts relevant to the particular industry or business at issue; (2) the condition of the industry or business before and after the alleged restraint; (3) the specific characteristics of the restraint in question and potential ramifications, either “actual or probable.”³⁹

C. *Generics Work Just as Well: The Hatch-Waxman Act*

As prices for pharmaceuticals skyrocketed, Congress stepped in through the Hatch-Waxman Act.⁴⁰ Through Hatch-Waxman, Congress sought to remedy this problem by removing many of the hoops a generic manufacturer would have to jump through to break into the pharmaceutical market with its significantly cheaper product.⁴¹ In so doing, Congress sought to increase access to generic medications and encourage brand-name pharmaceutical companies to lower their prices through economics.⁴² Congress achieved this by

39. *Id.* (“The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.”). The Supreme Court also encourages lower courts to look at the relative intent of the parties and the purpose of the restraint. *Id.*

For example, in *Board of Trade*, the Chicago Board of Trade enacted a Call Rule, which regulated board members buying or selling orders of grain after the close of business. *Id.* at 237. At the close of the call session and according to the new rule, the Board set the price of grain to be sold during off time. *Id.* In effect, no one could sell grain at a different price during the off time. *Id.* The United States filed suit against the Board claiming that the Call Rule equated to price fixing and was a violation of the Sherman Act. *Id.* at 238.

The Supreme Court proceeded with a rule of reason analysis. *Id.* at 238. The Court first looked to the nature of the rule and determined that the rule simply forced Board members to decide the price at which they would buy grain until the next session of the Board (usually the next day). *Id.* at 239. Next, the Court looked to the scope of the rule and determined that it applied only to a small portion of grain during a specific time of day and had little effect outside of Chicago. *Id.* Lastly, the Court looked to the effects of the rule, noting a list of benefits from its implementation. *Id.* at 240. The list included bringing buyers and sellers together during the Call, which resulted in an “open interchange of bids and offers” and enabled the Board to increase pay to farmers. *Id.* Thus, the Court determined, the Call Rule did not violate the Sherman Act because it served to regulate and improve efficiency within the Chicago grain market and did little harm to marketplace competition. *Id.* at 241.

40. Hatch-Waxman Act, 21 U.S.C. § 355(j) (2012); FAMILIES USA, OVERVIEW OF THE HATCH-WAXMAN AMENDMENTS 1 (2002) (“A new brand-name drug generally enters the market with many years of patent protection. During that time, the manufacturer enjoys monopoly status—there is no generic available that can be substituted for the brand-name drug. This monopoly status keeps competition at bay and the brand-name drug price high. When a generic version of the drug becomes available, price competition begins, and consumers finally have access to a lower-priced alternative: The average price per prescription for brand-name drugs is approximately three times the prescription price for generic drugs.”) (footnotes omitted).

41. Hatch-Waxman Act § 355(j).

42. FAMILIES USA, *supra* note 40, at 1 (“Recognizing that generic competition in the drug industry is good for consumers, Congress passed the Drug Price Competition and Patent Term Restoration Act in

lessening the filing requirements mandated by the Food and Drug Administration (FDA) for introducing generic drugs.⁴³ A manufacturer interested in producing a generic drug need only file an Abbreviated New Drug Application (ANDA).⁴⁴ The ANDA does not require the extensive—and often expensive—scientific research and data usually necessary for the standard application so long as the generic applicant can prove that their product is the “bioequivalent”⁴⁵ of the already patented drug.⁴⁶ The applicant is then able to use the research and safety testing performed by the brand-name patent holder to receive FDA approval of their generic drug.⁴⁷

While Hatch-Waxman relaxed the process for seeking FDA approval, the ANDA requires that generic applicants certify that their proposed drug will not create friction among the patents already contained in the FDA’s Orange Book.⁴⁸ A generic applicant may file one of four possible certifications.⁴⁹ Each certification ensures that there is no direct patent infringement.⁵⁰ It is the fourth method of

1984 to decrease the ‘time and expense of bringing generic drugs to market.’ This statute, commonly known as the Hatch-Waxman Amendments, creates incentives for manufacturers to seek early approval for generic drugs from the Food and Drug Administration (FDA).” (footnotes omitted).

43. Larissa Burford, Note, *In re Cardizem & Valley Drug Co.: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform*, 19 BERKELEY TECH. L.J. 365, 368 (2004) (“Hatch-Waxman . . . reduc[ed] the filing requirements for Food and Drug Administration (FDA) approval of drug products that are bioequivalent to previously approved patented drugs.”).

44. Hatch-Waxman Act § 355(j)(1).

45. To establish bioequivalency, a generic applicant must scientifically establish that their generic product performs in the same manner as the already FDA-approved drug. FDA, *Abbreviated New Drug Application (ANDA): Generics*, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm> (last visited Oct. 26, 2013).

46. Hatch-Waxman Act § 355(j)(2)(A)(iv).

47. *Id.*

48. The FDA’s Orange Book is a compilation of information regarding existing generic drugs and forthcoming generic products. Hatch-Waxman Act § 355(j)(2)(A)(vii); FAMILIES USA, *supra* note 40, at 2.

49. A generic drug manufacturer can file a Paragraph I, II, III, or IV Certification. Hatch-Waxman Act § 355(j)(2)(A)(vii)(I)–(IV).

50. Hatch-Waxman Act § 355(j)(2)(A)(vii); FAMILIES USA, *supra* note 40, at 2. A Paragraph I Certification indicates that there is no patent data on the drug in the Orange Book. Hatch-Waxman Act § 355(j)(2)(A)(vii)(I); FAMILIES USA, *supra* note 40, at 2. A Paragraph II Certification indicates that the relevant patent has expired. Hatch-Waxman Act § 355(j)(2)(A)(vii)(II); FAMILIES USA, *supra* note 40, at 2. A Paragraph III Certification indicates that the manufacturer only wants approval to market the generic after the brand-name patent expires. Hatch-Waxman Act § 355(j)(2)(A)(vii)(III); FAMILIES USA, *supra* note 40, at 2.

certification that gives rise to reverse payment settlements.⁵¹ When a generic manufacturer files a Paragraph IV Certification, the applicant is assuring that an existing patent should not hinder approval by the FDA “because the listed patent is either invalid or not infringed by the ANDA.”⁵² As part of the Paragraph IV Certification, the generic applicant must notify the brand-name manufacturer of its intent to enter the market.⁵³ The brand-name manufacturer then has forty-five days to file suit for patent infringement.⁵⁴ If suit is filed, the FDA is barred from granting approval for up to thirty months.⁵⁵ If a court rules on the patent or the patent in question expires, the FDA may approve the generic drug.⁵⁶

51. Hatch-Waxman Act § 355(j)(2)(A)(vii)(IV); FAMILIES USA, *supra* note 40, at 2 (“The anticompetitive practices flowing from loopholes in Hatch-Waxman relate to Paragraph IV Certifications.”).

52. FAMILIES USA, *supra* note 40, at 3; Hatch-Waxman Act § 355(j)(2)(A)(vii)(IV).

53. Hatch-Waxman Act § 355(j)(2)(A)(viii)(B)(iii) (“An applicant required under this subparagraph to give notice shall give notice to—(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and (II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).”).

54. Hatch-Waxman Act § (j)(5)(B)(iii) (“If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to substantially complete, was submitted.”).

55. *Id.* (“If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order . . .”).

56. *Id.* The issuance of notice required under a Paragraph IV Certification leaves generic drug companies open to potential patent infringement claims. *See* FAMILIES USA, *supra* note 40, at 3. Realizing this, the drafters of the Hatch-Waxman Act built an incentive into the regulatory framework. *Id.* The first generic manufacturer to file a Paragraph IV Certification is allowed to remain the sole provider of the generic drug for nearly six months. *Id.* During which time, the FDA will not approve another generic form of the drug. *Id.* Thus, the only competition a generic manufacturer would face is from the brand-name manufacturer. This is known as the “exclusivity period.” *Id.* The 180 days begins either the day the generic is released, or the day that a court holds the brand-name patent invalid or unenforced by the generic. *Id.* For a discussion on the necessity of the regulatory exclusivity period in light of the existing exclusionary power of a patent, see Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419 (2012).

D. Renewing the Prescription: The Affordable Care Act (ACA)

“In 2010, Congress enacted the Patient Protection and Affordable Care Act in order to increase the number of Americans with health insurance and decrease the cost of health care.”⁵⁷ This sentence opened the opinion in one of the most surprising Supreme Court decisions of the decade.⁵⁸ The Court’s approval of the ACA in *National Federation of Independent Business v. Sebelius* was the end of a long, hard-fought battle for access to quality, affordable healthcare.⁵⁹ As one of the central tenets of the ACA, insurance companies can choose to be placed into “Exchanges,”⁶⁰ and those seeking to acquire insurance will be able to easily and efficiently compare the costs and benefits of a particular policy.⁶¹ As a result, in order to remain competitive and appeal to shoppers, insurance providers will be forced to adopt lower, more affordable premiums.⁶² Supporters contend that the ACA “will give [consumers] a better range of choices, make the health care market more competitive, and keep insurance companies honest.”⁶³ It is the element of competition

57. Nat’l Fed’n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2571 (2012).

58. Kate Uptergrove, *Surprising Supreme Court Decision Leaves Many Confused About Health Care*, NEWSMAGAZINE NETWORK, (June 29, 2012, 10:48 AM), <http://www.newsmagazinenetwork.com/2012062921222/surprising-supreme-court-decision-leaves-many-confused-about-the-future-of-health-care/>.

59. See U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, KEY FEATURES OF THE AFFORDABLE CARE ACT, <http://www.healthcare.gov/law/timeline/> (last visited Oct. 26, 2013).

60. Exchanges will serve as online marketplaces where individuals seeking to buy insurance can browse, compare, and research options available to them. Ctrs. for Medicaid & Medicare Servs., *Affordable Insurance Exchanges: Seamless Access to Affordable Coverage Overview Fact Sheet: August 12, 2011*, CMS.GOV, <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2011-Fact-Sheets-Items/2011-08-125.html> (Aug. 12, 2011). Consumers will have the majority of the information needed in order to make the best decision as to what insurance plan is best for their needs. *Id.* While individual states will establish and operate the exchanges, the federal government can and will step in to ensure the exchange is being operated appropriately. *Id.* The federal government will also offer technical assistance to the states establishing exchanges. *Id.*

61. Ctrs. for Medicaid & Medicare Servs., *Affordable Insurance Exchanges*, HHS.GOV, <http://www.hhs.gov/cciio/programs/exchanges/index.html> (last visited Oct. 26, 2013) (“The Affordable Care Act helps create a competitive private health insurance market through the creation of Affordable Insurance Exchanges.”).

62. *Id.* (“These State-based, competitive marketplaces, which launch in 2014, will provide millions of Americans and small businesses with ‘one-stop shopping’ for affordable coverage. They will also provide the sole venue where Members of Congress will get their health insurance.”).

63. Letter from President Barack Obama to Sen. Edward M. Kennedy and Sen. Max Baucus (June 2, 2009), available at http://www.whitehouse.gov/the_press_office/Letter-from-President-Obama-to-Chairmen-Edward-M-Kennedy-and-Max-Baucus.

that links the Act with the current split regarding reverse payment settlements. Congress recently established a massive regulatory framework pitting insurance companies head-to-head in order to improve the healthcare system in the United States.⁶⁴ Should this legislative shift also serve as a guiding light to both the Supreme Court and lower courts faced with pharmaceutical reverse payment settlements?

II. TREATMENT OPTIONS: APPROACHES TO REVERSE PAYMENT SETTLEMENTS

A. *The Scope of the Patent*

1. *Valley Drug Company v. Geneva Pharmaceuticals*

In *Valley Drug Co. v. Geneva Pharmaceuticals* the Eleventh Circuit reviewed a grant of partial summary judgment out of the Southern District of Florida in a case brought by several pharmaceutical companies against three drug manufacturers.⁶⁵ The pharmaceutical companies alleged that two of the agreements between those manufacturers were per se violations of section one of the Sherman Act.⁶⁶ The question before the court was whether these agreements were injurious to competition and thus restraints of trade in violation of the Sherman Act.⁶⁷

The first of these agreements was between Abbott Laboratories (Abbott) and Zenith Goldline Pharmaceuticals (Zenith).⁶⁸ Instead of filing a Paragraph IV certification with its ANDA, Zenith sued the brand-name patent holder, Abbott, in order to force Abbott to

64. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

65. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1295–96 (11th Cir. 2003). *Valley Drug* was a consolidated class action suit brought against three pharmaceutical manufacturers: Abbott, Geneva, and Zenith. *Id.* In a joint motion for summary judgment, the plaintiffs alleged that the agreements between the pharmaceutical manufacturers were per se violations of the Sherman Act. *Id.* at 1295. The district court granted the motion and Abbott, Geneva, and Zenith filed an interlocutory appeal to the Eleventh Circuit. *Id.*

66. *Id.*

67. *Id.* at 1295, 1303.

68. *Id.* at 1296.

“delist”⁶⁹ its claim on the patents at issue.⁷⁰ Abbott filed a counterclaim against Zenith for patent infringement.⁷¹ Zenith sought an injunction that would prevent Abbott from being able to claim the patents at issue but was unsuccessful in the district court and appealed to the Federal Circuit.⁷² At this juncture, Abbott and Zenith entered into an agreement that set aside both the delisting claim and the infringement counterclaim.⁷³ The agreement also recognized the validity of the patents Abbott held and acknowledged that if Zenith had pursued the distribution of its proposed generic,⁷⁴ Zenith would have infringed upon Abbott’s patents.⁷⁵ Further, Zenith agreed not to market or sell any pharmaceutical containing the patented substance.⁷⁶ Zenith would be held to the agreement until either a different generic manufacturer introduced a similar product or Abbott’s patent expired.⁷⁷ In addition, Zenith agreed to refrain from giving, selling, or otherwise transferring its rights relating to the drug at issue.⁷⁸ Zenith also waived its right to assist any other generic manufacturer in gaining FDA approval of a similar generic drug.⁷⁹ Finally, Zenith agreed not to assist any other entity in opposing Abbott’s patent involving the drug at issue.⁸⁰

Under the agreement, Abbott would pay Zenith based on an established schedule: \$3 million upon entering into the agreement, \$3 million three months later, and \$6 million every three months until

69. A patent is delisted when it is removed from the FDA Orange Book. FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 44 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

70. *Valley Drug*, 344 F.3d at 1299.

71. *Id.*

72. *Id.* at 1299–1300.

73. *Id.* at 1300.

74. Zenith sought to create a generic form of a terazosin-based drug known as Hytrin. *Id.* at 1296. Hytrin relaxes blood vessels in the bladder and prostate allowing urine to flow freely. *Hytrin*, DRUGS.COM, <http://www.drugs.com/hytrin.html> (last visited Oct. 26, 2013) [hereinafter *Hytrin Information*]. It is generally prescribed to treat the symptoms of an enlarged prostate and it can be effective in treating hypertension. *Id.*

75. *Valley Drug*, 344 F.3d at 1300.

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

March 1, 2000, or until the agreement was no longer enforceable.⁸¹ In the event that a different manufacturer completed a successful ANDA and sold a similar drug, the total payments would be halved.⁸² Abbott also gave up its right to sue Zenith for future infringement of the patent if Zenith behaved in accordance with the agreement.⁸³

The second agreement at issue in *Valley Drug* was between Abbott and Geneva Pharmaceuticals (Geneva).⁸⁴ This agreement, in part, mirrored the Abbott-Zenith agreement.⁸⁵ Notably different, however, was a clause stating that Geneva would be able to introduce its drug into the market if it received a valid “final judgment[,] from which no further appeal could be taken,” that their proposed drug would not infringe upon Abbott’s existing patents.⁸⁶

Geneva agreed not to enter into the market with any product containing the drug at issue in any form.⁸⁷ This prohibition would remain in effect until either (1) Abbott’s patent expired; (2) another company debuted a similar generic drug; (3) Geneva received a valid final judgment that its proposed generic product would not infringe on Abbott’s existing patent; or (4) a court declared Abbott’s existing patent invalid.⁸⁸ Geneva also agreed not to sell or otherwise transfer its rights under the established ANDA (including the right to the 180-day exclusivity period).⁸⁹ In addition, Geneva agreed to oppose any future attempt by a generic manufacturer to pick up where Geneva left off and continue to seek approval for a similar generic drug.⁹⁰ Geneva further agreed to assist Abbott in seeking an extension of the stay on the FDA’s approval of the Geneva ANDA.⁹¹

81. *Valley Drug*, 344 F.3d at 1300.

82. *Id.*

83. *Id.*

84. *Id.* Geneva sought to create a generic version of the Abbott-created Hytrin. *Id.* at 1296.; *Hytrin Information*, *supra* note 74.

85. *See Valley Drug*, 344 F.3d at 1300.

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. *Valley Drug*, 344 F.3d at 1300.

In exchange for Geneva's waiver of rights associated with its proposed drug, Abbott agreed to shell out \$4.5 million every month until either another generic manufacturer brought a similar product into the market or Abbott successfully argued its infringement claim in district court.⁹² Conversely, if Geneva won the day in district court, Abbott's payments would go into escrow pending an appeal.⁹³ Abbott maintained the right to cease its payments after February 8, 2000 if no other manufacturer had introduced a generic product into the market.⁹⁴

Overall, the lower court concluded that "[t]he essence of the [a]greements . . . was to dissuade[] Geneva and Zenith from marketing the first generic [drug of its type] in the United States for an indefinite period [and] eliminat[e] the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim."⁹⁵ This characterization of the "essence" of the agreements led to the lower court's finding that the agreements were per se unlawful.⁹⁶ The Eleventh Circuit rejected the lower court's ruling.⁹⁷

The Eleventh Circuit noted that the lower court overlooked a critical fact surrounding the agreements—Abbott owned a patent.⁹⁸ Faced with determining the validity of payments from a brand-name drug manufacturer to a would-be generic competitor to stay out of the market, the Eleventh Circuit adopted an analysis of reverse payment settlements that took into account the exclusionary power of the

92. *Id.*

93. *Id.*

94. *Id.* at 1300–01.

95. *Id.* at 1302 (quoting *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1349 (S.D. Fla. 2000)).

96. *Id.* The lower court identified three elements of the Geneva agreement that were anticompetitive: (1) Geneva's agreement not to market or sell its generic drug until the contract ran its course; (2) Geneva's promise not to sell its rights associated with the ANDA; and (3) Geneva's promise to aid Abbott in opposing any other generic manufacturer's attempt to market a drug based on Geneva's ANDA. *Id.* at 1301–02. The lower court also identified three anticompetitive elements of the Zenith agreement: (1) Zenith's agreement to dismiss its pending delisting claim; (2) Zenith's promise not to aid any other company's challenge to the patent at issue; and (3) Zenith's promise not to market or sell its generic drug until the agreement terminated. *Id.* at 1302.

97. The court reversed because a decision regarding antitrust violation would be "premature" without looking to the specifics of both the patent and the agreement. *Valley Drug*, 344 F.3d at 1304.

98. *Id.*

patent.⁹⁹ The court looked to see if, by entering into the agreement at issue, the patent holder went beyond the exclusionary power derived from the patent.¹⁰⁰ In what came to be known as the “scope of the patent” test, the court analyzed the patent itself and determined its outer limits.¹⁰¹ The court then examined the terms of the reverse payment agreement.¹⁰² The outer limits of the patent served as the boundary for the Eleventh Circuit’s analysis.¹⁰³ The terms of the agreement were then measured against the patent.¹⁰⁴ If the terms of the agreement went beyond the boundaries set forth by the patent, the agreement would be a restraint of trade and violate the Sherman Act.¹⁰⁵

The court parsed out the specifics of the patent to determine the extent to which it precluded use by others and looked to see what kind of exclusion it allowed for.¹⁰⁶ The court then turned to the agreements at issue.¹⁰⁷ Again, the court parsed out the agreements in order to understand the extent of restraint under the proposed settlements.¹⁰⁸ During both inquiries, the court paid particular attention to the generic drug’s potential entry date.¹⁰⁹ The court determined that, because the patent would preclude the generic’s market entry until October 2014 and the agreement did not go beyond that date, the agreements were not anticompetitive and thus not a violation of the Sherman Act.¹¹⁰

99. *Id.*

100. *Id.* at 1304–05.

101. *Id.*

102. *Id.* at 1305.

103. *Valley Drug*, 344 F.3d at 1304.

104. *Id.* at 1305.

105. *Id.* at 1304–05.

106. *Id.* at 1305.

107. *Id.* at 1305–06.

108. *Id.*

109. *Valley Drug*, 344 F.3d at 1305–06.

110. *Id.* at 1305. Based on the terms of the Zenith agreement, market entry could actually occur before the expiration of the patent. *Id.*

2. Joblove v. Barr Labs, Inc.

The scope of the patent test has been favored by a majority of courts tasked with assessing reverse payment settlements in the context of the pharmaceutical industry.¹¹¹ One such court was the Second Circuit in *Joblove v. Barr Labs, Inc.*¹¹² In *Joblove*, Barr Laboratories (Barr) filed an ANDA with the FDA and Paragraph IV Certification with the brand-name patent holder, AstraZeneca.¹¹³ AstraZeneca filed suit against Barr claiming that the generic medication Barr intended to produce infringed upon AstraZeneca's patent.¹¹⁴ A district court found the patent to be invalid and thus marketing of the generic medication could proceed.¹¹⁵ AstraZeneca filed an appeal.¹¹⁶

With the appeal still pending, Barr and AstraZeneca entered into a settlement agreement.¹¹⁷ In exchange for \$21 million and the opportunity to sell the brand-name version of the drug at issue under its own name,¹¹⁸ Barr agreed to change its method of certification from Paragraph IV to III and not enter the market until AstraZeneca's patent expired.¹¹⁹ AstraZeneca also agreed to pay Barr's raw material

111. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012); *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *Joblove v. Barr Labs, Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 212–13 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005); *Valley Drug*, 344 F.3d at 1308. This Note discusses the Second Circuit's decision in *In re Tamoxifen* to illustrate the way in which courts adopting the scope of the patent test treat reverse payment settlements and to highlight the amounts of money exchanged during these settlements.

112. *Joblove*, 466 F.3d at 207. Several entities under the AstraZeneca corporate umbrella were implicated in this case. *Id.* at 190. For clarity, they will all be referred to as AstraZeneca. The Eastern District of New York dismissed a class action antitrust complaint filed by private plaintiffs against AstraZeneca and Barr claiming that their agreements violated the Sherman Act. *Id.* at 196–97. Plaintiffs appealed to the Second Circuit. *Id.* at 198.

113. *Id.* at 193.

114. *Id.* The drug at issue, Tamoxifen, is used to block a specific type of estrogen in women with breast cancer. *Tamoxifen*, DRUGS.COM, <http://www.drugs.com/tamoxifen.html> (last visited Oct. 26, 2013). Certain cancers require this estrogen to grow and spread. *Id.*

115. *Joblove*, 466 F.3d at 193.

116. *Id.*

117. *Id.*

118. *Id.* at 193. Because Barr could sell the drug at issue under its own name, little incentive remained to continue researching and developing its proposed generic.

119. *Id.* at 193–94. AstraZeneca's patent expired in 2002. *Id.* at 194. While a Paragraph IV Certification would require an inquiry into AstraZeneca's patent to determine validity and the extent to

supplier \$9.5 million upfront and \$35.9 million over the next ten years.¹²⁰ If another generic manufacturer or marketer succeeded—through a separate lawsuit—in proving that the proposed generic did not infringe on AstraZeneca’s patent, or the patent was invalid, Barr could proceed as though the agreement never took place.¹²¹

Like the Eleventh Circuit in *Valley Drug*, the Second Circuit held that the mere presence of reverse payment settlements did not constitute per se violations of the Sherman Act.¹²² The allegations of antitrust violation in *Joblove*, however, presented a second question: did the large amount of money exchanged between Barr and AstraZeneca kick the settlement agreement into the realm of an unreasonable restraint of trade?¹²³ Specifically, *Joblove* asserted that as a result of settlement payments, AstraZeneca would actually lose more than it would if Barr’s generic drug entered the market.¹²⁴ Conversely, Barr stood to gain much more from the settlement than it would have if its drug hit the market.¹²⁵ *Joblove* pointed to the unbalanced consideration resulting from the large payment to indicate a violation of the Sherman Act.¹²⁶ While the court noted that these types of settlements do raise questions, they refused to break away from the scope of the patent test set forth by the Eleventh Circuit in *Valley Drug*.¹²⁷ Thus, even though the bargained-for consideration was questionable when compared to projected profits and losses, because the agreement did not exceed the scope of the patent there was no prima facie evidence of an unreasonable restraint

which the generic would have infringed upon the patent, a Paragraph III Certification indicates that the generic manufacturer would only seek market entry after the brand-name patent expired. Hatch-Waxman Act, 21 U.S.C. § 355(j) (2012); *FAMILIES USA*, *supra* note 40, at 2.

120. *Joblove*, 466 F.3d at 194. Because the production and marketing of the proposed generic would have benefitted not only Barr, but Barr’s suppliers, AstraZeneca also made a substantial payout to Barr’s raw material supplier.

121. *Id.* Once litigation began, the plaintiffs also argued that Barr “understood” that, as part of the agreement, it must attempt to block other manufacturers from releasing a generic into the market through any exclusionary power it retained from being the first to file a Paragraph IV Certification. *Id.*; *see supra* note 56 (discussing the exclusivity period).

122. *Joblove*, 466 F.3d at 206.

123. *Id.* at 208.

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.* at 212–13.

of trade.¹²⁸ In addition to adopting the scope of the patent test, the court further noted that unless there was something inherently wrong with the patent—for example, it was obtained through fraud—or if the suit challenging the validity of the patent was without merit, there is no anticompetitive element to the agreement.¹²⁹

*B. Quick-Look Rule of Reason: In re K-Dur*¹³⁰

K-Dur involved a challenge to the settlement of a patent infringement claim filed by Schering-Plough (Schering) against Upsher-Smith Laboratories (Upsher).¹³¹ Schering, a brand-name drug manufacturer, owned a patent for a timed-release coating that covered certain medications.¹³² Upsher, a generic manufacturer, wanted to create a generic version of this coating and thus began the ANDA process.¹³³ Subsequently, Upsher filed a Paragraph IV Certification with the FDA and Schering.¹³⁴ Schering then filed suit for patent infringement.¹³⁵ Hours before the scheduled release of a ruling on Schering and Upsher's patent infringement claim, the parties entered into a settlement agreement.¹³⁶

128. *Joblove*, 466 F.3d at 213.

129. *Id.*

130. The Third Circuit's ruling in *In re K-Dur* was not the first time the terms of the agreement between Schering and Upsher came under fire. See *Schering-Plough v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005). As one of the agencies responsible for administering the Sherman Act, the FTC has a right to enforce compliance by filing suits against alleged violators. Foer, *supra* note 28, at 622. When the FTC caught wind of the agreement between Schering and Upsher, it filed suit against both companies. *Schering-Plough*, 402 F.3d at 1061. The case first went before an Administrative Law Judge (A.L.J.) who ruled in favor of Schering and Upsher. *Id.* at 1061. The FTC appealed and the A.L.J. decision was overruled. *Id.* at 1061–62. Schering and Upsher appealed to the Eleventh Circuit. *Id.* The Eleventh Circuit employed the scope of the patent test that it first developed in *Valley Drug*. *Id.* at 1068. The court reversed and the agreement between Schering and Upsher stood. *Id.* at 1075–76.

131. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 202 (3d Cir. 2012). Private plaintiffs filed antitrust suits against Schering-Plough and Upsher-Smith Laboratories. *Id.* The plaintiffs alleged that the settlement of a patent infringement suit between the defendants violated the Sherman Act. *Id.* at 208. A district court granted Schering and Upsher's motions for summary judgment. *Id.* Plaintiffs appealed. *Id.* at 202.

132. *Id.* at 203. K-Dur is a supplement used to treat hypokalemia, a condition that causes low levels of potassium in patients. *K-Dur*, DRUGS.COM, <http://www.drugs.com/k-dur.html> (last visited Oct. 26, 2013).

133. *In re K-Dur Antitrust Litig.*, 686 F.3d at 205.

134. *Id.*

135. *Id.*

136. *Id.*

Although Upsher did not admit that Schering's patent was valid or that release of the generic infringed upon the patent, it nonetheless agreed to withhold its product from the market until September 1, 2001, at which time Upsher could market a generic version of the drug at issue.¹³⁷ In addition, Upsher gave Schering several licenses for smaller, less prominent generics.¹³⁸ For all of this, Schering handed \$60 million to Upsher.¹³⁹ Opponents of the settlement agreement contended that Schering and Upsher used the licenses of smaller products to distract from the true reason the \$60 million changed hands.¹⁴⁰ During the course of litigation, opponents of the settlement agreement alleged that Schering paid millions of dollars to Upsher for one reason: to avoid competition.¹⁴¹

Beginning its analysis of the anticompetitive nature of the reverse payment settlement, the Third Circuit outright rejected the scope of the patent test.¹⁴² Instead, the court required that the finder of fact look to the presence of a reverse payment settlement in the pharmaceutical context as *prima facie* evidence of an unreasonable restraint of trade.¹⁴³ The resulting test is referred to as the "quick look rule of reason."¹⁴⁴ The rule embodies the "economic realities" of the pharmaceutical industry and looks at the effects of reverse payment settlements.¹⁴⁵ In practice, this creates the presumption of an antitrust violation when reverse payment settlements take place between a generic and brand-name drug manufacturer.¹⁴⁶ The parties may then rebut this presumption by showing that the payment was not made in exchange for delayed entry or that the payment actually encourages

137. *Id.*

138. *Id.*

139. *In re K-Dur Antitrust Litig.*, 686 F.3d at 205.

140. *Id.* at 205–06.

141. *Id.*

142. *Id.* at 218. The court also discussed the fact that their ruling may have a negative impact on a party's willingness to settle patent litigation. *Id.* at 217–18. Also, they noted that their decision contravenes a general judicial policy toward settling as opposed to fully litigating a case. *Id.* at 217. However, the court noted that, even in light of the judicial policy toward settling, it is much more egregious to blatantly ignore the purpose and history of a regulatory framework like Hatch-Waxman. *Id.*

143. *Id.* at 218.

144. *Id.*

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

146. *See id.*

competition.¹⁴⁷ Because the Third Circuit determined that a reverse payment settlement occurred between Schering and Upsher, which resulted in delayed market entry, the court reversed the lower court's decision and remanded the case to be assessed under a quick-look rule of reason.¹⁴⁸

III. A PRESCRIPTION FROM THE HIGH COURT: *FTC v. ACTAVIS*

In 1999, Solvay Pharmaceuticals (Solvay) filed a New Drug Application in order to begin the process of introducing a generic version of a drug called AndroGel,¹⁴⁹ which the FDA approved in 2000.¹⁵⁰ Solvay obtained the “relevant patent” in 2003.¹⁵¹ In that same year, generic pharmaceutical manufacturers Actavis¹⁵² and Paddock Laboratories (Paddock)—seeking to introduce generic forms of AndroGel—filed ANDAs as permitted by Hatch-Waxman.¹⁵³ Both Actavis and Paddock submitted Paragraph IV Certifications stating that Solvay's patent was invalid and that their drugs did not infringe upon it.¹⁵⁴ Alongside Paddock was Par Pharmaceutical (Par), which did not file an ANDA, but agreed to assist Paddock in funding the patent litigation in return for a share of any potential profits from a successful generic drug.¹⁵⁵

In turn, Solvay sued both Actavis and Paddock—two of the generic manufacturers—for patent infringement.¹⁵⁶ Despite the fact that just thirty months later the FDA approved Actavis's generic product, in 2006 all parties settled.¹⁵⁷ “Under the terms of the settlement [agreement,] Actavis agreed that it would not bring its

147. *Id.*

148. *Id.*

149. AndroGel is a topical solution that replaces or supplements testosterone in men, which results from a lack of natural testosterone. *AndroGel*, DRUGS.COM, <http://www.drugs.com/androgel.html> (last visited Oct. 26, 2013).

150. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013).

151. *Id.*

152. Actavis was formerly known as Watson Pharmaceuticals. *Id.*

153. *Id.* at 2228.

154. *Id.* at 2229.

155. *Id.*

156. *Actavis, Inc.*, 133 S. Ct. at 2229.

157. *Id.*

generic to market until August 31, 2015, 65 months before Solvay's patent expired[,]” unless a third party marketed a generic prior to the agreed upon date.¹⁵⁸ Additionally, Actavis agreed to promote AndroGel to urologists.¹⁵⁹ Solvay reached similar agreements with Paddock and Par.¹⁶⁰

As a result of the agreements, Solvay agreed to pay \$12 million to Paddock; \$60 million in total to Par; and a whopping \$19–\$30 million annually, for nine years, to Actavis.¹⁶¹ According to the companies, these payments represented “compensation for other services the generics promised to perform.”¹⁶²

On January 29, 2009, the FTC filed suit against all parties to these settlements.¹⁶³ The district court, relying on Eleventh Circuit precedent by way of *Valley Drug*, dismissed the case, holding that the FTC's allegations did not constitute a violation of antitrust law.¹⁶⁴ On appeal, the FTC again met defeat.¹⁶⁵ In affirming the district court, the Eleventh Circuit reiterated its mantra regarding reverse payment settlements: “[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”¹⁶⁶ Despite recognizing that antitrust law prohibits competitors from paying one another to stay out of the relevant markets, the court hung its hat on the strong public

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

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

163. *Id.* The FTC alleged a violation of § 5 of the Federal Trade Commission Act. *Id.* Section 5 of the Act enables the FTC to pursue and “prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.” 15 U.S.C. § 45(a)(2) (2013). Moreover, violations of the Sherman Act fall within the scope of Section 5 of the Act. *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 454 (1986).

164. *Actavis*, 133 S. Ct. at 2230; *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010) (dismissing the FTC's claim due to failure to establish an antitrust violation).

165. *Actavis*, 133 S. Ct. at 2230; *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012) (affirming the district court's dismissal of the FTC's complaint).

166. *Watson*, 677 F.3d at 1312 (citing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1307–09 (11th Cir. 2003); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005); *Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3d 1227, 1234 (11th Cir. 2005)).

policy favoring settlement of disputes.¹⁶⁷ Capitalizing on the discord among the federal circuit courts regarding the treatment of reverse payment settlements, the FTC next turned to the Supreme Court.¹⁶⁸

A. *Scope of the Patent Postmortem*

In its evaluation of the varying approaches to judicial treatment of reverse payment settlements, the Supreme Court first addressed the validity of the scope of the patent test.¹⁶⁹ Specifically, the Court noted that by simply stating what the “holder of a valid patent could do does not by itself answer the antitrust question.”¹⁷⁰ Additionally, the majority noted that while a valid patent does empower its owner to exclude others, “an *invalidated* patent carries with it no such right.”¹⁷¹ Moreover, even a valid patent will not permit its owner “to exclude products or processes that do not actually infringe” the patented product.¹⁷² The Court recognized that the purpose of the underlying litigation “in [reverse payment settlement cases] put[s] the patent’s validity at issue,” and “[t]he parties’ settlement ended that litigation.”¹⁷³ Because of the importance of both patent and antitrust policy “in determining the scope of the patent monopoly,”¹⁷⁴ the Court held that simply because one of the parties holds a patent for the brand-name drug the agreement is not “immunize[d] . . . from antitrust attack.”¹⁷⁵

B. *Striking a Balance: Settlements or Competitive Marketplaces?*

Next, the Court addressed the Eleventh Circuit’s use of “general legal policy favoring the settlement of disputes” in support of its holding.¹⁷⁶ Although the underlying patent litigation may be costly

167. See *Watson*, 677 F.3d at 1313–14.

168. *Actavis*, 133 S. Ct. 2223.

169. *Id.* at 2230–31.

170. *Id.*

171. *Id.* at 2231.

172. *Id.*

173. *Id.*

174. *Actavis*, 133 S. Ct. at 2231 (internal quotations omitted).

175. *Id.* at 2230.

176. *Id.* at 2234. See *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1313–14 (11th Cir. 2012).

and time consuming, the Court noted five considerations that support the majority's holding.¹⁷⁷

The Court first noted “the specific restraint at issue has the ‘potential for genuine adverse effects on competition.’”¹⁷⁸ Specifically, reverse payment settlements result in incentives for generic manufacturers to stay out of the market, thereby leaving little to no marketplace competition for the brand-name manufacturer.¹⁷⁹ The large-sum payments to generic manufacturers and the continued marketplace dominance of brand-name drugs benefit all *except* the consumer, who must now continue to foot the bill for high-priced medication.¹⁸⁰

Second, the anticompetitive effects of the agreements may be “unjustified.”¹⁸¹ The Court reiterated the potential for the reverse payment settlement to serve as an avenue for avoiding costly litigation.¹⁸² But, standing alone, “that possibility does not justify dismissing the [antitrust] complaint.”¹⁸³ Based on the majority's holding, 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.”¹⁸⁴

Third, in the context of the reverse payment settlement, the brand-name manufacturer has the power to “charge prices higher than the competitive level.”¹⁸⁵ The majority noted that the strongest indicator of that power is the brand-name manufacturer's ability to pay the generic manufacturer to stay out of the market.¹⁸⁶ The Court also cited “studies showing that reverse payment agreements are

177. *Id.* at 2234–37.

178. *Id.* at 2234 (quoting *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460–61 (1986)).

179. *Id.* at 2234–35.

180. *Actavis*, 133 S. Ct. at 2235 (“The patentee and the challenger gain; the consumer loses.”).

181. *Id.* at 2235–36.

182. *Id.* at 2236.

183. *Id.*

184. *Id.*

185. *Id.*

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

associated with the presence of higher-than-competitive profits”¹⁸⁷

Fourth, allowing the FTC or a private plaintiff to pursue an antitrust claim is not necessarily overly burdensome.¹⁸⁸ The Court noted that the Eleventh Circuit’s holding—while avoiding patent litigation—”throws the baby out with the bath water[.]”¹⁸⁹ The Court explained that parties would not need to litigate the patent claims in every case because “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”¹⁹⁰

Lastly, the threat of antitrust attack against the reverse payment settlement does not preclude settlement entirely.¹⁹¹ Parties would be free to settle in a variety of other ways.¹⁹² For example, the brand-name manufacturer could allow “the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”¹⁹³ The Court states that while “parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons?”¹⁹⁴ If it comes to light that the reason for the settlement is to avoid competition, the settlement is likely a violation of antitrust law.¹⁹⁵

C. *No Quick-Look for Reverse Payment Settlements*

Despite the FTC’s ardent plea for the quick-look rule of reason, the Court took a different approach.¹⁹⁶ Looking to prior Supreme Court precedent, the majority noted that presumptive rules, like the quick-

187. *Id.*

188. *Id.*

189. *Id.*

190. *Id.* at 2236–37.

191. *Id.* at 2237.

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

193. *Id.*

194. *Id.*

195. *Id.*

196. *See id.*

look rule of reason, should only be called upon in cases where “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”¹⁹⁷ The Court held that pharmaceutical reverse payment settlements did not rise to a level of obvious danger warranting a presumptive rule.¹⁹⁸ The anticompetitive effects of a particular reverse payment settlement depend on the size of the payment, the relative cost of litigation, whether the payment also represents consideration for other goods or services, the industry in which the payment is taking place, as well as other circumstances surrounding the settlement.¹⁹⁹ Because of these “complexities,” the Court concluded that a presumptive rule would be inappropriate in light of prior treatment of similar cases.²⁰⁰ Accordingly, while the FTC or any private plaintiff need not litigate the validity of the patent at issue, a party alleging an antitrust violation in the reverse payment settlement context will be unaided by a presumption of anticompetitive effects.²⁰¹

IV. TOUGH MEDICINE: A CALL FOR MORE AGGRESSIVE TREATMENT

While the *Actavis* ruling cannot, by any stretch of the imagination, be termed a total loss, the Court did, however, miss the mark by failing to hand the FTC the tools it needs to properly combat reverse payment settlements. Of course, through the adoption of the rule of reason analysis, the FTC is now at least able to survive a motion to dismiss which, prior to the Third Circuit’s *K-Dur* ruling, proved nearly impossible.²⁰² The remainder of this Note discusses why the Supreme Court fell short in its *Actavis* ruling and then explains why the Third Circuit’s approach in *K-Dur* should have been adopted.

197. *Id.* (quoting *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999) (internal quotation marks omitted)).

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

199. *Id.*

200. *Id.*

201. *See id.*

202. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d Cir. 2012).

A. A “Supreme” Misdiagnosis

The Supreme Court’s rationale for refusing to adopt the quick-look rule of reason approach is rooted in prior Court precedent.²⁰³ In *California Dental Association v. FTC*, the Court held that “quick-look analysis carries the day when the great likelihood of anticompetitive effects can easily be ascertained.”²⁰⁴ Specifically, the Court stated an abbreviated or quick-look analysis is appropriate when “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”²⁰⁵

Pharmaceutical reverse payment settlements, contrary to the Court’s determination, “meet [these] criterion.”²⁰⁶ These settlements involve, as the Court states, “large, unjustified” payments from a brand-name manufacturer to a generic manufacturer that then agrees to refrain from entering the market, leaving no competition whatsoever for the patent-holder.²⁰⁷ This notion is contrary to the principles of antitrust.²⁰⁸ If a reverse payment settlement results in a would-be competitor delaying market entry, competition is decreased—if not eliminated—and the consumer is left to pay the (high) price. This arrangement between potential competitors alone warrants the burden-shifting framework provided by the quick-look rule of reason.

B. The Better Course of Treatment: A Quick-Look Rule of Reason

The Third Circuit discarded the scope of the patent test and instead adopted a quick-look rule of reason test.²⁰⁹ The court’s decision in *In re K-Dur* does not specifically detail the factors of the analysis;

203. See, e.g., *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999).

204. *Id.*

205. *Id.* See also, e.g., *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 98–99 (1984).

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

207. *Id.*

208. See *supra* Part I.B.

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

however, the basic premise is clear.²¹⁰ The rule of reason analysis, in the context of pharmaceutical antitrust, provides a strong base upon which to build a test for reverse payment settlements and their effects on marketplace competition. The analysis looks to the unique characteristics of the particular industry as well as the actual or probable effects of the agreement.²¹¹

1. Doctor's Notes: Applying the Quick-Look Rule of Reason

Reverse payment settlements must be evaluated in the context of the pharmaceutical industry. As history has shown—and Hatch-Waxman sought to rectify—if left unchecked, the prices of pharmaceuticals will rise and become increasingly inaccessible because of high costs.²¹² This economic reality is true of most products. Thus, it becomes increasingly important to look to agreements that may circumvent Hatch-Waxman with a keen eye. If these agreements continue to pervade the pharmaceutical world to the extent the FTC predicts, the ramifications are clear.²¹³ The generic versions of these expensive drugs serve to drive down and stabilize prices through marketplace competition.²¹⁴ If these generic drugs are kept off the market, the effects are all too predictable: expensive, inaccessible medications.

The quick-look rule of reason would treat any payment from a brand-name pharmaceutical company to a generic manufacturer that results in a delay of market entry as prima facie evidence of an unreasonable restraint of trade and a violation of antitrust law.²¹⁵ This does not, however, leave pharmaceutical companies without recourse.²¹⁶ As discussed previously, the presumption of a violation of antitrust law is rebuttable.²¹⁷ Parties can avoid FTC sanctions by

210. *Id.*

211. *See id.*

212. FAMILIES USA, *supra* note 40, at 1.

213. *See* Leibowitz, *supra* note 3, at 2; *Anticompetitive Patent Settlements*, *supra* note 7, at 14–20 (discussing the economic impact of the *Schering-Plough* and *Joblove* cases).

214. FAMILIES USA, *supra* note 40, at 1.

215. *In re K-Dur Antitrust Litig.*, 686 F.3d at 207.

216. *Id.* at 218.

217. *Id.*

showing either that the money exchanged between companies was not for a prohibited purpose—for example, delayed market entry—or that the settlement is actually a way to increase competition.²¹⁸

2. *Policy Steroids: The Affordable Care Act*

Congress has adopted, with the Supreme Court's approval, a massive overhaul of the healthcare industry.²¹⁹ To remain competitive in the marketplace, insurance companies must compete head-to-head with one another in statewide insurance exchanges.²²⁰ The congressional end game for the ACA was to increase access to affordable healthcare for all citizens.²²¹ To continue condoning these reverse payment settlements would work against the objectives of the ACA and impede the momentum built by this revolutionary piece of legislation.²²²

The particulars of the ACA cannot, of course, be directly applied to reverse payment settlements. However, the spirit and overall energy of the Act—competition and increased access to affordable healthcare—can be extrapolated and extended to legal issues affecting the healthcare industry. Specifically, the competition encouraged by the ACA should be kept in the back of the Supreme Court's mind when deciding how to treat reverse payment settlements between a brand-name and generic drug manufacturer. These entities are responsible for the inception, fabrication, and distribution of medication. Although it is not the only aspect of healthcare, medication is pivotal. It logically follows that a country pushing for affordable, accessible healthcare would insist that the same treatment applied to insurance companies through the ACA should apply to pharmaceutical producers.

218. *Id.*

219. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). *See* Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2571–72 (2012).

220. Ctrs. for Medicaid & Medicare Servs., *supra* note 61.

221. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); Elder Justice Act, Pub. L. No. 111-148, §§ 6701–03, 124 Stat. 119 (2010); Ctrs. for Medicaid & Medicare Servs., *supra* note 61.

222. *See supra* Part I.D.

CONCLUSION

It goes without saying that the current state of healthcare in the United States is in flux. The adoption of the ACA sent shockwaves through the nation. Will citizens of the United States finally have access to quality, affordable healthcare? Only time will tell. In the meantime, reverse payment settlements present a problem for each and every citizen who presently uses prescription drugs, or will in the future. While the Supreme Court, in discarding the scope of the patent test, moves us one step closer to affordable medications and generic alternatives, the Court could have—and should have—done more. These agreements stand in direct opposition to the history and purpose of the Hatch-Waxman Act and contravene the spirit of the ACA. Unlikely to overturn its *Actavis* ruling any time in the near future, it is up to the lower courts to establish the guidelines for treatment of reverse payment settlements. But the onus is not on lower courts alone. Members of Congress have an opportunity, through legislation and increased regulations, to stand up for the consumer and demand, on behalf of their constituents, a competitive pharmaceutical marketplace with affordable medications for all.²²³

223. Such action on the part of the legislature is not uncommon. *See, e.g.*, ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553 (overruling *Sutton v. United Air Lines, Inc.*, 527 U.S. 471 (1999) and *Toyota Motor Mfg., Ky. v. Williams*, 534 U.S. 184 (2002)).

