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

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COMMENT

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INTRODUCTION
In March 2013, the U.S. Supreme Court heard oral arguments in FTC v. Actavis, Inc. 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. The Court’s decision in this case could have a significant impact on rising health care costs in this country. The high cost of prescription drugs has put crippling economic pressure on the U.S. health care system. In 2010, forty-eight

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. 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. 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. These settlement arrangements, known as “reverse payments” or “pay-for-delay” agreements, derive from the regulatory framework of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Though Hatch-
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. As a result, drug prices remain inflated and American health care consumers bear the burden. According to the Federal Trade Commission (“FTC”), these anticompetitive agreements, which rose to a record number in 2012, cost consumers $3.5 billion per year.

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. Three circuit courts have applied antitrust scrutiny to find that reverse payments unreasonably restrain trade in violation of federal antitrust law. 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


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


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 Pharm., 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 Pharm., 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 Pharm., Inc., 256 F.3d at 799.
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. 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. 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.

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.


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

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. 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. 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. 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. This delay created a lapse of several years

between expiration of the patent term and availability of a generic version to consumers. Indeed, the FDA rules created “the practical extension of the monopoly position of the patent holder beyond the expiration of the patent.” 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.

In addition, the lengthy drug approval process deprived patent holders of years of patent protection. 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. 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. With these additional tests, the total cost of developing a new drug skyrocketed into the hundreds of millions of dollars. The 1962 amendments significantly eroded the term of exclusivity because the testing delayed

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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.
commercialization of the drug. As a result, a drug’s average effective patent life had fallen to less than seven years by 1981.

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. 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.

First, Congress sought to remedy the decline in a patent’s life by offering patent term restoration and non-patent exclusivity. 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. 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.

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. 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. The generic drug manufacturer

36. 35 U.S.C. § 156 (e), (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).
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
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”).


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”).


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

\(^{55}\) 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 bottlenecking. 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. \(\text{id}\). Then, if the generic filed a paragraph IV certification, the pioneer could sue and receive another thirty-month stay. \(\text{id}\). § 355(q)(G). The second amendment to Hatch-Waxman created forfeiture events that resulted in generics forfeiting their 180-day exclusivity period. \(\text{id}\). § 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. \(\text{id}\). Then, the exclusivity period would last to the subsequent court decision, which could occur after the FDA’s approval. \(\text{id}\). 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. \(\text{id}\).


\(^{58}\) 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. \(\text{id}\). 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. 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.

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

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. In general, antitrust law preserves the fundamental rules of competition to protect and encourage lower prices, spark innovation, and maintain efficient industry production. Specifically, section 1 of the Sherman Act prohibits unreasonable restraints of trade. Courts seventy-five percent. *Id.*

60. CBO REPORT, supra note 26, at xiii.
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).
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.” Under the rule of reason analysis, the factfinder must decide whether the questioned practice imposes an unreasonable restraint on competition. 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. Courts generally perform this inquiry in three steps. First, the plaintiff must show that the conduct produced anticompetitive effects in the market. 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.” Finally, the plaintiff may rebut the defendant’s evidence by demonstrating that the restraint is not reasonably necessary to achieve the stated procompetitive objective.

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 competition and “lack any redeeming virtue.” 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.” When the per se approach applies, the court does not...
consider the intent behind the restraint, any claimed procompetitive justifications, or the restraint’s actual effect on competition.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{81} Because reverse payments are horizontal agreements,\textsuperscript{82} they appear to be clear antitrust violations.\textsuperscript{83} However, the presence of patent rights,
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


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


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.  94 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.”  95 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.


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, 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. This Section explains the first two of these cases to set the backdrop for a discussion of the circuit split in Part II.

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. In early 1996, HMRI sued for patent infringement, triggering the thirty-month waiting period during which the FDA cannot provide final approval to any ANDA applications. Soon after, in June 1997, Biovail, another generic manufacturer, filed an ANDA for the same drug. The FDA issued a tentative approval of Andrx’s ANDA on September 15, 1997. 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 Pharm., 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.


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 Pharm., 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 Pharm., 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. 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. Though the parties maintained that the agreement did not settle the litigation, 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.

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. On July 9, 1998, the FDA issued its final approval of Andrx’s ANDA. Pursuant to the agreement, HMRI began making quarterly payments to Andrx, and in exchange, Andrx did not bring its generic drug to market. 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.

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. 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.”

Andrx argued that it simply acted within its rights under
the Hatch-Waxman Act. The court found that although Hatch-
Waxman allowed for these settlements, the Act did not insulate
defendants from antitrust liability. 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.

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. 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. The Sixth Circuit

alleging that Andrx violated sections 1 and 2 of the Sherman Act. Brief of Appellant Biovail
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
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,

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.


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.”\textsuperscript{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.\textsuperscript{117} The court also rejected defendants’ argument that this “novel” area of law entitled it to avoid per se treatment.\textsuperscript{118} Instead, the Sixth Circuit found that the Sherman Act “establishes one uniform rule applicable to all industries alike.”\textsuperscript{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.\textsuperscript{120}

II. DISCUSSION

While the D.C. and Sixth Circuits applied antitrust scrutiny to reverse payments in the Cardizem CD cases,\textsuperscript{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.\textsuperscript{122} This purpose was to ensure competitive prices for consumers and protect the “economic freedom of participants in the relevant market.” \textit{In re Cardizem CD}, 332 F.3d at 908 (citing \textit{Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters}, 459 U.S. 519, 538 (1983)). \textit{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.”).

\textsuperscript{116.} \textit{In re Cardizem CD}, 332 F.3d at 908.

\textsuperscript{117.} Id.

\textsuperscript{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, \textit{In re Cardizem CD Antitrust Litig.}, 332 F.3d 896 (6th Cir. 2001) (No. 00-2483).

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

\textsuperscript{120.} Id. at 909.

\textsuperscript{121.} \textit{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).

\textsuperscript{122.} \textit{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); \textit{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*. 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. 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.

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. 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.

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

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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.


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. 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.

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. Reversing the district court, the Eleventh Circuit found that the agreements were not per se illegal. The court reasoned that the district court failed to accurately weigh the exclusionary power of the patent. 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. Further,

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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 Pharmas., 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.

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.

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 licensor’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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{137}

The Eleventh Circuit expressly rejected the Sixth Circuit’s opinion in \textit{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.\textsuperscript{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.\textsuperscript{139} The Eleventh Circuit further

\begin{itemize}
\item \textsuperscript{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.” \textit{Valley Drug Co.}, 344 F.3d at 1305. For a discussion of patent exceptionalism theory, see Hemphill, \textit{Paying for Delay}, supra note 7, at 1597–604.
\item \textsuperscript{135} \textit{Valley Drug Co.}, 344 F.3d at 1305.
\item \textsuperscript{136} \textit{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. \textit{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.” \textit{Id. at} 1307–08 (quoting \textit{PHILLIP E. AREEDA & HERBERT HOVENKAMP}, \textit{ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION} ¶ 1780a (1999)). \textit{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 . . . .").
\item \textsuperscript{137} \textit{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. \textit{Id. at} 1308 n.20 (citing Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976)).
\item \textsuperscript{138} \textit{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)).
\item \textsuperscript{139} \textit{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{142}

\textbf{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 \textit{In re K-Dur}.\textsuperscript{143} In \textit{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...
Upsher for patent infringement. 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. 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. 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.

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


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. The Commission reversed the ALJ’s decision, concluding that the settlements violated the Sherman Act. 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. 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.

Upon review, the Eleventh Circuit reversed the FTC’s determination, holding that the settlement agreement was not anticompetitive in line with Valley Drug. 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.

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. 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.


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 Pharm. 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. 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. Further, the court noted that the general policy in the law to favor settlements applied to patent litigation lawsuits. The court concluded that Schering reasonably used its patent power.

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. The court again relied on public policy support for settlements to bolster its finding that the agreements were not anticompetitive. Because the agreement covered only the patents at issue, the restraint was sufficiently narrow. 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.
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.\textsuperscript{163}

The \textit{Schering-Plough} decision further solidified the Eleventh Circuit’s reasoning in \textit{Valley Drug} and entrenched the scope of the patent test as an attractive way to analyze reverse payment settlements.\textsuperscript{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.\textsuperscript{165}

\textbf{C. In re Tamoxifen Citrate: Making the Scope of the Patent Test More Deferential}

Similar to the Eleventh Circuit’s holdings in \textit{Valley Drug} and \textit{Schering-Plough}, the Second Circuit found that a reverse payment settlement within the scope of the patent did not violate antitrust laws.\textsuperscript{166} In \textit{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.\textsuperscript{167} The parties entered into a settlement agreement while an appeal of the patent infringement suit was pending.\textsuperscript{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.\textsuperscript{169} In return, Barr agreed not to market its own generic version until Zeneca’s patent expired.\textsuperscript{170}

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\textsuperscript{163} Schering-Plough Corp., 402 F.3d at 1074.

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

\textsuperscript{165} Holman, \textit{supra} note 6, at 491; Carrier, \textit{Unsettling Drug Patent Settlements}, \textit{supra} note 52, at 55.

\textsuperscript{166} \textit{In re Tamoxifen Citrate}, 466 F.3d at 213.

\textsuperscript{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.

\textsuperscript{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.” \textit{Imperial Chem. Indus., PLC}, 795 F. Supp. at 622.

\textsuperscript{169} \textit{In re Tamoxifen Citrate}, 466 F.3d at 193–94.

\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.”\textsuperscript{173}

Yet, the court reasoned that due to the presumption of patent validity, the settlement legitimately extended the valid patent monopoly.\textsuperscript{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.\textsuperscript{175} The Second Circuit analyzed Zeneca’s agreement and found it was neither fraudulent nor baseless.\textsuperscript{176} The court also determined that the agreement did not exceed the patent’s scope.\textsuperscript{177} Distinguishing the case from \textit{In re Cardizem CD}, the court noted that the settlement did not restrict the marketing of non-infringing products.\textsuperscript{178} The court added that the settlement allowed other potential generics to challenge the validity of the patent.\textsuperscript{179} Further, the Second Circuit followed the

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\textbf{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. \textit{Id.} Further, if the court declared the Tamoxifen patent invalid or unenforceable, Barr would be able to market the generic version of the drug. \textit{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. \textit{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-exclusivity period as the first paragraph IV certification filer. \textit{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. \textit{Id.} }
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\textbf{171. In re Tamoxifen Citrate, 466 F.3d at 196–97.}

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

\textbf{173. In re Tamoxifen Citrate, 466 F.3d at 211.}

\textbf{174. Id. at 211–12.}

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

\textbf{176. In re Tamoxifen Citrate, 466 F.3d at 213.}

\textbf{177. Id.}

\textbf{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. \textit{Id.}}

\textbf{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.


185. Id. at 1327–28. Bayer owns U.S. Patent No. 4,670,444, which covers the compound ciprofloxin 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. In addition, Bayer agreed to provide Barr with Cipro for resale or to make quarterly payments to Barr for five years.

Similar to the Second and Eleventh Circuits, the Federal Circuit found that the payments did not violate federal antitrust laws. 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. Applying the presumption of validity principle, the court reasoned that the patent confers a power to exclude others from profiting from the patented product. Further, it noted that the agreements only prevented Barr from benefiting from the patent and therefore, fell within Bayer’s rights as the patentee. 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 patent and, absent sham or


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).


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 Pharm., 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.  

To begin, the court explained that the scope of the patent test created an “almost unrebuttable presumption of patent validity,” which presupposed the issue in the patent suit. 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. More importantly, a court ignores that the underlying suit concerns a patent infringement case, not patent validity. 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. Instead, the court offered empirical and legal support for the public interest in judicial testing and eliminating weak patents. 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. 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. Aeroquip 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)).  
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. Additionally, the patent holder may still settle with the subsequent challengers. 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.”

Further, the Third Circuit found that U.S. Supreme Court precedent supports freeing the competitive economy of narrow or invalid patents. 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. 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. In its opinion, the Court found support in the public policy behind freeing the competitive economy in the patent context. The Third Circuit in *In re K-Dur* found that the


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).


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.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{213}

Finally, the court articulated a test for district courts to follow in future reverse payment cases.\textsuperscript{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.”\textsuperscript{215} The patent holder may then...
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.\textsuperscript{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.\textsuperscript{217}

In sum, while the D.C. Circuit in \textit{Andrx} and the Sixth Circuit in \textit{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 \textit{Schering-Plough}, the Third Circuit decision in \textit{In re K-Dur} created a circuit split that highlights the importance of the Supreme Court’s upcoming resolution of this complex issue in \textit{Actavis}.\textsuperscript{218}

\textbf{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.
A. Presumption of Patent Validity

The Second, Eleventh, and Federal Circuits improperly interpreted the presumption of patent validity in the previously discussed case law. The Patent Act states that patents “shall be presumed valid.” However, this presumption is merely procedural and governs the order in which parties carry the burden of proof. 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. Instead, courts using the scope of the patent test essentially make every PTO decision a final one. 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. Citing the FTC, the Third Circuit observed that generic drug

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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 Pharm., 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).


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)).


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.”).

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. 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.

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. 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.\textsuperscript{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.\textsuperscript{232} In addition, the settling innovator firm can, and often does, pay off multiple challengers at once.\textsuperscript{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.\textsuperscript{234} Even though the underlying reason courts generally give to support settlement is cost efficiency,\textsuperscript{235}

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\item 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))).
\item 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).
\item 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.").
\item 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).
\item 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
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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. Specifically, early competition benefits consumers because it lowers drug prices sooner. 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.”

Although settling patent litigation cases may save major pharmaceutical companies substantial sums of money, 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.


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.\textsuperscript{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.”\textsuperscript{241} In essence, these courts reason that cost efficiency matters at the courts, but not at the pharmacy.\textsuperscript{242}

Similarly unpersuasive, the Second, Eleventh, and Federal Circuits have warned that scrutinizing patent settlements could hinder patent innovation, the foundation of patent law.\textsuperscript{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.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{246} Specifically, the Supreme

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\item See Robert Kneuper, \textit{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.
\item 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.
\item See supra note 235 and accompanying text (providing examples of courts that cite cost efficiency as the public policy behind settling patent disputes).
\item 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 Pharmns, 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.
\end{enumerate}
\end{footnotesize}
Court has instructed that “[a]ntitrust analysis must sensitively recognize the distinctive economic and legal setting of the regulated industry to which it applies.” 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. 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.

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. 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. 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)).


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).


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. 2011) (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.\textsuperscript{257} The Second, Eleventh, and Federal Circuits improperly applied the scope of the patent test to reverse payment settlements.\textsuperscript{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 \textit{per se} legal.\textsuperscript{259} Doing so has cost the American public millions of dollars.\textsuperscript{260} Fortunately, the \textit{In re K-Dur} court wisely rejected the scope of the patent test and instead applied antitrust scrutiny.\textsuperscript{261}

\textbf{C. Applying Antitrust Scrutiny}

After rejecting the scope of the patent test, the Third Circuit in \textit{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 \textit{per se} analysis.\textsuperscript{262} The majority of courts have correctly rejected the \textit{per se} approach, though the Second Circuit and Sixth Circuit have misapplied this test to reverse payment settlements.\textsuperscript{263} \textit{Per se} treatment is

\begin{itemize}
  \item 257. See Hemphill, \textit{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., \textit{Anticompetitive Settlement}, supra note 232, at 1758 (observing that because the law allows reverse payments to occur does not immunize them from antitrust liability).
  \item 258. See Brief for the United States in Response to the Court’s Invitation at 11–15, \textit{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 \textit{In re Tamoxifen} “distorts the statutory process that leads to competition in the face of patent claims”).
  \item 259. Non-Confidential Reply Brief for Plaintiffs-Appellants at 2, \textit{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 \textit{per se} legal and urging against this holding).
  \item 260. 2010 FTC REPORT, supra note 6, at 2 (concluding that reverse payments cost the American public $3.5 billion a year). See Hemphill, \textit{Aggregate Approach}, supra note 236, at 651 (finding that reverse payment settlements cost the American public up to $12 billion annually).
  \item 261. \textit{In re K-Dur Antitrust Litig.}, 686 F.3d 197, 214–18 (3d Cir. 2012).
  \item 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).
  \item 263. See \textit{In re Ciprofloxacin Hydrochloride}, 544 F.3d at 1332 (rejecting the \textit{per se} approach); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) (same); Valley Drug Co. v. Geneva Pharmas., Inc., 344 F.3d 1294, 1308 (11th Cir. 2005) (same); Andrx Pharmas., Inc. v. Biovail Corp. Int’l, 256 F.3d 799, 809 (D.C. Cir. 2001) (same). \textit{But see In re Tamoxifen Citrate Antitrust Litig.}, 466 F.3d 187, 206 (2d Cir. 2006) (finding reverse payment settlements \textit{per se} illegal because restricting patent settlements might hinder innovation); \textit{In re Cardizem CD Antitrust Litig.}, 332 F.3d 896, 915 (6th Cir. 2003) (finding reverse payment settlements \textit{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
potentially justify a reverse payment if it reflected the parties’ reasonable assessments of patent validity.\textsuperscript{269} Therefore, the Third Circuit and other courts have properly rejected applying the per se rule to reverse payments.\textsuperscript{270}

The Third Circuit also appropriately decided against applying a rule of reason analysis to reverse payments.\textsuperscript{271} Because reverse payment settlements are generally anticompetitive, a rule of reason analysis would be illogical.\textsuperscript{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.\textsuperscript{273} Plaintiffs, however, usually cannot make this showing because it carries a heavy evidentiary and financial burden.\textsuperscript{274}

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

\textbf{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.”).

\textsuperscript{269} See Carrier, \textit{Unsettling Drug Patent Settlements}, supra note 52, at 67 (arguing that per se invalidity is inappropriate). \textit{See also} MICHAEL A. CARRIER, \textit{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, \textit{An Incentives Approach}, supra note 83, at 1784–86 (describing potential objective indicators of patent validity).

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


\textsuperscript{272} Hovenkamp et al., \textit{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, \textit{Probabilistic Patents}, supra note 189, at 93 (noting that reverse payments are presumptively anticompetitive).


\textsuperscript{274} \textit{See} Michael A. Carrier, \textit{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).

\textsuperscript{275} \textit{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.\footnote{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.\footnote{277} Accordingly, courts should not apply the burdensome rule of reason test in reverse payment cases.\footnote{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.\footnote{279} This position recognizes the potentially severe anticompetitive effects of reverse payment settlements.\footnote{280} Further, it follows the Supreme Court’s instruction that antitrust analysis should mind the constructs of the regulated industry.\footnote{281} Treating reverse payment settlements as prima facie
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. Thus, the Third Circuit correctly framed the antitrust analysis.

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. The rebuttal option is appropriate because, for example, a reverse payment could reflect the parties’ reasonable expectations of litigation costs. Also, the court reasoned that the second rebuttal option would account for the instances in which the reverse payment could increase competition. This option is appropriate because there are some (albeit rare) situations where a reverse payment could increase competition among pharmaceutical companies.

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

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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. 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. 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. 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.

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. 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).

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. 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.

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

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.


296. See Brief of American Antitrust Institute and 26 Professors, supra note 255, at 4 (explaining how high pharmaceutical costs impact consumers); Hempill, Aggregate Approach, supra note 236, at 636 (“Pay-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.\textsuperscript{298} When patients do not follow doctors’ orders due to high costs, medical conditions worsen, leading to even more dangerous conditions and expensive treatments.\textsuperscript{299} Additionally, a healthier population is a more economically productive population.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{303} If the patent at hand is invalid, severe anticompetitive harm results because there is seemingly no justification


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

\textsuperscript{300} \textit{See} P’SHIP 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., \textit{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[.]”).

\textsuperscript{301} \textit{See}, e.g., \textit{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); \textit{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 Pharm., Inc., 344 F.3d 1294, 1308 (11th Cir. 2003) (reasoning that patent litigation is especially costly, time-consuming, and creates too much uncertainty).

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

\textsuperscript{303} \textit{See id. at} 19–20 (“In the absence of countervailing considerations, such an agreement is a plain violation of antitrust laws.”); Carrier, \textit{Unsettling Drug Patent Settlements, supra} note 52, at 71–72 (explaining the antitrust harm of reverse payment settlements); Hemphill, \textit{Aggregate Approach, supra} note 236, at 635 (explaining why reverse payments violate antitrust law).
for the monopoly. Market allocation, whether by geography or time, can be the most dangerous anticompetitive activity because it deprives consumers of any competition. Even price fixing permits companies to compete in the market on factors other than price.

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. 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. Similarly, reverse payment settlements allocate market division to parties, but instead of allocating based on geography, they allocate based on time. 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. 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).


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.” DEPARTMENT 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.


[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).
315. 2006 FTC REPORT, supra note 313, at 4.
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 invalidity lawsuits.\footnote{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.”).}

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.”\footnote{319 Hovenkamp et al., Anticompetitive Settlement, supra note 232, at 1761–62.} A patent conveys a right to “try to exclude,”\footnote{320 Shapiro, Antitrust Limits, supra note 279, at 395 (arguing that patents are partial property rights).} not an absolute right to exclude. As noted above, courts ultimately deem many patents invalid or infringed.\footnote{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).} 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.\footnote{322 Hovenkamp et al., Anticompetitive Settlement, supra note 232, at 1761–62.} Accordingly, the Supreme Court should adopt the Third Circuit’s reasoning and conclusion in In re K-Dur.

\textbf{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.\footnote{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.} 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.”\footnote{324 Id.} Though the Third Circuit in In re K-Dur determined that evaluating the merits of the underlying patent suit was unnecessary,\footnote{325 Id.} whether the agreement violates antitrust law depends, in part, on...
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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{335} In the remaining situations, where the lawfulness of the reverse payment agreement

\textsuperscript{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).

\textsuperscript{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).


\textsuperscript{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

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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.\textsuperscript{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.\textsuperscript{341} Litigation costs here would include the party’s out-of-pocket costs and attorneys’ fees from settlement until the end of the matter.\textsuperscript{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.\textsuperscript{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.”\textsuperscript{344} For example, in \textit{Schering-Plough}, the FTC analyzed the reasonableness of a single specified rate.\textsuperscript{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.\textsuperscript{346} Following the FTC’s analysis in \textit{Schering-Plough}, the parties would be required to show that the justifications are plausible to be upheld.\textsuperscript{347}

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

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\textsuperscript{340} Carrier, \textit{Unsettling Drug Patent Settlements}, supra note 52, at 76. See Shapiro, \textit{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.”).

\textsuperscript{341} Hemphill, \textit{Paying for Delay}, supra note 7, at 1594–95.

\textsuperscript{342} Hovenkamp et al., \textit{Anticompetitive Settlement}, supra note 232, at 1760 n.177.

\textsuperscript{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.

\textit{Id.} at 1757 n.168.


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

\textsuperscript{346} Id.

\textsuperscript{347} Id. at 963–66.

\textsuperscript{348} See Roger D. Blair & Thomas F. Cotter, \textit{Are Settlements of Patent Disputes Illegal Per Se?}, 47 \textit{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. 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. 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. 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. 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).


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.


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).
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.