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Reverse Payment Settlements: The Ongoing Dilemma After *FTC v. Actavis*

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REVERSE PAYMENT SETTLEMENTS: THE ONGOING DILEMMA AFTER *FTC V. ACTAVIS*

INTRODUCTION

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act—also known as the Hatch-Waxman Act[1]—in an effort to lower the cost of pharmaceuticals by promoting competition in the generic drug market and incentivizing pharmaceutical innovation.[2] The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act[3] and provided an expedited process for the entry of generic drugs into the marketplace.[4] An unintended result of the Hatch-Waxman Act is the phenomenon of reverse payment settlements.[5] These settlements arise out of patent infringement suits brought by brand-name drug manufacturers against generic drug manufacturers that are trying to enter the market through the expedited process provided for under the Hatch-Waxman Act.[6] The typical reverse payment settlement involves payment by the brand-name drug manufacturer to the generic drug manufacturer in exchange for a promise to delay the release of the generic version of a given drug to the marketplace.[7] These settlements are often coined "pay-for-delay" settlements, particularly by those who oppose them such as the Federal Trade Commission (the FTC).[8]

The practice of reverse payment settlements has both its opponents and proponents. Reverse payment settlements are highly opposed by the FTC, wholesale and retail pharmacies, and consumers.[9] By blocking entry of generic drug manufacturers and thereby eliminating competition, the FTC claims that these settlements raise potential antitrust violations under the

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1. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at scattered sections of 21 U.S.C. and 35 U.S.C.); Colleen Kelly, Article, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011).

2. H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

3. Kelly, *supra* note 1, at 417.

4. *See* 21 U.S.C. § 355 (2012).

5. *See* Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 283 (2011); Francis P. Newell & Jonathan M. Grossman, *Increased Scrutiny of Reverse Payment Settlements; Recent Cases in E.D. of PA and 2nd Circuit Suggest Change May Be Ahead for Pharma Clients*, LEGAL INTELLIGENCER, June 22, 2010, at LIT7.

6. *See* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494–95 (2007).

7. *See id.* (defining various types of reverse payment settlements).

8. *E.g.*, FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010) [hereinafter 2010 FTC STUDY], *available at* 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.

9. *Id.*; *see also In re* K-Dur Antitrust Litig., 686 F.3d 197, 202 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

Sherman Act, which prohibits certain restraints on trade.[10] Furthermore, because of the delayed release of generic versions of drugs, reverse payment settlements have a significant financial impact on the consumers of pharmaceutical products.[11] Due to these concerns, among others, many reverse payment settlements lead to antitrust litigation.[12] Proponents of reverse payment settlements argue that these settlements help avoid hefty costs that arise from lengthy litigation[13] and can promote competition by leading to earlier generic market entry than would have been allowed under the brand-name drug patent.[14]

Reverse payment settlements present issues about how to deal with the intersection of patent law and antitrust law and balance the concerns of the various stakeholders. Recognizing this dilemma, Congress has attempted to resolve the problems caused by reverse payment settlements for several years through two pending bills.[15] One legislative attempt is the Preserve Access to Affordable Generics Act bill, which would create a presumption that reverse payment settlements are unlawful[16] and would grant broad authority to the FTC to regulate these settlements.[17] The other major legislative attempt is the Protecting Consumer Access to Generic Drugs Act bill proposed by Congressmen Rush and Waxman.[18] This bill would prohibit the generic drug manufacturer from receiving anything of value in exchange for delay or other inactivity in the market.[19]

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10. *See* 2010 FTC STUDY, *supra* note 8, at 3, 5; *see also* 15 U.S.C. § 1 (2012); Jon Leibowitz, Chairman, FTC, Address at the Center for American Progress, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution) 4 (June 23, 2009), *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 (arguing that reverse payment settlements are anticompetitive).

11. 2010 FTC STUDY, *supra* note 8, at 2.

12. *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190 (2d Cir. 2006), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1295–96 (11th Cir. 2003).

13. Newell & Grossman, *supra* note 5, at LIT7.

14. Holman, *supra* note 6, at 495 (explaining how certain reverse payment settlements "can promote competition by providing a guaranteed reduction in the effective patent term that would not have occurred absent the patent challenge").

15. Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013); Protecting Consumer Access to Generic Drugs Act of 2013, H.R. 3709, 113th Cong. (2013); Tania Khatibifar, Note, *The Need for a Patent-Centric Standard of Antitrust Review to Evaluate Reverse Payment Settlements*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1351, 1355 n.17 (2013).

16. S. 214 § 28(a)(2).

17. *Id.* § 28(e).

18. H.R. 3709.

19. *Id.* § 2(a).

In addition to the public policy concerns expressed by executive agencies, consumers, and congressmen, reverse payment settlements divided the circuit courts for years until the Supreme Court granted certiorari to resolve the split in *FTC v. Actavis*.[20] The Court adopted the "rule of reason" test, which requires courts to determine whether the reverse payment settlement in question unreasonably restrains competition.[21] Under the "rule of reason" test, the Court held that "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."[22] However, the Court left many questions unanswered,[23] which will likely result in significant discrepancies amongst the lower courts.

While the Court's efforts were an improvement for invoking antitrust scrutiny, a major problem with reverse payment settlements remains—the underlying patents of brand-name manufacturers are not being examined on their merits.[24] This latest action by the Court represents a swing of the pendulum away from protecting the exclusionary rights provided by a patent under the "scope of the patent" test, toward enforcing stricter antitrust scrutiny under the "rule of reason" test.[25]

This Note argues that the Supreme Court, by adopting the "rule of reason" test, failed to achieve the proper balance between pharmaceutical patent rights and concerns about the anticompetitive effects of reverse payment settlements. While the Court addressed the antitrust concern by invoking antitrust scrutiny that had been lacking, the Court failed to sufficiently protect the property interests and economic incentives that guide the pharmaceutical industry, which might ultimately stifle competition. Consequently, the balance intended by the Hatch-Waxman Act has not been achieved and must be resolved. Part I will present a background on the generic drug FDA approval process, how this process creates the reverse payment settlement phenomenon, the arguments for and against reverse payment settlements, and the antitrust standards that are typically applied by the courts when an agreement raises antitrust concerns. Part II will briefly analyze the circuit split leading up to the *Actavis*

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20. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2230 (2013).

21. *Id.* at 2237.

22. *Id.*

23. Kevin McDonald et al., *Antitrust Alert: Supreme Court Holds Reverse Payment Settlements Potentially Anticompetitive—Further Guidance Awaits*, JONES DAY (June 2013), http://www.jonesday.com/Antitrust-Alert--Supreme-Court-Holds-Reverse-Payment-Settlements-Potentially-Anticompetitive--Further-Guidance-Awaits-06-29-2013/?RSS=true (last visited Apr. 11, 2014).

24. Elai Katz, *'Reverse Payments' Shot Down in Third Circuit*, N.Y.L.J., Aug. 24, 2012, at 3.

25. *Actavis*, 133 S. Ct. at 2230–37.

decision, highlighting the strengths and weaknesses of both the "scope of the patent" test adopted by the Second, Eleventh, and Federal Circuit courts and the "quick look rule of reason" adopted by the Third Circuit. Part III will analyze *Actavis*, the Supreme Court's adoption of the "rule of reason" test, and why this new test fails to sufficiently protect patent rights. Part IV proposes that legislative action is necessary following the *Actavis* decision to fully address the inherent conflict between antitrust considerations and patent rights posed by reverse payment settlements.

I. A HISTORICAL ANALYSIS OF REVERSE PAYMENT SETTLEMENTS

A. REGULATORY BACKGROUND

For a prescription drug to be produced and marketed in the United States, it must first be approved by the Food and Drug Administration (the FDA).[26] In order to obtain approval by the FDA, the drug manufacturer must submit a New Drug Application (NDA), which requires extensive information on the development of the drug, including results of safety testing and any patents granted for the drug.[27] The process of completing safety testing is very time-consuming and expensive.[28] In order to protect the expenditures that go into the research and development of a brand-name drug and the profits that will flow from its sales, brand-name drug manufacturers typically apply for a patent based on the chemical formulation of the drug prior to applying to the FDA.[29] These patents can be granted for up to twenty years,[30] which allows the brand-name manufacturer to reap the benefits of higher, brand-name prices for a significant amount of time. Meanwhile, generic drug manufacturers are unable to introduce a generic version while the exclusionary protection provided under the brand-name drug patent is in effect.[31]

The approval process for generic drug approval by the FDA is less cumbersome than that of a brand-name drug because of the Hatch-Waxman Act, which was enacted in part to "jumpstart generic competition" by shortening the application process and therefore the time it takes for generic drugs to make it to market.[32] To this end, generic drug manufacturers can apply for FDA approval using the Abbreviated New Drug Application (the

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26. 21 U.S.C. § 355(a) (2012).

27. Kelly, *supra* note 1, at 417.

28. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 203 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013) (citing 21 U.S.C. § 355(b)(1)).

29. *Generic Drugs: Questions and Answers*, FDA, http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last updated Sept. 3, 2013).

30. *Id.*

31. *See* Kelly, *supra* note 1, at 418.

32. *In re K-Dur*, 686 F.3d at 203 (citing 21 U.S.C. § 355(j)).

ANDA).[33] The ANDA allows the generic drug manufacturer to "rely on the FDA's prior determinations of safety and efficacy made in considering the application of the patented drug."[34] This statutory provision allows the generic drug manufacturer to avoid "the major investment in inventing and developing the drug."[35]

As a part of this process, the generic drug manufacturer must certify that the generic drug does not infringe upon a valid brand-name drug patent by choosing one of four options.[36] The fourth option, commonly known as a "paragraph IV certification," is itself an act of patent infringement.[37] After the generic drug manufacturer has filed the ANDA and provided notice to any brand-name manufacturers with potentially affected patents, the brand-name manufacturer has forty-five days to bring a patent infringement suit against the generic drug manufacturer.[38] If litigation is initiated by a brand-name drug patent holder, then the FDA approval is granted either at the end of a thirty-month period after the date of the paragraph IV certification filing or, if earlier, then "on—(aa) the date on which the court enters judgment reflecting the decision; or (bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed."[39] Given this "automatic stay" that occurs,[40] settlement is a "natural consequence" of the Hatch-Waxman Act.[41] These settlements are known as "reverse payment settlements" or "exclusion agreements" because they typically involve funds flowing from the brand-name drug patent holder to the generic drug manufacturer, which is atypical in patent infringement cases.[42]

The Hatch-Waxman Act also encourages generic drug manufacturers to enter the market by providing for a 180-day exclusivity period during which

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33. 21 U.S.C. § 355(j)(2)(A).

34. *In re K-Dur*, 686 F.3d at 203 (citing 21 U.S.C. § 355(j)(2)(A)).

35. Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Settlements*, 20 FED. CIR. B.J. 47, 50 (2010).

36. Under 21 U.S.C. § 355(j)(2)(A)(vii), a generic drug company can certify that the given generic drug does not infringe upon a brand-name patent by claiming

> (i) that such patent information has not been filed, (ii) that such patent has expired, (iii) of the date on which such patent will expire, or (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

37. 35 U.S.C. § 271(e)(2)(A) explains that it is an act of infringement to file an ANDA application under 21 U.S.C. § 355(j) when the brand-name drug that the ANDA is based on has a patent, which is the case in a paragraph IV certification.

38. 21 U.S.C. § 355(j)(5)(B)(iii).

39. *Id.* § 355(j)(5)(B)(iii)(I).

40. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 204 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

41. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1074 (11th Cir. 2005).

42. *See In re K-Dur*, 686 F.3d at 204; Holman, *supra* note 6, at 494.

the FDA will not approve any other ANDA applications made by other generic manufacturers of the given drug.[43] This 180-day period does not begin until the original ANDA filer begins to offer its generic version on the market.[44] In addition, it is only available to the first ANDA filer of a given drug, "meaning that even if the first filer never becomes eligible to use its 180-day exclusivity period because it settles, loses, or withdraws the litigation that potential benefit will not pass to subsequent filers."[45]

The Hatch-Waxman Act was amended in 2003 in order to address antitrust concerns of monopoly and collusion and "to put an end to this exploitation of the provision in Hatch-Waxman that grants a short-term protection from competition to the first manufacturer to bring a generic version of a brand-name drug to market."[46] Through the 2003 amendments, the FTC and the U.S. Department of Justice (the DOJ) became major players in the scrutiny of reverse payment settlements.[47] One of the provisions of the amended Hatch-Waxman Act provides that brand-name and generic drug manufacturers that enter into settlements of their patent litigation cases must notify both the FTC and DOJ of the settlements so that the settlements can be analyzed for potential antitrust violations.[48] Both the FTC and the DOJ can review the settlements for potential antitrust violations and are able to challenge the legality of the settlements in court.[49]

B. ARGUMENTS AGAINST REVERSE PAYMENT SETTLEMENTS

The FTC has long been opposed to reverse payment settlements and has urged the courts to find them per se illegal.[50] The FTC reports that "brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time."[51] A 2010 FTC study reported that these settlements delay generic entry for roughly seventeen months.[52] Under the influence of the Obama administration, the DOJ has

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43. 21 U.S.C. § 355(j)(5)(B)(iv).
44. *Id.*
45. *In re K-Dur*, 686 F.3d at 204 (citing 21 U.S.C. § 355(j)(5)(D)(iii)).
46. *See* S. REP. NO. 107-167, at 4 (2002).
47. 21 U.S.C. § 355(j).
48. *Id.*; *see also* 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, 61 n.5 (2010).
49. Butler & Jarosch, *supra* note 48, at 61 n.5.
50. Brief of the Federal Trade Commission as Amicus Curiae Supporting Appellants and Urging Reversal at 22, *In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012) (Nos. 10-2078, 10-2077, 10-2079), 2011 WL 2115235 at *22.
51. 2010 FTC STUDY, *supra* note 8, at 2.
52. *Id.*

also recently begun to take up the position argued by the FTC that reverse payment settlements should be subject to a presumption of invalidity.[53]

In addition to these government agencies, reverse payment settlements are opposed by consumers,[54] as well as wholesale and retail pharmacies.[55] Like consumers, pharmacies are subject to the higher costs of brand-name drugs when generics are excluded from the market.[56] However, the crux of the burden is carried by consumers.[57] The FTC estimates that consumers would pay up to ninety percent less for generic drugs than they currently spend on brand-name drugs.[58] The 2010 FTC study reported that pay-for-delay settlements cost consumers an additional $3.5 billion each year for their drug expenses.[59] These high consumer costs are a major concern of consumer advocacy groups[60] and the FTC.[61]

C. ARGUMENTS SUPPORTING REVERSE PAYMENT SETTLEMENTS

Proponents of reverse payment settlements argue that these settlements actually allow generics to enter the market prior to the expiration of valid patents.[62] Therefore, these settlements provide lower-cost, generic drugs to consumers sooner than if generic drug manufacturers were to simply wait for brand-name patents to expire.[63] Furthermore, these settlements protect the exclusivity granted to the brand-name drug manufacturer through its patent, which encourages further research and development of pharmaceuticals.[64] In addition, reverse payment settlements are supported by both courts[65] and litigants[66] as a way to reduce the time, money, and uncertainty that accompanies litigation.[67]

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53. Butler & Jarosch, *supra* note 48, at 61.
54. 2010 FTC STUDY, *supra* note 8, at 2.
55. *In re K-Dur*, 686 F.3d at 202.
56. *Id.* at 221–22.
57. 2010 FTC STUDY, *supra* note 8, at 2.
58. *Id.* at 1.
59. *Id.*
60. *See generally* Motion for Leave to File Brief and Brief of AARP and the Prescription Access Litigation Project as Amici Curiae in Support of Petitioner, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2454841 (explaining how reverse payment settlements that delay entry of generics harm consumers by preventing access to lower cost generic drugs).
61. 2010 FTC STUDY, *supra* note 8, at 2.
62. Sophia Pearson & Jeff Bliss, *Schering-Plough's K-Dur Pay-for-Delay Ruling Reversed*, BLOOMBERG (July 16, 2012, 3:28 PM), http://www.bloomberg.com/news/2012-07-16/schering-plough-s-k-dur-pay-for-delay-ruling-reversed.html.
63. *See* Nanci Bompey, *More Pay-for-Delay Challenges Possible as SCOTUS, FTC Weigh Options*, FDA WK., Aug. 31, 2012, at 11.
64. *See* Kelly, *supra* note 1, at 418.
65. Sobel, *supra* note 35, at 69–70.
66. Newell & Grossman, *supra* note 5, at LIT7.
67. *Id.*

D. HOW REVERSE PAYMENT SETTLEMENTS PRESENT AN ANTITRUST CONCERN

Under section 1 of the Sherman Act, "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal."[68] Nonetheless, the courts have traditionally only held *unreasonable* restraints of trade to be violations of the Sherman Act.[69] The default standard of analysis for an antitrust claim is known as the "rule of reason" test,[70] which the Supreme Court has delineated:

> The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. 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.[71]

The burden-shifting involved in the "rule of reason" test includes three parts.[72] First, anti-competitive effects must be demonstrated by the plaintiffs.[73] Then, "the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective."[74] Finally, this showing may be rebutted if the plaintiff can show that the conduct is not necessary to the pro-competitive objective given by the defendant.[75]

While a full analysis under the "rule of reason" test is typically required, there are some restraints of trade that have such a harmful and predictable effect without providing any pro-competitive benefits that they are per se unlawful.[76] When per se unlawful agreements occur, "no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement."[77] Examples of practices that are per se

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68. 15 U.S.C. § 1 (2012).

69. *See* State Oil Co. v. Khan, 522 U.S. 3, 10 (1997); Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 343 (1982).

70. *See State Oil Co.*, 522 U.S. at 10.

71. Bd. of Trade v. United States, 246 U.S. 231, 238 (1918).

72. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 209 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

73. United States v. Brown Univ., 5 F.3d 658, 668 (3d Cir. 1993).

74. *Id.* at 669.

75. *Id.*

76. State Oil Co. v. Khan, 522 U.S. 3, 10 (1997); N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958).

77. Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 692 (1978).

unlawful include price fixing, tying arrangements,[78] and market allocation.[79]

Finally, a level of intermediate scrutiny exists between these two extremes known as the "quick look rule of reason."[80] This test is used when the per se unlawful analysis is not suitable because the negative effects of a particular restraint on trade are not immediately obvious.[81] Under the "quick look rule of reason" test, anticompetitive behavior is presumed to have occurred and "the defendant must promulgate 'some competitive justification' for the restraint."[82] If the defendant is unable to justify its behavior, then the presumption of harm stands.[83] These three tests—the "rule of reason," per se unlawfulness, and the "quick look rule of reason"—make up the traditional approaches to antitrust litigation and form the basis of review for the antitrust claims of reverse payment settlement litigation.

Based on this framework, reverse payment settlements raise antitrust concerns as unreasonable restraints on trade.[84] The FTC has argued that they illegally preserve the brand-name manufacturer's monopoly through the delay of the generic drug.[85] Specifically, it is commonly argued that reverse payment settlements are a classic example of per se illegal horizontal agreements[86] in that they "permit the sharing of monopoly rents between would-be competitors."[87] Not only do these agreements present the concern that the brand-name drug manufacturers will collude in order to reap the benefits of higher drug prices, but another concern exists that relates to potential generic drug manufacturers. Due to the 180-day exclusivity period that is granted to the first ANDA filer, any settlement between the first ANDA filer and the brand-name manufacturer will not only benefit those two parties, but will also block any other generic manufacturers during this period.[88] Both the Sixth and D.C. Circuits have expressed concern over this type of antitrust violation.[89]

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78. *N. Pac. Ry. Co.*, 356 U.S. at 5.
79. Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984).
80. *Brown Univ.*, 5 F.3d at 669.
81. *Id.*
82. *Id.* (citing NCAA v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85, 110 (1984)).
83. *Id.*
84. Kelly, *supra* note 1, at 463–64.
85. *See* 2010 FTC STUDY, *supra* note 8, at 2.
86. Kelly, *supra* note 1, at 464.
87. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 216 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).
88. While the 180-day exclusionary period can potentially block competition, this has been ameliorated by an amendment to the Hatch-Waxman Act made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Kelly, *supra* note 1, at 465. The amendment, known as the "failure to market" provision, requires that the 180-day exclusionary period be forfeited when the settlement agreement holds that the patent was invalid or not infringed and the first ANDA filer fails to market its approved generic drug. However, this new amendment does not prevent all situations in which market entry can be blocked by the 180-day exclusivity period,

E. OVERVIEW OF PATENT LAW

Intersecting with antitrust law in the reverse payment settlement cases is patent law, which governs the treatment of the underlying drug patent. When a brand-name drug manufacturer is granted a patent, it has a right to exclude others from producing its patented drug and to seek injunctive relief for any infringement of the patent.[90] This grant is made in order to provide an appropriate incentive to the patentee for investing in research and development.[91] This type of exclusionary power is allowed, even though it can decrease competition and result in high prices.[92] Another benefit of obtaining a patent is that when the patent is challenged, it is presumed to be valid.[93]

Antitrust claims are considered against this strong support of patents. However, although the patent does provide exclusionary rights, it does not grant power to violate antitrust law.[94] The Sherman Act limits the exclusionary power of a patent, as anything outside of the patent's scope is subject to antitrust review.[95]

II. THE CIRCUIT SPLIT LEADING UP TO *ACTAVIS*

A. "SCOPE OF THE PATENT" TEST

Until the *Actavis* decision, circuit courts routinely applied the "scope of the patent" test to analyze reverse payment settlements.[96] Under this test, "reverse payments are permitted so long as (1) the exclusion does not exceed the patent's scope, (2) the patent holder's claim of infringement was

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such as when the agreement does not make a finding of patent invalidity or lack of patent infringement. *Id.*

89. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) (holding that the settlement in that case was "a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade"); Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 811 (D.C. Cir. 2001) (holding that the settlement in that case could "reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions").

90. *See* 35 U.S.C. §§ 271(a), 283 (2012); Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294, 1304–05 (11th Cir. 2003).

91. *Valley Drug Co.*, 344 F.3d at 1304.

92. *Id.* at 1305.

93. *See* 35 U.S.C. § 282.

94. Standard Sanitary Mfg. Co. v. United States, 226 U.S. 20, 49 (1912); *see also* Joseph Vardner, *The Statutory Presumption of Patent Validity in Antitrust Cases*, 25 HARV. J.L. & TECH. 225, 226 (2011).

95. Vardner, *supra* note 94, at 226.

96. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212 (2d Cir. 2006), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005); *Valley Drug Co.*, 344 F.3d at 1312.

not objectively baseless, and (3) the patent was not procured by fraud."[97] The test included an underlying assumption that the patent in question was valid and, therefore, not reviewed on its merits.[98] The courts applying the "scope of the patent" test did not apply antitrust scrutiny.[99] Essentially, as long as the agreement was within the scope of the exclusions allowed under the patent, the court did not question whether an antitrust violation had occurred.[100] Only if the settlement resulted in an arrangement that exceeded the patent would the settlement be subjected to antitrust scrutiny.[101]

Several policy reasons supported the "scope of the patent" test.[102] Arguably the strongest reason in favor of this test was that it encouraged settlement by not subjecting the reverse payment settlements to antitrust scrutiny as long as they were within the scope of the patent.[103] Historically, the courts have favored settlement: "there is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation."[104] Settlements are especially encouraged in patent cases because litigation can significantly drain resources of both the courts and parties involved due to the complex issues involved.[105] The strong presumption of patent validity[106] and the exclusionary powers of the patent[107] are also strong policy reasons supporting this test. Additionally, by encouraging settlement, generic drug manufacturers have an incentive to bring a paragraph IV certification as they have more options for a favorable outcome when challenging a brand-name drug patent.[108]

Although the "scope of the patent" test was strongly supported among the Second, Eleventh, and Federal Circuits,[109] its major weakness was that

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97. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013); *see also, e.g.*, *In re Tamoxifen*, 466 F.3d at 212–13 (adopting the "scope of the patent" test); *Schering-Plough Corp.*, 402 F.3d at 1076 (upholding the "scope of the patent" test).

98. *In re K-Dur*, 686 F.3d at 214.

99. *Id.*

100. *Id.*

101. *Valley Drug Co.*, 344 F.3d at 1312.

102. *See, e.g.*, *id.* at 1294; *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); *In re Tamoxifen*, 466 F.3d 187; *Schering-Plough Corp.*, 402 F.3d 1056.

103. *See Valley Drug Co.*, 344 F.3d at 1308.

104. *In re Tamoxifen*, 466 F.3d at 202 (citing *Schering-Plough Corp.*, 402 F.3d at 1075).

105. *See Valley Drug Co.*, 344 F.3d at 1308 n.20 (discussing the cost and complexity of patent litigation); *see also* Ehrheart v. Verizon Wireless, 609 F.3d 590, 595 (3d Cir. 2010) (explaining that settlements should be encouraged as they decrease the burden on federal courts).

106. 35 U.S.C. § 282 (2012).

107. *See Valley Drug Co.*, 344 F.3d at 1308 (explaining how the incentive for obtaining a patent would be undermined by subjecting reverse payment settlements that are within the scope of the patent to antitrust liability).

108. *See* 35 U.S.C. § 271(e)(2)(A); Kelly, *supra* note 1, at 462–63.

109. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); *In re Tamoxifen*, F.3d at 212; *Schering-Plough Corp.*, 402 F.3d at 1066; *Valley Drug Co.*, 344 F.3d at 1312.

it presumed the validity of the patent,[110] which in turn "assumes away the question being litigated in the underlying patent suit, enforcing a presumption that the patent holder would have prevailed."[111] This is troublesome, particularly when it allows settlements based on weak or invalid patents to be protected without any judicial scrutiny, which has occurred in many instances.[112] In essence, this presumption allows a brand-name manufacturer who knows it has a weak patent "to buy [its] way out of both competition with the challenging competitor and possible invalidation of the patent,"[113] a potential concern admitted by the Second Circuit.[114] Overall, the test is criticized for being overly simplistic as it "assumes issues of validity and infringement that cannot possibly be determined from the mere issuance of the patent."[115]

Ultimately, the "scope of the patent" test failed to protect consumers because it was used to uphold reverse payment settlements based on weak or invalid patents.[116] By allowing settlement, the generic drug faces a delayed introduction to the market, during which time the higher costs of the brand-name drug are passed on to the consumer.[117] Since the Hatch-Waxman Act was designed to protect the consumer, the "scope of the patent" test did not adequately achieve this goal; it only facially protected the patent, not based on its underlying merits, but on the patent holder's ability to pay the generic drug manufacturer off in order to prolong increased drug prices for consumers.[118]

B. PER SE AND PRIMA FACIE EVIDENCE OF VIOLATION TREATMENT IN EARLY CASES

Earlier in the history of reverse payment settlement litigation, the Sixth and D.C. Circuits applied stricter antitrust scrutiny by deeming the settlements to be per se violations of the Sherman Act[119] and prima facie evidence of an unreasonable restraint on trade, respectively.[120] In *Andrx*

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110. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013); *see also* 35 U.S.C. § 282 ("A patent shall be presumed valid.").

111. *In re K-Dur*, 686 F.3d at 214.

112. *Id.* at 214–15 (stating that "[m]any patents issued by the PTO are later found to be invalid or not infringed, and a 2002 study conducted by the FTC concluded that, in Hatch-Waxman challenges made under paragraph IV, the generic challenger prevailed seventy-three percent of the time").

113. *Id.* at 215 (citing *In re Tamoxifen*, 466 F.3d at 211).

114. *Id.*

115. Michael Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 2012 STAN. TECH. L. REV. 1, 6.

116. 2010 FTC STUDY, *supra* note 8, at 11 n.3.

117. *Id.* at 2.

118. *In re K-Dur*, 686 F.3d at 217.

119. *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).

120. Andrx Pharms., Inc. v. Biovail Corp. Int'l., 256 F.3d 799, 811 (D.C. Cir. 2001).

Pharmaceuticals, Inc. v. Biovail Corp. International, the D.C. Circuit held the settlement to be prima facie evidence of an antitrust violation because the agreement could "reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions."[121] The Sixth Circuit, in *In re Cardizem CD Antitrust Litigation*,[122] held the reverse payment settlement in question to be a per se violation of antitrust laws because it was a "horizontal agreement to eliminate competition."[123] These cases are instructive in developing a solution to addressing the reverse payment settlement dilemma as they illustrate how some courts that addressed this issue early on felt the need for a more stringent level of antitrust review.

C. "QUICK LOOK RULE OF REASON" TEST

The Third Circuit in *In re K-Dur Antitrust Litigation* followed in the footsteps of the D.C. Circuit's *Andrx* decision by treating reverse payment settlements as prima facie evidence of an antitrust violation.[124] In doing so, the Third Circuit broke from the more recent trend of applying the "scope of the patent" test and adopted the "quick look rule of reason" test, which applies an intermediate level of antitrust scrutiny.[125] In using this test,

> the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.[126]

Under this test, the Third Circuit aligned itself with the FTC's stance that the underlying patent does not need to be analyzed based on its merits because "it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[127]

Several policy reasons favored the "quick look rule of reason" test.[128] Most significantly, this test subjected reverse payment settlements to antitrust scrutiny and thereby encouraged competition.[129] Therefore, the test worked to incorporate balance between patent protection and the antitrust

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121. *Id.* This case has been distinguished because it did not involve a settlement that ended litigation, but rather it involved compensation from the brand-name manufacturer to the generic manufacturer while the litigation was ongoing. *In re K-Dur*, 686 F.3d at 210.
122. *In re Cardizem*, 332 F.3d at 908.
123. *Id.*
124. *In re K-Dur*, 686 F.3d at 218.
125. *Id.*
126. *Id.*
127. *Id.* (citing *In re* Schering-Plough Corp., 136 F.T.C. 956, 988 (2003)).
128. *In re K-Dur*, 686 F.3d at 217–18.
129. *Id.*

concerns that arose in response to the increased competition the Hatch-Waxman Act aimed to obtain.[130] The "quick look rule of reason" test also protected the consumer by prohibiting unreasonable restraints to trade in the pharmaceutical industry that excessively prolonged the entry of generics under the given brand-name drug patent.[131]

While the *In re K-Dur Antitrust Litigation* holding had some advantages over the "scope of the patent" test, it also had its weaknesses. First, just as the "scope of the patent" test did not analyze the merits of the underlying patent, neither did the Third Circuit's test.[132] By not analyzing the underlying patent, the "quick look rule of reason" test could potentially fail to provide enough protection for valid or infringed patents. It is possible that a brand-name manufacturer would rationally choose to pay off a generic manufacturer to stop litigation or market entry, even if the brand-name manufacturer knew it had a strong patent,[133] but the Third Circuit's test would make it harder for this type of agreement to be upheld. Furthermore, this test would likely discourage patent infringement litigation because the parties would know that any resulting settlements would be seen as presumptively illegal.[134] This could then lead to fewer drug manufacturers pursuing the introduction of a generic drug into the market.[135]

III: *FTC V. ACTAVIS*: A RESOLUTION TO THE ANTITRUST PROBLEM TO THE EXCLUSION OF PATENT PROTECTION

Given these two very different approaches to resolving antitrust claims based on reverse payment settlements, a clear need existed for the Supreme Court to step in and provide guidance.[136] This guidance came with the *FTC v. Actavis* case, in which the Supreme Court adopted the "rule of reason" test for analyzing these settlements.[137]

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130. *Id.* at 217.

131. *Id.* at 217–18.

132. *Id.* at 214.

133. *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206 (2d Cir. 2006), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (citing Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1807 (2003) (explaining that "the plaintiff often will have an incentive to pay the defendant not to enter the market, regardless of whether the former expects to win at trial")).

134. *In re Tamoxifen*, 466 F.3d at 206 (citing Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003)).

135. *See* Nanci Bompey, *Upsher-Smith Follows Merck in Seeking SCOTUS Review of Pay-for-Delay*, FDA WK., Sept. 7, 2012, at 2 (explaining that fewer generic manufacturers will file paragraph IV certifications).

136. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2230 (2013).

137. *Id.* at 2237.

The case began when Actavis, Inc. (known as Watson Pharmaceuticals at the time) and Paddock Laboratories, Inc. both filed for an ANDA for approval of a generic version of AndroGel based on paragraph IV certifications, which stated that the AndroGel patent was not valid and that their generics would not infringe upon the AndroGel patent.[138] Solvay Pharmaceuticals, Inc., the brand-name manufacturer of AndroGel, then initiated a patent infringement suit which eventually led to a settlement in which Solvay agreed to pay the generic drug manufacturers millions of dollars in order to delay market entry.[139] The FTC then brought an antitrust claim against all of the parties to the settlement, claiming that they had unlawfully agreed to share in Solvay's monopoly profits in violation of the Sherman Act.[140] The district court dismissed the FTC's complaint for failing to state an antitrust violation, and the Court of Appeals for the Eleventh Circuit affirmed based on the "scope of the patent" test.[141]

A. MAJORITY OPINION ADOPTING THE "RULE OF REASON" TEST

The Supreme Court first discarded the "scope of the patent" test as the correct standard for reverse payment settlement antitrust cases.[142] The Court noted that the "scope of the patent" test failed to consider antitrust issues, stating that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy."[143] The value of settlements was also addressed, but the Court summarily set aside that principle in this context.[144] The Court also rejected the "quick look rule of reason" test argued for by the FTC,[145] finding that this type of test is only 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" and that reverse payment settlements did not meet that standard.[146]

Instead, the Court adopted the "rule of reason" test[147] and "answered the antitrust question by considering traditional antitrust factors, such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such

138. *Id.* at 2229.
139. *Id.*
140. *Id.* at 2229–30.
141. *Id.* at 2230.
142. *Id.* at 2231.
143. *Id.*
144. *Id.* at 2234.
145. *Id.* at 2237.
146. *Id.*
147. *Id.*

as here those related to patents."[148] In analyzing these antitrust factors, the Court highlighted "five sets of considerations" as to why the antitrust claim should have moved forward.[149] These included (1) that a reverse settlement payment can have anticompetitive effects, (2) that sometimes these anticompetitive effects are unjustified, (3) "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice," for example by paying off a generic to maintain monopoly profits, (4) "an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed," and (5) that parties may settle patent cases through methods other than large, unjustified reverse payments like early entry without a payment.[150] Finally, the Court concluded by leaving "to the lower courts the structuring of the present rule-of-reason antitrust litigation."[151]

B. DISSENTING OPINION ARGUING FOR THE CONTINUED USE OF THE "SCOPE OF THE PATENT" TEST

The dissent, written by Chief Justice John Roberts, argued for the continued use of the "scope of the patent" test, emphasizing that patents are an important exclusion to antitrust law.[152] The dissent also noted that brand-name manufacturers may have rational reasons for paying off generics, even if they are nearly sure that their patents are valid or infringed.[153] In criticizing the "amorphous"[154] and "unruly"[155] test adopted by the majority, the dissent argued that the "rule of reason" test may discourage the settlement of patent litigation.[156]

C. ANALYSIS OF THE COURT'S RESPONSE: A CONTINUING LACK OF BALANCE

To assess *Actavis* and determine whether it will help to resolve the dilemma presented by reverse payment settlements, it is important to revisit the goals of the Hatch-Waxman Act. One of its overarching goals was to provide incentives that would allow for an appropriate balance between encouraging innovation in the pharmaceutical industry and encouraging the entry of generic versions of drugs to the market.[157] Indeed, the Court in *Actavis* emphasized the need to consider both antitrust and patent policies in

148. *Id.* at 2231.
149. *Id.* at 2234.
150. *Id.* at 2234–37.
151. *Id.* at 2238.
152. *Id.* at 2238–39 (Roberts, C.J., dissenting).
153. *Id.* at 2244–45.
154. *Id.* at 2238.
155. *Id.* at 2245.
156. *Id.* at 2247.
157. 130 CONG. REC. 24,425 (1984); Kelly, *supra* note 1, at 417.

this context.[158] At the core of encouraging innovation among brand-name drug manufacturers is the protection provided by patents, which makes research and development costs worthwhile.[159] Meanwhile, antitrust scrutiny should be applied to ensure that generic drug manufacturers are not being bought out of the market by brand-name drug manufacturers attempting to retain their monopoly rents.[160] Thus, the principles of patent and antitrust law stand in conflict with one another in the reverse payment settlement context[161] and should be carefully balanced to protect all stakeholders.

The Supreme Court took a positive step forward in appropriately resolving the reverse payment settlement dilemma by determining that antitrust scrutiny must be applied to reverse payment settlements.[162] Antitrust scrutiny was sorely lacking from the "scope of the patent" test line of decisions as discussed at length by the court in *Actavis*.[163] Antitrust concerns can arise in settlements that involve both valid and invalid patents,[164] and the Supreme Court filled the void that was missing in cases that were decided under the "scope of the patent" test. Furthermore, by choosing the "rule of reason" test, the court provided for a flexible, case-by-case approach,[165] which is also consistent with the balance intended by the Hatch-Waxman Act. However, to achieve true balance, patent law concerns must be addressed as well.

Throughout the history of reverse payment settlements, there has been a significant lack of analysis of the underlying patent issues in these cases.[166] *Actavis* proved to be no exception.[167] While the Court indicated early on in its opinion that one of the "traditional antitrust factors" included "those related to patents,"[168] the court also stated that "it is normally not necessary

158. *Actavis*, 133 S. Ct. at 2231.

159. Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 398 (2010).

160. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).

161. Dolin, *supra* note 5, at 318.

162. *Actavis*, 133 S. Ct. at 2231; *see also* Brianna Ford, Comment, *Using Reverse Payment Agreements as an Effective Way to Maintain a Patent Monopoly in the Pharmaceutical Industry*, 21 AM. U. J. GENDER SOC. POL'Y & L., 919, 931 (2013).

163. *Actavis*, 133 S. Ct. at 2230–37.

164. *See, e.g.*, *In re* K-Dur Antitrust Litig., 686 F.3d 197, 216 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013) (explaining how reverse payment settlements can allow for the settling parties to share monopoly rents, whether or not the patent is valid).

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

166. *E.g.*, Vardner, *supra* note 94, at 226; Khatibifar, *supra* note 15, at 1392–93.

167. *See* Aaron Kesselheim & Nathan Shiu, FTC v. Actavis*: The Supreme Court Issues a Reversal on Reverse Payments*, HEALTH AFF. (June 21, 2013), http://healthaffairs.org/blog/2013/06/21/ftc-v-actavis-the-supreme-court-issues-a-reversal-on-reverse-payments/.

168. *Actavis*, 133 S. Ct. at 2231.

to litigate patent validity to answer the antitrust question."[169] The Court further elaborates:

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubt about the patent's survival. . . . [T]he 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.[170]

This analysis left it unclear how the lower courts should deal with the patent's merits.[171] In fact, this nearly implies that a large reverse payment settlement can be presumed to be unlawful, which makes this test seem more like the "quick look rule of reason."[172] By failing to give sufficient consideration to the patent issues, the Court's decision represents a change from the lower courts' emphasis on the protection provided for by the patent to the exclusion of the antitrust concerns, to a focus on the antitrust concerns to the exclusion of the protections provided by the patent. Reverse payment settlements arise due to patent infringement litigation.[173] Since the original claim in the patent infringement litigation centers on the validity or infringement of a patent, it is natural to begin analysis of reverse payment settlements with the merits of the underlying patent.[174]

Several policy reasons also support the need for analysis of the underlying patent. On a fundamental level, patents that have not been subjected to any type of review and are merely presumed to be valid should not be allowed to prevent a generic drug manufacturer from entering the market.[175] The Supreme Court has supported the need for testing patents to eliminate those that are undeserving in prior cases, so that weak patents are

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169. *Id.* at 2236.

170. *Id.* at 2236–37.

171. *See* Joshua D. Wright, Comm'r, FTC, Remarks at the Concurrences Journal Annual Dinner: *FTC v. Actavis* and the Future of Reverse Payments 15 (Sept. 26, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf; McDonald et al., *supra* note 23.

172. Wright, *supra* note 171, at 9 (citing PHILLIP AREEDA, THE "RULE OF REASON" IN ANTITRUST ANALYSIS: GENERAL ISSUES 37–38 (1981), *available at* http://www.fjc.gov/public/pdf.nsf/lookup/antitrust.pdf/$file/antitrust.pdf).

173. *See e.g.*, *In re* K-Dur Antitrust Litig., 686 F.3d 197, 204 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

174. *See* Dickey et al., *supra* note 159, at 399; *see also* Peter Picht, *New Law on Reverse Payment Settlements—The Agenda for Courts and the Legislature After the Supreme Court's* Actavis *Ruling*, 16 TUL. J. TECH. & INTELL. PROP. 105, 124 (2013) (explaining how patent validity and infringement are the key to whether reverse payment settlements are anticompetitive).

175. C. Scott Hemphill, *Milton Handler Antitrust Lecture: Collusive and Exclusive Settlements of Intellectual Property Litigation*, 2010 COLUM. BUS. L. REV. 685, 706; *see also* Vardner, *supra* note 94, at 226.

not used to harm the public.[176] Moreover, the process through which patents are issued by the U.S. Patent and Trademark Office (the USPTO) has been criticized as resulting in undeserving patents.[177] Many recently challenged patents have later been declared invalid.[178]

Although these considerations suggest a need for a review of the underlying patent, doing so would create a conundrum. If the lower courts must resolve the underlying patent claims, this could remove the reasons for entering into a reverse payment settlement in the first place.[179] Thus, the incentives for challenging a patent through paragraph IV certification could decrease,[180] as the generic drug manufacturer will not have as many options when challenging the patent.

Additional problems with the "rule of reason" test adopted in *Actavis* could also have dampening effects on reverse payment settlements.[181] As the analysis required under a "rule of reason" test is typically quite extensive and costly,[182] the incentives for settling will be lowered. It is also possible that companies will be more hesitant to enter into reverse payment settlements if they will face stricter antitrust scrutiny.[183] Since the Court left it to lower courts to develop the structure of the "rule of reason" test in this context,[184] how exactly these cases will actually be handled remains to be seen.[185] However, more confusion will certainly follow this decision as the lower courts once again try to address the problems associated with reverse payment solutions.[186]

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176. *See* Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 100–01 (1993); Cory Ingle, *Reverse Payment Settlements: A Patent Approach to Defending the Argument for Illegality*, 7 ISJLP 503, 526 (2012) (citing Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892)).

177. *See* Ian Hastings, *Dynamic Innovative Inefficiency in Pharmaceutical Patent Settlements*, 13 N.C. J.L. & Tech. 31, 62 (2011); *see also* Hemphill, *supra* note 175, at 706 (stating that patents receive limited scrutiny during the examination process at the USPTO).

178. Picht, *supra* note 174, at 119; Vardner, *supra* note 94, at 225 (citing *Decisions for 2000–2004*, PATSTATS, http://www.patstats.org/2000-04.htm (last visited Apr. 11, 2014)).

179. Picht, *supra* note 174, at 124.

180. *See* Bompey, *supra* note 135, at 11 (explaining that fewer generic manufacturers will file paragraph IV certifications).

181. *See* Jonathan Gardner, *Limited Win for Both Sides in "Pay-for-Delay" Judgment*, EP VANTAGE (June 18, 2013), http://www.epvantage.com/Universal/View.aspx?type=Story&id=436414&isEPVantage=yes; Bradley Graveline & Jennifer Driscoll-Chippendale, FTC v. Actavis*: What Does It Mean for Reverse Payment Settlements?*, FDA L. UPDATE BLOG (June 20, 2013), http://www.fdalawblog.com/2013/06/articles/ip-and-technology-transactions/ftc-v-actavis-what-does-it-mean-for-reverse-payment-settlements/.

182. Butler & Jarosch, *supra* note 48, at 114.

183. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2243 (2013) (Roberts, C.J., dissenting).

184. *Id.* at 2238 (majority opinion).

185. Wright, *supra* note 171, at 15.

186. Graveline & Driscoll-Chippendale, *supra* note 181; McDonald et al., *supra* note 23.

IV: THE NEED FOR A LEGISLATIVE APPROACH TO THE REVERSE PAYMENT SETTLEMENT DILEMMA

To resolve the ongoing legal problems and questions presented by reverse payment settlements,[187] Congress should step in once again to provide guidance on how to properly balance the tension between antitrust law and patent law. At times, this tension can seem irreconcilable.[188] Under the "rule of reason" test articulated in *Actavis*, if a brand-name drug manufacturer can raise the defense of having a valid or infringed patent, then the antitrust suit may evolve into the very patent suit the reverse payment settlement was designed to avoid.[189] However, at the core of whether a reverse payment settlement is anticompetitive is whether it is based on a valid or infringed patent. Since the reverse payment settlement dilemma raises important policy considerations about whose interests to protect and how to deal with the intersection of patent law and antitrust law, a legislative approach would leave these questions in the hands of policy makers.[190] Congress could alleviate the numerous questions remaining after *Actavis* once all of the policy considerations have been carefully balanced. Finally, legislation could help to benefit consumers more swiftly—those who are hurt the most by the delay of generic entry caused by reverse payment settlements[191]—by avoiding the years of judicial uncertainty that are likely to follow *Actavis*.[192]

The two currently pending bills, The Protecting Consumer Access to Generic Drugs Act of 2013 and The Preserve Access to Affordable Generics Act, provide potential solutions.[193] By allowing for more flexibility in cases where reverse payment settlements are not anticompetitive, the Preserve Access to Affordable Generics Act provides a superior legislative resolution.[194] This bill would create a presumption of illegality for reverse payment settlements that delay generic entry into the market.[195] The obvious advantage of this bill would be to provide a clear rule to be applied by the courts, thereby preserving judicial resources. Furthermore, by creating a presumption of illegality, it is highly likely that

187. *See* Wright, *supra* note 171, at 8; *see also* McDonald et al., *supra* note 23.

188. Wright, *supra* note 171, at 15.

189. McDonald et al., *supra* note 23.

190. Timothy A. Cook, Note, *Pharmaceutical Patent Litigation Settlements: Balancing Patent & Antitrust Policy Through Institutional Choice*, 17 MICH. TELECOMM. & TECH. L. REV. 417, 442 (2011).

191. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2235 (2013).

192. *See* McDonald et al., *supra* note 23.

193. Preserve Access to Affordable Generics Act, S. 214, 113th Cong. § 3 (2013); Protecting Consumer Access to Generic Drugs Act of 2013, H.R. 3709, 113th Cong. (2013); *see also* Picht, *supra* note 174, at 131–33.

194. S. 214; *see also* Picht, *supra* note 174, at 133.

195. S. 214 § 3; *see also* Cook, *supra* note 190, at 442.

fewer reverse payment settlements would be entered into, thus cutting down on the chances of potential delay in the market entry of generic drugs. In turn, consumers would benefit by gaining access to lower-cost generic drugs.[196] The major disadvantage to legislation is that reverse payment settlement suits would not be decided based on a flexible, case-by-case approach.[197] The presumption of illegality could be over-inclusive and prevent some settlements that are not anticompetitive.[198] However, the reverse payment settlement dilemma raises important policy considerations about whose interests to protect and how to deal with the intersection of patent law and antitrust law, and a legislative approach would at least leave these questions in the hands of policy-makers.[199] After all, the reverse payment settlement dilemma was created by legislators, and likewise it should be resolved by legislators.

CONCLUSION

With generics typically costing thirty to eighty percent less than their brand-name versions, and ten percent of the nation's health care costs spent on prescription drugs, the generic drug market must be encouraged.[200] However, it is only through innovation, research, and development of drugs protected by patents that future advances in the pharmaceutical industry will become available to consumers.[201] In analyzing any reverse payment settlement, a balance between these areas of law must be achieved in order to protect the various stakeholders. Before *Actavis*, the majority of the circuit courts upheld the exclusivity of the patent, but they presumed that antitrust scrutiny was unnecessary as long as the agreement was within the scope of the patent.[202] Under *Actavis*, the Supreme Court went too far in correcting this shortcoming by downplaying the need for review of the underlying patent. Ultimately, as the reverse payment settlement dilemma presents important policy concerns, this issue should be dealt with by

196. Laura J. Grebe, Comment, *Generic Entry in a Rough Economy—Proposed Legislation May Ease Health Care Costs*, 14 MARQ. INTELL. PROP. L. REV. 167, 188 (2010) (explaining how consumers stand to benefit from a prior version of the Preserve Access to the Affordable Access of Generics Act).

197. *See* Cook, *supra* note 190, at 442.

198. *See* Alyssa L. Brown, Comment, *Modest Proposals for a Complex Problem: Patent Misuse and Incremental Changes to the Hatch-Waxman Act as Solutions to the Problem of Reverse Payment Settlements*, 41 U. BALT. L. REV. 583, 603 (2012).

199. Cook, *supra* note 190, at 442.

200. *See* Grebe, *supra* note 196, at 188 (citing S. 3582, 109th Cong. (2006)).

201. Dickey et al., *supra* note 159, at 398.

202. *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1341 (Fed. Cir. 2008), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190 (2d Cir. 2006), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005).

Congress, which has addressed this issue in the past and continues to work toward a reasonable solution.[203]

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203. *See* Preserve Access to Affordable Generics Act, S. 214, 113th Cong. § 3 (2013); Protecting Consumer Access to Generic Drugs Act of 2013, H.R. 3709, 113th Cong. (2013).

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