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Waiting is the Hardest Part: Why the Supreme Court Should Adopt the Third Circuit's Analysis of Pay-for-delay Settlement Agreements

Marlee P. Kutcher
Loyola University Chicago, School of Law

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COMMENT

Waiting is the Hardest Part: Why the Supreme Court Should Adopt the Third Circuit's Analysis of Pay-for-Delay Settlement Agreements

*Marlee P. Kutcher**

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INTRODUCTION

In March 2013, the U.S. Supreme Court heard oral arguments in *FTC v. Actavis, Inc.*¹ The *Actavis* decision, expected later this year, will give the Court the opportunity to answer the multibillion-dollar question of whether brand-name and generic pharmaceutical companies violate antitrust laws when they enter into payment agreements to delay generic drugs from entering the market.² The Court’s decision in this case could have a significant impact on rising health care costs in this country.³ The high cost of prescription drugs has put crippling economic pressure on the U.S. health care system.⁴ In 2010, forty-eight

1. 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 133 S. Ct. 787 (U.S. Dec. 7, 2012) (No. 12-416).

2. For a summary of *Actavis* oral arguments, see Lyle Denniston, *Argument Recap: No Easy Rule on Drug “Pay For Delay”?*, SCOTUSBLOG (Mar. 25, 2013, 2:21 PM), <http://www.scotusblog.com/2013/03/argument-recap-no-easy-rule-on-drug-pay-for-delay/>. A “brand-name” drug, also known as a “pioneer drug,” is a drug “marketed under a proprietary, trademark-protected name.” *FDA Glossary of Terms*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm> (last visited Jan. 29, 2013). A “generic” drug is equivalent to a brand-name drug in dosage, safety, strength, and quality. *Id.*

3. David Balto, a former Federal Trade Commission (“FTC”) policy director, described *Watson* as “the health care reform case of 2013.” “There’s no other case that can have as much impact on reducing health care costs.” Brett Norman, *Supreme Court Takes Up Case on Generic Drugs*, POLITICOPRO (Dec. 10, 2012), <http://www.politico.com/story/2012/12/supreme-court-generic-drugs-pay-for-delay-84810.html?hp=r6>.

4. See DAVID A. SQUIRES, EXPLAINING HIGH HEALTH CARE SPENDING IN THE UNITED STATES: AN INTERNATIONAL COMPARISON 5 (2012) (finding that the prices for the thirty most commonly prescribed drugs are one-third higher in the United States than in Canada and Germany, and more than double the prices in Australia, France, the Netherlands, New Zealand, and the United Kingdom, which contributes to unsustainably high health care costs in the United States); U.S. GOV’T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUG TRENDS: TRENDS IN USUAL AND CUSTOMARY PRICES FOR COMMONLY USED DRUGS 1 (2011) (finding that the average usual and customary price for brand-name prescription drugs increased six percent each year from

million Americans sacrificed filling essential drug prescriptions due to cost, often leading to life-threatening consequences and additional health care expenses.⁵ Although many factors contribute to high drug prices, collusive settlements between brand-name pharmaceutical companies and generic drug manufacturers play a major role by presenting a barrier to lowering drug costs.⁶ Brand-name pharmaceutical companies have long been settling patent litigation by paying generic manufacturers large sums of money to drop patent lawsuits, thereby delaying generic drugs from entering the market.⁷ These settlement arrangements, known as “reverse payments” or “pay-for-delay” agreements,⁸ derive from the regulatory framework of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act.⁹ Though Hatch-

January 2000 through January 2010); KAISER FAMILY FOUND., HEALTH CARE COSTS: A PRIMER, KEY INFORMATION ON HEALTH CARE COSTS AND THEIR IMPACT 7 (2012) [hereinafter 2012 KFF REPORT] (reporting that spending on prescription drugs increased one-hundred fourteen percent from 2000 to 2010).

5. See COMMONWEALTH FUND, THE COMMONWEALTH FUND 2010 BIENNIAL HEALTH INSURANCE SURVEY 13 (2011) (reporting that out of uninsured and insured Americans ages nineteen to sixty-four, forty-eight million did not fill a prescription due to cost, up sixty-six percent since 2001); 2012 KFF REPORT, *supra* note 4, at 23 (finding that twenty-five percent of families failed to fill a prescription for medicine and seventeen percent cut pills in half or skipped doses due to cost).

6. See FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010) [hereinafter 2010 FTC REPORT], available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> (reporting that pay-for-delay agreements cost Americans \$3.5 billion per year); Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494–502 (2007) (defining reverse payment settlements).

7. See FTC, AGREEMENTS FILED WITH THE FTC UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2010, A REPORT BY THE BUREAU OF COMPETITION 1–2 (2011) [hereinafter 2011 FTC REPORT] (reporting that reverse payment deals increased by sixty percent in 2010 and involved combined annual sales of about \$9 billion); Scott C. Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1553 (2006) [hereinafter Hemphill, *Paying for Delay*] (explaining the antitrust implications of reverse payment settlements); Marcy L. Lobanoff, Comment, *Anti-Competitive Agreements Cloaked as “Settlements” Thwart the Purpose of the Hatch-Waxman Act*, 50 EMORY L.J. 1331, 1338 (2001) (“[P]ioneer brand-name drug companies are paying generic drug companies, which challenge the brand-name drug patents, not to compete or to delay litigation.”).

8. See Daniel A. Crane, *Ease over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 698–99 (2004) (explaining that these types of payments are known as “reverse,” “exit,” or “exclusion” payments). See, e.g., *Pay-for-Delay: When Drug Companies Agree Not to Compete*, FTC (Oct. 19, 2012), <http://www.ftc.gov/opa/reporter/competition/payfordelay.shtml> (commentators and the FTC refer to the payments as “pay-for-delay” agreements). This Comment will use the term “reverse payment.”

9. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C. (2006)). The Act is known as the Hatch-Waxman Act due to its sponsors, Senator Orrin Hatch and

Waxman's goal was to increase generic drug competition in the pharmaceutical drug market while still fostering patent innovation, reverse payment settlements largely prevent generic drugs from timely entering the marketplace.¹⁰ As a result, drug prices remain inflated and American health care consumers bear the burden.¹¹ According to the Federal Trade Commission ("FTC"), these anticompetitive agreements, which rose to a record number in 2012,¹² cost consumers \$3.5 billion per year.¹³

Due to the complex intersection of the regulatory scheme of Hatch-Waxman, antitrust principles, and patent law, circuit courts have reached divergent conclusions on whether reverse payment settlements are anticompetitive.¹⁴ Three circuit courts have applied antitrust scrutiny to find that reverse payments unreasonably restrain trade in violation of federal antitrust law.¹⁵ Conversely, three other circuit courts have reasoned that a reverse payment is legal so long as it remains within the "scope of the patent," meaning within the

Representative Henry Waxman.

10. See H.R. REP. NO. 98-857, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 ("The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962."); Brief of Rep. Henry A. Waxman as *Amicus Curiae* in Support of Petitioners at 2, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 601 F.3d 1359 (Fed. Cir. 2010) (No. 10-844) (noting that the goal of Hatch-Waxman was to "get generic drugs into the hands of patients at reasonable prices—fast").

11. 2010 FTC REPORT, *supra* note 6, at 2.

12. See FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2012, A REPORT BY THE BUREAU OF COMPETITION 1–2 (2013), *available at* <http://www.ftc.gov/os/2013/01/130117mmareport.pdf> (finding that reverse payment settlements reported rose from twenty-eight in 2011 to forty in 2012). The reverse payment settlements reported in 2012 "involve branded pharmaceutical products with combined annual U.S. sales of approximately \$8.3 billion." *Id.*

13. 2010 FTC REPORT, *supra* note 6, at 2.

14. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (finding that reverse payments are prima facie evidence of anticompetitive conduct); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1340 (Fed. Cir. 2008) (reasoning that absent fraud or sham, the court need not consider the patent validity and finding no antitrust violation); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 220 (2d Cir. 2006) (reasoning that the patent conferred monopoly power and finding no antitrust violation); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (finding that absent sham or fraud, a reverse payment does not violate antitrust laws if it exists within the scope of the patent); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (reasoning that the court must consider the exclusionary scope of the patent to determine whether an antitrust violation occurred); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003) (determining that the agreement was a horizontal market allocation device, and thus per se illegal); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 819 (D.C. Cir. 2001) (applying antitrust scrutiny to find that the agreement constituted prima facie evidence of an unreasonable restraint of trade).

15. *In re K-Dur*, 686 F.3d at 218; *In re Cardizem CD*, 332 F.3d at 896; *Andrx Pharms., Inc.*, 256 F.3d at 799.

exclusionary patent rights granted to the patent holder with regard to both the product and the time period.¹⁶

In fact, the Third Circuit and Eleventh Circuit reviewed the exact same settlement agreement, in 2012 and 2005 respectively, but reached opposite conclusions as to the agreement's legality.¹⁷ While the Eleventh Circuit applied the scope of the patent test to find that the payments were legal, the Third Circuit expressly rejected the scope of the patent test and found that the payments constituted prima facie evidence of an antitrust violation.¹⁸ Beyond settling the differences in opinion among the lower courts, the U.S. Supreme Court's forthcoming decision in *Actavis* will have significant implications for the pharmaceutical industry and American consumers.¹⁹

This Comment contains four Parts. Part I provides background information regarding the reverse payment settlement problem, including: Congress's reasons for passing the Hatch-Waxman Act; the Act's basic mechanisms; basic principles of antitrust and patent law; and the first two cases to deal with reverse payments after the Act's passage. Next, Part II discusses how the Second Circuit, Eleventh Circuit, and Federal Circuit have applied the scope of the patent test to reverse payment settlements, and how the Third Circuit has rejected the test. Part III then analyzes these circuit court decisions, reasoning that the Third Circuit has properly considered reverse payments as prima facie evidence of an unreasonable restraint of trade. Finally, Part IV proposes that the Supreme Court should adopt the Third Circuit's reasoning and consider additional factors regarding the reasonableness of reverse payments.

16. *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1323; *In re Tamoxifen Citrate*, 466 F.3d at 187; *Schering-Plough Corp.*, 402 F.3d at 1056; *Valley Drug Co.*, 344 F.3d at 1294; *In re K-Dur*, 686 F.3d at 214–18.

17. See *In re K-Dur*, 686 F.3d at 212 (“*Schering-Plough Corp. v. FTC* arose out of the same settlement agreement as the instant appeal.”). See also Alison Frankel, *3rd Circuit Shocker: Pay-for-Delay Drug Settlements are Illegal*, THOMAS REUTERS NEWS & INSIGHT (July 16, 2012), [http://newsandinsight.thomsonreuters.com/Legal/News/2012/07_-_July/3rd_Circuit_shocker__Pay-for-delay_drug_settlements_are_illegal/\(highlighting the circuit split controversy\)](http://newsandinsight.thomsonreuters.com/Legal/News/2012/07_-_July/3rd_Circuit_shocker__Pay-for-delay_drug_settlements_are_illegal/(highlighting%20the%20circuit%20split%20controversy)); Michelle Olsen, *Circuit Split Watch: A Division over Deals to Delay Generic Drugs*, THE NAT'L L.J. (Aug. 1, 2012), <http://www.law.com/jsp/nlj/PubArticleSCL.jsp?id=1202565650711&slreturn=20120925004723> (reporting the circuit split).

18. *In re K-Dur*, 686 F.3d at 218; *Schering-Plough Corp.*, 402 F.3d at 1075.

19. See Greg Stohr, *'Pay for Delay' Drug Accords Get U.S. High Court Scrutiny*, BLOOMBERG BUSINESSWEEK (Dec. 7, 2012), <http://www.businessweek.com/news/2012-12-07/pay-for-delay-drug-accords-get-u-dot-s-dot-high-court-scrutiny> (reporting that Ralph Neas, president of the Generic Pharmaceutical Association, said, “This case could determine how an entire industry does business because it would dramatically affect the economics of each decision to introduce a generic drug”).

I. BACKGROUND

The landscape of the pharmaceutical industry prior to the Hatch-Waxman Act, and Congress's intent in drafting the Act, provide an important backdrop for cases involving reverse payments. First, this Part explains the impetus behind the Hatch-Waxman Act and describes the Act's key provisions. Next, it will briefly explain antitrust and patent law principles that courts apply in reverse payment cases. Lastly, this Part discusses the D.C. Circuit and the Sixth Circuit's holdings in the *In re Cardizem CD* litigation to show how the law has developed since reverse payments first reached the courts.

A. Regulation of the Pharmaceutical Industry prior to Hatch-Waxman

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a pharmaceutical company must receive approval of a new drug application ("NDA") from the Food and Drug Administration ("FDA") before it may market a prescription drug.²⁰ Among other requirements, the company must provide full reports on the investigations that demonstrate the drug product is safe and effective for its intended use.²¹ Prior to the passage of Hatch-Waxman, the FDA required generic drug manufacturers to duplicate the expensive and time-consuming safety and effectiveness studies already performed on the patented drugs.²² Because merely beginning the required tests amounted to patent infringement, manufacturers could not start the lengthy FDA approval process for a generic drug until the patent term for the brand-name counterpart ended.²³ This delay created a lapse of several years

20. 21 U.S.C. § 355(a) (2006).

21. See Hearing Procedures for Refusal or Withdrawal of Approval of New Drug Applications and for Issuance, Amendment, or Repeal of Antibiotic Drug Regulations, Interpretative Description of Adequate and Well-Controlled Clinical Investigations, 34 Fed. Reg. 14,596 (Sept. 19, 1969) (to be codified at 21 C.F.R. pts. 130 and 146); Hearing Regulations and Regulations Describing Scientific Content of Adequate and Well-Controlled Clinical Investigations, 35 Fed. Reg. 7,250 (May 8, 1970) (to be codified at 21 C.F.R. pts. 130 and 146).

22. From 1938 to 1962, drugs could obtain FDA approval with relative ease. *Roche Prods. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984). The law formerly required innovator drug manufacturers to submit drug safety information for approval. *Id.* When Congress passed the Drug Amendments of 1962, the law required that before marketing, drug companies had to prove that all new drugs, generic and pioneer, would be safe and effective. H.R. REP. NO. 98-857, at 16 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2649. Performing expensive safety and efficacy testing led to an increase in drug prices. Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 313-14 (2005). For a description of the Drug Amendments of 1962, see Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 587-88 (2003).

23. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003). See Greene, *supra* note 22, at 313 (describing the generic manufacturers' lobbying efforts).

between expiration of the patent term and availability of a generic version to consumers.²⁴ Indeed, the FDA rules created “the practical extension of the monopoly position of the patent holder beyond the expiration of the patent.”²⁵ At the time when Congress passed the Hatch-Waxman Act, there was no generic equivalent for an estimated 150 drugs whose patent term had expired, and only thirty-five percent of the best-selling drugs with expired patents had generic counterparts.²⁶

In addition, the lengthy drug approval process deprived patent holders of years of patent protection.²⁷ Prior to the 1962 amendments to the FDA approval requirements, a drug’s effective patent life lasted almost as long as its expected seventeen-year patent term.²⁸ The 1962 amendments, however, required pioneer brand owners to undertake additional years of testing and clinical trials after the patent’s issuance to ensure that the drug was effective for its intended use.²⁹ With these additional tests, the total cost of developing a new drug skyrocketed into the hundreds of millions of dollars.³⁰ The 1962 amendments significantly eroded the term of exclusivity because the testing delayed

24. H.R. REP. NO. 98-857, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

25. H.R. REP. NO. 98-857, at 4, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688 (providing the legislative intent of the Hatch-Waxman Act).

26. H.R. REP. NO. 98-857, at 4, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688; CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, at xii (July 1998) [hereinafter CBO REPORT].

27. *See* Greene, *supra* note 22, at 313 (explaining why patent holders also lobbied for reforms to the Drug Amendments of 1962); Colleen Kelly, *The Balance between Innovation and Competition: The Hatch-Waxman Act, The 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 418 (2011) (discussing the reduced patent life resulting from onerous efficacy tests).

28. Thomas B. Leary, Comm’r, FTC, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes at the Sixth Annual Health Care Antitrust Forum at Northwestern University School of Law (Nov. 3, 2000) [hereinafter Leary, Antitrust Issues], *available at* <http://www.ftc.gov/speeches/leary/learypharma.shtm>.

29. Hearing Regulations and Regulations Describing Scientific Content of Adequate and Well-Controlled Clinical Investigations, 35 Fed. Reg. 7,250 (May 8, 1970) (to be codified at 21 C.F.R. pts. 130 and 146). *See* Weiswasser & Danzis, *supra* note 22, at 588 (stating that the requirement that the drug be effective for its intended use means that the drug provides some health benefit to the consumer). The FDA requires that most applicants perform at least two “adequate and well-controlled clinical investigations” demonstrating statistically significant benefits for consumers. *Id.*

30. *See* OFFICE OF TECH. ASSESSMENT, U.S. CONG., PHARMACEUTICAL R & D: COSTS, RISKS AND REWARDS 214 (1993), *available at* <http://www.fas.org/ota/reports/9336.pdf> (“Total estimated preclinical pharmaceutical R&D constituted approximately \$450 million in 1988.”); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003) (reporting costs at \$802 million). Developing an average NDA drug takes an average of fifteen years of research and costs more than \$1.5 billion. PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 764 n.6 (3d ed. 2007).

commercialization of the drug.³¹ As a result, a drug's average effective patent life had fallen to less than seven years by 1981.³²

B. Hatch-Waxman's Mechanisms to Promote Competition and Innovation

Congress enacted the Hatch-Waxman Act in 1984 to address these problems with the FDA drug approval process.³³ Congress intended the Hatch-Waxman Act to provide incentives for research-based companies to develop new drugs and to drive down drug prices by increasing generic drug entry into the pharmaceutical market.³⁴

First, Congress sought to remedy the decline in a patent's life by offering patent term restoration and non-patent exclusivity.³⁵ The Act restored the term of an eligible patent for a time equal to the time it took the FDA to review and approve the product.³⁶ Congress also provided additional market exclusivity periods independent of patent protection, which ran concurrently with any remaining patent life, starting on the date of marketing approval.³⁷

Second, in seeking to increase the number of generic drugs available to consumers, Congress created the abbreviated new drug application ("ANDA"), which allows generic manufacturers to rely on the previously approved NDA information.³⁸ Instead of providing the FDA with duplicative clinical data demonstrating the safety and efficacy of the drug, the generic manufacturer may rely on the FDA's prior findings on safety and efficacy if it can show that the generic drug is "bioequivalent" to the patented drug.³⁹ The generic drug manufacturer

31. Weiswasser & Danzis, *supra* note 22, at 588. See also Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 301 (1985) (noting the substantial decrease in patent term life).

32. James J. Wheaton, *Generic Competition, and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 451-52 (1986).

33. H.R. REP. NO. 98-857, at 10 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2694; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C. (2006)).

34. H.R. REP. NO. 98-857, at 4, reprinted in 1984 U.S.C.C.A.N. 2686, 268. See also Kelly, *supra* note 27, at 421 (discussing the legislative history and intent of Hatch-Waxman).

35. 35 U.S.C. § 156 (2006); Kelly, *supra* note 27, at 425.

36. 35 U.S.C. § 156 (c), (g)(6). The extension is half the time the drug is in clinical trials plus the period spent waiting for FDA approval after the trials. For a detailed description of the patent term extension provisions, see Weiswasser & Danzis, *supra* note 22, at 591-93.

37. Weiswasser & Danzis, *supra* note 22, at 592 (detailing the non-patent exclusivity options).

38. 21 U.S.C. § 355(j) (2006).

39. *Id.* § 355(j)(2)(A)(iv). The FDA publishes patent information submitted in NDAs in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." See FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE

must also prove that: (1) the active ingredient of the patented drug and generic drug are the same;⁴⁰ (2) the generic drug has the same “route of administration, dosage form and strength as the pioneer drug”;⁴¹ and (3) the pioneer drug and generic drug have the same labeling.⁴² Generics have an incentive to challenge the brand-name patents because the first generic drug manufacturer to file its application can obtain 180 days of market exclusivity, during which it is the only generic drug on the market.⁴³

In the ANDA, the generic manufacturer must certify that its drug does not infringe on the relevant patents of the pioneer drug manufacturer or that the relevant patents are invalid.⁴⁴ This statement is known as the paragraph IV certification.⁴⁵ Within twenty days of filing its certification, the ANDA filer must notify the patent holder and provide details to support its claim of non-infringement or invalidity.⁴⁶ When the patent holder receives notice of a certification relating to one of its patents, it may challenge the generic manufacturer’s declaration and sue to determine whether the relevant patents are infringed and valid.⁴⁷ Though the generic has not entered the market before filing an ANDA, the paragraph IV certification serves as an “artificial act of

EVALUATIONS (33d ed. 2013), available at <http://www.fda.gov/cder/ob/>. To see procedures for determining the bioequivalence of drug products, see 21 C.F.R. § 320.21–63 (2012). Overall, the FDA considers the active ingredient in a generic product to be the same as the pioneer if it meets the standards set forth in *United States Pharmacopeia*. Weiswasser & Danzis, *supra* note 22, at 594 n.47. See FDA, BIOEQUIVALENCE RECOMMENDATIONS FOR SPECIFIC PRODUCTS (Sept. 25, 2012), available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075207.htm> (detailing bioequivalence guidelines).

40. 21 U.S.C. § 355(j)(2)(A)(ii).

41. *Id.* § 355(j)(2)(A)(iii).

42. *Id.* § 355(j)(2)(A)(i). The law includes certain exceptions to this element. See *id.*

43. *Id.* § 355(j)(5)(B)(iv). The first company to submit an ANDA including a paragraph IV certification is commonly known as the “first filer” and later companies that submit an ANDA for the same drug are called “subsequent filers.” Weiswasser & Danzis, *supra* note 22, at 603 n.93. See *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1298 (11th Cir. 2003) (describing the delay in approval of subsequent ANDAs where the prior ANDA contained a paragraph IV certification). See also Weiswasser & Danzis, *supra* note 22, at 603 (noting the purpose of the 180-day market exclusivity period is to incentivize generics to challenge patent lawsuits).

44. 21 U.S.C. § 355(j)(2)(A). This is the certification that gives rise to controversial reverse payment settlements under Hatch-Waxman.

45. *Id.* § 355(j)(2)(A)(vii). An ANDA applicant must provide a certification with respect to each patent listed in the Orange Book, which claims the reference drug or a method of using it. The applicant must certify one of the following statements: (1) no patent information appears in the Orange Book; (2) the patent has expired; (3) it will not seek approval until the patent expires; or (4) the patent is invalid or will not be infringed by the generic drug. *Id.*

46. *Id.* § 355(j)(2)(B)(ii)–(iv). The twenty-day notification rule was included in the 2003 amendments. See *infra* note 55 (explaining the 2003 amendments).

47. 21 U.S.C. § 271(e)(2)(A).

infringement,” allowing the pioneer drug owner to sue within forty-five days.⁴⁸ If a pioneer drug owner files a patent infringement suit within the allotted forty-five day time period, the FDA automatically stays ANDA approval until the earliest of: (1) the date the patent expires; (2) a court determines that the generic drug does not infringe on the patent or the patent is invalid; or (3) the expiration of thirty months from notice of the paragraph IV certification.⁴⁹ If the pioneer drug owner does not sue during the forty-five day period, the FDA may approve the ANDA on an accelerated time schedule.⁵⁰

The expense and uncertainty of patent litigation often moves pharmaceutical companies to settle disputes with generic drug manufacturers.⁵¹ The generic drug manufacturer actually can receive more money through settlement than through successful litigation, thus aligning the parties’ interests.⁵² That is to say, the Hatch-Waxman Act inadvertently offers great incentives for generics to file first, but not necessarily to aggressively pursue patent litigation.⁵³ In settling disputes, many brand-name drug companies pay generic drug companies to delay market entry until the patent life has ended or soon before, which has raised significant antitrust disputes.⁵⁴ Though

48. *Id.* See also *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (finding that the provision creates a “new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications”).

49. 21 U.S.C. § 355(j)(5)(B)(iii). See also *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 203 (3d Cir. 2012) (providing the statutory and regulatory framework for the case); FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY*, at viii (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (summarizing key provisions of the Act).

50. 21 U.S.C. § 355(j)(5)(B)(iii).

51. See ANTHONY L. MIELE, *PATENT STRATEGY: THE MANAGER’S GUIDE TO PROFITING FROM PATENT PORTFOLIOS* 15 (2000) (reporting that a 1999 study by the Intellectual Property Law Association found that the median total cost through the end of suit for patent litigation was \$2,225,000 in cases where the valued risk was between \$10 and \$100 million); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 757 (2002) (noting the direct and indirect costs of patent litigation); Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act while Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 443 (2008) (explaining that “patent litigation between a brand-name drug company and a generic drug company often settles so that both parties can minimize risk of financial damages”).

52. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39 (2009) [hereinafter Carrier, *Unsettling Drug Patent Settlements*] (reasoning that the parties’ aligned incentives to settle and delay generic drug market entry makes the antitrust harm more severe).

53. Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III*, 30 SEATTLE U. L. REV. 377, 381 (2007). See Hemphill, *Paying for Delay*, *supra* note 7, at 1586 (noting that the settlement removes the most vigorous challenger, an “important source of early competition”).

54. See Leary, *Antitrust Issues*, *supra* note 28 (highlighting the problems with reverse

Congress amended Hatch-Waxman in 2003 to stop brand-name firms from exploiting the Act, pharmaceutical companies continue to arrange reverse payment settlements to the detriment of American consumers.⁵⁵

In many ways, Hatch-Waxman's attempt to promote innovation and competition in the pharmaceutical industry was successful.⁵⁶ Since the Act passed in 1984, the generic drug industry has grown to more than \$16 billion in annual sales, comprising more than fifty-three percent of all prescriptions filled in 2004.⁵⁷ Before its passage, only thirty-five percent of the best-selling drugs had generic equivalents; now nearly all do.⁵⁸ Further, increased generic drug entry has effectively lowered drug prices.⁵⁹ The Congressional Budget Office reports that such decreased

payment settlements); Hemphill, *Paying for Delay*, *supra* note 7, at 1553 (explaining the likely antitrust risk of reverse payment settlements). An FTC study reported that fourteen out of twenty final settlement agreements resolving patent litigation between pioneers and first generic ANDA filers included provisions requiring the generic to wait for a specified amount of time before entering the market. FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* 26 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. Further, the study determined that nine out of twenty settlements included payments from the pioneer to the generic, which ranged from \$1.75 million to \$132.5 million. *Id.*

55. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. No. 108-173, 117 Stat. 2006 (codified as amended in scattered sections of 21, 26, and 42 U.S.C. (2006)), which, in part, amended the Hatch-Waxman Act. Congress intended to stop firms from making agreements with "smaller rivals to delay or limit competition." 146 CONG. REC. S1538 (daily ed. Sept. 20, 2000) (statement of Rep. Waxman); S. REP. NO. 107-167, at 4 (2002). First, the 2003 revisions limited the stays to patents submitted to the FDA before submission of the ANDA, which reduced the prevalence of bottlenecks. 21 U.S.C. § 355(j)(5)(B). Under Hatch-Waxman, a pioneer firm could list an additional patent in the Orange Book after the generic filed an ANDA. *Id.* Then, if the generic filed a paragraph IV certification, the pioneer could sue and receive another thirty-month stay. *Id.* § 355(q)(G). The second amendment to Hatch-Waxman created forfeiture events that resulted in generics forfeiting their 180-day exclusivity period. *Id.* § 355(j)(5)(D). Now, the first filer loses exclusivity if it fails to market the drug by the later of: (1) seventy-five days after FDA approval, or (2) seventy-five days after an appellate court decision finding invalidity or non-infringement. *Id.* Then, the exclusivity period would last to the subsequent court decision, which could occur long after the FDA's approval. *Id.* Finally, the Act required brand-name and generic companies to file settlement agreements concerning the 180-day exclusivity period or the production, sale, or marketing of a drug with the FTC and Department of Justice within ten days of the agreement. *Id.*

56. See Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 175 (2008) (noting that Hatch-Waxman "effectively created the modern generic pharmaceutical industry"). See also Kelly, *supra* note 27, at 426-27 (highlighting the successes of the Act).

57. Mary W. Bourke & M. Edward Danberg, *Current Trends in Hatch-Waxman Patent Litigation: A System Still in Flux*, in PHARMACEUTICAL LAW 2006: ACROSS THE PRODUCT LIFE CYCLE 939 (Practicing Law Inst. ed., 2006).

58. CBO REPORT, *supra* note 26, at xii.

59. FDA, *GENERIC COMPETITION AND DRUG PRICES* (Apr. 4, 2006). The generic entry only drives down the cost of the innovator drug price by five percent. *Id.* The entry of the second generic competitor drives down the innovator drug price by fifty percent, and the sixth by

drug prices save consumers eight to ten billion dollars a year.⁶⁰ Simultaneously, incentives for innovation have contributed to significant progress in U.S. pharmaceutical development, and the United States continues to dominate the world's pharmaceutical drug market.⁶¹

Notwithstanding the Hatch-Waxman Act's successes, high drug prices remain a significant concern for consumers and policymakers.⁶² Reverse payment settlements are a contributing factor to such high prices, thwarting a fully effective implementation of the Hatch-Waxman Act.⁶³

C. Relevant Principles of Antitrust and Patent Law

Antitrust and patent law issues dominate a court's analysis of reverse payments. The legality of reverse payments rests on whether they are anticompetitive even though the brand-name drug company owns a patent.⁶⁴ In general, antitrust law preserves the fundamental rules of competition to protect and encourage lower prices, spark innovation, and maintain efficient industry production.⁶⁵ Specifically, section 1 of the Sherman Act prohibits unreasonable restraints of trade.⁶⁶ Courts

seventy-five percent. *Id.*

60. CBO REPORT, *supra* note 26, at xiii.

61. See GENIA LONG & JUSTIN WORKS, ANALYSIS GRP., INNOVATION IN THE BIOPHARMACEUTICAL PIPELINE: A MULTIDIMENSIONAL VIEW 1 (2013), available at http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/2012_Innovation_in_the_Biopharmaceutical_Pipeline.pdf (reporting that the United States "leads the world in the development of new medicines"). The average marketing period increased from nine years before Hatch-Waxman to eleven-and-a-half years in the following decade. CBO REPORT, *supra* note 26, at 39. Ten of the "blockbuster" drugs in 1997 received extensions for at least two years. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 426 (1999).

62. See, e.g., Peter B. Bach, Leonard B. Saltz & Robert E. Wittes, Op-Ed., *In Cancer Care, Cost Matters*, N.Y. TIMES, Oct. 14, 2012, at A25 (noting criticism from doctors at Memorial Sloan-Kettering Cancer Center of unsustainably high drug prices); CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE PROJECTIONS 2010–2020, at 2 (Jan. 2011) (finding that prescription drug spending is expected to grow at an average of 7.2% from 2015 through 2020, "reflecting slower increases in generic drugs' share of the market and the costs of new drugs becoming available during these years").

63. See *supra* note 6 (explaining the effect of reverse payments on drug prices).

64. See generally *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (analyzing the intersection of antitrust and patent law to resolve the reverse payment problem).

65. MICHAEL D. WHINSTON, LECTURES ON ANTITRUST ECONOMICS 1 (2006).

66. The Sherman Antitrust Act, 15 U.S.C. § 1 (2006). The Sherman Act provides, "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 nations, is declared to be illegal." *Id.* The Supreme Court has interpreted the statute to prohibit only unreasonable restraints of trade. See *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885 (2007) ("Congress intended to outlaw only unreasonable restraints." (citing *State Oil Co. v. Khan*, 522 U.S. 3, 10

traditionally determine whether a restraint is reasonable by applying the “rule of reason.”⁶⁷ Under the rule of reason analysis, the factfinder must decide whether the questioned practice imposes an unreasonable restraint on competition.⁶⁸ The factfinder may consider specific characteristics of the relevant business, the impact of the restraint on the condition of the business, and the history, nature, and effect of the restraint to determine the reasonableness of a challenged business practice.⁶⁹ Courts generally perform this inquiry in three steps.⁷⁰ First, the plaintiff must show that the conduct produced anticompetitive effects in the market.⁷¹ Next, if the plaintiff meets this initial burden, “the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently procompetitive objective.”⁷² Finally, the plaintiff may rebut the defendant’s evidence by demonstrating that the restraint is not reasonably necessary to achieve the stated procompetitive objective.⁷³

Although courts typically apply the rule of reason analysis, courts also have recognized that certain types of restraints are per se illegal because they result in “predictable and pernicious anticompetitive effect[s]” on competition⁷⁴ and “lack any redeeming virtue.”⁷⁵ A restraint is per se illegal when it “facially appears to be one that would always or almost always tend to restrict competition or decrease output.”⁷⁶ When the per se approach applies, the court does not

(1997)); *Chi. Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918) (“Every agreement concerning trade, every regulation of trade, restrains. To bind, to restrain, is of their very essence.”).

67. *State Oil Co.*, 522 U.S. at 10.

68. *Id.*

69. *Id.* (citing *Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 343 & n.13 (1982)).

70. *Id.*

71. *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993). The plaintiff may satisfy this burden by offering proof of the existence of actual anticompetitive effects. *Id.* See, e.g., *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 460–61 (1986) (reduction of output); *Tunis Bros. Co. v. Ford Motor Co.*, 952 F.2d 715, 722 (3d Cir. 1991) (increase in price and deterioration in quality of goods or services). If the plaintiff is unable to offer this proof, the plaintiff may offer proof of defendant’s market power. *Tunis Bros. Co.*, 952 F.2d at 727; *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 110 (1984).

72. *Brown Univ.*, 5 F.3d at 669. Social welfare concerns are insufficient objectives. See, e.g., *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 695 (1978) (“The fact that engineers are often involved in large-scale projects significantly affecting the public safety does not alter our analysis.”).

73. *Brown Univ.*, 5 F.3d at 669.

74. *State Oil Co.*, 522 U.S. at 10.

75. *Brown Univ.*, 5 F.3d at 669 (citing *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)).

76. *Broad. Music, Inc. v. CBS, Inc.*, 441 U.S. 1, 19–20 (1979). See, e.g., *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984) (identifying horizontal price fixing as preventing competition); *N. Pac. Ry. Co.*, 356 U.S. at 5 (identifying output limitations, market

consider the intent behind the restraint, any claimed procompetitive justifications, or the restraint's actual effect on competition.⁷⁷ Classic examples of behavior subject to the per se rule include price fixing, group boycotts, and horizontal restraints of trade restricting prices or territories.⁷⁸

In addition, courts apply an intermediate standard, known as the "quick look" rule of reason analysis, when per se condemnation and rule of reason analyses are inappropriate.⁷⁹ Under the quick look rule, once the plaintiff shows that the defendant's practices are similar to those subject to per se treatment, the plaintiff is not required to demonstrate the anticompetitive market effects. Instead, the defendant must provide a procompetitive justification for a restraint on trade.⁸⁰

Antitrust laws seek not only to protect consumers from artificially high prices, maximize market efficiency, and prevent predatory behavior by dominant companies, but also to promote innovation.⁸¹ Because reverse payments are horizontal agreements,⁸² they appear to be clear antitrust violations.⁸³ However, the presence of patent rights,

allocation, and group boycotts as evidence of competition restrictions).

77. *NCAA*, 468 U.S. at 100. The courts rationalize that while there is a risk that applying per se illegality will invalidate a restraint that the rule of reason would otherwise permit, it is a necessary cost of this more efficient approach. See *Ariz. v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 344 (1982) ("As in every rule of general application, the match between the presumed and the actual is imperfect. For the sake of business certainty and litigation efficiency, we have tolerated the invalidation of some agreements that a full-blown inquiry might have proved to be reasonable.").

78. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907 (6th Cir. 2003). See, e.g., *Bd. of Regents*, 468 U.S. at 100 ("Horizontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal per se' approach because the probability that these practices are anticompetitive is so high.").

79. *Brown Univ.*, 5 F.3d at 669. It applies where "no elaborate industry analysis is required to demonstrate the anticompetitive character" of an inherently suspect restraint. *Id.*

80. See *id.* ("Because competitive harm is presumed, the defendant must promulgate 'some competitive justification' for the restraint, 'even if the absence of detailed market analysis' indicating actual profit maximization or increased costs to the consumer resulting from the restraint." (citing *Bd. of Regents*, 468 U.S. at 110)).

81. Frank H. Easterbrook, *Workable Antitrust Policy*, 84 MICH. L. REV. 1696, 1703 (1986). See Hemphill, *Paying for Delay*, *supra* note 7, at 1598-99 (arguing that innovation is an internal norm of antitrust law).

82. Horizontal agreements are agreements to cooperate between competitors at the same level in the market. See *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 730 (1988) ("Restrictions imposed by agreement between competitors have traditionally been denominated as horizontal restraints, and those imposed by agreement between firm at different levels of distribution as vertical restraints.").

83. See *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 128 (E.D.N.Y. 2003) ("[A]n agreement between a monopolist and a potential competitor to divide between them and exclude other competition is per se illegal under Section 1 [of the Sherman Act]."), *aff'd*, 429 F.3d 370 (2d Cir. 2006). Several commentators argue that reverse payments are per se illegal.

which confer a monopoly power on the patent owner, has confounded the courts on the issue of reverse payments.⁸⁴

As antitrust law fosters innovation through competition, the intellectual property system promotes innovation through “government-sanctioned monopolies.”⁸⁵ The U.S. Constitution grants Congress the power to enact patent legislation to advance scientific progress.⁸⁶ The Patent Act gives a patent holder the right to exclude others from making, using, or selling the product throughout the United States.⁸⁷ After receiving a patent from the U.S. Patent and Trademark Office (“PTO”), the patent is presumed valid for procedural purposes at trial.⁸⁸ This right-to-exclude gives the patentee a monopoly that would otherwise violate antitrust laws.⁸⁹ The patentee “can grant exclusive territorial licenses carving up the United States among its licensees.”⁹⁰ However, that right exists only within the “limits of the patent monopoly.”⁹¹ That is, a valid patent does not give the patent holder any exemption from the Sherman Act’s provisions, which “imposes strict limitations on the concerted activities in which patent owners may lawfully engage.”⁹²

See, e.g., Maureen A. O’Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 MINN. L. REV. 1767, 1769 (2003) [hereinafter O’Rourke & Brodley, *An Incentives Approach*]; Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers*, 26 SANTA CLARA COMPUTER & HIGH TECH. L.J. 141, 141 (2009); Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should be Per Se Illegal*, 41 RUTGERS L.J. 255, 255 (2009).

84. *See* cases cited *supra* note 14 (examining courts applying different analysis and finding different conclusions on similar facts).

85. Joel Graham, *The Legality of Hatch-Waxman Pharmaceutical Settlements: Is the Terazosin Test the Proper Prescription?*, 84 WASH. U. L. REV. 429, 441 (2006).

86. U.S. CONST. art. I, § 8, cl. 8.

87. 35 U.S.C. § 154(a)(1) (2006).

88. 35 U.S.C. § 282. The Federal Circuit has interpreted section 282 of the Patent Act of 1952 as requiring clear and convincing evidence to overcome the presumption of patent validity. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1354–55 (Fed. Cir. 2007); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983). The “burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. § 282. A principal drafter of the 1952 Act, Judge Rich, explained that the drafters derived the premise from the basic proposition that the PTO “is presumed to do its job.” *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984) (reversing a holding that claims were invalid for obviousness). Judge Rich reasoned that the court owes deference to the PTO, unless a party presents new evidence on validity. *Id.* at 1360.

89. *See Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1304–05 (11th Cir. 2003).

90. *Id.* at 1305.

91. *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196–97 (1963) (quoting *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942)).

92. *Id.* at 197 (citation omitted).

D. The Cardizem CD Cases

Although the first two circuit courts to consider reverse payments applied strict antitrust scrutiny to the agreements,⁹³ the next three circuit courts to consider the issue leniently applied the scope of the patent test, finding that such agreements are permissible if they do not exceed the potential exclusionary scope of the patent.⁹⁴ This Section explains the first two of these cases to set the backdrop for a discussion of the circuit split in Part II.⁹⁵

In *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, Andrx Pharmaceuticals (“Andrx”) filed an ANDA on September 22, 1995, seeking FDA approval of a generic form of Hoechst Marion Russell, Inc.’s (“HMRI”) Cardizem CD, a heart drug.⁹⁶ In early 1996, HMRI sued for patent infringement,⁹⁷ triggering the thirty-month waiting period during which the FDA cannot provide final approval to any ANDA applications.⁹⁸ Soon after, in June 1997, Biovail, another generic manufacturer, filed an ANDA for the same drug.⁹⁹ The FDA issued a tentative approval of Andrx’s ANDA on September 15, 1997.¹⁰⁰ Only nine days later, HMRI and Andrx entered into an

93. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003) (determining that the agreement was a horizontal market allocation device, and thus illegal per se); *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 819 (D.C. Cir. 2001) (applying antitrust scrutiny to find that the agreement constituted prima facie evidence of an unreasonable restraint of trade).

94. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1340 (Fed. Cir. 2008) (reasoning that absent fraud or sham, it need not consider the patent validity, the court found no antitrust violation); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 220 (2d Cir. 2006) (reasoning that the patent confers a monopoly power, and the court found no antitrust violation); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (finding that absent sham or fraud, a reverse payment does not violate antitrust laws if it exists within the scope of the patent); *Valley Drug Co.*, 344 F.3d at 1308 (reasoning that the court must consider the exclusionary scope of the patent to determine whether an antitrust violation occurred).

95. *See infra* Part II.

96. 256 F.3d at 803. Cardizem CD carries U.S. Patent No. 5,470,584. Defendants-Appellants’ Brief at 8, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2001) (No. 00-2483).

97. *Andrx Pharms., Inc.*, 256 F.3d at 803.

98. *Id.*

99. *Id.* Here, Biovail is a “subsequent filer” to Andrx. *See supra* note 43 (noting the nomenclature of “first filer” and “subsequent filer”).

100. *Andrx Pharms., Inc.*, 256 F.3d at 803. Tentative approval means that the FDA sent a letter to the ANDA applicant “stating that all scientific and procedural conditions for approval of generic drug have been met, but final approval has been delayed, usually because the FDA has concluded that the statutory marketing exclusivity period of a prior generic drug has not yet expired.” Brief of Appellant Biovail Corporation at ix, *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799 (D.C. Cir. 2000) (Nos. 00-5050, 00-5396). Interestingly, when Biovail filed its ANDA, HMRI offered a Biovail a lucrative arrangement “under which Biovail would be compensated for postponing the marketing of its generic version of Cardizem CD and for refraining from assisting Andrx in marketing that first-filer’s competing generic version,” but

agreement, providing that HMRI would pay Andrx \$40 million per year, starting when Andrx received final approval from the FDA.¹⁰¹ HMRI would stop paying Andrx if the court found Andrx liable for patent infringement, and if not, when Andrx began selling the generic version of Cardizem CD.¹⁰² Though the parties maintained that the agreement did not settle the litigation,¹⁰³ it created a bottleneck by delaying commencement of Andrx's 180-day marketing exclusivity period, thereby delaying entry of any generic on the market—namely, Biovail's attempt at producing the generic drug.¹⁰⁴

As evidence of the intent and effect of the settlement agreement, Andrx did not begin marketing and selling the generic version of Cardizem CD until a year after it was eligible to do so.¹⁰⁵ On July 9, 1998, the FDA issued its final approval of Andrx's ANDA.¹⁰⁶ Pursuant to the agreement, HMRI began making quarterly payments to Andrx, and in exchange, Andrx did not bring its generic drug to market.¹⁰⁷ Because Andrx was the first generic applicant for Cardizem CD and the company effectively delayed the 180-day marketing exclusivity period, the FDA could not approve any subsequently filed ANDAs and no generic versions of the drug could enter the market.¹⁰⁸

Subsequently, Biovail filed an action in the D.C. Circuit, claiming that Andrx and HMRI violated the Sherman Act by creating a bottleneck in the market.¹⁰⁹ The D.C. Circuit held for Biovail,

Biovail rejected the offer. *Id.* at 7.

101. *Andrx Pharms., Inc.*, 256 F.3d at 803.

102. *Id.*

103. *Id.* Andrx and HMRI argued that the agreement “purported to maintain the status quo pending the outcome of HMRI's patent infringement suit against Andrx.” *Id.*

104. *Id.* at 804.

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.* See also Weiswasser & Danzis, *supra* note 22, at 600–01 (offering a detailed explanation of the exclusivity provisions). On September 11, 1998, Andrx filed a supplement to its original ANDA seeking approval for a reformulated generic version of Cardizem CD. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 903 (6th Cir. 2003). In doing so, Andrx notified HMRI and certified that the reformulated product did not infringe on HMRI's patent. *Id.* Finally, on June 9, 1999, the FDA approved Andrx's reformulated generic product and after one year of payments, HMRI and Andrx terminated the agreement and settled the litigation. *Id.* HMRI paid Andrx a final sum of \$50.7 million, bringing the total payments to \$89.83 million. *Id.* Shortly thereafter, Andrx began marketing the generic version of Cardizem, Cartia XT, which captured a substantial share of the market. *Id.*

109. In 1998, Andrx sued the FDA and other ANDA applicants, including Biovail, to quiet its right as the first-time applicant, which entitles the applicant to 180-day market exclusivity. *Andrx Pharms., Inc.*, 256 F.3d at 804. Andrx sought injunctive relief, requiring the FDA to provide Andrx with the 180-day market exclusivity and prohibiting the FDA from approving any other ANDAs, such as Biovail's, until the 180-day period terminated. *Id.* Biovail counterclaimed,

reasoning that a payment from a drug-innovator to the challenging generic drug firm strongly suggested “the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement.”¹¹⁰ Andrx argued that it simply acted within its rights under the Hatch-Waxman Act.¹¹¹ The court found that although Hatch-Waxman allowed for these settlements, the Act did not insulate defendants from antitrust liability.¹¹² Further, the court noted that because a reasonable juror could consider payment from HMRI to Andrx as a quid pro quo for Andrx’s delay of market entry, the agreement served as prima facie evidence of an illegal agreement not to compete.¹¹³

The Sixth Circuit considered the same agreement in *In re Cardizem CD*. In this case, the plaintiffs were direct and indirect consumers of Cardizem CD, whereas in the first litigation, Biovail brought the lawsuit.¹¹⁴ Like the D.C. Circuit in *Andrx*, the Sixth Circuit affirmed the district court’s holding that the agreement was a per se illegal restraint of trade because it sought to delay Andrx’s market entry, as well as other products not covered by the patent.¹¹⁵ The Sixth Circuit

alleging that Andrx violated sections 1 and 2 of the Sherman Act. Brief of Appellant Biovail Corporation at 2, *Andrx Pharms., Inc. v. Biovail Corp.* Int’l, 256 F.3d 799 (D.C. Cir. 2000) (Nos. 00-5050, 00-5396). The District Court granted Andrx’s motion to dismiss Biovail’s counterclaim, finding that as a private plaintiff that had not yet entered the market, it could not plead an antitrust injury. *Andrx Pharms., Inc. v. Friedman*, 83 F. Supp. 2d 179, 185–87 (D.D.C. 2000). Biovail was required to establish standing as a private plaintiff under the section 4 of the Clayton Act, 15 U.S.C. § 15 (2006). According to the Clayton Act, a competitor that has not entered the market suffers injury from antitrust violation if it can demonstrate its intention to enter the market and its preparedness to do so. *Andrx Pharms., Inc.*, 256 F.3d at 807 (citing *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 882 (Fed. Cir. 1985)). The D.C. Circuit held that even if it was appropriate for the lower court to dismiss for lack of standing, the district court should not have dismissed with prejudice because the Biovail could still allege intent and preparedness to enter the market. *Andrx Pharms., Inc.*, 256 F.3d at 807.

110. *Andrx Pharms., Inc.*, 256 F.3d at 809. “Typically, in patent infringement cases the payment flows from the alleged infringer to the patent holder. A payment flowing from the innovator to the challenging generic firm . . . may indicate whether the generic firm has the incentive or ability to enter the market or to pursue fully the litigation.” David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 335 (2000).

111. *Andrx Pharms., Inc.*, 256 F.3d at 811.

112. *Id.* See also Hemphill, *Paying for Delay*, *supra* note 7, at 1577–78 (discussing a common argument of brand-name pharmaceutical companies that the payments are a “natural byproduct” of regulation).

113. *Andrx Pharms., Inc.*, 256 F.3d at 813.

114. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003).

115. *Id.* at 908–09. The district court had concluded that the plaintiffs adequately alleged antitrust injury by applying the test the Supreme Court set forth in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*: antitrust injury is an “injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants’ acts unlawful.” 429 U.S. 477, 489 (1977). Further, the district court noted that the Supreme Court had stated that the Sherman Act’s

reasoned that the agreement was a plain and obvious “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.”¹¹⁶ Further, the Sixth Circuit rejected the defendants’ arguments that the agreement solely sought to enforce patent rights, reasoning that there was a difference between exercising patent holder rights and “bolstering” the patent’s monopoly power with an illegal arrangement.¹¹⁷ The court also rejected defendants’ argument that this “novel” area of law entitled it to avoid per se treatment.¹¹⁸ Instead, the Sixth Circuit found that the Sherman Act “establishes one uniform rule applicable to all industries alike.”¹¹⁹ Thus, because the court applied the per se rule, it did not need to consider the defendants’ claims that the agreement had procompetitive benefits.¹²⁰

II. DISCUSSION

While the D.C. and Sixth Circuits applied antitrust scrutiny to reverse payments in the Cardizem CD cases,¹²¹ more recent cases in the Second, Eleventh, and Federal Circuits have instead applied the scope of the patent test to similar cases, favoring judicial efficiency over promotion of a competitive and fair prescription drug market.¹²² This

purpose was to ensure competitive prices for consumers and protect the “economic freedom of participants in the relevant market.” *In re Cardizem CD*, 332 F.3d at 908 (citing *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 538 (1983)). See *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972) (“Antitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise.”).

116. *In re Cardizem CD*, 332 F.3d at 908.

117. *Id.*

118. *Id.* The defendants argued that the district court’s errors concerning Hatch-Waxman showed that there had been insufficient judicial experience to condemn the agreement as per se illegal. Defendants-Appellants’ Brief at 44–45, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2001) (No. 00-2483).

119. *In re Cardizem CD*, 332 F.3d at 908 (citing *Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 349 (1982)).

120. *Id.* at 909.

121. See *id.* at 914–15; *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809–10 (D.C. Cir. 2001) (applying antitrust scrutiny to find that the agreement constituted prima facie evidence of an unreasonable restraint of trade).

122. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1337 (Fed. Cir. 2008) (reasoning that absent fraud or sham, it need not consider the patent validity, leading the court to find no antitrust violation); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006) (reasoning that the patent confers a monopoly power and finding no antitrust violation); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075–76 (11th Cir. 2005) (finding that absent sham or fraud, a reverse payment does not violate antitrust laws if it exists within the scope of the patent); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308–09 (11th Cir. 2003) (reasoning that the court must consider the exclusionary scope of the patent to determine whether an antitrust violation occurred, leading the court to find the payment was legal).

Part discusses the cases that form the current state of the law, illustrating a clear circuit split over whether reverse payment settlements are anticompetitive.

A. Valley Drug Co.: *Creating the Scope of the Patent Test*

The Eleventh Circuit was the first circuit to depart from the antitrust analysis applied in *Andrx* and *In re Cardizem CD*.¹²³ The first reverse payment case the Eleventh Circuit considered, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, revolved around two settlement agreements Abbott Laboratories (“Abbott”) made with two manufacturers that aimed to produce a generic version of Abbott’s highly profitable drug, Hytrin.¹²⁴ Abbott sued the generic drug manufacturers, Zenith Pharmaceuticals, Inc. (“Zenith”) and Geneva Pharmaceuticals, Inc. (“Geneva”), for patent infringement when the manufacturers claimed that Abbott’s patent for Hytrin was invalid in their respective ANDAs.¹²⁵

Abbott and Zenith entered into an agreement (“Zenith Agreement”) in which Zenith admitted the validity of Abbott’s patents and agreed not to sell or distribute any pharmaceutical product containing any form of Hytrin’s main compound, terazosin hydrochloride, until another generic introduced that compound or Abbott’s Patent No. 4,215,532 expired.¹²⁶ In exchange, Abbott agreed to pay Zenith \$3 million up front, \$3 million after three months, and \$6 million every three months until a certain date or until the Zenith Agreement terminated.¹²⁷

Similarly, Abbott entered into an agreement with Geneva (“Geneva Agreement”), in which Geneva agreed to the same terms as Zenith, not

123. Later courts would follow the Eleventh Circuit’s lead in applying the scope of the patent test. See, e.g., *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1340; *In re Tamoxifen Citrate*, 466 F.3d at 220; *Schering-Plough Corp.*, 402 F.3d at 1075.

124. *Valley Drug Co.*, 344 F.3d at 1299–300. In 1987, Abbott began marketing Hytrin, a drug used in the treatment of hypertension and benign prostatic hyperplasia. *Id.* at 1298. Abbott generated \$540 million in sales in 1998 alone, which constituted more than twenty percent of Abbott’s net sales of United States pharmaceutical products that year. Defendants-Appellants’ Opening Brief at 5, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2002) (No. 02-12091-J). Abbott’s Hytrin patent covered the basic terazosin hydrochloride compound. Sherman Act Class Plaintiffs-Appellees’ Brief at 9, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2002) (No. 02-12091-J) [hereinafter Sherman Act Brief].

125. Sherman Act Brief, *supra* note 124, at 9. First, Geneva filed four ANDAs based on Hytrin’s main chemical compound between 1993 and 1996, and made paragraph IV certifications regarding Abbott’s listed patents each time. *Valley Drug Co.*, 344 F.3d at 1299. Abbott sued Geneva for patent infringement and Geneva claimed the patent was invalid. *Id.* Meanwhile, Zenith filed an ANDA for a generic based on Hytrin and patent infringement litigation ensued. *Id.*

126. *Id.* at 1300.

127. *Id.*

to transfer or sell its right to the 180-day marketing exclusivity period, and not to oppose any subsequent ANDAs.¹²⁸ In return, Abbott would pay Geneva \$4.5 million each month until either another generic manufacturer brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court patent infringement case.¹²⁹

A class of generic drug manufacturers, pharmacies, and interest groups sued Abbott and Geneva, claiming that the Geneva Agreement violated section 1 of the Sherman Act.¹³⁰ Reversing the district court, the Eleventh Circuit found that the agreements were not per se illegal.¹³¹ The court reasoned that the district court failed to accurately weigh the exclusionary power of the patent.¹³² Because a patent-owner has the lawful right to exclude others, the court found that the patentee could exploit the exclusionary right to gain market share.¹³³ Further,

128. *Id.*

129. *Id.* Pursuant to the Geneva Agreement, if Geneva won in district court, Abbott's payments would go into escrow pending resolution of appeal. *Id.* On September 1, 1998, the district court granted Geneva's motion for summary judgment in the patent infringement suit, holding the '207 patent was invalid due to the on-sale bar. *Abbott Labs. v. Geneva Pharms., Inc.*, Nos. 96-C-3331, 96-C-5868, & 97-C-7587, 1998 WL 566884, at *7 (N.D. Ill. Sept. 1, 1998). See 35 U.S.C. § 102(b) (2006) (providing that a patent is invalid or cannot be granted if a form of the compound was on sale in the United States or another country for more than one year prior to the application date for the patent). Abbott and Geneva terminated the settlement agreement earlier than intended because the FTC initiated an investigation. *Valley Drug Co.*, 344 F.3d at 1301. Abbott and Geneva entered into consent decrees with the FTC, prohibiting Abbott and Geneva from entering into brand-generic agreements similar to the one they terminated. *In re Abbott Labs.*, No. C-3945, 2000 WL 681848, at *7 (F.T.C. May 22, 2000). The orders prohibited Abbott and Geneva from entering into brand-generic agreements that would raise antitrust risks. See Uche Ewelukwa, *Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203, 261 (2005) (detailing the specifics of the FTC orders). Pursuant to the Geneva Agreement, Abbott paid Geneva a total of \$27 million. Sherman Act Class Plaintiffs-Appellees' Brief at 9–12, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2002) (No. 02-12091-J).

130. *Valley Drug Co.*, 344 F.3d at 1295–96.

131. *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1354 (S.D. Fla. 2000), *rev'd sub nom.* 344 F.3d 1294 (11th Cir. 2003). The district court found that the settlement agreement was a horizontal market allocation between competitors. *Valley Drug Co.*, 344 F.3d at 1304.

132. *Valley Drug Co.*, 344 F.3d at 1304–07. See *In re Terazosin Hydrochloride*, 164 F. Supp. 2d at 1345–46 (discounting the exclusionary patent right in its antitrust analysis).

133. See 35 U.S.C. § 271(a) (defining patent infringement); 35 U.S.C. § 283 (offering injunctive relief for infringement); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989) (reasoning that allowing patentees to exploit market share is a key incentive for innovation); *Dawson Chem. Co. v. Rohm & Hass Co.*, 448 U.S. 176, 215 (1980) (“[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.”); *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 189 (permitting a license restricting the licensee's sales to non-commercial customers); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 1981) (finding that a patentee can choose to exclude everyone from

the court noted that because patents offer patentees the unique opportunity to “grant exclusive territorial licenses,” the patent was an exception to the traditional antitrust rule that market allocation is an unreasonable restraint of trade.¹³⁴ Applying this concept to the settlement agreement, the Eleventh Circuit reasoned that the effect of the Geneva Agreement or the Zenith Agreement would not extend beyond the exclusionary right of the patent itself.¹³⁵

In considering the intersection of patent and antitrust law, the court concluded that scrutinizing settlements for antitrust liability would undermine patent incentives, which it favored over promoting competition.¹³⁶ In addition, the court noted that patent litigation was too expensive, created too much uncertainty, and took too much time to justify limiting settlements by subjecting them to antitrust scrutiny.¹³⁷

The Eleventh Circuit expressly rejected the Sixth Circuit’s opinion in *In re Cardizem CD*, reasoning that where the issue involved the exclusionary power of a patent, the antitrust analysis could not ignore the scope of the patent.¹³⁸ Instead, the court held that the patent was an exception to antitrust liability, which required courts to consider the scope of the patent, whether the agreement exceeded the scope, and the anticompetitive effects of the excess.¹³⁹ The Eleventh Circuit further

producing the patented articles). *But see* *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 380 (1952) (holding that patentees cannot pool patents and fix prices).

134. The court reasoned that “a patentee’s allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability” because “the patent gives its owner a lawful exclusionary right.” *Valley Drug Co.*, 344 F.3d at 1305. For a discussion of patent exceptionalism theory, see Hemphill, *Paying for Delay*, *supra* note 7, at 1597–604.

135. *Valley Drug Co.*, 344 F.3d at 1305.

136. *Id.* at 1307–08. The court was responding to the class claim that a patent exception to antitrust liability did not apply in this case because Abbott’s ’207 patent was eventually deemed invalid. *Id.* at 1306–07. The court sought to strike a balance between antitrust law’s free competition requirement and patent law’s incentive system, noting that they both “seek the same object: the welfare of the public.” *Id.* at 1307–08 (quoting PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* ¶ 1780a (1999)). *See also* *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1352 (Fed. Cir. 1999) (“The patent and antitrust laws are complementary in purpose in that they promote innovation and competition . . .”).

137. *Valley Drug Co.*, 344 F.3d at 1308 (“Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.”). The court noted that the cost savings of settlement benefit the parties and the public. *Id.* at 1308 n.20 (citing *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976)).

138. *See Valley Drug Co.*, 344 F.3d at 1310 (“[T]he protection of the patent laws and the coverage of antitrust laws are not separate issues.”) (quoting *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981)) (alteration in original)).

139. *Valley Drug Co.*, 344 F.3d at 1311–12. Commentators would later term this inquiry the

held that instead of per se branding, the district court could apply rule of reason antitrust analysis to the provisions of the settlement agreement that could impact the market beyond the effect of Abbott's patents.¹⁴⁰

Departing from the Sixth Circuit's characterization of reverse payments as per se antitrust violations, the Eleventh Circuit emphasized the importance of the exclusionary right of the patent and created a new test for reverse payment settlements.¹⁴¹ Although the Eleventh Circuit instructed the lower court to apply the rule of reason analysis to the provisions outside the scope of the patent, later courts would extend this inquiry essentially to foreclose any antitrust scrutiny of reverse payment settlements.¹⁴²

B. Schering-Plough v. FTC: Expanding the Scope of the Patent Test

Three years later, the Eleventh Circuit heard a case that stemmed from the same settlement agreement that the Third Circuit would later find anticompetitive in *In re K-Dur*.¹⁴³ In *Schering-Plough v. FTC*, Upsher-Smith Laboratories ("Upsher") sought FDA approval to market the generic version of one of Schering-Plough Corporation's ("Schering") patented drugs, K-Dur 20, and Schering promptly sued

"scope of the patent test." See, e.g., Michael C. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 5–6 (2012) [hereinafter Carrier, "Scope of the Patent" Test]; Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47, 60 n.87 (2010). The appellate court instructed the district court to identify the protections afforded by the patents and consider whether the agreements reflected these policy objectives. *Valley Drug Co.*, 344 F.3d at 1312. The Eleventh Circuit further instructed the district court to compare certain provisions of the agreements to the protections offered by a preliminary injunction, as well as to consider the provision in light of the likelihood that Abbott would obtain those protections. *Id.*

140. *Valley Drug Co.*, 344 F.3d at 1312. On remand, the district court found that at the time the parties entered into the settlement agreement, Abbott would not have been able to receive a preliminary injunction, and the litigation would have found the '207 patent invalid. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1306 (S.D. Fla. 2005). Following the appellate court's instructions, the district court established that the provision of the settlement agreement indeed exceeded the exclusionary scope of the '207 patent, and then applied "normal" antitrust principles to find that the provision was anticompetitive. *Id.* at 1310.

141. *Valley Drug Co.*, 344 F.3d at 1310 ("We recognize that the Sixth Circuit appeared to take the opposite view . . ."). See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003) (holding that the agreement was a horizontal market allocation device, and was therefore per se illegal).

142. *Valley Drug Co.*, 344 F.3d at 1312. The Eleventh Circuit instructed the district court to apply traditional antitrust analysis to provisions outside the exclusionary effects of Abbott's patent to "assess their probable anticompetitive effects." *Id.* However, since *Schering-Plough* extended this inquiry to the scope of the patent test, no court applying the test has reached an antitrust analysis or found an antitrust violation. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 212 (3d Cir. 2012).

143. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065–66 (11th Cir. 2005). See *In re K-Dur*, 686 F.3d at 211.

Upsher for patent infringement.¹⁴⁴ The parties immediately settled the case, agreeing that Upsher would not enter the market until a certain date and that Schering would license other Upsher products in return, including a product called Niacor.¹⁴⁵ Schering had previously explored investing in a Niacor license and then declined due to disappointing sales of a very similar drug owned by Kos Pharmaceuticals, Niaspan.¹⁴⁶ On the eve of the trial, Schering and Upsher finalized the agreement, providing that Schering would pay: (1) \$60 million in initial royalty fees; (2) \$10 million in milestone royalty payments; and (3) ten or fifteen percent royalties on sales.¹⁴⁷

The FTC filed an administrative complaint alleging that the settlement agreement violated section 1 of the Sherman Act.¹⁴⁸ The

144. *Schering-Plough Corp.*, 402 F.3d at 1059. Schering-Plough manufactured an “extended-release microencapsulated potassium chloride product, K-Dur 20,” which treated high blood pressure and congestive heart disease. *Id.* at 1058. Though the active ingredient in K-Dur 20, potassium chloride, is commonly used and unpatentable, Schering-Plough owned a formulation patent on the extended-release coating, which surrounds the potassium chloride in K-Dur 20. U.S. Patent No. 4,863,743 (filed Feb. 19, 1986). The patent expired on September 5, 2006. *Id.*

145. *Schering-Plough Corp.*, 402 F.3d at 1059. Before reaching a final agreement, Schering refused to pay Upsher to stay out of the market and proposed that the two companies agree on the date Upsher would introduce the generic version to market. *Id.* In exchange for setting this date, Schering agreed to purchase an exclusive license to market Niacor, a sustained-release niacin product used to reduce cholesterol, which Schering had been interested in pursuing. *Id.* In June 1997, Schering received five licenses to market five Upsher products, one of which was Niacor. *Id.* Along with the license, Schering received the results of Niacor’s clinical studies. *Id.* James Audibert, the head of Schering’s Global Marketing Division for cardiovascular products, evaluated the profitability and effectiveness of Niacor and found that Niacor’s net value at the time was between \$245 and \$265 million. *Id.* at 1059–60. Audibert’s assessment was independent from the settlement agreement and he was unaware of the amount of money Upsher requested for the license rights. Answering Brief of Upsher-Smith Labs., Inc. at 9, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688).

146. After determining that the deal was profitable for Schering, the board approved the licensing transaction. *Schering-Plough Corp.*, 402 F.3d at 1060. The profitability forecast corresponded to an independent profitability assessment that Schering performed regarding Kos Pharmaceutical’s Niaspan, a product similar to Niacor. *Id.* Schering estimated that Niaspan sales would reach \$174 million by 2005 for the U.S. market and predicted Niacor would reach \$136 million for a global market segment larger than the U.S. market alone. *Id.* Unfortunately, Niaspan reported disappointing first-quarter sales, causing Kos Pharmaceutical’s stock price to drop dramatically from \$30.94 to \$6.00. *Id.* As a result, Upsher and Schering refrained from investing further in Niacor. Petition for Writ of Certiorari at 8, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273).

147. *Schering-Plough Corp.*, 402 F.3d at 1060; Brief of Petitioner Upsher-Smith Laboratories, Inc. at 4, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688-AA).

148. The FTC also alleged that the agreement violated section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2006). In addition, the FTC filed an administrative complaint against ESI Lederle (“ESI”), which also sought to market its generic version of K-Dur 20. *Schering-Plough Corp.*, 402 F.3d at 1060. Patent litigation ensued, but unlike Schering and Upsher, Schering and ESI participated in court-mandated mediation, which “resulted in nothing more than an impasse.” *Id.* Ultimately, ESI and Schering agreed that ESI could enter the market

Administrative Law Judge (“ALJ”) found that the settlements were lawful and the FTC appealed this decision to the full Commission.¹⁴⁹ The Commission reversed the ALJ’s decision, concluding that the settlements violated the Sherman Act.¹⁵⁰ The Commission observed that even though Niacor had potentially serious safety and market concerns, Schering failed to include key employees in the negotiations, to request sales projections, to pursue unfulfilled requests, and to object when Upsher suspended its investigative work—all of which demonstrated Schering’s lack of genuine interest in Niacor and revealed that the purpose of Schering’s payment was only to delay the generic drug from entering the market.¹⁵¹ Therefore, the Commission found that Schering’s payment to Upsher was illegitimate consideration for the licenses and that the settlement agreement violated the Sherman Act.¹⁵²

Upon review, the Eleventh Circuit reversed the FTC’s determination, holding that the settlement agreement was not anticompetitive in line with *Valley Drug*.¹⁵³ Reasoning that patents naturally confer a monopoly power that limits competition, the court found that neither the rule of reason nor the per se analysis was appropriate in analyzing reverse payment settlements.¹⁵⁴

Instead, applying the scope of the patent test from *Valley Drug*, the court found that Schering’s patent entitled it to exclude Upsher from the market until a court determined the patent was invalid or Upsher proved its product did not infringe on the patent.¹⁵⁵ Further, the court found

three years before the patent would expire and if the FDA approved ESI’s ANDA by a certain date, Schering would pay ESI \$10 million. *Id.* at 1060–61. On October 21, 2001, the FTC withdrew the complaint against American Home Products (“AHP”), the parent company of ESI, to consider a proposed consent agreement. *Id.* at 1061. On April 2, 2002, the FTC approved a final consent order. *Id.* at 1061 n.9. Though AHP was not a party in this litigation, Schering’s settlement with ESI/AHP “remained at issue with respect to Schering.” *Id.*

149. *Schering-Plough Corp.*, 402 F.3d at 1061.

150. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 985 (2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005).

151. *Id.* at 1019, 1037, 1043, 1051–52. To see a comparison of Schering’s sales projections for Niacor and Niaspan, see Opening Brief of Schering-Plough Corporation at 18, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688-AA).

152. *Schering-Plough Corp.*, 402 F.3d at 1061–62. Additionally, the Commission ruled that it would invalidate any agreement by which the generic receives value for deferring its own research, development, or production, unless the value of the payment was a reasonable estimate of litigation costs and the parties notified the FTC of the agreement. *Id.*

153. *Id.* at 1063–76.

154. *Id.* at 1065. The court elaborated, “‘What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.’” *Id.* at 1066 (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003)).

155. *Schering-Plough Corp.*, 402 F.3d at 1066, 1072 (examining the scope of the exclusionary

that the agreement did not provide exclusionary rights exceeding the scope of the patent.¹⁵⁶ The negotiations leading up to the settlement, the fact that licensed products often do not ultimately enter the market in the pharmaceutical industry, and that the parties intended “royalty” to mean that Schering would pay Upsher for licenses and production rights led the court to find that Schering paid Upsher a fair price for licenses, which did not restrict competition.¹⁵⁷ Further, the court noted that the general policy in the law to favor settlements applied to patent litigation lawsuits.¹⁵⁸ The court concluded that Schering reasonably used its patent power.¹⁵⁹

Finally, in analyzing whether the agreements were indeed an unfair method of competition, the Eleventh Circuit found that the restrictions on competition were ancillary restraints necessary to the settlement’s utility and efficiency.¹⁶⁰ The court again relied on public policy support for settlements to bolster its finding that the agreements were not anticompetitive.¹⁶¹ Because the agreement covered only the patents at issue, the restraint was sufficiently narrow.¹⁶² Further, the court

potential of the patent, the extent to which the agreements exceed that scope, and the resulting anticompetitive effects).

156. *Id.* at 1069.

157. *Id.* at 1071 (citing *Sierra Club, Inc. v. C.I.R.*, 86 F.3d 1526, 1531 (9th Cir. 1996)). The court noted that the parties intended “royalty” to reflect its traditional meaning: payments made to the owner of property for permitting another to use the property. *Id.*

158. *See id.* (citing *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001)); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 477 (Fed. Cir. 1991).

159. *Schering-Plough Corp.*, 402 F.3d at 1072.

160. *Id.* The court noted that an ancillary restraint defines the parameters of an agreement to prevent future litigation. *See id.* (“The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose.”) (quoting *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986)). In addition, the court observed that the settlement agreement was a natural byproduct of the Hatch-Waxman Act. *Id.* at 1074 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)). The court hypothesized that pre-Hatch-Waxman, Upsher and ESI “would have had to enter the market with their products,” performed costly clinical trials, produced, and marketed the drug before entering into a long and painful patent infringement suit with Schering. *Id.* at 1073. Instead, Hatch-Waxman “essentially redistributes the relative risk assessments.” *Id.*

161. *Id.* at 1072–73. The court stated that settlements provide many private and social benefits. *Id.* at 1075 (citing *Crane, supra* note 51, at 760). The court also noted that patent litigation costs \$1 billion annually. *Id.* (citing Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 *YALE J. ON REG.* 359, 380 (1999)).

162. *Schering-Plough Corp.*, 402 F.3d at 1073. The court reasoned that the agreement did not delay any other products. *Id.* Generally, the court reinforced its holding in *Valley Drug*: “It is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit . . . litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.” *Id.* (quoting *Valley Drug Co. v. Geneva*

rationalized that forbidding reverse payment settlements would reduce the generic manufacturer's incentive to challenge patents.¹⁶³

The *Schering-Plough* decision further solidified the Eleventh Circuit's reasoning in *Valley Drug* and entrenched the scope of the patent test as an attractive way to analyze reverse payment settlements.¹⁶⁴ The FTC, with the support of thirty-four states and a patent policy think tank, sought Supreme Court review of the Eleventh Circuit decision. The Supreme Court, however, denied certiorari, leaving courts to choose between applying the scope of the patent test or antitrust scrutiny to reverse payment settlements.¹⁶⁵

C. In re Tamoxifen Citrate: Making the Scope of the Patent Test More Deferential

Similar to the Eleventh Circuit's holdings in *Valley Drug* and *Schering-Plough*, the Second Circuit found that a reverse payment settlement within the scope of the patent did not violate antitrust laws.¹⁶⁶ In *In re Tamoxifen Citrate Antitrust Litigation*, Barr Laboratories ("Barr") filed an ANDA relating to Zeneca, Inc.'s ("Zeneca") patent for Tamoxifen, prompting Zeneca to sue for patent infringement.¹⁶⁷ The parties entered into a settlement agreement while an appeal of the patent infringement suit was pending.¹⁶⁸ Pursuant to the agreement, Zeneca would pay Barr \$21 million and allow Barr to sell Zeneca-manufactured Tamoxifen in the United States under Barr's label.¹⁶⁹ In return, Barr agreed not to market its own generic version until Zeneca's patent expired.¹⁷⁰

Pharms., Inc., 344 F.3d 1294, 1309 (11th Cir. 2003)).

163. *Schering-Plough Corp.*, 402 F.3d at 1074.

164. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1340 (Fed. Cir. 2008) (applying the scope of the patent test); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006) (same).

165. Holman, *supra* note 6, at 491; Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 55.

166. *In re Tamoxifen Citrate*, 466 F.3d at 213.

167. *Id.* at 193. Imperial Chemical Industries ("ICI") received a patent on Tamoxifen in August 1985. *Id.* at 191. Zeneca obtained the rights to the patent and manufactured the drug. *Id.* Tamoxifen was the most prescribed cancer drug in the world at the time. *Id.*

168. *Id.* In the patent infringement suit, the district court found that ICI intentionally withheld crucial information from the PTO regarding safety and effectiveness tests, and therefore declared the patent invalid. *Id.* (citing *Imperial Chem. Indus., PLC v. Barr Labs.*, 795 F. Supp. 619, 626–27 (S.D.N.Y. 1992)). Specifically, the tests revealed hormonal effects "opposite to those sought in humans," which could lead to "unpredictable and at times disastrous consequences." *Imperial Chem. Indus., PLC*, 795 F. Supp. at 622.

169. *In re Tamoxifen Citrate*, 466 F.3d at 193–94.

170. *Id.* To delay market entry, Barr changed its ANDA paragraph IV certification to a paragraph III certification, removing the patent invalidity allegation. Brief for Plaintiffs

The Second Circuit affirmed the district court decision, holding that the reverse payment settlement was not anticompetitive.¹⁷¹ The court, in considering whether the reverse settlement payments were excessive, observed that reverse payment settlements are facially “suspicious,” especially when patentees settle litigation against potential generic challengers by paying more than what the generic would earn if it prevailed in the litigation and entered the market.¹⁷² Further, the court noted that “[s]o long as the law encourages settlements, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.”¹⁷³

Yet, the court reasoned that due to the presumption of patent validity, the settlement legitimately extended the valid patent monopoly.¹⁷⁴ The court held that as long as the patent litigation was not a sham, otherwise baseless, or did not extend beyond the scope of the patent, the patentee could legally enter into a reverse payment settlement.¹⁷⁵ The Second Circuit analyzed Zeneca’s agreement and found it was neither fraudulent nor baseless.¹⁷⁶ The court also determined that the agreement did not exceed the patent’s scope.¹⁷⁷ Distinguishing the case from *In re Cardizem CD*, the court noted that the settlement did not restrict the marketing of non-infringing products.¹⁷⁸ The court added that the settlement allowed other potential generics to challenge the validity of the patent.¹⁷⁹ Further, the Second Circuit followed the

Appellants at 10, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) (No. 03-7641). In addition, Zeneca would pay Barr’s raw materials supplier \$9.5 million at the time and an additional \$35.9 million over the following ten years. *Id.* Further, if the court declared the Tamoxifen patent invalid or unenforceable, Barr would be able to market the generic version of the drug. *Id.* The plaintiffs alleged that Barr “understood” that it would seek to block any other generic manufacturer’s attempt to market a generic version of Tamoxifen by invoking the 180-day exclusivity period. *Id.* Five years later, only a few weeks before other generic manufacturers could start marketing generic versions of Tamoxifen, Barr successfully invoked the start of the 180-day exclusivity period as the first paragraph IV certification filer. *In re Tamoxifen Citrate*, 466 F.3d at 193–94. Barr did not begin marketing its own generic version because it could already market Zeneca’s version, thereby preventing other manufacturers from entering the market. *Id.*

171. *In re Tamoxifen Citrate*, 466 F.3d at 196–97.

172. *Id.* at 208. In fact, this is almost always the case, giving generic manufacturers a huge incentive to settle. Leary, *supra* note 53, at 381.

173. *In re Tamoxifen Citrate*, 466 F.3d at 211.

174. *Id.* at 211–12.

175. *Id.* at 208–09. This statement resulted in increased deference toward reverse payment settlements. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 63.

176. *In re Tamoxifen Citrate*, 466 F.3d at 213.

177. *Id.*

178. *Id.* at 213–14. The court reasoned that, because Zeneca’s patent precluded all generic versions of Tamoxifen, another generic would also infringe the patent. *Id.*

179. *Id.* at 214–15.

Eleventh Circuit's lead by emphasizing public interest in settlements.¹⁸⁰

Though the court followed the Eleventh Circuit in finding the agreements legal, Judge Pooler dissented.¹⁸¹ Balancing the same interests as the majority, Judge Pooler more heavily weighed the significant public interest in testing weak patents, particularly because of the impact of reverse payment settlements on health care costs.¹⁸² Respecting the importance of these public interests alongside those favoring settlements, Judge Pooler reasoned that the court should apply a reasonableness standard to consider the patent's strength at the time of settlement, the size of the payment, the amount the generic firm would earn during its exclusivity period, and other anticompetitive effects.¹⁸³

D. In re Ciprofloxacin Hydrochloride: Entrenching the Scope of the Patent Test as a Toothless Test

Like the Second and Eleventh Circuits, the Federal Circuit applied the scope of the patent test and found no antitrust violation in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.¹⁸⁴ When Barr filed an ANDA referencing Bayer's drug, Cipro, Bayer sued Barr for patent infringement.¹⁸⁵ The parties entered into a settlement agreement in which Bayer agreed to pay Barr over \$49 million to delay market entry

180. *Id.* at 202. The court explained, "[W]here a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement. The trial court must protect the public interest, as well as the interests of the parties, by encouraging the most fair and efficient resolution." *Id.* (quoting *United States v. Glens Falls Newspapers, Inc.*, 160 F.3d 853, 856–57 (2nd Cir. 1998)). See also *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1071 (11th Cir. 2005) (noting that scrutinizing settlements would disincentive generics from challenging patents); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003) (underlining that settlements are in the public's interest).

181. *In re Tamoxifen Citrate*, 466 F.3d at 221–32 (Pooler, J., dissenting).

182. *Id.* at 225–26. Judge Pooler reasoned that the modern trend toward capping the amount that insurers and public benefit plans spend on medication diminishes consumers' access to medications. *Id.*

183. *Id.* at 228. Judge Pooler concluded that plaintiffs' pleading was sufficient to survive a motion to dismiss because they claimed: (1) The court would have affirmed the patent's invalidity determination; (2) Barr earned more money through settlement than it would have through successful litigation; and (3) Barr agreed to "deploy its paragraph IV certification to defeat other potential generic entrants." *Id.*

184. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).

185. *Id.* at 1327–28. Bayer owns U.S. Patent No. 4,670,444, which covers the compound ciprofloxacin hydrochloride, the active ingredient in Cipro, a drug that treats bacterial illnesses. *Id.* Barr asserted that the patent was invalid based upon obviousness under 35 U.S.C. § 103, obviousness type double patenting under 35 U.S.C. § 101, and unenforceable due to inequitable conduct. See 35 U.S.C. § 103 (2006) (supplying the conditions for patentability for non-obvious subject matter); 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.").

until six months before Bayer's patent expired.¹⁸⁶ In addition, Bayer agreed to provide Barr with Cipro for resale or to make quarterly payments to Barr for five years.¹⁸⁷

Similar to the Second and Eleventh Circuits, the Federal Circuit found that the payments did not violate federal antitrust laws.¹⁸⁸ The Federal Circuit began its analysis by stressing the general public policy favoring patent litigation settlements, adding that patent litigation settlements usually require the alleged infringer to refrain from challenging the patent's validity.¹⁸⁹ Applying the presumption of validity principle, the court reasoned that the patent confers a power to exclude others from profiting from the patented product.¹⁹⁰ Further, it noted that the agreements only prevented Barr from benefiting from the patent and therefore, fell within Bayer's rights as the patentee.¹⁹¹ Finally, the court agreed with the Second and Eleventh Circuits' conclusions that courts must analyze whether the anticompetitive effects exceed the exclusionary scope of the patent¹⁹² and, absent sham or

186. *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1328–29. See also 21 U.S.C. § 355(j)(2)(A)(vii)(III) (2006) (providing for paragraph III certification).

187. *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1329. After Bayer and Barr entered into a consent decree, four companies filed paragraph IV certifications, and Bayer sued each for patent infringement. *Id.*

188. See *id.* at 1332–35 (reviewing the district court's analysis and finding no error). The district court granted Bayer's motion for summary judgment, finding that Bayer had legitimate market power in the ciprofloxacin market. *Id.* at 1330. The court reasoned that any anticompetitive effects from the agreement remained "within the exclusionary zone" of the patent and thus, it could "not be redressed by antitrust law." *Id.* Applying analysis from the Second and Eleventh Circuits, the district court rejected plaintiffs' argument that a patent's exclusionary power should be "tempered by the patent's potential invalidity." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 520–40 (E.D.N.Y. 2005).

189. *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1333. The Federal Circuit has jurisdiction over appeals from final decisions of federal district courts in patent cases where the trial court's jurisdiction "was based, in whole or in part" on 28 U.S.C. § 1338. 28 U.S.C. § 1295(a)(1) (2006). It is essentially a national appellate court for patents. Jack Q. Lever, Jr., *The New Court of Appeals for the Federal Circuit (Part I)*, J. PAT. & TRADEMARK OFF. SOC'Y 178, 186 (1982). Unsurprisingly, because it has favored patent settlements over competition, the Federal Circuit has been criticized for eroding antitrust laws. See Scott A. Stempel & John F. Terzaken III, *Casting a Long IP Shadow over Antitrust Jurisprudence: The Federal Circuit's Expanding Jurisdictional Reach*, 69 ANTIRUST L.J. 711, 711 (2002). In general, "many observers believe that the creation of the Federal Circuit has led to decisions more favorable to patent holders." Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPS. 75, 79 (2005) [hereinafter Lemley & Shapiro, *Probabilistic Patents*].

190. *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1337. See also *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 211–12 (2d Cir. 2006) (noting that the patent confers a right to exclude); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005) (same).

191. *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1332–33.

192. *Id.* at 1336. The court added that when the "anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court" applies a "rule of reason approach to evaluate the anti-competitive effects, or under patent

fraud, “the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”¹⁹³ By following the Eleventh Circuit’s lead, the Second and Federal Circuits further tilted the balance away from any vigorous antitrust analysis of reverse payment settlements.¹⁹⁴

E. In re K-Dur: Rejecting the Scope of the Patent Test

In *In re K-Dur Antitrust Litigation*, the Third Circuit reviewed the same settlement agreement that the Eleventh Circuit had reviewed in *Schering-Plough*, but reached an opposite conclusion.¹⁹⁵ Contrary to the Second, Eleventh, and Federal Circuits, the Third Circuit began its analysis by noting the cost of reverse payment settlements to consumers, rather than highlighting the potential cost of discouraging settlements.¹⁹⁶ The court decided against applying the scope of the

law by analyzing the right to exclude afforded by the patent.” *Id.*

193. *Id.* See *In re Tamoxifen Citrate*, 466 F.3d at 208–09 (holding that the court need not apply antitrust scrutiny where the settlement was not fraudulent or otherwise baseless).

194. See *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1340 (finding payments permissible despite not applying antitrust scrutiny); *In re Tamoxifen Citrate*, 466 F.3d at 220 (refraining from applying antitrust analysis because of the presumption of patent validity); *Schering-Plough Corp.*, 402 F.3d at 1075 (holding that, without a showing of sham or fraud, a reverse payment does not violate antitrust laws if it exists within the scope of the patent); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (holding that the court must consider the exclusionary scope of the patent to determine whether an antitrust violation occurred).

195. Compare *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (holding that the settlement agreements were anticompetitive), with *Schering-Plough Corp.*, 402 F.3d at 1074 (finding settlement agreements were not anticompetitive). The Third Circuit’s occasion to review the same settlement agreements arose when, separate from the FTC’s challenge, various private parties filed antitrust suits targeting the settlements. *In re K-Dur*, 686 F.3d at 207. The Judicial Panel on Multidistrict Litigation consolidated those suits before the District of New Jersey. *Id.* The Special Master certified a class of plaintiffs of forty-four wholesalers and retailers who purchased K-Dur directly from Schering. *Id.* at 207–08. In the Special Master’s Report and Recommendation, he applied the presumption that Schering’s patent was valid, giving Schering the right to exclude infringing products until the end of the term through the reverse payment settlements. Special Master’s Amended Report and Recommendation on Defendants’ Motions for Summary Judgment as to the Upsher and ESI Settlements and Direct Purchaser Plaintiffs’ Partial Motions for Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments and the Exclusionary Scope of the ’743 Patent at 24–26, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (No. 01-1652) [hereinafter Special Master’s Amended Report]. Adopting the Eleventh Circuit’s reasoning and conclusion, the Special Master found that the settlements would only be subject to antitrust scrutiny if: (1) they exceeded the scope of the patent, or (2) the underlying patent infringement suits were objectively baseless. *Id.* Because the settlement agreements did not fit into either of these categories, the Special Master recommended granting defendants’ motions for summary judgment, which the district court adopted in full. *Id.*; *In re K-Dur Antitrust Litig.*, 162 F. Supp. 2d 688 (J.P.M.L. 2001).

196. Compare *In re K-Dur*, 686 F.3d at 208 (focusing on the cost of reverse payments to the public), with *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1333 (emphasizing the public policy in favor of settlements); *In re Tamoxifen Citrate*, 466 F.3d at 202 (same); *Schering-Plough Corp.*, 402 F.3d at 1071 (same); *Valley Drug Co.*, 344 F.3d at 1307–08 (same).

patent test, holding that it both fails to subject reverse payment settlements to antitrust scrutiny and ignores the policies underlying the Hatch-Waxman Act and Supreme Court precedent concerning patent litigation and competition.¹⁹⁷

To begin, the court explained that the scope of the patent test created an “almost un rebuttable presumption of patent validity,” which presupposed the issue in the patent suit.¹⁹⁸ The Third Circuit observed that when a court presumes that patent validity extends to the patent holder’s ability to exclude competitors from the market, it forgets that the presumption of patent validity is a procedural device, rather than a substantive conclusion.¹⁹⁹ More importantly, a court ignores that the underlying suit concerns a patent infringement case, not patent validity.²⁰⁰ The key distinction is that in a patent infringement suit, the patent holder bears the burden of demonstrating infringement, whereas in a patent validity lawsuit, the challenger bears the burden of proof.²⁰¹

Instead, the court offered empirical and legal support for the public interest in judicial testing and eliminating weak patents.²⁰² The court cited an FTC study showing that generic challengers prevailed seventy-three percent of the time in Hatch-Waxman challenges made under paragraph IV certifications.²⁰³ Though the ability for subsequent patent

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

198. *Id.*

199. *Id.* “The presumption, like all legal presumptions, is a procedural device, not substantive law.” *Stratoflex, Inc. v. Aeroqip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).

200. *In re K-Dur*, 686 F.3d at 214. When a generic manufacturer files an ANDA with a paragraph IV certification, the manufacturer effectively “infringes” on the patent, giving the patentee the right to sue for patent infringement. 1 U.S.C. § 271(e)(2)(A) (2006). *See supra* note 48 and accompanying text. In response to the patent infringement suit, the generic manufacturer typically counterclaims by alleging the patent is invalid. *See, e.g., Valley Drug Co.*, 344 F.3d at 1299.

201. *In re K-Dur*, 686 F.3d at 214 (citing *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008)).

202. *See id.* at 215 (citing *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 100–01 (1993)) (noting both the public policy in resolving questions of patent validity and the danger of granting monopoly privileges to the holders of invalid patents). The court reasoned that patent laws embody “‘a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.’” *Id.* at 216 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989)). Indeed, the Supreme Court has noted that a patent “affords no immunity for a monopoly not fairly or plainly within the grant.” *Id.* (quoting *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942)). The Court also has announced, “‘It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.’” *Id.* (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

203. *In re K-Dur*, 686 F.3d at 215 (citing FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* 16 (2002)). *See* Kimberly A. Moore, *Judges, Juries, and Patent Cases – An*

challengers to eliminate weak patents assuaged the Second Circuit's concerns, the Third Circuit was not convinced. Instead, the Third Circuit found that the settlement actually removes the most motivated challenger because the first challenger has the potential to secure the 180-day marketing exclusivity period.²⁰⁴ Additionally, the patent holder may still settle with the subsequent challengers.²⁰⁵ In reality, allowing reverse payment settlements does not reward patent holders based on the strength of their patents, but rather, on the "strength of [their] wallets."²⁰⁶

Further, the Third Circuit found that U.S. Supreme Court precedent supports freeing the competitive economy of narrow or invalid patents.²⁰⁷ The Third Circuit looked at *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co.*, where the Supreme Court analyzed whether a patentee could contractually prohibit a patent licensor from challenging the validity of the patent under a licensing agreement that also included a price-fixing provision.²⁰⁸ The Court found that the patentee could not stop the licensor from challenging the patent because the price-fixing agreement would violate federal antitrust law if the patent were invalid.²⁰⁹ In its opinion, the Court found support in the public policy behind freeing the competitive economy in the patent context.²¹⁰ The Third Circuit in *In re K-Dur* found that the

Empirical Peek inside the Black Box, 99 MICH. L. REV. 365, 385 (2000) (reporting that alleged infringers prevailed in forty-two percent of patent cases that reached trial from 1983 to 1999).

204. *In re K-Dur*, 686 F.3d at 215. See 21 U.S.C. § 355(j)(5)(B)(iv) (2006) (providing the 180-day marketing exclusivity provision).

205. *In re K-Dur*, 686 F.3d at 215. See e.g., *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 521–22 (involving a brand-name manufacturer that settled infringement suits with four different generic challengers).

206. *In re K-Dur*, 686 F.3d at 217 (quoting Hemphill, *Paying for Delay*, *supra* note 7, at 1614).

207. *Id.* at 215–16.

[T]he judicial preference for settlement, while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress's determination—which is evidence from the structure of the Hatch-Waxman Act and the statements in the legislative record that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.

Id. at 217.

208. 329 U.S. 394, 401 (1947). The court sought to expound on Supreme Court precedent supporting testing of weak patents. *In re K-Dur*, 686 F.3d at 216.

209. *Edward Katzinger Co.*, 329 U.S. at 401–02. The Court reasoned that it would have "permitted a licensor to be protected on an illegal contract." *Id.* at 399.

210. The court explained the "necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid." *Id.* at 400 (citing *Scott Paper Co. v. Marcalue Mfg. Co.*, 326 U.S. 249 (1945)). The court reiterated the policy that "it is the public interest which is dominant in the patent system." *Id.* at 401 (quoting *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944)).

Supreme Court's reasoning in *Edward Katzinger Co.* applied to reverse payments because reverse payments allow the brand-name manufacturer and generic manufacturer to share monopoly rents without providing the public with any assurance of the underlying patent's validity.²¹¹

Weighing policies supporting settlements and competition, the Third Circuit reasoned that antitrust analysis must pay particular attention to the "distinctive economic and legal setting of the regulated industry to which it applies."²¹² The court referred to the legislative intent behind Hatch-Waxman as evidence that the court should apply antitrust analysis to reverse payment settlements in the pharmaceutical industry.²¹³

Finally, the court articulated a test for district courts to follow in future reverse payment cases.²¹⁴ First, the court need not review the merits of the underlying patent infringement suit 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."²¹⁵ The patent holder may then

Moreover, that the right to challenge a patent "is not only a private right to the individual, but it is founded on public policy which is promoted by his making the defense, and contravened by his refusal to make it." *Id.* at 401 (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 235 (1892)).

211. *In re K-Dur*, 686 F.3d at 216. *See also* *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1136 (D.C. Cir. 1981) (implying that a settlement agreement might be anticompetitive if it "give[s] potential competitors incentives to remain in cartels rather than turning to another product, inventing around the patent, or challenging its validity"). The Third Circuit observed that the Special Master overlooked these aspects of Supreme Court jurisprudence. *In re K-Dur*, 686 F.3d at 216. Notably, the Special Master in this case expressly followed the lead of the Eleventh Circuit in making his recommendation, which the district court adopted in full. *In re K-Dur Antitrust Litig.*, 176 F. Supp. 2d 1377 (J.P.M.L. 2001); Special Master's Amended Report, *supra* note 195, at 24–26.

212. *In re K-Dur*, 686 F.3d at 216 (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004)). *See generally* Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 68 (arguing that courts should adopt the reasoning in *Trinko* to the pharmaceutical industry).

213. *In re K-Dur*, 686 F.3d at 216–17. In addition, the Third Circuit noted that applying the rule of reason test to reverse payments from the brand-name manufacturer to the generic challenger would not affect the majority of other pharmaceutical patent settlements because seventy-five percent of Hatch-Waxman Act infringement suits settled in 2010 did so without reverse payments. *Id.* at 218 (citing 2011 FTC REPORT, *supra* note 7, at 2).

214. *In re K-Dur*, 686 F.3d at 218. The court adopted a test similar to that applied in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, 256 F.3d 799, 813 (D.C. Cir. 2001). *See infra* Part V (arguing that the Supreme Court should adopt this test).

215. *In re K-Dur*, 686 F.3d at 218 (quoting *In re Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003) (italics omitted)). *See* Holman, *supra* note 6, at 558–59 (noting that the court and the FTC generally agree that an analysis of the validity of the underlying patent is unnecessary). The FTC has made clear that an analysis of patent validity would be inappropriate:

An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a

attempt to rebut plaintiff's prima facie case of an unreasonable restraint of trade by demonstrating that there was no reverse payment because the settlement amount was consideration for something other than a delay in market entry.²¹⁶ As a second defense, the patent holder may argue that the reverse payment offers a competitive benefit that could not have been achieved without a reverse payment.²¹⁷

In sum, while the D.C. Circuit in *Andrx* and the Sixth Circuit in *In re Cardizem CD* applied strict antitrust scrutiny to reverse payment settlements, all other circuit courts have applied a scope of the patent test until the recent Third Circuit decision. Having reviewed the same settlement agreement as the Eleventh Circuit in *Schering-Plough*, the Third Circuit decision in *In re K-Dur* created a circuit split that highlights the importance of the Supreme Court's upcoming resolution of this complex issue in *Actavis*.²¹⁸

III. ANALYSIS

This Part evaluates why the scope of the patent test (as applied by the Second, Eleventh, and Federal Circuits) is an inappropriate analytical tool for reverse payment settlements because it ignores the antitrust harm of these settlements, arbitrarily favors settlements over the often overlooked strong public interest in competition, and fails to adequately account for the legislative intent of the Hatch-Waxman Act. Next, this Part contends that the Third Circuit's antitrust analysis has presented the best method to analyze reverse payment settlements.

general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

In re Schering-Plough Corp., 136 F.T.C. 956, 997 (2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005).

216. *In re K-Dur*, 686 F.3d at 218.

217. *Id.*

218. See Jon Leibowitz, Remarks of FTC Chairman Jon Leibowitz as Prepared for Delivery at the Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium at 4 (Sept. 19, 2012), available at <http://www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownsspeech.pdf> ("[T]here is a clear circuit split on the legality of pay-for-delay deals between the Third (and possibly the Sixth and the D.C. Circuits), on the one hand, and the Second, Eleventh, and Federal Circuits on the other."); Edward Wyatt, *Justices to Take Up Generic Drug Case*, N.Y. TIMES, Dec. 7, 2012, at B1 (discussing the Supreme Court's decision to hear the pay-for-delay case and its importance to the industry and U.S. consumers).

A. Presumption of Patent Validity

The Second, Eleventh, and Federal Circuits improperly interpreted the presumption of patent validity in the previously discussed case law.²¹⁹ The Patent Act states that patents “shall be presumed valid.”²²⁰ However, this presumption is merely procedural and governs the order in which parties carry the burden of proof.²²¹ When courts presume that the patent in question is valid in reverse payment cases, they never reach the issue of whether the patent is valid and infringed.²²² Instead, courts using the scope of the patent test essentially make every PTO decision a final one.²²³ This is dangerous because, as the Third Circuit noted in *In re K-Dur*, many of the patents the PTO issues are later found invalid.²²⁴ Citing the FTC, the Third Circuit observed that generic drug

219. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (“[I]n the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (“Unless and until the patent is shown to have been procured by fraud, or a suit of its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.”); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (finding reverse payments legal because they did not exceed the patents); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308, 1311 (11th Cir. 2003) (instructing the district court to consider the scope of the patent and whether the agreements exceeded the scope).

220. 35 U.S.C. § 282 (2006). See sources cited in note 88 and accompanying text (describing the burdens and presumptions of patent validity). See also George W. Jordan III, *Managing the Presumption of Patent Validity*, 4 LANDSLIDE 50, 50–51 (2012) (discussing the impact of *Microsoft Corp. v. i4i Ltd. Partnership* on the presumption of patent validity).

221. Note that the Federal Circuit, which also employed the scope of the patent test, has made this observation. See *supra* note 199. See also *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1336 (using the procedural presumption of patent validity to come to a substantive conclusion on an issue of antitrust law). As one scholar recently explained, a “presumption of validity does not entitle a patentee to evade the test of patent litigation any more than a criminal defendant’s presumption of innocence entitles him to avoid trial.” Corrected Brief for *Amici Curiae* of 28 Professors of Law, Business, and Economics in Support of Appellants at 12, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097).

222. *In re K-Dur*, 686 F.3d at 214 (citing *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008)).

223. See *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (“A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office.”).

224. *In re K-Dur*, 686 F.3d at 215 (“Many patents issued by the PTO are later found to be invalid or not infringed . . .”). Many economists and scholars previously thought of patents as definite property rights, which tended to be valid, and conferred power of market control over product improvement or a low-cost method of production. WILLIAM NORDHAUS, *INVENTION, GROWTH AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE* 64 (1969). More recently, economists and scholars have observed that the empirical evidence regarding the issuance of patents undermines this theory of patent validity. See Lemley & Shapiro, *Probabilistic Patents*, *supra* note 189, at 75–76 (“Nearly half of all litigated patents are found to be invalid, including some of great commercial significance.”).

companies prevailed in seventy-three percent of challenges between 1992 and 2000 in Hatch-Waxman lawsuits.²²⁵ In addition, courts invalidated forty-six percent of patents between 1989 and 1996,²²⁶ and alleged infringers prevailed in forty-two percent of patent cases reaching trial between 1983 and 1999.²²⁷

Moreover, determining whether the patent is valid is critical to the outcome of the antitrust analysis. If the patent is valid, then the brand-name pharmaceutical company can exclude others from that specific product's market for the life of the patent.²²⁸ If the patent is invalid, however, the patented drug does not have any scope at all, and the manufacturer has no right to exclude other manufacturers from the market.²²⁹

The Third Circuit, therefore, properly reasoned that extending this analysis to reverse payment settlements is especially dangerous because settlements prevent any factfinder from considering the validity of the patent.²³⁰ The Second Circuit incorrectly reasoned that other generic

225. *In re K-Dur*, 686 F.3d at 215 (citing FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 16 (2002) [hereinafter 2002 FTC STUDY]). Sales were far higher in the cases in which brand-name firms sued generics. 2002 FTC STUDY, *supra*, at 16. "For the seventy-five drug products subject to litigation, the first generic applicant gained \$190 million in median net sales the year it filed its ANDA," and "most of the twenty-nine new drug applications not subject to suit had net sales of less than \$100 million in the year of filing." *Id.* But see RBC CAPITAL MKTS., PHARMACEUTICALS: ANALYZING LITIGATION SUCCESS RATES 4 (2010), available at <http://www.amlawdaily.typepad.com/pharmareport.pdf> (reporting that from 2000 to 2009, generics prevailed in forty-eight percent of patent validity challenges that went to trial).

226. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 184, 205 (1998) (reviewing cases resulting in a final judgment of validity). The process of patent approval provides some insight as to why so many patents are later found invalid. For example, the PTO carries the burden to offer a reason *not* to issue a patent sought by a patent applicant. Lemley & Shapiro, *Probabilistic Patents*, *supra* note 189, at 78. For further exploration of how the patent application process can later produce many patent invalidity determinations, see *id.* at 78–79.

227. Moore, *supra* note 203, at 385.

228. See Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 139 (2000) ("[T]he patent law model we have is quite simple: the government issues you a patent; the patent gives you the right to exclude . . ."); Mark A. Lemley & Phillip J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783, 783 (2007) (basing their economic analysis on the principle that the "foundational notion of property law is that 'the right to exclude' is the essence of a true property right").

229. See Carrier, "Scope of the Patent" Test, *supra* note 139, at 6 (pointing out the inadequacies of the scope of the patent test); Leary, Antitrust Issues, *supra* note 28 (warning that collusive agreements to share monopoly profits from an invalid patent threaten especially severe anticompetitive harm).

230. See *In re K-Dur*, 686 F.3d at 215 ("[W]e question the assumption underlying the view of the Second Circuit and other courts that subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger.").

drug manufacturers would work to eliminate weak patents.²³¹ To the contrary, other generic manufacturers may not adequately challenge the patent because settling with the first filer naturally removes the most motivated challenger.²³² In addition, the settling innovator firm can, and often does, pay off multiple challengers at once.²³³

*B. Policy Arguments: Balancing Settlement and Innovation with
Judicial Testing and Competition*

While courts applying the scope of the patent test have found support in public policy arguments for innovation and settlements, they have not properly weighed the public policy arguments for challenging invalid patents and promoting competition.²³⁴ Even though the underlying reason courts generally give to support settlement is cost efficiency,²³⁵

231. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 211–12 (2d Cir. 2006) (“[W]hile the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.” (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 514, 534 (E.D.N.Y. 2005))).

232. See Hemphill, *Paying for Delay*, *supra* note 7, at 1584–86 (positing that settling the patent litigation removes the most motivated challenger because of the potential for 180 days of marketing exclusivity); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758 (2003) [hereinafter Hovenkamp et al., *Anticompetitive Settlement*] (noting that even with this rationality, payments can be anticompetitive); Joel Schrag, *The Value of a Second Bite at the Apple: The Effect of Patent Dispute Settlements on Entry and Consumer Welfare* 3–4 (FTC, Working Paper No. 281, 2006) (maintaining that reverse payment settlements undermine subsequent generic manufacturer’s incentive to challenge the patent, thereby harming consumers).

233. *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 521–22 (E.D. Pa. 2010) (applying the scope of the patent test and finding no antitrust violation with a drug manufacturer paying four generic firms to delay market entry for large payments, supply agreements, and research and development plans). See also *In re K-Dur*, 686 F.3d at 215 (“[T]he high profit margins of a monopolist drug manufacturer may enable it to pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation.”).

234. See *In re K-Dur*, 686 F.3d at 217 (maintaining that the legislative intent of Hatch-Waxman and the countervailing public policy interests in competition and judicial testing of weak patents displace any general policy for settlement).

235. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (noting the “long-standing policy in the law” favoring patent settlements); *In re Tamoxifen Citrate*, 466 F.3d at 202 (reasoning that the court must encourage the most efficient resolution of costly disputes); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (reasoning that patent litigation is especially costly, time-consuming, and creates too much uncertainty). The Eleventh Circuit declared that the general policy to encourage settlements applies equally to patent infringement suits. *Valley Drug Co.*, 344 F.3d at 1308; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005). The *Schering* court further reasoned that “litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.” *Schering-Plough Corp.*, 402 F.3d at 1073 (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003)). This reasoning is flawed in the first instance because it presumes that exclusion will ultimately occur, regardless

these courts overlook that antitrust law also saves the public money by protecting the basic rules of competition to keep prices low, production efficient, and innovation robust.²³⁶ Specifically, early competition benefits consumers because it lowers drug prices sooner.²³⁷ Reverse payment settlements merely transfer “wealth from consumers to drug makers, in the form of continued high pharmaceutical prices, with brand-name firms sharing a portion of that transfer with the generic firm.”²³⁸

Although settling patent litigation cases may save major pharmaceutical companies substantial sums of money,²³⁹ consumer welfare losses from delayed generic drug market entry are eighty-five

whether the path is litigation or settlement. Offering another perspective, some commentators point out that judges have a “reflex” favoring settlement, in part because judges may want to avoid highly technical pharmaceutical patent cases. Hemphill, *Paying for Delay*, *supra* note 7, at 1574.

236. WHINSTON, *supra* note 65, at 1; Scott C. Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 629 (2009) [hereinafter Hemphill, *Aggregate Approach*].

237. Hemphill, *Aggregate Approach*, *supra* note 236, at 636. Hemphill explains that the benefit to the consumer of lower drug prices is probabilistic because the brand-name firm could win the patent infringement suit.

Settlements without payment reflect the perceived strength of the patent. For example, a generic firm’s fifty percent chance of success would yield, roughly speaking, an entry date halfway between immediate entry and patent expiration. That result is equal to average result of litigation, in which the consumer has a fifty percent chance of receiving no benefit. By contrast, bargains that reflect not only perceived patent strength but also payments from brand-name to generic manufacturers will induce the generic firm to accept a later entry date, which decreases consumer welfare.

Id. at 635–36. For an explanation of how the 180-day exclusivity period affects this calculation, see Hemphill, *Paying for Delay*, *supra* note 7, at 1588–94.

238. Hemphill, *Aggregate Approach*, *supra* note 236, at 636. In addition, high pharmaceutical drug costs force consumers and insurance providers to adjust purchasing decisions, which also contributes to consumer welfare loss. *Id.* Hemphill explains,

In an ordinary market, setting a price above marginal cost produces an allocative distortion and accompanying welfare loss for consumers, because consumers who value the good above its marginal cost, but below the prevailing price, are deflected to less desired substitutes. To the extent that public and private insurance secures the purchase of a drug, this distortion is reduced, though it is not eliminated (as insurance is incomplete). Moreover, the higher price produces new distortions (and hence inefficiency) in the decisionmaking process of the insurance provider, through decisions to charge higher premiums and not to reimburse drugs whose value exceeds their marginal cost. In a similar manner, the existence of incomplete insurance affects the assessment of the size of the transfer.

Id. at 636 n.21.

239. See AM. INTELLECTUAL PROP. LAW ASS’N, REPORT OF THE ECONOMIC SURVEY 2005, at 22 (2005) (reporting that median expense of patent litigation was \$4.5 million, compared to \$25 million of risk); Carlson, *supra* note 161, at 380 (finding that U.S. patent litigation costs \$1 billion annually).

times greater than the loss the public suffers from costly litigation.²⁴⁰ Even though courts favor settlements because they benefit the public, the courts found that settling parties owe no duty to “preserve the public’s interest in lower prices.”²⁴¹ In essence, these courts reason that cost efficiency matters at the courts, but not at the pharmacy.²⁴²

Similarly unpersuasive, the Second, Eleventh, and Federal Circuits have warned that scrutinizing patent settlements could hinder patent innovation, the foundation of patent law.²⁴³ The Supreme Court has declared that patent law also strongly supports the public interest in testing patents as a way to promote innovation and prevent invalid patent holders from maintaining monopolies.²⁴⁴ The Court also has explained that patent laws must recognize that “imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.”²⁴⁵

Further, when a court faces two competing policies in an antitrust lawsuit, it must scrutinize the regulatory framework and legislative intent to determine its course of action.²⁴⁶ Specifically, the Supreme

240. See Robert Kneuper, *Four Economic Principles underlying the FTC’s Position against Reverse Payments in Patent Settlement Agreements*, THE ANTITRUST SOURCE, Jan. 2006, at 1. As noted, the FTC reports that reverse payments cost the American public \$3.5 billion a year. 2010 FTC REPORT, *supra* note 6, at 2.

241. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 541 (E.D.N.Y. 2005). The court also declared that the public has “no public property right in the outcome of private lawsuits.” *Id.* at 531.

242. See *supra* note 235 and accompanying text (providing examples of courts that cite cost efficiency as the public policy behind settling patent disputes).

243. The Eleventh Circuit reasoned that finding settlements anticompetitive would increase enforcement efforts and hinder innovation because of “uncertainty around the drug manufacturer’s ability to research, develop, and market the patented product.” *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005). The Second and Eleventh Circuits noted that “severely restricting” settlements could “heighten the uncertainty” and “delay innovation.” *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006); *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003). Patent policies favor settlements because they increase the patentees’ profits, which increase the patentee’s incentive to innovate. *Crane*, *supra* note 51, at 749.

244. *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 100–01 (1993). Congress designed the Patent Act to encourage innovation, but it also reflects the “important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.” *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

245. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). In fact, the Court stated that the public interest for a patent system also includes a private right of the individual to challenge a patent. *Edward Katzinger Co. v. Chi. Metallic Mfg. Co.*, 329 U.S. 394, 401 (1947).

246. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411–12 (2004) (“Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue.”); *United States v. Citizens & S. Nat’l Bank*, 422 U.S. 86, 91 (1975) (holding that “careful account must be taken of the pervasive federal and state

Court has instructed that “[a]ntitrust analysis must sensitively recognize the distinctive economic and legal setting of the regulated industry to which it applies.”²⁴⁷ The Third Circuit in *In re K-Dur* recognized that the scope of the patent test encourages settlement—a policy the court has historically supported.²⁴⁸ However, the Third Circuit properly reasoned that a general preference for settlement should not displace a specific congressional determination or opposing public policy objectives unique to the pharmaceutical industry.²⁴⁹

Because Hatch-Waxman explicitly balances the same interests that courts have struggled to balance in reverse payment cases, the legislative intent of the Act should control a court’s holding.²⁵⁰ Statements of Senator Hatch and Representative Waxman reveal that reverse payment settlements disrupt the balance between competition and innovation that they designed by weighing far more heavily on the side of innovation.²⁵¹ Subverting Hatch-Waxman’s goals, brand-name

regulation characteristic of the industry”).

247. *Trinko*, 540 U.S. at 411–12 (quoting *Concord v. Bos. Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990)).

248. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217–18 (3d Cir. 2012) (citing *Ehrheart v. Verizon Wireless*, 609 F.3d 590, 595 (3d Cir. 2010)). *But see Carrier, Unsettling Drug Patent Settlements*, *supra* note 52, at 61 (arguing that the Hatch-Waxman regulatory scheme displaces any general preference in the law for settlement); *cf.* Brief Amici Curiae of 78 Intellectual Property Law, Antitrust Law, Economics, and Business Professors in Support of Appellant at 5, *Karyn McGaughey v. Bayer Corp.*, No. D056361, 2010 WL 6275183 (Cal. App. 4th Dist. 2010) (urging the court to condemn reverse payment settlements, in part, because they subvert the purpose of Hatch-Waxman).

249. *In re K-Dur*, 686 F.3d at 217. The court further noted that it would only apply antitrust scrutiny to reverse payment settlements from brand-name manufacturers to generic manufacturers. *Id.* at 218. It reasoned that narrowly applying antitrust scrutiny would leave the majority of pharmaceutical patent settlements unaffected. *Id.* (citing 2011 FTC REPORT, *supra* note 7, at 2). An FTC study reported that seventy-five percent of Hatch-Waxman Act infringement suits settled in 2010 without reverse payments. *Id.* Hatch-Waxman’s regulatory framework shows that it intended to promote patent challenges because it offered a 180-day period of marketing exclusivity for the first ANDA filer to seek to enter before the end of the patent term. 21 U.S.C. § 355(j)(5)(B)(iv) (2006). *See supra* Part I.B (explaining the key provisions of the Hatch-Waxman Act). The patentees also have incentive to file suit after receiving notice of the paragraph IV certification because they will receive a thirty-month stay. Petition for Writ of Certiorari at 8, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273).

250. *See Carrier, Unsettling Drug Patent Settlements*, *supra* note 52, at 62 (arguing that any fear of hindering innovation is secondary in the context of the Hatch-Waxman Act).

251. H.R. REP. NO. 98-857, pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2713, 2715 (underscoring that the bill completes “what the Congress has traditionally done in the area of intellectual property law[:] balance the need to stimulate innovation against the goal of furthering the public interest”); 130 CONG. REC. 24425 (Sept. 6, 1984) (statement of Rep. Waxman) (highlighting the “fundamental balance of the bill”). *See also* Hemphill, *Paying for Delay*, *supra* note 7, at 1614 (noting that Congress took explicit steps to fill the gaps where innovators sought to set innovation policy by self-help through reverse payments).

manufacturers with weak patents who are unlikely to prevail in court benefit the most from reverse payments.²⁵² Furthermore, the Third Circuit appropriately emphasized that allowing reverse payment settlements is “bad policy from the perspective of the consumer, precisely the constituency Congress was seeking to protect.”²⁵³ Therefore, the Third Circuit was correct to favor competition in the pharmaceutical drug market over reverse payment settlements.

In response to arguments that courts should consider the legislative intent of Hatch-Waxman, the Second, Eleventh, and Federal Circuits reasoned that the reverse payment settlements were a natural byproduct of Hatch-Waxman.²⁵⁴ Reverse payment settlements, however, are an unintended consequence of Hatch-Waxman and counteract the explicit intent of the Act.²⁵⁵ In broadly analogizing to antitrust principles, one commentator notes that the law would not permit rival companies to collude simply because doing so takes little effort.²⁵⁶ Similarly, simply

252. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 211 (2d Cir. 2006) (allowing reverse payment settlements, while recognizing the reality that they disproportionately reward brand-name manufacturers with weak patents). See *In re K-Dur*, 686 F.3d at 213 (summarizing the Second Circuit’s holding that the judicial preference for settlements counterbalanced the troubling result of upholding the validity of reverse payment settlements).

253. *In re K-Dur*, 686 F.3d at 217. The fact that Congress was seeking to protect the public interest in creating Hatch-Waxman is especially important in the context of patent law, where the public interest is paramount. See *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944) (describing the determination of patent validity as a matter of “the protection of the public in a system of free enterprise”).

254. See *In re Tamoxifen Citrate*, 466 F.3d at 206 (pointing out that reverse payment settlements were “particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them”); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 n.11 (Fed. Cir. 2008) (“Indeed, a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed.”); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005) (“Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude.”).

255. See 148 CONG. REC. 15354 (July 30, 2002) (statement of Sen. Hatch) (explaining that “[w]e did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition”); Brief of Amici Curiae American Antitrust Institute and 26 Professors in Support of Appellants and Reversal at 11, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 3011) (No. 10-2078, 10-2077, 10-2079) (noting that Hatch-Waxman did not intend for parties to settle in this manner); Timothy A. Weil, *Devising a Legislative Solution to the Reverse Payment Dilemma: How Congress Can Balance Competition, Innovation, and the Public Policy Favoring the Settlement of Disputes without Litigation*, 55 ST. LOUIS U. L.J. 741, 742 (2011) (“Settlement agreements between brand-name drug manufacturers and generic firms have limited the type of generic competition the Hatch-Waxman Act was designed to encourage.”).

256. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 66–67 (arguing that the courts’ reliance on reverse payment settlements as a natural product of Hatch-Waxman is unfounded). Further, he noted that this line of reasoning exemplifies the flawed reasoning of the courts reviewing reverse payment cases. *Id.*

because Hatch-Waxman allows for parties to make reverse payments does not mean that such settlements do not violate antitrust laws.²⁵⁷

The Second, Eleventh, and Federal Circuits improperly applied the scope of the patent test to reverse payment settlements.²⁵⁸ By disregarding the explicit intent of Hatch-Waxman, favoring policies of settlement over competition, and giving the presumption of patent validity more weight than it is entitled, these courts have essentially made reverse payment settlements per se legal.²⁵⁹ Doing so has cost the American public millions of dollars.²⁶⁰ Fortunately, the *In re K-Dur* court wisely rejected the scope of the patent test and instead applied antitrust scrutiny.²⁶¹

C. Applying Antitrust Scrutiny

After rejecting the scope of the patent test, the Third Circuit in *In re K-Dur* properly instructed the lower court to apply a quick look rule of reason analysis instead of a traditional rule of reason or per se analysis.²⁶² The majority of courts have correctly rejected the per se approach, though the Second Circuit and Sixth Circuit have misapplied this test to reverse payment settlements.²⁶³ Per se treatment is

257. See Hemphill, *Paying for Delay*, *supra* note 7, at 1577–78 (“True, paying for delay is ‘natural,’ in the sense that the result is not unexpected given the incentives of the parties; the parties if not legally constrained, will prefer pay-for-delay settlement to litigation. But that fact in no way justifies payments for delay.”); Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1758 (observing that because the law allows reverse payments to occur does not immunize them from antitrust liability).

258. See Brief for the United States in Response to the Court’s Invitation at 11–15, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON)) (arguing that the test the court applied in *In re Tamoxifen* “distorts the statutory process that leads to competition in the face of patent claims”).

259. Non-Confidential Reply Brief for Plaintiffs-Appellants at 2, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097) (arguing that courts applying the scope of the patent test have found reverse payments per se legal and urging against this holding).

260. 2010 FTC REPORT, *supra* note 6, at 2 (concluding that reverse payments cost the American public \$3.5 billion a year). See Hemphill, *Aggregate Approach*, *supra* note 236, at 651 (finding that reverse payment settlements cost the American public up to \$12 billion annually).

261. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214–18 (3d Cir. 2012).

262. *Id.* at 218. See Brief of Amici Curiae American Antitrust Institute and 26 Professors, *supra* note 255, at 14–15 (arguing that reverse payments are presumptively illegal).

263. See *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1332 (rejecting the per se approach); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (same); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2005) (same); *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (same). *But see In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006) (finding reverse payment settlements per se legal because restricting patent settlements might hinder innovation); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003) (finding reverse payment settlements per se illegal because a reduction in competition was sufficient to demonstrate an anticompetitive

inappropriate because it ignores the weight of the patent holder's proper right to exclude.²⁶⁴ Considering the balance necessary to promote innovation and preserve competition, it is important to recognize the patentee's true rights under patent law, which counsel against adopting a per se rule.²⁶⁵

Further, the Supreme Court largely resists the use of per se rules.²⁶⁶ The Court has cautioned against using per se rules until the "judiciary obtains considerable rule-of-reason experience with the particular type of restraint challenged."²⁶⁷ Here, although the reverse payment problem has engendered much press and attention, relatively few courts have considered the legality of such agreements. Still further, the few courts that have heard reverse payment cases have actually applied antitrust scrutiny.²⁶⁸ In addition, the antitrust defendants could

effect); cf. Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25–26 (2004) [hereinafter Hovenkamp, *Sensible Antitrust*] (arguing that applying a per se rule is inappropriate, but pointing out that it may have been justified in *In re Cardizem CD* because of the facts).

264. Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1039 (2004).

265. See Kristopher L. Reed, *A Return to Reason: Antitrust Treatment of Pharmaceutical Settlements under the Hatch-Waxman Act*, 40 GONZ. L. REV. 457, 475 (2004–05) (noting that commentators who advocate a strict per se approach misunderstand patent laws). For example, some commentators argue that without a final court resolution of validity and scope of the patent, a patentee's right is uncertain. Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33, 35 n.9 (2004). While patents do not allow patentees to pay competitors not to enter the market outside the scope of the patent, they do offer the power to "exclude others from making, using, offering for sale, or selling the invention" for the patent term. 35 U.S.C. § 154(a)(1) (2006). However, supporters of the per se rule note that approximately half of all patents are invalidated. Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 11–12 (2005). Though the Eleventh Circuit improperly extended the presumption of patent validity to prevent any antitrust analysis, patents are still entitled to the *procedural* presumption of patent validity under the Patent Act. See 35 U.S.C. § 282 ("The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."). The patent owner bears the burden of proving infringement. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). For more commentary arguing that reverse payments should be per se illegal, see Davis, *supra* note 83, at 255; O'Rourke & Brodley, *An Incentives Approach*, *supra* note 83, at 1787; Sandoval, *supra* note 83, at 141.

266. See *Texaco, Inc. v. Dagher*, 547 U.S. 1, 5 (2006) (resisting the application of a per se rule to a horizontal price-fixing agreement); *Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 349 n.19 (1982) (same).

267. *Maricopa Cnty. Med. Soc'y*, 457 U.S. at 349 n.19. See *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 607–08 (1972) ("It is only after considerable experience with certain business relationships that courts classify them as *per se* violations . . .").

268. Anne-Marie C. Yvon, Note, *Settlements between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments*, 75 FORDHAM L. REV. 1883, 1909 (2006). Yet, some argue that Congress should adopt a per se rule, which would sidestep the courts' perceived inexperience. See Ken Letzler & Sonia Pfaffenroth, *Patent Settlement*

potentially justify a reverse payment if it reflected the parties' reasonable assessments of patent validity.²⁶⁹ Therefore, the Third Circuit and other courts have properly rejected applying the per se rule to reverse payments.²⁷⁰

The Third Circuit also appropriately decided against applying a rule of reason analysis to reverse payments.²⁷¹ Because reverse payment settlements are generally anticompetitive, a rule of reason analysis would be illogical.²⁷² If courts applied the rule of reason analysis, the plaintiff would be required to demonstrate the anticompetitive effect of the defendant's conduct by offering proof of the defendant's market share.²⁷³ Plaintiffs, however, usually cannot make this showing because it carries a heavy evidentiary and financial burden.²⁷⁴

Moreover, reverse payment settlements tend to be anticompetitive, rendering a full-blown, expensive, onerous rule of reason analysis unnecessary.²⁷⁵ Absent countervailing public policy concerns and the

Legislation: Good Medicine or Wrong Prescription?, 23 ANTITRUST 81, 83 (2009) (“[S]upporters would argue that this is a routine application of the per se rule to an agreement not to compete.”).

269. See Carrier, *Unsettling Drug Patent Settlements*, supra note 52, at 67 (arguing that per se invalidity is inappropriate). See also MICHAEL A. CARRIER, *INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW* 56 (2009) (explaining that courts apply per se treatment to price fixing, bid rigging, and market-allocation agreements, which are likely to engender competitive harm and unlikely to offer competitive benefits); O'Rourke & Brodley, *An Incentives Approach*, supra note 83, at 1784–86 (describing potential objective indicators of patent validity).

270. See Hovenkamp et al., *Anticompetitive Settlement*, supra note 232, at 1735 (arguing that the per se rule is inappropriate in the context of reverse payment settlements).

271. See Carrier, *Unsettling Drug Patent Settlements*, supra note 52, at 67 (arguing that reverse payments settlements should be presumptively illegal); Hovenkamp et al., *Anticompetitive Settlement*, supra note 232, at 1729 (arguing that rule of reason approach does not make sense in the context of reverse payment settlements). But see Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 57 (2010) (arguing that courts should analyze reverse settlements under the traditional rule of reason analysis); John Fazio, *Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property and Antitrust Law Require a Return to the Rule of Reason*, 11 J. TECH. L. & POL'Y 1, 28–29 (2006) (same).

272. Hovenkamp et al., *Anticompetitive Settlement*, supra note 232, at 1731 (“[A]pplication of the rule of reason is not likely to tell us anything that we do not already know.”); Lemley & Shapiro, *Probabilistic Patents*, supra note 189, at 93 (noting that reverse payments are presumptively anticompetitive).

273. Carrier, *Unsettling Drug Patent Settlements*, supra note 52, at 67 n.210. See supra Part I.C (explaining the rule of reason analysis method).

274. See Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 B.Y.U. L. REV. 1265, 1268 (reporting that after applying the rule of reason test, the court dismissed eighty-four percent of cases because the plaintiff failed to show the defendant's market share); Graham, supra note 85, at 440 (noting the large evidentiary burden the rule of reason analysis places on plaintiffs).

275. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907–09 (6th Cir. 2003) (reasoning

unique protection patent law provides, horizontal agreements between pioneer drug manufacturers and generic competitors would be per se illegal.²⁷⁶ As stated above, these agreements are anticompetitive because one party exits or delays entry into the market in exchange for a cash payment, thus decreasing competition.²⁷⁷ Accordingly, courts should not apply the burdensome rule of reason test in reverse payment cases.²⁷⁸

Instead of applying the rule of reason analysis or per se illegality, the Third Circuit properly treated reverse payment settlements as prima facie evidence of anticompetitive behavior.²⁷⁹ This position recognizes the potentially severe anticompetitive effects of reverse payment settlements.²⁸⁰ Further, it follows the Supreme Court's instruction that antitrust analysis should mind the constructs of the regulated industry.²⁸¹ Treating reverse payment settlements as prima facie

that horizontal payments are per se illegal); Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 71 ("Of all the types of business activity, agreements by which competitors divide markets threaten the most dangerous anticompetitive effects.").

276. See Graham, *supra* note 85, at 430 (explaining that "the presence of patents alters the antitrust analysis"); Lobanoff, *supra* note 7, at 1338 (noting the anticompetitive effects of reverse payments).

277. *In re Cardizem CD*, 332 F.3d at 896; Graham, *supra* note 85, at 441.

278. See Hovenkamp, *Sensible Antitrust*, *supra* note 263 (reasoning that presumptive illegality makes more sense in the reverse payment context); Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 67 ("Because these agreements are not generally pro-competitive in nature, deferential review under the [r]ule of [r]eason is not appropriate.").

279. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012). See also Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 393 (2003) (arguing that courts should treat reverse payment settlements as presumptively illegal).

280. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 68 (noting that reverse payment settlements are particularly dangerous because of the "aligned incentives of the parties and windfalls received by generics"). Carrier argues that treating reverse payment settlements as presumptively illegal minimizes potential errors in antitrust analysis:

Courts committing Type I errors wrongfully punish lawful activity such as reasonable payments on valid patents. Type II errors, in contrast, wrongfully allow illegal activity such as excessive payments on invalid patents. In encouraging settlements and giving effect to the presumption of patent validity, courts have sought to minimize Type I errors. In the process, however, they have increased the frequency of Type II errors. This is a mistake. The Hatch-Waxman framework was designed to encourage patent challenges, reduce delay in entering the market, and promote generic competition. Type II errors, in allowing parties to delay entry on invalid patents, fly in the face of the Act's text and intent. The Act's preference for Type I errors confirms the propriety of presumptive illegality.

Id.

281. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 412 (2004) (considering the effect of a regulatory framework in selecting the appropriate analysis). In *Trinko*, the Court reasoned that courts must carefully consider the "pervasive federal and state regulation characteristic of the industry." *Id.* at 411 (quoting *United States v. Citizens & S. Nat'l Bank*, 422 U.S. 86, 91 (1975)). See generally Michael A. Carrier, *Of Trinko, Tea Leaves, and*

evidence of an unreasonable restraint of trade respects the goals articulated in the Hatch-Waxman Act because it favors competition, while still recognizing the significance of patent rights.²⁸² Thus, the Third Circuit correctly framed the antitrust analysis.²⁸³

Furthermore, the Third Circuit has appropriately reflected the delicate balance between patent law and antitrust law by allowing the antitrust defendants to rebut the prima facie evidence of an antitrust violation by showing that the payment: (1) was for a purpose other than delayed entry, or (2) offered a procompetitive benefit.²⁸⁴ The rebuttal option is appropriate because, for example, a reverse payment could reflect the parties' reasonable expectations of litigation costs.²⁸⁵ Also, the court reasoned that the second rebuttal option would account for the instances in which the reverse payment could increase competition.²⁸⁶ This option is appropriate because there are some (albeit rare) situations where a reverse payment could increase competition among pharmaceutical companies.²⁸⁷

Although the Third Circuit in *In re K-Dur* properly balanced the interests of innovation and competition in setting forth its reverse payment settlement test, it failed to include any factors that would

Intellectual Property, 31 J. CORP. L. 357 (2006) (expounding on the principles the Court articulated in *Trinko*).

282. See Hemphill, *Paying for Delay*, *supra* note 7, at 1596 (“A settlement that contains a cash payment or retention of exclusivity eligibility raises a ‘red flag,’ and an accompanying presumption of illegality.”); Hovenkamp, *Sensible Antitrust*, *supra* note 263, at 26–31 (reasoning that the presumption of illegality appropriately weighs the incentives of Hatch-Waxman).

283. See Brief of the Federal Trade Commission as Amicus Curiae Supporting Appellants and Urging Reversal at 22–24, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (Nos. 10-2078, 10-2077, 10-2079) (arguing that the court should apply presumptive illegality to reverse payments).

284. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012). See Hemphill, *Paying for Delay*, *supra* note 7, at 1596 (a rule making reverse payments presumptively illegal and allowing rebuttal options “gives proper weight to the high likelihood of allocative harm arising from these settlements, while leaving space for defendants, the parties best positioned to come forward with justifications, to explain why the settlement is necessary to achieve some procompetitive end”).

285. See Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 76–77 (“A reverse payment that does not exceed these costs does not present significant concern since the parties would have been required to spend this money in any event.”). See also Hemphill, *Paying for Delay*, *supra* note 7, at 1594–95 (reasoning that if the payment reflects reasonable litigation costs, it may not be anticompetitive).

286. *In re K-Dur*, 686 F.3d at 218. There are, in fact, some instances where a reverse payment could have a procompetitive benefit. See generally Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367 (2010) (arguing that patent settlements, including reverse payment settlements, between brand and generic drug manufacturers can benefit consumers).

287. For example, consumers would benefit if a generic company on the verge of bankruptcy received a cash payment that enabled it to avoid bankruptcy. *In re K-Dur*, 686 F.3d at 218.

account for the parties' reasonable assessment of patent validity.²⁸⁸ Even though the Third Circuit focused on the scope of the patent's improper extension of the presumption of patent validity, the patent does convey a patentee some exclusionary rights *within* the scope of a valid patent.²⁸⁹ Though the Third Circuit criticized courts applying the scope of the patent test for ignoring the underlying patent suit, it too ignores the underlying patent suit with its approach.²⁹⁰ Although an inquiry of the merits in an underlying patent suit is burdensome and impractical, given the importance of the underlying patent validity, courts should consider reasonable ways to incorporate a merits inquiry into an antitrust analysis.²⁹¹

IV. PROPOSAL

This Part proposes that the Supreme Court resolve the circuit split between *In re K-Dur* and *Schering-Plough* by accepting the Third Circuit's reasoning and concluding that reverse payment settlements are prima facie evidence of anticompetitive conduct.²⁹² Further, this Part recommends that the Court supplement the Third Circuit's test by allowing defendants in reverse payment cases to offer indicators of patent validity as a way to show that the payment was for a purpose other than delayed entry.

288. *Id.* Note that the court simply stated, "We agree, moreover, with the FTC that there is no need to consider the merits of the underlying patent suit . . ." *Id.* See Brief of the Federal Trade Commission, *supra* note 283, at 26–27 (arguing that the court need not delve into the merits of the patent validity).

289. *In re K-Dur*, 686 F.3d at 215. Some commentators note, "If the patent rights are valid, the settlement is likely to be lawful because, . . . in that event[,] the settlement is [no] more anticompetitive than a likely outcome of the litigation." O'Rourke & Brodley, *An Incentives Approach*, *supra* note 83, at 1781 (citation and internal quotation marks omitted).

290. *In re K-Dur*, 686 F.3d at 214 (citing *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008)). The Third Circuit criticized the scope of the patent test's improper use of the procedural presumption of patent validity, claiming that "[t]his presumption assumes away the question being litigated in the underlying patent suit." *Id.*

291. See Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1765 (proposing alternative ways to address the uncertainty of patent validity); O'Rourke & Brodley, *An Incentives Approach*, *supra* note 83, at 1781 (observing that because the validity of the patent is often uncertain, courts must consider different ways to address this difficult issue).

292. The FTC has long sought Supreme Court review of this issue. See *Protecting Consumer Access to Generic Drugs: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Prot. of the H. Comm. on Energy and Commerce*, 110th Cong. 3 (2007) (statement of Jon Leibowitz, Comm'r, FTC), available at <http://www.ftc.gov/speeches/leibowitz/070502reversepayments.pdf> ("We'll continue to be vigilant in looking for ways to challenge anticompetitive deals. It's public knowledge that we're looking to bring a case [to the Supreme Court] that will create a clearer split in the circuits . . .").

A. *The Supreme Court Should Adopt the Third Circuit's Reasoning from In re K-Dur*

The Supreme Court should resolve the circuit split by rejecting the scope of the patent test and adopting the Third Circuit's reasoning in *In re K-Dur*.²⁹³ The Supreme Court should not apply the scope of the patent test to reverse payment settlement cases because it lacks any genuine antitrust scrutiny, wrongly assumes the patent in question is valid, and counteracts the explicit goals of the Hatch-Waxman Act.²⁹⁴

As the Court weighs public policy interests in reaching its decision, it must recognize that reverse payment settlements have severe public health consequences.²⁹⁵ Allowing brand-name pharmaceutical companies to pay generic manufacturers to delay market entry directly impacts drug prices for American consumers.²⁹⁶ The cost of health care in the United States is already unsustainably high.²⁹⁷ Expensive prescription medications are a significant part of these costs, forcing many patients to ultimately forego prescription drugs or to self-limit

293. See *In re K-Dur*, 686 F.3d at 214–18 (rejecting the scope of the patent test, balancing policy interests, and finding reverse payments as unreasonable restraints of trade).

294. See Carrier, “*Scope of the Patent*” Test, *supra* note 139, at 5–8 (explaining the failures of the scope of the patent test and praising the Third Circuit's application of antitrust scrutiny); *supra* Part III (revealing the failures of the scope of the patent test and arguing that the Third Circuit's reasoning was correct). As the Third Circuit noted, the scope of the patent test has always led to a victory for antitrust defendants. *In re K-Dur*, 686 F.3d at 214.

295. See *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing on H.R. 1706 before the Subcomm. on Commerce, Trade, and Consumer Prot. of the H. Comm. on Energy and Commerce*, 111th Cong. 2 (2009) (statement of FTC) (arguing that reverse payments harm American consumers and public health issues require Congress to resolve the problem).

296. See Brief of American Antitrust Institute and 26 Professors, *supra* note 255, at 4 (explaining how high pharmaceutical costs impact consumers); Hemphill, *Aggregate Approach*, *supra* note 236, at 636 (“[P]ay-for-delay settlement transfers wealth from consumers to drug makers in the form of continued high pharmaceutical prices . . .”); Oral Statement of Commissioner Jon Leibowitz, Hearing of the Senate Judiciary Committee (Jan. 17 2007), available at <http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf> (“These increased costs will burden not only individual consumers but also the federal government's new Medicare drug program, state governments, and American businesses striving to compete in a global economy—like General Motors, which reports that employee health care costs add \$1,500 to the price of each car that rolls off its assembly line.”).

297. See Nirmita Panchal et al., *Visualizing Health Policy*, 308 J. AM. MED. ASS'N 1197, 1197 (2012) (reporting that U.S. health care spending has risen over the past fifty years, rapidly outpacing the economy); SOC. SEC. ADVISORY BD., *THE UNSUSTAINABLE COST OF HEALTH CARE* 1–4 (2009) (concluding that the rapidly rising cost of health care represents the most significant threat to the long-term economic sustainability of workers and retirees); Christopher J. Truffer et al., *Health Spending Projections through 2019: The Recession's Impact Continues*, 29 HEALTH AFF. 1, 1 (2010) (reporting that health care costs in 2009 reached 17.3% of gross domestic product and projecting that the trend will continue).

their prescribed dosage.²⁹⁸ When patients do not follow doctors' orders due to high costs, medical conditions worsen, leading to even more dangerous conditions and expensive treatments.²⁹⁹ Additionally, a healthier population is a more economically productive population.³⁰⁰ While reducing health care costs would not be a valid reason alone to condemn reverse payment settlements, given that the lower courts have relied heavily on public policy support in reaching conclusions in this matter, the Supreme Court should weigh all of the relative policies in deciding which course to follow.³⁰¹ Therefore, in light of these concerns, the Court should reject the scope of the patent test.

Instead, the Court should find that a reverse payment from a patent holder to a generic patent challenger is prima facie evidence of an unreasonable restraint of trade.³⁰² Settlement agreements that allow brand-name manufacturers to pay generic manufacturers to delay market entry essentially permit the brand-name manufacturer to enjoy a temporary monopoly on the market. This monopoly divides the market and stymies competition.³⁰³ If the patent at hand is invalid, severe anticompetitive harm results because there is seemingly no justification

298. Brief for the American Antitrust Institute as Amicus Curiae Supporting Petitioners at 8, *In re Tamoxifen Citrate Antitrust Litig.*, 127 S. Ct. 3001 (No. 06-830). See Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors*, 61 MED. CARE RES. & REV. 415, 420, 427–28 (2004) (finding the negative effects of cost-sharing on health outcomes, and the particularly expensive and catastrophic results for seniors).

299. Brief of American Antitrust Institute and 26 Professors, *supra* note 255, at 4 (“Such consumer-coping strategies expose patients to worsening symptoms, escalating medical conditions, and even death.”); Rice & Matsuoka, *supra* note 298, at 420, 427–28 (observing the adverse health outcomes resulting from not taking medications).

300. See P’SHP FOR PREVENTION, HEALTHY WORKFORCE 2010: AN ESSENTIAL HEALTH PROMOTION SOURCEBOOK FOR EMPLOYERS, LARGE AND SMALL 7 (2001) (compiling studies showing that a healthier workforce is a more productive one); Special Comm. on Health, Productivity & Disability Mgmt., *Healthy Workforce/Healthy Economy: The Role of Health, Productivity, and Disability Management in Addressing the Nation’s Health Care Crisis*, 51 J. OCCUPATIONAL & ENVTL. MED. 114, 114 (2009) (“[A]n emphasis on the health of the workforce is vital to the health of the economy[.]”).

301. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (noting the “long-standing policy in the law” favoring patent settlements); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 202 (2d Cir. 2006) (reasoning that the court must encourage the most efficient resolution of costly disputes); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (reasoning that patent litigation is especially costly, time-consuming, and creates too much uncertainty).

302. See Brief of the Federal Trade Commission, *supra* note 283, at 23–26 (advocating that the court determine that reverse payments are presumptively unlawful).

303. See *id.* at 19–20 (“In the absence of countervailing considerations, such an agreement is a plain violation of antitrust laws.”); Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 71–72 (explaining the antitrust harm of reverse payment settlements); Hemphill, *Aggregate Approach*, *supra* note 236, at 635 (explaining why reverse payments violate antitrust law).

for the monopoly.³⁰⁴ Market allocation, whether by geography or time, can be the most dangerous anticompetitive activity because it deprives consumers of any competition.³⁰⁵ Even price fixing permits companies to compete in the market on factors other than price.³⁰⁶

A market allocation agreement, such as a reverse payment settlement, is similar to a territorial market allocation agreement, which the Supreme Court has categorized as a per se antitrust violation.³⁰⁷ For instance, in *Palmer v. BRG of Georgia, Inc.*, the Supreme Court applied per se illegality to an agreement foreclosing competition between two companies in a specified geographical territory, thus dividing the market.³⁰⁸ Similarly, reverse payment settlements allocate market division to parties, but instead of allocating based on geography, they allocate based on time.³⁰⁹ While courts that find no antitrust violation maintain that reverse payment settlements prevent only potential competitors from entering the market, courts generally recognize that the Sherman Act prevents monopolists from blocking certain or “nascent, albeit unproven” competition.³¹⁰ Thus, the Court should treat

304. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 71–72 (highlighting the antitrust concerns raised by reverse payments); O’Rourke & Brodley, *An Incentives Approach*, *supra* note 83, at 1781–82 (reasoning that “if the patents are invalid or not infringed, the settlement will most likely be unlawful” because it would create a monopoly).

305. The Supreme Court has held repeatedly that “[h]orizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition.” *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49 (1990) (quoting *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972)) (alterations in original).

306. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 71. “Price fixing is an agreement among competitors to raise, fix, or otherwise maintain the price at which their goods or services are sold. It is not necessary that the competitors agree to charge exactly the same price, or that every competitor in a given industry join the conspiracy.” DEP’T OF JUSTICE, PRICE FIXING, BID RIGGING, AND MARKET ALLOCATION SCHEMES: WHAT THEY ARE AND WHAT TO LOOK FOR: AN ANTITRUST PRIMER 2 (2010), available at <http://www.justice.gov/atr/public/guidelines/211578.pdf>.

307. *Palmer*, 498 U.S. at 50.

308. *Id.* at 49–50. “Agreements among competitors are not exempt from scrutiny under the Sherman Act just because a patent is involved.” Brief of the Federal Trade Commission, *supra* note 283, at 20. See, e.g., *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) (concluding that agreements to pool patents violated antitrust laws); *United States v. Masonite Corp.*, 316 U.S. 265, 282 (1942) (holding that patent agency agreements violated antitrust laws).

309. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 968–74 (2003), *vacated*, 402 F.3d 1056, 1058 (11th Cir. 2005).

[The settlement agreement] avoided the risks of litigation by entering into agreements that allowed the companies effectively to divide the market. Exclusion payments exclude competition no matter how weak or narrow a patent claim is—an opportunity *not* provided by the patent system itself, under which weak patents can be invalidated and narrow patents can be declared not infringed.

Brief of the Federal Trade Commission, *supra* note 283, at 21.

310. *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc). See also

reverse payment settlements as prima facie evidence of an unreasonable restraint on trade rather than a per se violation due to the complex nature of the patent's potential exclusionary rights.³¹¹

Finally, applying antitrust scrutiny to reverse payment settlements will neither unduly prevent patent litigation settlements nor hinder innovation because reverse payments are not essential to patent litigation settlements.³¹² An FTC study showed that between 1992 and 1999, fifty-seven percent of settlements between brands and generics involved reverse payments.³¹³ Then, in 2000, the FTC declared its intention to challenge these settlements.³¹⁴ Consequently, from 2000 through 2004, none of the twenty reported agreements involved a reverse payment from a brand-name company to a generic drug firm.³¹⁵ Instead, brand-name companies and generics settled by allowing early generic drug entry through license arrangements, which did not stymie innovation.³¹⁶ Yet, reverse payment settlements increased substantially after the *Schering-Plough* and *In re Tamoxifen Citrate* courts sanctioned the scope of the patent test.³¹⁷ Should the Supreme Court apply

12 HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2030, at 213 (2d ed. 2005) [hereinafter HOVENKAMP, ANTITRUST LAW] (“[T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition.”).

311. See HOVENKAMP, ANTITRUST LAW, *supra* note 310, ¶ 2046, at 327 (claiming that treating reverse payments as presumptively illegal works best to handle the reverse payment problem); *supra* Part III.C (arguing that presumptive illegality is the most appropriate analysis to handle reverse payment cases).

312. See Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 74–75 (2009) (presenting evidence that reverse payments are not essential in settling disputes between brands and generics).

313. FTC, AGREEMENTS FILED WITH THE FTC UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2005, A REPORT BY THE BUREAU OF COMPETITION 4 (2006) [hereinafter 2006 FTC REPORT], available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf> (noting that eight of the fourteen payments during this time were reverse payments).

314. Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary, 65 Fed. Reg. 17506 (April 3, 2000), available at <http://www.ftc.gov/os/2000/03/hoeschtandrxcmmstmt.htm>.

315. 2006 FTC REPORT, *supra* note 313, at 4.

316. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 75.

317. In 2005, twenty-seven percent of settlements included reverse payment settlements, rising to fifty percent in 2006. FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006, A REPORT BY THE BUREAU OF COMPETITION 4 (2007), available at <http://www.ftc.gov/reports/mmact/MMAreport2006.pdf>. In 2007, forty-two percent of reported agreements included reverse payment compensation. FTC, AGREEMENTS FILED WITH THE FTC UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2007, A REPORT BY THE BUREAU OF COMPETITION 3 (2008), available at <http://www.ftc.gov>.

antitrust scrutiny and hold that reverse payments are prima facie evidence of unreasonable restraints of trade, brand-name and generic pharmaceutical companies would likely find other legal (and not anticompetitive) ways to settle patent infringement or patent validity lawsuits.³¹⁸

In addition, contrary to the view of the Eleventh Circuit, restricting reverse payment settlements would not “reduce the legitimate value of the pharmaceutical patent rights.”³¹⁹ A patent conveys a right to “try to exclude,”³²⁰ not an absolute right to exclude. As noted above, courts ultimately deem many patents invalid or infringed.³²¹ Thus, the reverse payment confers a value greater than the true value of the patent—guaranteed insulation from competitors in the market without the risk of the patent being held invalid.³²² Accordingly, the Supreme Court should adopt the Third Circuit’s reasoning and conclusion in *In re K-Dur*.

B. The Court Should Outline Specific Factors for Lower Courts to Consider in Analyzing Rebuttal Evidence by Defendants

In addition to embracing the Third Circuit’s test from *In re K-Dur*, the Supreme Court should further outline specific factors for lower federal courts to consider when evaluating the antitrust defendants’ rebuttal.³²³ According to the Third Circuit’s test, antitrust defendants may attempt to rebut the prima facie evidence of an unreasonable restraint of trade by: (1) showing that the payment “was for a purpose other than delayed entry,” or (2) offering “some pro-competitive benefit.”³²⁴ Though the Third Circuit in *In re K-Dur* determined that evaluating the merits of the underlying patent suit was unnecessary,³²⁵ whether the agreement violates antitrust law depends, in part, on

gov/os/2008/05/mmaact.pdf.

318. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (“Data analyzed by the FTC suggest[s] that this [test] will leave the vast majority of pharmaceutical patent settlements unaffected.”).

319. Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1761–62.

320. Shapiro, *Antitrust Limits*, *supra* note 279, at 395 (arguing that patents are partial property rights).

321. See Allison & Lemley, *supra* note 226, at 205–07 (determining that forty-six percent of litigated patents are held invalid); Moore, *supra* note 203, at 390 (reporting that thirty-three percent of fully litigated patents are held invalid).

322. Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1761–62.

323. See *In re K-Dur*, 686 F.3d at 218. Though the court thoroughly explained its reasoning and reached a proper conclusion, it only offered guidance for the lower court by providing a test. See *id.* This Section offers suggestions on how best to expand that test.

324. *Id.*

325. *Id.*

whether the patent is valid.³²⁶ The patent's exclusionary power derives from the scope of the patent and the chance of it being held valid or infringed.³²⁷ Thus, the Court should consider whether the patent itself is valid.³²⁸

In doing so, the Court should allow antitrust defendants to offer indicators of patent validity, rather than fully exploring the merits of the underlying patent.³²⁹ Some scholars argue against patent settlements because patent litigation is the only appropriate way to assess the scope and validity of a patent.³³⁰ Other authors suggest that a "trial within a trial" is possible and that a court must consider whether the patent is valid before reaching any antitrust claims.³³¹ However, the FTC and

326. See Graham, *supra* note 85, at 443 (noting that if the patent is valid and the agreement does not extend beyond the patent, it does not violate antitrust laws); Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1735 (observing that the settlement could potentially be legal if the patent is valid and the agreement does not extend the monopoly).

327. Several commentators support a limited inquiry into the patent merits. See 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, 1795 (2003) (arguing that in certain circumstances, the antitrust analysis is ultimately about whether the patent is valid); Crane, *supra* note 51, at 785 ("Where a preliminary injunction motion has not been litigated, courts or agencies evaluating the competitive impact of an exit payment settlement should make an abbreviated examination of the merits."); Graham, *supra* note 85, at 443 (arguing that courts should undertake a limited inquiry into the merits of the patent); Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1735 ("Permitting ex post judicial queries into the validity and coverage of settled payments may sound onerous, and may sometimes even be a deal breaker. But it is necessary in our 'middle set' of cases in order to distinguish pro- from anticompetitive agreements."); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, 17 ANTITRUST 68, 75 (2003) (arguing that the antitrust analysis must begin by measuring the patent); Shapiro, *Antitrust Limits*, *supra* note 279, at 392 (reasoning that the courts should consider some limited inquiry into patent validity).

328. Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1735. See also Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, ANTITRUST, Summer 2002, at 53 ("[A]ny precise identification of the antitrust risk would require assessment of patent validity and scope."). In fact, Judge Pooler's dissent in *In re Tamoxifen* espouses this view. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 228 (2d Cir. 2006) (Pooler, J., dissenting) ("Of course, the strength of a patent must be central to any antitrust analysis involving a patent."). But see Abbott & Michel, *supra* note 265, at 22 ("[A]ny analysis of whether a patentee's exclusionary right includes the right to make exclusion payments and preempts antitrust scrutiny of those payments must [consider] all characteristics and features of patent policy including the probabilistic nature of the patent right at the time of settlements.").

329. See Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1760 ("[W]e think it important that the court make at least some limited inquiry into the merits of a settlement that requires the defendant to exit the market."). Hovenkamp, Janis, and Lemley propose, "The infringement plaintiff can defend by showing both: (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit." *Id.* at 1759.

330. Brodley & O'Rourke, *supra* note 328, at 53.

331. McDonald, *supra* note 327, at 70-71.

the majority of judicial opinions have expressed the view that antitrust analysis should not involve an assessment of the merits of the underlying patent.³³² The FTC has explained that inquiring into the merits of the patent would be unreliable and not necessarily helpful because the parties will have already settled the dispute and aligned their interests.³³³

Balancing these competing views, the U.S. Department of Justice (“DOJ”) has supported limited inquiry into the merits of a patent case by examining the relative merits of the patent claims and circumstantial factors surrounding the agreement.³³⁴ Offering a way to implement the DOJ’s approach, three prominent commentators—Herbert Hovenkamp, Mark Janis, and Mark Lemley—recommend that courts do not need to consider the merits of patent validity if: (1) the agreement would not violate antitrust laws even without the intellectual property dispute, or (2) if the agreement would be unlawful under antitrust laws even if the patentee successfully defended the patent.³³⁵ In the remaining situations, where the lawfulness of the reverse payment agreement

332. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 524–30 (E.D.N.Y. 2005); *In re Tamoxifen Citrate*, 466 F.3d at 204–05; *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003). See *In re Schering-Plough Corp.*, 136 F.T.C. 956, 968 (2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005); Holman, *supra* note 6, at 559 (explaining the courts’ and FTC’s position on considering the merits on underlying patent suit). However, some commentators have interpreted the Eleventh Circuit’s decision in *Valley Drug* as inquiring into the merits of the patent dispute before reaching antitrust claims. See Petition for Writ of Certiorari at 8, *In re Tamoxifen Citrate Antitrust Litig.*, 75 U.S.L.W. 3333 (U.S. Dec. 16, 2006) (No. 06–830) (citing *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003)). Notably, the petitioner only made this assertion in the introduction of the brief; it did not explain where exactly in the *Valley Drug* opinion this alleged test appears and did not offer a pincite to the location in the opinion of this test. *Id.* Professor Lemley, and other professors of economics, law, and business make the same assertion in their amici curiae brief urging the Court to grant certiorari in *Tamoxifen*. Brief for Professors of Economics, Business and Law as Amici Curiae Supporting Petitioner at 2, *In re Tamoxifen Citrate Antitrust Litig.*, 75 U.S.L.W. 3333 (U.S. Dec. 16, 2006) (No. 06–830) (citing *Valley Drug*, 344 F.3d 1294).

333. *In re Schering-Plough Corp.*, 136 F.T.C. at 967–68. In addition, commentators point to the FTC’s lack of technical proficiency to analyze the merits of a patent case. See Holman, *supra* note 6, at 559 n.437 (noting that the Federal Circuit’s reversal of so many patent infringement findings, even after the district court hears the full litigation, demonstrates why neither the FDA nor FTC would have the capacity to make these decisions). Even the FDA refuses to consider patent validity when listing drugs in the Orange Book. *Id.* See also 21 C.F.R. § 314.95 (2012) (explaining the process by which a generic drug company applies to the FDA when there is a patent for the drug already).

334. Brief for United States as Amicus Curiae Supporting Respondent at 11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05–273).

335. Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1725. See also Cotter, *supra* note 327, at 1790 (evaluating the Hovenkamp, Janis, and Lemley approach and arguing for a refined version); O’Rourke & Brodley, *An Incentives Approach*, *supra* note 83, at 1782 (describing and analyzing the Hovenkamp, Janis, and Lemley approach).

depends on the lawfulness of the underlying patent, these authors argue for a limited, non-exhaustive inquiry into the merits of the underlying patent infringement suit.³³⁶

Because fully analyzing patent validity would be overly burdensome and potentially unreliable, allowing antitrust defendants to present evidence of the patent's validity offers a suitable middle-ground approach.³³⁷ Specifically, reverse payments allow courts to address the issue by considering whether the reverse payment represents an objective assessment of the patent's value or an excessive payment to delay market entry of a generic drug.³³⁸ In its attempt to show that the reverse payment is not solely intended to delay market entry, the brand-name manufacturer could show that: (1) the payment was not higher than litigation costs would have been, or (2) the payment was reasonable based on the brand-name manufacturer's business assessment of the drug.³³⁹

First, the brand-name pharmaceutical company could show that the

336. Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1726, 1759–60. *See also* Cotter, *supra* note 327, at 1792 (clarifying and criticizing Hovenkamp, Janis, and Lemley's approach).

337. *See* O'Rourke & Brodley, *An Incentives Approach*, *supra* note 83, at 1782 (concluding that a limited inquiry approach is the best solution when patent rights are uncertain).

338. Reverse payments alert courts that the brand-name pharmaceutical company pays more than the cost of litigation because the parties have aligned incentives. Brand-name pharmaceutical companies and generic manufacturers generally have aligned incentives because the brand-name company can make more money by preventing the generic manufacturer from entering the market than if the two competed in the market. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 73. Naturally, the parties can make more money because they decrease competition. In fact, the generic usually makes more money by settling than if it won the patent infringement case and brought the drug to market, giving it strong incentives to file its ANDA first and to settle. *Id.* However, in some situations, the parties' interests do not clearly align.

For example, if a generic pays a brand-name pharmaceutical company to enter the market under a licensing agreement, the brand-name company desires higher royalties and the generic seeks lower payments. These types of licensing agreements are not as likely to create antitrust harm. *Id.* at 74. Another example involves agreement of the date of generic entry. In this scenario, the brand-name company seeks late entry and the generic wants early entry. Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1762. The parties' incentives may align more if the generic prefers the certainty of an exclusivity period over early commencement. Hemphill, *Paying for Delay*, *supra* note 7, at 1593. Distinctly, the reverse payments do not "offer any deviation from wholly aligned incentives." Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 74.

339. *See* Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 76 (proposing these rebuttal options for antitrust defendants). In many cases, the "patentee would not pay more than its litigation costs unless it believed it was buying later generic entry than litigation would provide." *Id.* Conversely, a "naked cash payment flowing from the patentholder to the challenger (in excess of avoided litigation costs) is a clear signal that the settlement is likely to be anticompetitive." Shapiro, *Antitrust Limits*, *supra* note 279, at 408.

payment represented its objective assessment of the patent's strength by offering evidence that the payment did not exceed the likely litigation costs.³⁴⁰ If the reverse payment does not exceed litigation costs, the reverse payment does not present antitrust concern because the parties may have had to pay those costs anyway.³⁴¹ Litigation costs here would include the party's out-of-pocket costs and attorneys' fees from settlement until the end of the matter.³⁴² However, if the patentee were willing to pay the generic drug company more than the costs of litigation, the payment would suggest that the patentee is uncertain of the patent's validity or scope.³⁴³

Second, antitrust defendants could demonstrate the reasonableness of a payment by offering "evidence of sales projections, market analyses, payments for similar products, and the brand's interest in the product and due diligence."³⁴⁴ For example, in *Schering-Plough*, the FTC analyzed the reasonableness of a single specified rate.³⁴⁵ After exhaustively documenting the company's lack of interest in the transaction and finding that Schering's licenses significantly exceeded the value of the products it received in return, the FTC concluded that the Schering agreement was an unreasonable restraint on trade.³⁴⁶ Following the FTC's analysis in *Schering-Plough*, the parties would be required to show that the justifications are plausible to be upheld.³⁴⁷

Further, placing the burden on defendants to show that the payment was reasonable is appropriate because defendants have access to the necessary information.³⁴⁸ Indeed, due to the increasing complexity of

340. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 76. See Shapiro, *Antitrust Limits*, *supra* note 279, at 408 ("[S]uch payments are not necessarily anticompetitive if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as 'reverse cash payments' may be important in more complex settings for successful settlement.").

341. Hemphill, *Paying for Delay*, *supra* note 7, at 1594–95.

342. Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1760 n.177.

343. *Id.* at 1757–58. Hovenkamp explains,

For example, a pioneer's willingness to pay [ten percent] of its profits as an exclusion payment to a generic rival suggests that the pioneer's profit-maximizing price is at least [ten percent] above its costs. That market power may well have been legally conferred by an IP right, but the validity of that right is the very subject at issue in a settlement case.

Id. at 1757 n.168.

344. Carrier, *Unsettling Drug Patent Settlements*, *supra* note 52, at 71–72.

345. *In re Schering-Plough Corp.*, 36 F.T.C. 956, 1003–52 (2003), *vacated*, 402 F.3d 1056, 1058 (11th Cir. 2005).

346. *Id.*

347. *Id.* at 963–66.

348. See Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 534–35 (2002) (arguing that the courts should place the burden of

reverse payment settlements, plaintiffs and the FTC may have a difficult time identifying and gathering data regarding the agreements.³⁴⁹ Therefore, as a part of the antitrust defendant's attempt to prove that the reverse payment's intent was not simply to delay market entry, it may offer evidence that: (1) the payment did not exceed litigation costs, or (2) the payment represented a reasonable, objective assessment of the patent's validity.

CONCLUSION

Though antitrust law and patent law are fundamentally at odds, they both seek to improve consumer welfare through competition and innovation.³⁵⁰ By treating reverse payments as presumptively illegal, the Supreme Court can strike the proper balance between these two conflicting areas of law and reach these shared goals.³⁵¹ While antitrust law prohibits brand-name drug manufacturers from paying generic drug manufacturers large sums of money to delay generic drug entry, allowing patent holders to prove that the payment was for something other than delayed entry recognizes the exclusionary power of the patent.³⁵² Ultimately, the Third Circuit's decision in *In re K-Dur* offers

proof on the antitrust defendants due to their access to relevant information); Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 232, at 1733–34 (observing that antitrust defendants will be in a better position to offer evidence of patent validity).

349. Commissioner Thomas Leary has also noted that placing the burden of proving invalidity and non-infringement on antitrust plaintiffs, such as the FTC, is impractical because the FTC lacks the institutional capability to make such determinations. See Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II*, 34 J. HEALTH L. 657, 661–62 (2001). However, some argue that placing the burden on antitrust defendants is inconsistent with the procedural presumption of patent validity in the Patent Act, 35 U.S.C. § 282 (2006). See Cotter, *supra* note 327, at 1796 n.40; Kevin D. McDonald, *Patent Settlements and Payments That Flow the "Wrong" Way: The Early History of a Bad Idea*, 15 ANTITRUST HEALTH CARE CHRON. 4, 12–13 (2002) (arguing that placing the burden of proof on the patent holder contradicts the Patent Act). Instead, Thomas Cotter suggests,

A court could resolve this tension, however, by concluding that the statutory presumption was intended to apply in patent infringement actions only, and not in other settings; to hold otherwise might undermine the equally important federal policies embedded in the antitrust laws. In addition, or alternatively, a court could incorporate the statutory presumption into the analysis by requiring the patent plaintiff/antitrust defendant to prove that it would have prevailed in the patent infringement action in light of, *inter alia*, the statutory presumption.

Cotter, *supra* note 327, at 1795 n.40 (citing Blair & Cotter, *supra* note 348, at 533).

350. See Crane, *supra* note 51, at 748 n.1 (“It is generally recognized that antitrust and patent law, although polar opposites in their treatment of monopolies, share common objectives.”).

351. See *supra* Part III (arguing that the Third Circuit in *In re K-Dur* properly weighed policy interests and employed sound legal reasoning to reject the scope of the patent test, and treated reverse payments as *prima facie* evidence of unreasonable restraints of trade).

352. See *supra* Part IV (explaining why the Supreme Court should adopt the Third Circuit's test).

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the Supreme Court a clear opportunity to rule on reverse payment settlements. The long-awaited Supreme Court decision in *Actavis* will have significant implications given the split among the circuit courts and skyrocketing health care costs in the United States.