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Susan Schipper

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BAD MEDICINE: FTC v. ACTAVIS, INC. AND THE MISSED OPPORTUNITY TO RESOLVE THE PAY-FOR-DELAY PROBLEM

SUSAN SCHIPPER*

In *Federal Trade Commission v. Actavis, Inc.*,¹ the Supreme Court of the United States considered whether the U.S. Court of Appeals for the Eleventh Circuit correctly dismissed the Federal Trade Commission's ("FTC") antitrust challenge to a reverse payment settlement agreement² between brand-name and generic drug manufacturers,³ in the context of patent litigation, for the hormone medication AndroGel.⁴ This type of settlement is colloquially referred to as a "pay-for-delay" arrangement.⁵ The Court

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^{*} J.D. Candidate, 2015, University of Maryland Francis King Carey School of Law. The author wishes to thank Professors Danielle Citron and William Reynolds for their wisdom and guidance, and her editors, Tyler Silvey and Kari D'Ottavio, for their direction and feedback throughout the writing process. The author is grateful to her parents, Terri and Steven, for their unwavering support, Michael Brown, for his constant motivation, and her friends and family for their encouragement.

^{1. 133} S. Ct. 2223 (2013).

^{2.} *Id.* at 2227. Briefly, a reverse payment settlement is a settlement wherein a brand-name drug company pays a potentially competitive generic drug company to defer putting its approved generic version of the brand-name's drug on the market for a certain period of time. *See infra* Parts I and II.A (elaborating upon the concept and details of reverse payment settlements). This agreement takes place within litigation where the brand-name, as the plaintiff, sues the generic for infringement on the brand-name's patented drug. *Id.* The reverse payment settlement is so called because a plaintiff paying a defendant in settlement is the reverse of a typical litigation outcome. *Id.*

^{3.} Companies that test, produce, and obtain patents for new drugs or drug composites that are filed and sold under a trade name, such as Tylenol, are known as brand-name companies. Companies that obtain a patent to market generic, bioequivalent versions of brand-name drugs under the name of the active ingredient(s) of the drug, or under a different name than the brand-name, are known as generic companies. *See What are Generic Drugs?*, FDA.GOV (May 12, 2009),

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Understan dingGenericDrugs/ucm144456.htm; *see also, e.g., List of Marketed Acetaminophen-Containing Prescription Products*, FDA.GOV (Jan. 21, 2011), http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm239821.htm#list (listing in a chart the "brand name" and "generic name" of certain types of prescription medications containing acetaminophen). This Note will hereinafter refer to brand-name drug companies as either "brand-names" or "brand-name companies," and will refer to generic drug companies as "generics" or "generic companies."

^{4.} Actavis, 133 S. Ct. at 2229–30; FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd sub nom.* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

^{5.} See, e.g., Watson Pharm., Inc., 677 F.3d at 1301 ("This case involves a type of patent litigation settlement known as a 'pay for delay' or 'reverse payment' agreement."); Ark. Carpenters Health & Welfare Fund v. Bayer AG, 625 F.3d 779, 780 (2d Cir. 2010) ("In the industry par-

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held that the Eleventh Circuit erred in failing to allow the FTC to challenge the legality of the settlement, where a brand-name pharmaceutical company, Solvay Pharmaceuticals, agreed to pay the named generic, Actavis, Inc., and other generic drug companies, hundreds of millions of dollars to refrain from marketing a generic version of AndroGel until 2015.⁶ The FTC alleged in its complaint against the settling drug companies that the reverse payment component of their settlement was a collusive, horizontal restraint on trade and was therefore a violation of antitrust law.⁷ The Eleventh Circuit dismissed the FTC's challenge and held that the monopoly powers conferred to pharmaceutical patent-holders precluded the FTC from bringing an antitrust action against the parties engaging in pay-for-delay as long as the anti-competitive effects of the pay-for-delay do not exceed the scope of the patent's monopoly.⁸ The U.S. Supreme Court reversed, holding instead that reverse payment settlements are not impervious to antitrust challenges and can be decided using a traditional antitrust framework.⁹

The Court was correct in holding that antitrust challenges to pay-fordelay arrangements are indeed justiciable and that questions surrounding the legality of the settlements should be decided against an antitrust framework.¹⁰ Ultimately, though, the Court failed to embrace one of the competing standards that lower federal courts have used when applying antitrust principles to reverse payment settlements in the pharmaceutical context.¹¹ The Court should have adopted the rigorous "quick look rule of reason" analysis as the definitive standard for adjudging reverse payment agreements.¹² As a matter of policy, the Court should have also recommended that reverse payment settlements be subject to judicial approval to ensure that they do not exceed the anticipated costs of litigation.¹³ This recommendation would likely limit the number of patent challenges that are settled using a reverse payment model, thereby decreasing the risk of antitrust violations.¹⁴ Further, it would strike a balance between allowing early mar-

- 10. See infra Part IV.A.
- 11. See infra Parts II.B and IV.B.1.
- 12. See infra Part IV.B.2.
- 13. See infra Part IV.C.
- 14. See infra Part IV.C.

lance, [a reverse payment settlement] is called a 'reverse exclusion payment,' or, more evocatively, a 'pay-for-delay settlement.''). This Note will hereinafter refer to reverse payment settlements either as "reverse payment settlements" or "pay-for-delay arrangements."

^{6.} Actavis, 133 S. Ct. at 2227, 2229.

^{7.} Watson Pharm., Inc., 677 F.3d at 1305.

^{8.} Id. at 1312.

^{9.} Actavis, 133 S. Ct. at 2227, 2237-38.

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ket entry for generic companies while ensuring that brand-name companies continue to receive the patent protections afforded to them.¹⁵

I. THE CASE

Belgian pharmaceutical company Besins Healthcare, S.A. ("Besins") developed a formula for a prescription gel used to treat male hypogonadism, a condition where the body does not produce normal levels of testosterone; the company called this new drug "AndroGel."¹⁶ In August 1995, Besins entered into an agreement with another brand-name drug manufacturer, Solvay Pharmaceuticals ("Solvay"), to supply Solvay with AndroGel once Solvay received government approval to sell the drug in the United States.¹⁷ In 1999, Solvay filed a New Drug Application ("NDA")¹⁸ with the Food and Drug Administration ("FDA") to market AndroGel, which the FDA approved in 2000.¹⁹ Solvay subsequently obtained a relevant patent from the Patent and Trademark Office to sell AndroGel in 2003, and disclosed its patent to the FDA.²⁰ Solvay's patent for AndroGel, Patent Number 6,503,894 ("#894 patent"), expires in 2020.²¹ According to the Hatch-Waxman Act, a main governing body of law for the U.S. pharmaceutical industry, the FDA must grant a drug manufacturer three years of drug exclusivity for a new drug application containing an active ingredient that has already been approved by the FDA, but which still includes important clinical investigations.²² The FDA is only authorized to approve generic versions of a brand-name drug once the brand-name's exclusivity period is over.²³ Since Solvay's NDA contained crucial clinical investigations regarding the active ingredients in AndroGel, the FDA granted the company exclusivity for the drug for three years.²⁴ AndroGel is a profitable drug; between 2000 and 2007, U.S. sales of AndroGel totaled more than \$1.8 billion.²⁵

^{15.} See infra Part IV.C.

^{16.} In re AndroGel Antitrust Litig. (No. II), 687 F. Supp. 2d 1371, 1372-73 (N.D. Ga. 2010).

^{17.} Id. at 1373.

^{18.} *Id.*; *see* 21 U.S.C. § 355(a)(b) (2012) (explaining the Hatch-Waxman Act's requirements and process for a New Drug Application); *see also infra* Part II.A (elaborating on the NDA requirements).

^{19.} In re Androgel, 687 F. Supp. 2d at 1373.

^{20.} *Id.*; *see infra* Part II.A (explaining the requirements and process for filing an Abbreviated New Drug Application).

^{21.} FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1304 (2012), rev'd sub nom. FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

^{22. 21} U.S.C. § 355(c)(3)(E)(iii).

^{23.} Id.

^{24.} In re Androgel, 687 F. Supp. 2d at 1373.

^{25.} Id.

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While brand-name pharmaceutical manufacturers must undertake extensive drug testing before their NDAs can be approved, manufacturers applying to market generic versions of already-existing drugs do not need to file rigorous NDAs, and instead can file less costly and time-consuming applications called Abbreviated New Drug Applications ("ANDAs").²⁶ Within their ANDAs, generics assert that the version of the drug they seek to market is the biological equivalent of an already-FDA-approved medication.²⁷ It is also incumbent on generic manufacturers to certify that their generic drug, despite its bioequivalency, will not infringe on the brandname's patent for the drug.²⁸ In late 2003, Actavis, Inc. (formerly named Watson Pharmaceuticals²⁹ and referred to hereinafter as "Actavis"), a generic drug manufacturer, filed an ANDA with the FDA to market a generic version of AndroGel.³⁰ In its application, Actavis certified that despite its bioequivalency to AndroGel, its generic version of the drug would not infringe on Solvay's patent because Solvay's patent was overly broad and thereby invalid.³¹ Following Actavis's ANDA submission, another generic manufacturer, Paddock Laboratories, Inc. ("Paddock"), also filed an ANDA to market a generic version of AndroGel.³² Consequently, Solvay filed a patent infringement suit against both Actavis and Paddock.³³ Solvay's infringement action triggered the requisite thirty-month waiting period before the FDA could approve Actavis's application.³⁴

From 2003 to 2005, Solvay, Actavis, and Paddock engaged in litigation regarding the #894 AndroGel patent; following discovery, the generics filed motions for summary judgment on the patent's (in)validity.³⁵ The motions were "fully briefed and ready for decision" in January 2006 when the

^{26. 21} U.S.C. § 355(j); *see infra* Part II.A (discussing the ANDA process stipulated by the Hatch-Waxman Act). An ANDA is a speedier route for patent approval available to generic drug manufacturers, allowing them to apply for market approval from the FDA for a new, generic version of an already existing drug without conducting extensive testing when a brand-name manufacturer has already gone through the testing and received FDA approval to market its biologically similar medicine. 21 U.S.C. § 355(j)(2)(A).

^{27.} FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1302 (2012) (citing 21 U.S.C. § 355(j)(2)(a) (2012)), *rev'd sub nom.* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

^{28. 21} U.S.C. § 355(j)(2)(A)(vi).

^{29.} *Actavis*, 133 S. Ct. at 2229 ("Actavis, Inc. (then known as Watson Pharmaceuticals), filed an Abbreviated New Drug Application for a generic drug modeled after AndroGel.").

^{30.} Watson Pharm. Inc., 677 F.3d at 1304.

^{31.} *Id*.

^{32.} *Id.* Notably, as the second generic to file an ANDA, Paddock could not enjoy the same 180-day period of exclusivity that Actavis would receive as the first filer. *Id.*

^{33.} Id.

^{34.} *Id.*; *see also infra* Part II.A. Hatch-Waxman requires the FDA to wait thirty months before approving an ANDA when the generic filing the ANDA is involved in paragraph IV litigation. 21 U.S.C. \$\$ 355 (j)(5)(A)–(B) (2012).

^{35.} Watson Pharm., Inc., 677 F.3d at 1304.

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FDA approved Actavis's ANDA to market its generic version of Andro-Gel.³⁶ Recognizing that it would lose its exclusivity to market AndroGel if the court granted the generics' summary judgment motion, which could lead to a subsequent reduction of \$125 million per year in profit, Solvay of-fered Actavis a hefty settlement.³⁷ As part of the settlement, Actavis agreed to delay the entry of its generic into the market until August 2015; other generic manufacturers, including Paddock, made similar deals with Solvay.³⁸ In exchange for their delayed entry, Solvay agreed to give Actavis between \$19 and \$30 million of its AndroGel profits per year until September 2015, and to pay Paddock \$10 million per year for six years.³⁹

Solvay asserted that its proposed payments were compensation for "other services" that the generics agreed to perform, but the FTC countered that the payments were made to compensate the generics for agreeing not to compete against AndroGel until 2015.⁴⁰ The FTC filed suit in 2010 against all of the settling parties—Solvay, Actavis, Paddock, and another generic manufacturer, Par Pharmaceutical Companies, Inc.—in the U.S. District Court for the Northern District of Georgia.⁴¹ The FTC's complaint asserted that the respondents violated several federal antitrust laws by unlawfully agreeing to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.⁴²

The district court dismissed the case, holding that the FTC's allegations dealt in the patent arena, and thus did not properly invoke antitrust law.⁴³ On appeal, the Eleventh Circuit affirmed the district court's decision, reasoning that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."⁴⁴ Although the appellate court acknowledged that antitrust violations often occur when one company pays another company to stay out of a particular market, the court also noted that reverse payment settlements of patent litigation present "atypical cases" because patent holders have an inherent legal right to exclude others from the market.⁴⁵ By its very nature,

^{36.} Id.

^{37.} Id. at 1304–05.

^{38.} Id. at 1305.

^{39.} *Id*.

^{40.} *Id.*

^{41.} In re AndroGel Antitrust Litig. (No. II), 687 F. Supp. 2d 1371, 1375–76 (N.D. Ga. 2010).

^{42.} Id.

^{43.} *Id.* at 1380.

^{44.} Watson Pharm., Inc., 677 F.3d at 1312.

^{45.} Id. at 1307.

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the court reasoned, "a patent conveys the right to 'cripple competition.'"⁴⁶ Citing the need to resolve the competing standards used by different federal courts in adjudging antitrust challenges to reverse payment settlements, the Supreme Court granted the FTC's petition for certiorari.⁴⁷

II. LEGAL BACKGROUND

The Drug Price Competition and Patent Term Restoration Act of 1984, and its 2003 amendments,⁴⁸ commonly and collectively known as the Hatch-Waxman Act ("Hatch-Waxman" or "the Act"), regulates patent application and market approval for both brand-name and generic drug companies,⁴⁹ but contains no provision that specifically governs the applicability of antitrust law to patent litigation.⁵⁰ As such, for over ten years before the Supreme Court granted certiorari in *FTC v. Actavis, Inc.*, antitrust-reverse payment settlement disputes had been subject to various standards and levels of scrutiny in several different federal circuits.⁵¹ Reverse payment settlement jurisprudence was therefore largely unpredictable: federal courts identified the same stubborn legal issues inherent in charging a patent-related action—which is essentially a government-sanctioned monopoly—with violating government-established anti-monopoly principles, but came to different conclusions to resolve the tension and followed no over-arching formula.⁵²

Part II.A of this Note explores the relevant provisions of Hatch-Waxman that govern the patent filing process for both brand-name and generic drug companies and outlines the course of events within these filings that lead to paragraph IV litigation.⁵³ Part II.B highlights the three disparate standards that federal courts have used in resolving reverse payment set-tlement challenges in the context of pharmaceutical litigation.

^{46.} Id. at 1309 (quoting Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005)).

^{47.} FTC v. Actavis, Inc., 133 S. Ct. 2223, 2230 (2013).

^{48. 21} U.S.C. § 355 (2012).

^{49. 21} U.S.C. §§ 355(b)(1), (j)(2)(A)(vii); see also infra Part II.A.

^{50.} See Actavis, 133 S. Ct. at 2230 ("[D]ifferent courts have reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlements.").

^{51.} *See infra* Part II.C (discussing how the U.S. Courts of Appeals for the Second, Third, Sixth, Eleventh, and Federal Circuits have used different standards to resolve antitrust challenges to pay-for-delay arrangements).

^{52.} See infra Part II.C (discussing competing interests that several circuits have weighed when considering antitrust challenges to reverse payment settlements, such as the interest in preserving judicial preferences for settlement and the interest in ensuring that a settlement provision does not go beyond the scope of a patent-holder's rightly held monopoly on a particular drug).

^{53.} See infra notes 71–72 and accompanying text.

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A. Filing Requirements for Both Brand-Name and Generic Pharmaceutical Manufacturers Mandated by the Hatch-Waxman Act Provide a Mechanism for Paragraph IV Litigation and Reverse Payment Settlements

The 1984 Hatch-Waxman Act was intended to reframe drug patent approval laws in the United States to allow generic equivalents of patented brand-name drugs to gain expedited market approval and lower drug prices for consumers, while still providing adequate patent protections and incentives for brand-name manufacturers to continue to develop new drugs.⁵⁴ Prior to the passage of the Act, there was a large gap between the time that a patent expired on a brand-name drug and the time that a generic manufacturer was eligible to market its own version of the drug.⁵⁵ This delay ensued largely because, prior to the enactment of Hatch-Waxman, generic manufacturers were required to conduct full testing to prove the safety and efficacy of their drugs (even if the drugs were exact copies of a brand-name's drug), and they were not allowed to use the brand-name's data or drug as a template for their own testing.⁵⁶ With this required expensive testing,⁵⁷ it took generic manufacturers approximately three years after brand-name patent expiration to bring their generic drugs to market.⁵⁸ In

^{54.} See 130 CONG. REC. 24,430 (daily ed. Sept. 6, 1984) (statement of Rep. Henry Waxman) ("The public will benefit twice; by the further incentive for research and development for new, innovative drugs and by the immediate reduction in drug prices when a generic is on the market as a competitor."); see also Ian Jaquette, Comment, Merck KGAA v. Integra Life Sciences I, Ltd.: *Implications of the Supreme Court's Decision for the People Who Matter Most... the Consumer*, 33 AM. J.L. & MED. 97, 101–02 (2007) ("Title I of the Act created an abbreviated new drug application process designed to expedite the arrival of generic drugs.... Congress enacted Title II of the Hatch-Waxman Act as a means of mitigating the distortion to the [brand-name's] patent term.").

^{55.} H. REP. NO. 98-857, pt. 2, at 4 (1984).

^{56.} *Id.*; *see also* Jeff Thomas, Schering-Plough *and In re* Tamoxifen: *Lawful Reverse Payments in the Hatch-Waxman Context*, 22 BERKELEY TECH. L.J. 13, 18 (2007) ("Prior to passage of the [Hatch-Waxman Act] Amendments [to the Food, Drug, and Cosmetics Act], generic manufacturers were required to wait for the branded drug patent to expire before beginning development work on the patented product."); Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 174–75 (2008) ("Generic manufacturers could not use the NDA holder's data to demonstrate safety and efficacy, and were forced to conduct their own clinical trials.").

^{57.} See CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 15 (2006), available at http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf (finding that the development of new drugs take, on average, ten to fifteen years); see also Bret Dickey, Jonathan Orszag & Laura Tyson, An Economic Assessment of Patent Settlements in the Pharmaceutical Industry, 19 ANNALS HEALTH L. 367, 369 (2010) (estimating that a new drug takes ten to fifteen years to develop and costs more than \$1.3 billion).

^{58.} CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 38 (1998) [hereinafter INCREASED COMPETITION FROM GENERIC DRUGS], *available at*

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contrast, since Hatch-Waxman's enactment and the creation of the ANDA system, the typical timespan between brand-name patent expiration and generic drug entry is between one and three months.⁵⁹ Therefore, Senator Hatch and Representative Waxman sponsored the Act to strike a balance between extending patent terms to promote innovation in the pharmaceutical industry and incentivizing generic companies to introduce low-cost versions of drugs into the market more quickly.⁶⁰

Under the Act, brand-name drug manufacturers filing for new patents are required to submit an NDA to the FDA when seeking to market a new drug formula.⁶¹ The brand-name must still undertake the extensive—and expensive—health and safety testing that has always been required before the FDA will approve a drug for marketing.⁶² To encourage new drug development, however, the Act also extended brand-name companies' patent terms to make up for the time that brand-names' patents are stuck in the FDA approval process.⁶³ Once a drug is approved for marketing, the relevant patent is entered in an annual FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book."⁶⁴ Conversely, Hatch-Waxman allows generic manufacturers to

61. 21 U.S.C. §§ 355(a)–(b) (2012).

62. *Id.*; *see also* Dickey, Orszag & Tyson, *supra* note 57, at 369 (showing that it costs over one billion dollars and takes ten years to undergo new drug testing).

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http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf; see also Henry Grabowski & Margaret Kyle, Generic Competition and Market Exclusivity Periods in Pharmaceuticals, 28 MANAGERIAL & DECISION ECON. 491, 492 (2007).

^{59.} INCREASED COMPETITION FROM GENERIC DRUGS, *supra* note 58, at 38–39.

^{60.} See Drug Price Competition and Patent Term Restoration Act of 1984: Hearing Before the S. Comm. on Labor and Human Res., 98th Cong. 1 (1984) (statement of Sen. Orrin Hatch, Chairman, S. Comm. on Labor and Human Res.) ("On one hand, lower drug prices—tens of millions of dollars a year in total savings—will flow from increased generic competition made possible by a new abbreviated new drug application . . . for off-patent drugs approved after 1962."); see also Andrx Pharm., Inc. v. Biovail Corp. Int'l., 256 F.3d 799, 801–02 (2001) ("In 1984 the Congress enacted the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act (Amendments) to, *inter alia*, simplify the procedure for FDA approval. . . . Although the Congress was interested in increasing the availability of generic drugs, it also wanted to protect the patent rights of the pioneer applicants."); Grabowski & Kyle, *supra* note 58, at 492 ("[T]he Hatch-Waxman Act provided for partial restoration of the patent time lost during the [brand-name manufacturer's] regulatory review and clinical testing period [when the brand-name's patent time begins running even before the patent is approved].").

^{63.} *See* INCREASED COMPETITION FROM GENERIC DRUGS, *supra* note 58, at 39 ("The Hatch-Waxman Act allows for patent extensions based on the amount of time a drug spends in the FDA review process.").

^{64.} See FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) iv (34th ed. 2014) ("Th[is] publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under [Section 505, 21 U.S.C. § 355 of] the Federal Food, Drug, and Cosmetic Act.").

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"piggyback" on the testing carried out by the brand-name and to avoid conducting the same costly testing if the generic files for permission to market its own version of a certain drug after the brand-name manufacturer has already gained FDA approval.⁶⁵ Generics can file ANDAs and forgo the market testing requirements by asserting in their application that the generic is bioequivalent to the brand-name drug.⁶⁶ Hatch-Waxman has arguably achieved its goal of making more generics available; the generic drug share of the prescription drug market grew from thirteen percent of the market in 1984 to over fifty-eight percent in 1994.⁶⁷

In their ANDAs, generics must provide assurance to the FDA that the generic patent will not infringe on the brand-name's patent.⁶⁸ Generics can certify that their ANDAs will not infringe on a brand-name's patent in four distinct ways; the certification method relevant to this case requires a generic to demonstrate that any bioequivalent patent held by a brand-name is "invalid or will not be infringed by the manufacture, use, or sale" of the drug described in the generic's ANDA.⁶⁹ In this assertion, generic firms can argue, for example, that a brand-name's patent is invalid because it was obtained unfairly,⁷⁰ or because it was "inherently anticipated by a prior

70. See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1328 (Fed. Cir. 2008) (discussing a generic's argument that a brand-name's patent for ciprofloxacin hydrochloride would not be infringed because the brand-name had engaged in inequitable conduct in procuring its patent), *abrogated by* FTC v. Actavis, Inc. 133 S. Ct. 2223 (2013). Inequitable conduct is a defense to a claim of patent infringement in which a defendant argues that a patent-

^{65. 21} U.S.C. § 355(j) (2012).

^{66.} Id. §§ 355 (j)(1), (2)(A)(iii)–(iv). In order to establish bioequivalence, a generic must show that its drug has the same active ingredients as the brand-name drug and that the rate of absorption of the generic's drug at the site at which it takes effect in the body is the same as the brand-name's product. Id.

^{67.} INCREASED COMPETITION FROM GENERIC DRUGS, *supra* note 58, at 38.

^{68. 21} U.S.C. § 355(j)(2)(A)(vii).

^{69.} Id.; see, e.g., In re K-Dur Antitrust Litig., 686 F.3d 197, 203 (3d Cir. 2012), cert. granted and judgment vacated sub nom., Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013) (mem.). In K-Dur, brand-name pharmaceutical company Schering-Plough owned a patent for the extended-release coating of the drug K-Dur 20, a potassium chloride substance that is used to treat high blood pressure. Id. In 1995, prior to the expiration of Schering's patent, Upsher-Smith Laboratories filed an ANDA for approval of a generic version of K-Dur 20, prompting Schering to file suit against Upsher for patent infringement. Id. at 205. Within paragraph IV of its ANDA, and during discovery, Upsher certified that its generic product would not infringe on Schering's patent because the chemical composition of Upsher's controlled release coating was different from that of Schering's brand-name drug. Id. See also In re Nexium (Esomeprazole) Antitrust Litig., No. 12-MD-02409, 2013 WL 4832176 (D. Mass. Sept. 11, 2013). In Nexium, generic drug company Ranbaxy filed an ANDA for a generic version of brand-name AstraZeneca's heartburn medicine Nexium, alleging in a paragraph IV certification that Ranbaxy's manufacture or sale of any generic version of Nexium would not infringe any of AstraZeneca's patents for Nexium to the extent that they expired after October 2007. Id. at *5. Plaintiffs in Nexium asserted that AstraZeneca's patent for Nexium's active ingredient was issued in error and would have been invalidated in the course of litigation because the active ingredient, having already been discovered and in the public domain, was unpatentable. Id.

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art."⁷¹ This non-infringement certification is known as "paragraph IV" certification—named for its placement in paragraph IV of Section (j)(2)(A) of the Hatch-Waxman Act—and, likewise, disputes surrounding a generic's attempt to certify that there is no infringement on a brand-name's patent are known as "paragraph IV litigation."⁷²

A related statute, the Patent and Protection of Patent Rights Act,⁷³ makes filing an ANDA under Hatch-Waxman an automatic act of patent infringement.⁷⁴ Hatch-Waxman therefore allows a brand-name manufacturer forty-five days in which to respond to a generic's ANDA filing with a cause of action for infringement.⁷⁵ If a brand-name brings a patent infringement suit against a generic ANDA filer within the forty-five day limit, the FDA must withhold approval of the generic's patent until the later of thirty months from the date the suit is filed or the resolution of the lawsuit.⁷⁶ No-tably, once they enter the market, generic drugs become excessively popular as compared to their more costly brand-name alternatives.⁷⁷ FDA studies show that one year after market entry, the average generic pharmaceutical product takes over ninety percent of a brand-name's unit sales and sells at eighty-five percent of the price of the brand-name's drug.⁷⁸

Hatch-Waxman also provides generics with a major incentive to be the first to file an ANDA and allege that a brand-name's patent will not be infringed. The Act stipulates that, if its ANDA is approved, the generic applicant that is the first to file an abbreviated application ("first-to-file generic") will have 180 days of exclusivity from the first commercial marketing

73. 35 U.S.C. § 271 (2006).

76. Id.

78. Id.

holder's patent is invalid because the patent-holder misstated facts or misdescribed inventorship in the initial patent application. Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1300 (Fed. Cir. 2001).

^{71.} See, e.g., SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1342, 1346 (Fed. Cir. 2005) (discussing a generic's argument that a brand-name's patent was invalid on the grounds of inherent anticipation by a prior patent). Under the doctrine of inherent anticipation, a patent should be deemed invalid if a reference to prior art inherently discloses every feature of the claimed new invention. *Id.* at 1343.

^{72. 21} U.S.C. \$ 355(j)(2)(A)(iv) (2012). This Note will hereinafter refer to the litigation between brand-name and generic manufacturers in the context of a brand-name's patent infringement challenge triggered by a generic's filing an ANDA as "paragraph IV litigation."

^{74.} Id. § 271(e)(2).

^{75. 21} U.S.C. § 355(j)(5)(B)(iii) (2012).

^{77.} See, e.g., FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010) [hereinafter PAY-FOR-DELAY], available at http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (noting that approximately one year after the first generic company enters the market for a particular drug, pharmacists fill about ninety percent of all prescriptions for that drug with the generic version, rather than the brand-name version).

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of its drug, during which time no other generic can compete with the first generic filer's drug.⁷⁹ The 180-day exclusivity period is awarded to a generic as soon as its ANDA is granted, but only takes effect and begins running at the time that the generic first enters the market.⁸⁰ Thus, even if a generic's entry is delayed by a number of years due to a provision in a settlement agreement with its adversarial brand-name, discussed *infra*, the generic still retains its exclusivity rights for 180 days from the time when it finally markets its drug.⁸¹ This 180-day exclusivity period proves extremely lucrative for generic firms; during the time that they are the only generic on the market, companies can reap tens or hundreds of millions of dollars in extra sales.⁸²

Like most litigation, settlements are abundant in the paragraph IV context. An FTC study showed that between 1992 and 2002, approximately thirty-eight percent of pharmaceutical patent litigation related to ANDA paragraph IV certifications resulted in a settlement between brand-name and generic companies; and, of that thirty-eight percent, forty-five percent of the settlements resulted in payments, ranging from \$1.75 million to \$132.5 million, from the brand-name patent holder to the generic producer in exchange for delayed entry.⁸³ Many of these payments come as compensation to generics for agreeing to delay the marketing of their ANDA drug for a specified period of time.⁸⁴ This agreement to delay entry so that the brand-name can remain exclusive, even after the generic's approval for its ANDA drug, understandably piques antitrust interest. Agreements involving payments between manufacturers in the same industry, for the purpose of perpetuating a monopoly that otherwise would not exist, would appear to

83. See FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 17, 31, 35 (2002) [hereinafter GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION], available at http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (noting that twenty out of fifty-three (or thirty-eight percent) of patent litigation between a brand-name and the first generic ANDA filer resulted in settlement, and that of those twenty settlements, nine contained stipulations for payments from the brand-name to the generic, which equals a total of forty-five percent of settlements involving a reverse payment).

84. *See id.* at 31 ("Eight of the [nine] agreements [involving payments from brand-names to generics] followed the same basic model. Each prohibited the generic applicant from purchasing, manufacturing, using, selling, distributing, and shipping to third parties any form of the generic's drug product until the expiration of the [brand-name's] patents.").

^{79. 21} U.S.C. § 355(j)(5)(B)(iv).

^{80.} Id.

^{81.} Id.

^{82.} See Gregory Dolin, Reverse Settlements as Patent Invalidity Signals, 24 HARV. J.L. & TECH. 281, 290 (2011) (citing Matthew J. Higgins & Stuart J. H. Graham, Balancing Innovation and Access: Patent Challenges Tip the Scales, 326 SCIENCE 370, 370 (2009) (showing that 180 days of patent exclusivity is worth \$60 million per drug on average)).

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violate provisions of the Sherman Antitrust Act,⁸⁵ the main body of federal antitrust law.⁸⁶ For example, in one paragraph IV litigation settlement agreement between brand-name manufacturer Hoecsht Marion Roussel, Inc. and generic manufacturer Andrx Pharmaceuticals, the brand-name agreed to pay the generic \$40 million per year to delay entry into the market.⁸⁷ In a similar settlement agreement regarding the patent for the breast cancer drug Tamoxifen, a brand-name paid a generic \$21 million in exchange for vacating the district court's judgment that the brand-name's patent was invalid.⁸⁸

B. Federal Circuit Courts Have Scrutinized Reverse Payment Settlements Under Three Standards: the Strictest "Per Se Illegality" Standard; the Lenient "Scope of the Patent" Test, and the Middle Ground "Quick Look Rule of Reason Analysis"

1. The Strictest Per Se Illegality Standard

The Supreme Court has declared that "only unreasonable restraints" on trade violate Section 1 of the Sherman Antitrust Act,⁸⁹ and has deemed certain types of restraints unreasonable and unlawful *per se*, because they have a "predictable and pernicious anticompetitive effect."⁹⁰ Typical examples of *per se* unlawful violations of pro-competitive requirements are those that can be characterized as blatant restraints on competition pertaining to prices or territories.⁹¹

^{85. 15} U.S.C. § 1-7 (2012). The Sherman Act is aimed at preserving free competition and preventing concentrated economic power from restricting trade. Jeffrey C. Sun & Philip T.K. Daniel, *The Sherman Act Antitrust Provisions and Collegiate Action: Should There Be a Continued Exception for the Business of the University*?, 25 J.C. & U.L. 451, 453–54 (1999); *see also infra* Part II.B (discussing how reverse payment settlement agreements can potentially violate antitrust laws, primarily those contained in provisions of the Sherman Act).

^{86.} See 15 U.S.C. § 1 ("Every contract... or conspiracy, in restraint of trade or commerce among the several States ... is declared to be illegal."); Id. § 2 ("Every person who shall monopolize ... or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States ... shall be deemed guilty of a felony.").

^{87.} In re Cardizem CD Antitrust Litig., 332 F.3d 896, 899 (6th Cir. 2003).

^{88.} In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190 (2d Cir. 2006).

^{89.} State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

^{90.} Id.

^{91.} See PAY-FOR-DELAY, supra note 77, at 3 ("Absent compensation to the generic for the delay in its entry, such settlement agreements are unlikely to raise antitrust issues."); see also Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."); Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla., 468 U.S. 85, 100 (1984) ("Horizontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal *per se*' approach because the probability that these practices are anticompetitive is so high."); N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) ("Among the practices which the courts have heretofore

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The U.S. Court of Appeals for the District of Columbia was the first federal appellate court to expressly consider reverse payment settlements in a similar context to the challenge brought in Actavis, and it found those settlements to be per se violations of antitrust laws.⁹² In the pioneering D.C. Circuit case, Andrx Pharmaceuticals, Inc. v. Biovail Corp. International,⁹³ generic drug company Andrx Pharmaceuticals was the first ANDA filer for the heart medication Cardizem CD, to which Hoecsht-Marion Roussel, Inc. ("HMRI"), a brand-name company, held the patent.⁹⁴ When Andrx filed its ANDA, HMRI sued the generic for patent infringement, thereby triggering the thirty-month waiting period during which the FDA could not approve Andrx's application.⁹⁵ Andrx and HMRI never made it to court; after the thirty-month period, when the FDA finally approved Andrx's ANDA, HMRI and Andrx entered into a settlement agreement in which HMRI agreed to compensate Andrx with quarterly payments of \$10 million to delay marketing the generic product.⁹⁶ In effect, the HMRI-Andrx agreement allowed HMRI to pay off Andrx so that it could retain its monopoly on Cardizem CD even after the FDA had approved Andrx's generic version for marketing. The D.C. Circuit found that the agreement between HMRI and Andrx could "reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions," and treated the payment from the brand-name to the generic as prima facie evidence of an illegal agreement not to compete.⁹⁷

In 2003, the Sixth Circuit heard *In Re Cardizem CD Antitrust Litigation*,⁹⁸ which concerned the same agreement that the D.C. Circuit considered in *Andrx*.⁹⁹ The Sixth Circuit case was brought by direct and indirect purchasers of the medicine Cardizem CD, who alleged that they suffered antitrust injury in the form of unnecessarily inflated drug prices as a result of Andrx's agreement with HMRI to delay market entry of Andrx's drug.¹⁰⁰ The Sixth Circuit held that the Andrx–HMRI agreement was "a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal re-

- 92. Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 811 (D.C. Cir. 2001).
- 93. 256 F.3d 799 (D.C. Cir. 2001).

deemed to be unlawful in and of themselves are price fixing ... division of markets ... group boycotts ... and tying arrangements." (citations omitted)).

^{94.} Id. at 803.

^{95.} Id.

^{96.} Id.

^{97.} Id. at 811, 813.

^{98. 332} F.3d 896 (6th Cir. 2003).

^{99.} Id. at 902-03.

^{100.} Id. at 903–04 & n.7.

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straint of trade."¹⁰¹ The court also emphasized a serious concern that reverse payment settlements encourage one manufacturer to pay another to stay out of a particular market, which effectively prevents other competitors from entering the market as well.¹⁰² Though these two courts found the reverse payment agreement in question to be *per se* illegal, all other federal courts that have considered the applicability of antitrust law to reverse payment settlements have declined to be as harsh and have not found such settlements to be irrebuttably presumptively invalid.¹⁰³

2. The Lenient Scope of the Patent Test

Most federal courts have utilized the "scope of the patent test" when tasked with determining whether particular reverse payment settlements violate antitrust law.¹⁰⁴ The test presumes legality of reverse payment settlements on the grounds that the authority conferred by a patent on a patentholder allows the patent-holder to do whatever he likes related to the patent, including exclude others from the market.¹⁰⁵ Under the scope of the patent test, a reverse payment settlement is valid as long as it does not fall outside of the scope of the patent-holder's monopoly and the protections given to the patent-holder by virtue of his holding a patent.¹⁰⁶

The Eleventh Circuit has considered the issue of reverse payment settlements in three significant cases. The first case, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,¹⁰⁷ concerned two agreements in which a brandname manufacturer agreed to pay generic manufacturers \$30 million to refrain from entering the market until the end of the brand-name's patent

103. See infra Parts II.B.2–II.B.3.

^{101.} Id. at 908.

^{102.} Id. ("[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market."). The Sixth Circuit's concern regarding this reverse payment settlement partly stemmed from the fact that, in delaying Andrx's generic entry, the Andrx-HMRI settlement agreement also prevented other generics, whose ANDAs for Cardizem CD had been approved by the FDA, from entering the market. Id. at 907. Andrx, as the first generic ANDA filer, retained its right to a 180-day period of exclusivity, which would begin running the day that Andrx's generic product hit the market. Id. In stalling Andrx's market entry, HMRI and Andrx were also effectively stalling the entry of other generic competitors who could not market their versions of Cardizem CD until Andrx's 180-day period of exclusivity had run out. Id.

^{104.} *See infra* Part II.B.2 (discussing the U.S. Courts of Appeals for the Federal, Second, and Eleventh Circuits' use of the "scope of the patent test").

^{105.} See Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304–06, 1312 (11th Cir. 2003).

^{106.} *Id.* at 1312.

^{107. 344} F.3d 1294 (11th Cir. 2003). In this case, a brand-name drug manufacturer filed claims against generic manufacturers for patent infringement, and the generic manufacturers defended on the ground of patent invalidity. *Id.* at 1298–99.

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term.¹⁰⁸ Even though the patent at issue was subsequently declared invalid,¹⁰⁹ the Eleventh Circuit held that the patent gave the brand-name manufacturer the right to exclude competitors.¹¹⁰ In so ruling, the court emphasized policy considerations favoring the settlement of patent litigation.¹¹¹ The Eleventh Circuit remanded the case and directed the district court to determine whether any part of the agreement exceeded the protections afforded by the brand-name manufacturer's patent and, if so, to apply traditional antitrust scrutiny only to those portions of the agreement.¹¹² The court therefore articulated and employed a scope of the patent test to analyze the legality of the reverse payment settlement.¹¹³

A subsequent Eleventh Circuit case, *Schering–Plough Corp. v. Federal Trade Commission*,¹¹⁴ arose out of the settlement agreement between a brand-name, Schering-Plough, and a generic, Upsher-Smith Laboratories, regarding the marketing of, and patent for, the hypertension drug K-Dur 20.¹¹⁵ After the FTC determined, during an administrative proceeding, that the agreement violated antitrust laws, the defendants appealed the FTC's finding to the Eleventh Circuit.¹¹⁶ Applying the scope of the patent test articulated in *Valley Drug*, the Eleventh Circuit set aside the ruling of the FTC.¹¹⁷ The court rejected the FTC's conclusion that Schering's \$60 million payment to Upsher was in exchange only for a market entry delay, finding instead that the payment was only for the licenses that Schering obtained through the agreement to market five Upsher products.¹¹⁸ As such, the court found that there was no reverse payment from Schering to Upsher and, thus, no antitrust violation in that agreement.¹¹⁹

In *Federal Trade Commission v. Watson Pharmaceuticals, Inc.*,¹²⁰ the predecessor to this Note's principal case, the Eleventh Circuit explicitly articulated, in accordance with its past holdings regarding reverse payment

119. Id. at 1071.

^{108.} Id. at 1300.

^{109.} Id. at 1306.

^{110.} *Id.* at 1312 ("We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted to the patentee.... The appropriate analysis on remand will likely require an identification of the protection afforded by the patents").

^{111.} Id. at 1308 n.20.

^{112.} Id. at 1312.

^{113.} Id.

^{114. 402} F.3d 1056 (11th Cir. 2005).

^{115.} Id. at 1058-59.

^{116.} Id. at 1061.

^{117.} Id. at 1065–66, 1076.

^{118.} Id. at 1069–71.

^{120. 677} F.3d 1298 (11th Cir. 2012), rev'd sub nom. FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

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settlements, that the only determination required in such actions is whether, "absent sham litigation or fraud in obtaining the patent," the settlement agreement exceeded the scope of the patent.¹²¹

The Eleventh Circuit's standard is thus articulated in commentary as the scope of the patent test.¹²² Under this standard, the court examines: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."¹²³ Because this standard focuses on the nearly endless rights that a patent-holder retains as part of its patent monopoly—including the right to cripple competition and charge artificially higher prices¹²⁴—the scope of the patent test is viewed as giving a presumption of nearly irrefutable validity for reverse payment settlements.¹²⁵

In 2006, the Second Circuit heard *In re Tamoxifen Citrate Antitrust Litigation*¹²⁶ and affirmatively adopted the Eleventh Circuit's scope of the patent test.¹²⁷ The settlement at issue in *Tamoxifen* called for the brandname manufacturer to make a payment of \$21 million to the generic manufacturer in exchange for the generic's request that the district court vacate its decision that the brandname's patent for Tamoxifen was invalid.¹²⁸ Despite awareness of the district court's initial finding, the Second Circuit applied a presumption of patent validity and held that, absent the patent being obtained by fraud, there is "no injury to the market cognizable existing under antitrust law, as long as competition is restrained only within the scope

^{121.} Id. at 1312.

^{122.} See, e.g., Timothy A. Cook, Note, Pharmaceutical Patent Litigation Settlements: Balancing Patent & Antitrust Policy Through Institutional Choice, 17 MICH. TELECOMM. & TECH. L. REV. 417, 433 (2011) (referring to the Eleventh Circuit's test as a "patent-scope analysis"); Shannon U. Han, Note, Pay-to-Delay Settlements: The Circuit-Splitting Headache Plaguing Big Pharma, 15 VAND. J. ENT. & TECH. L. 913, 926, 939 (2013) (referring to the Eleventh Circuit's test as the "scope of the patent test").

^{123.} Schering-Plough Corp., 402 F.3d at 1066; Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003).

^{124.} See Valley Drug Co., 344 F.3d at 1304 ("A patent grants its owner the lawful right to exclude others. This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions. The exclusionary right cannot be exploited in every way—patentees cannot pool their patents and fix the prices at which licensees will sell the patented article, for example—but a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself" (citations omitted)).

^{125.} See In re K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012) ("[W]e take issue with the scope of the patent test's almost unrebuttable presumption of patent validity."), *cert. granted and judgment vacated sub nom.* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013) (mem.).

^{126. 466} F.3d 187 (2d Cir. 2006).

^{127.} Id. at 213.

^{128.} Id. at 190.

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of the patent."¹²⁹ The Second Circuit recognized the potentially troubling implications of its holding, that "[t]he less sound the patent . . . and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder."¹³⁰ Ultimately, however, the court determined that the judicial preference for settlement was too strong not to find the reverse payment settlement agreement presumptively lawful.¹³¹

The Federal Circuit also utilized the scope of the patent test in its adjudication of In re Ciprofloxacin Hydrochloride Antitrust Litigation,¹³² a case involving a pharmaceutical reverse payment settlement between a brand-name pharmaceutical giant, Bayer, and a generic manufacturer, Barr Laboratories, in paragraph IV litigation over Barr's ANDA for Ciprofloxacin, an antibiotic used to treat various infections, including anthrax infection.¹³³ In exchange for Barr dropping its patent validity challenge to Bayer's NDA drug and its paragraph IV certification, Bayer agreed to pay Barr \$398.1 million over a number of years, including an initial payment of \$49.1 million.¹³⁴ The Federal Circuit used the scope of the patent test and rejected the antitrust challenge to the Bayer-Barr reverse payment settlement, reasoning that "[s]ettlement of patent claims by agreement between the parties-including exchange of consideration-rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition."¹³⁵ The court thus gave weight to judicial partiality toward settlement in deciding that "in the absence of evidence of fraud ... 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."136

3. The Middle Ground "Quick Look Rule of Reason" Analysis

The Third Circuit did not adopt the "scope of the patent test" and instead applied a "quick look rule of reason" test in *In re K-Dur Antitrust Litigation*.¹³⁷ The determination of antitrust violations under this test is based on a three-step "rule of reason" analysis. First, the plaintiff "bears the ini-

^{129.} Id. at 212–13 (citation omitted).

^{130.} *Id.* at 211.

^{131.} Id.

^{132. 544} F.3d 1323 (Fed. Cir. 2008), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

^{133.} Id. at 1327–29.

^{134.} Id. at 1328–29 & n.5.

^{135.} Id. at 1333 (citing Standard Oil Co. v. United States, 283 U.S. 163, 171 & n.5 (1931)).

^{136.} Id. at 1333, 1336.

^{137. 686} F.3d 197, 218 (3d Cir. 2012), *cert. granted and judgment vacated sub nom.* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013) (mem.).

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tial burden of showing that the challenged action has had an actual adverse effect on competition in the relevant market."¹³⁸ Then, if the plaintiff succeeds, "the burden shifts to the defendant to establish the pro-competitive "redeeming virtues" of the action."¹³⁹ If the defendant carries his burden, the plaintiff must then show that "the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition."¹⁴⁰ In *K-Dur*, the Third Circuit chose a middle ground between the *per se* illegality standard and the "scope of the patent test," explaining that it would examine a pay-for-delay situation using a modified version of the rule of reason analysis: a "quick look rule of reason test."¹⁴¹ Under this analysis, any payment from a patent holder to a generic patent challenger that agrees to delay entry into the market is a presumptively illegal restraint of trade.¹⁴² This presumption can be rebutted, however, by a demonstration "that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."¹⁴³

The Third Circuit rejected the Eleventh, Sixth, and Second Circuits' presumption of patent validity under the scope of the patent test because many patents issued by the Patent and Trademark Office ("PTO") are later found invalid or not infringed. Therefore, the correct standard is one that adjudges patents based on the strong likelihood that "reverse payments enable the holder of a patent that the holder knows is weak to buy its way out of both competition with the challenging competitor and possible invalidation of the patent."¹⁴⁴ To resolve the standards dispute among the federal circuits, the U.S. Supreme Court decided to hear *Actavis*.¹⁴⁵

III. THE COURT'S REASONING

In *FTC v. Actavis, Inc.*, the U.S. Supreme Court reversed the Eleventh Circuit's holding that reverse payment settlement agreements are immune from antitrust proceedings and remanded the case for further proceed-

^{138.} Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir. 1997).

^{139.} *Id*.

^{140.} Id.

^{141.} In re K-Dur, 686 F.3d at 218.

^{142.} Id.

^{143.} Id.

^{144.} Id. at 215 (citing In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 211 (2005)).

^{145.} FTC v. Actavis, Inc., 133 S. Ct. 2223, 2230 (2013). This dispute was further exacerbated when the Eleventh Circuit rejected the Third Circuit's harsher quick look rule of reason analysis in favor of its own lenient scope of the patent test. FTC v. Watson Pharm. Inc., 677 F.3d 1298, 1309 (2012).

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ings.¹⁴⁶ In so doing, the Court made clear it was not ruling on whether the FTC had a legitimate claim against Actavis for anti-competition conspiracy; rather, the Court simply held that antitrust law was eligible to govern the instant patent dispute, and thus the case should not have been dismissed.¹⁴⁷ The Court placed great emphasis on Solvay Pharmaceutical's having been embroiled in a litigation dispute with Actavis and other generics regarding the validity of Solvay's patent because, according to the Court, only a definitively valid patent "excludes all except its owner from the use of the protected process or product."¹⁴⁸ An *invalid* patent, therefore, gives its owner no such power.¹⁴⁹ Because the paragraph IV litigation put Solvay's patent validity at issue, the Court concluded that the right to exclusivity that would normally be conferred to Solvay, by virtue of its holding the patent for AndroGel, did not apply.¹⁵⁰ The Court found that exclusivity and monopoly rights can only accompany valid patents; thus, where a patent may not be valid, a court logically cannot find that a patent-holder acted within the scope of his patent rights because those rights may not exist.¹⁵¹

The Court further held that the Eleventh Circuit's sole reliance on patent law, as opposed to antitrust law or pro-competitive policy, was erroneous, particularly given the FTC's stated concerns regarding the anticompetitive consequences of the settlement.¹⁵² From the FTC's perspective, the situation appeared clear: a brand-name pharmaceutical giant had paid off generic manufacturers to delay entry into a competitive drug market, thereby ensuring that the brand-name's monopoly would continue to thrive.¹⁵³

The Court substantiated its holding by looking to its prior decisions in antitrust-patent settlement cases outside of the pharmaceutical realm. In *United States v. Line Material Co.*,¹⁵⁴ *United States v. U.S. Gypsum Co.*,¹⁵⁵ and *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*,¹⁵⁶ which all involved antitrust attacks on patent-related settlements in various machinery industries, the Court resolved questions of settlement

^{146.} *Actavis*, 133 S. Ct. at 2237–38. Justice Breyer delivered the opinion of the Court, in which Justices Ginsburg, Kennedy, Sotomayor, and Kagan joined. Justice Alito took no part in the consideration or decision of the case.

^{147.} Id. at 2227.

^{148.} Id. at 2231 (quoting United States v. Line Material Co., 333 U.S. 287, 308 (1948)).

^{149.} Id.

^{150.} Id.

^{151.} Id. at 2230–31.

^{152.} Id. at 2231.

^{153.} Id. at 2230.

^{154. 333} U.S. 287 (1948).

^{155. 333} U.S. 364 (1948).

^{156. 382} U.S. 172 (1965).

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legality by balancing the "lawful restraint on trade of the patent monopoly and the illegal restraint prohibited by the Sherman Act."¹⁵⁷ According to the majority, in these historical cases the Court examined traditional antitrust principles, such as the probability that anti-competitive effects would flow from the settlement, instead of looking solely at the rights that the patent conferred.¹⁵⁸ Moreover, the majority noted that antitrust laws may be applicable to patent litigation because the Supreme Court has found that patent-related settlements can violate antitrust laws.¹⁵⁹

The Court concluded its analysis by summarizing policy and fairness considerations that favored giving the FTC an opportunity to litigate its antitrust claim.¹⁶⁰ First, the Court emphasized the importance of allowing an antitrust challenge to the reverse payment agreement between Solvay and Actavis (and other generics) because the pay-for-delay term in their agreement appeared on its face to have the potential for anti-competitive effects.¹⁶¹ The Court also asserted that because the payments made from brand-names to generics in reverse payment settlement agreements *might* be perfectly legitimate (for example, such a payment might be made to cover a generic's litigation costs, which is a valid settlement provision that does not violate antitrust law), this potential legitimacy does not justify dismissing an allegedly injured plaintiff's complaint.¹⁶² Just as the defendant should have an opportunity to explain his settlement payment and to avoid liability, so too should a plaintiff, in this case the FTC, retain the right to challenge that settlement payment if the plaintiff is suspicious about its collusive effects.¹⁶³

Although the Court acknowledged the possible applicability of antitrust law to pay-for-delay arrangements, it ultimately declined to conclude that reverse payment settlement agreements are unlawful, and even declined to decide the instant issue.¹⁶⁴ Instead, the Court held that the FTC's antitrust claim should have had an opportunity to be heard, and remanded the case.¹⁶⁵

^{157.} Line Material Co., 333 U.S. at 310.

^{158.} Actavis, 133 S. Ct. at 2231.

^{159.} *Id.* at 2232; *see also, e.g.*, United States v. Singer Mfg. Co., 374 U.S. 174, 190–92 (1963) (finding illegal and in violation of antitrust law a settlement between three sewing machine manufacturers with competing patent claims, in which the firms assigned the patent rights to the manufacturer best able to defend and to enforce the patent against future competition).

^{160.} Actavis, 133 S. Ct. at 2234-37.

^{161.} Id. at 2234.

^{162.} Id. at 2236.

^{163.} *Id*.

^{164.} Id. at 2237.

^{165.} Id. at 2238.

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In dissent, Chief Justice Roberts, joined by Justices Scalia and Thomas, relied on a precedential argument to dispute the majority's holding.¹⁶⁶ Chief Justice Roberts emphasized that a patent "provides an exception to antitrust law, and the scope of the patent—*i.e.*, the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability."¹⁶⁷ The Chief Justice noted that the Court had "never held that it violates antitrust law for a competitor to refrain from challenging a patent . . . [and had] long recognized that the settlement of patent litigation does not by itself violate the antitrust laws."¹⁶⁸ According to the dissent, the Court would be "cross[ing] [the] Rubicon," doing something that had never been done in the 123-year existence of the Sherman Act, in allowing antitrust law to dictate the legality of patent infringement settlements.¹⁶⁹ Further, the dissent argued that only patent law should apply in patent cases, where the subject matter is both unique in and of itself and insulated from punishment by other laws.¹⁷⁰

The dissent instead advocated for the use of the lenient "scope of the patent" standard, and argued that the majority should have adopted this standard as the fundamental test for adjudging reverse payment settlements.¹⁷¹ In so reasoning, Chief Justice Roberts opined that the majority had misinterpreted the essential holdings of prior cases that examined patent-related settlements in various industries, such as electrical devices and sewing.¹⁷² According to the dissent, these cases stand for the proposition that "patent settlements—and for that matter, any agreements relating to patents—are subject to antitrust scrutiny only if they confer benefits beyond the scope of the patent."¹⁷³ Moreover, the dissent stated the fact that patent-related settlement agreements *can sometimes* violate antitrust laws does not necessitate subjecting a patent settlement to antitrust scrutiny, particularly not, as the majority reasoned, because the validity of the patent is uncer-

^{166.} Id. at 2238–39 (Roberts, C.J., dissenting).

^{167.} Id. at 2238.

^{168.} Id. at 2239.

^{169.} *Id.* at 2242.

^{170.} Id. at 2240.

^{171.} *Id.* at 2239; *see also supra* Part II.B (explaining that the scope of the patent standard views reverse payment settlements as presumptively lawful exercises within the scope of the monopoly power conferred on patent-holders by the virtue of their holding patents).

^{172.} *Id.* at 2240–41. Chief Justice Roberts cited *United States v. Line Material Co.*, 333 U.S. 287 (1948), *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963), *United States v. New Wrinkle, Inc.*, 324 U.S. 371 (1952), and *Standard Oil Co. v. United States*, 283 U.S. 163 (1931), as examples of cases that the majority misinterpreted in Justice Breyer's opinion. *Id.*

^{173.} *Id.* at 2242. In contrast, in his majority opinion, Justice Breyer had held that cases like *Line Material* and *Standard Oil* stand for the proposition that antitrust law in fact *must* apply to patent-related settlements. *Id.* at 2232–33 (majority opinion).

tain.¹⁷⁴ Lastly, the dissent noted that the significant costs of patent litigation and the judicial preference for settlement should predominate over concerns about patent validity, and that these economic interests would therefore seem to mandate use of the scope of the patent test.¹⁷⁵

IV. ANALYSIS

The Court's holding in *Actavis* struck the correct balance in characterizing reverse payment settlements as not *per se* illegal, and yet not immune from antitrust attack.¹⁷⁶ The Court, however, missed two crucial opportunities to clarify this area of the law, particularly in light of the fact that *Actavis* was the first reverse payment settlement case the Court has chosen to hear.¹⁷⁷

First, in refusing to announce a comprehensive test for application of the rule of reason analysis, the Court did not fully resolve the issue of how to evaluate reverse payment settlements-an issue that has beleaguered federal circuit courts for the past two decades.¹⁷⁸ Rather than skirt the issue as it did, the Court should have declared that the Third Circuit's quick look rule of reason analysis is the proper standard by which to judge brandname-generic settlements that include pay-for-delay clauses.¹⁷⁹ Among the several disparate frameworks for judging reverse payment settlements adopted by the federal circuit courts, the Third Circuit's quick look rule of reason analysis most effectively balances the need to incentivize brandname drug development with the need to encourage generic market entry in order to create competition and lower drug prices, as Hatch-Waxman intended.¹⁸⁰ The quick look rule of reason analysis provides a stricter standard of scrutiny to ensure that a reverse payment settlement is legitimate and not a manifestation of anti-competitive practices or a desire to maintain an illegal market monopoly.¹⁸¹ Moreover, announcing an authoritative, comprehensive standard, and giving examples of how that standard would apply to typical reverse payment agreements, would ease administrability for

^{174.} Id. at 2242 (Roberts, C.J., dissenting).

^{175.} *Id.* at 2243–44.

^{176.} See infra Part IV.A.

^{177.} See infra Parts IV.B–C.

^{178.} See supra Part III.

^{179.} See infra Part IV.B.

^{180.} See 130 CONG. REC. 24,430 (daily ed., Sept. 6, 1984) (statement of Rep. Henry Waxman) ("[Proposed amendments to Hatch-Waxman that were later incorporated] do not upset the fundamental balance of the bill that assures consumers of more low-cost generic drugs when a valid patent expires and the drug industry of sufficient incentive to develop innovative pharmaceutical therapies.").

^{181.} See infra Part IV.B.

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courts determining the legality of reverse payment settlements going forward.¹⁸²

Second, although the Court explicitly refrained from finding reverse payment settlements *per se* illegal, the majority opinion reveals dissatisfaction with the reverse payment model that is the inevitable result of Hatch-Waxman's regulatory design.¹⁸³ As such, the Court should have recommended, as a policy consideration for lower courts, a requirement of judicial settlement approval for future reverse payment agreements.¹⁸⁴ This policy would likely discourage brand-name drug manufacturers from bringing frivolous suits to defend knowingly weak or non-infringed patents, and would also allow generic manufacturers to more easily defend their patent claims and disincentivize their knee-jerk settlement reaction.¹⁸⁵ Such a policy recommendation would target and eliminate the risk-seeking and risk-averse behavior that induces brand-names and generics to settle, and would therefore address the root problem of ubiquitous reverse payment settlements that negatively impact consumers.¹⁸⁶

A. The Court's Holding Struck the Correct Balance Between Per Se Illegality of Reverse Settlement Payments and Immunity from Antitrust Attack

1. The Court Appropriately Found That Reverse Payment Settlements Are Not Per Se Illegal

In *Actavis*, the Supreme Court declined to find reverse payment settlements *per se* illegal restraints on trade,¹⁸⁷ despite their essential character as a collusive market allocation in the pharmaceutical sphere.¹⁸⁸ Two spec-

^{182.} See infra Part IV.B; see also Steven J. Cernak & Kelly L. Morron, District Courts Struggle to Apply Direction from Actavis in Reverse Payment Cases Re: Antitrust Litigation, NAT'L L. REV. (Mar. 9, 2014), http://www.natlawreview.com/article/district-courts-struggle-to-applydirection-actavis-reverse-payment-cases-re-antitru ("In its 2013 opinion in FTC v. Actavis, the Supreme Court . . . instructed lower courts to apply antitrust law's rule of reason to so-called 'reverse payment' cases.").

^{183.} See FTC v. Actavis, Inc., 133 S. Ct. 2223, 2233 (2013) ("[T]here is nothing novel about our approach. What *does* appear novel [as a legal doctrine] are the dissent's suggestions that a patent holder may simply 'pa[y] a competitor to'... quit its patent invalidity or noninfringement claim without any antitrust scrutiny."); *Id.* at 2230 ("[W]e do not agree that [holding a patent]... can immunize [a reverse payment] agreement from antitrust attack."); *see also* Dolin, *supra* note 82, at 283 ("The rise of reverse settlement agreements is a direct consequence of the incentives created by the Hatch-Waxman Act.").

^{184.} See infra Part IV.C.

^{185.} See infra Part IV.C.

^{186.} See infra Part IV.C.

^{187.} See supra Part II.B.1 (explaining per se illegal restraints on trade).

^{188.} *See, e.g., In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 907–08 (6th Cir. 2003) ("The [settlement] [a]greement guaranteed to [the brand-name manufacturer] that its only potential com-

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ulative reasons exist for the Court's decision not to find the pay-for-delay process presumptively unlawful. First, courts are generally unwilling to apply *per se* proscriptions to potentially violative conduct that arises in new industries or in areas where such a finding of anti-competitive infringement has not previously been made or considered.¹⁸⁹ Because only the Sixth and D.C. Circuits have concluded that reverse payment settlements are pre-sumptively unlawful,¹⁹⁰ it is likely the Court was hesitant to announce a strict *per se* illegal standard in an unfamiliar area. This conjecture is especially credible in light of the fact that it is often unclear how a court would acquire enough experience in an area to deem a seemingly horizontal agreement as a naked, *per se* violation.¹⁹¹

Second, and more significantly, the Court would have been erroneous in concluding that reverse payment settlements are *per se* illegal because, in paragraph IV litigation, the brand-name's patent is not always invalid or the generic's patent does not always infringe. The FTC has shown that generics prevail in seventy-three percent of patent challenge cases; but, that figure leaves over twenty-five percent of cases in which the generic's attempt-

petitor at that time . . . would, for the price of \$10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval. . . . There is simply no escaping the conclusion that the [a]greement . . . was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade."). Federal courts have found that market allocations in other arenas are also facially blatant horizontal restraints on trade such that they are *per se* unlawful. *See, e.g.*, Palmer v. BRG of Ga., Inc., 498 U.S. 46, 49–50 (1990) (finding a market allocation where two bar exam companies agreed not to compete with one another in certain areas was facially unlawful); United States v. Brown, 936 F.2d 1042, 1044–45 (9th Cir. 1991) (finding *per se* illegal an agreement between billboard advertising companies that prohibited one another from competing from each other's former leaseholds for one year after a billboard space was "lost or abandoned").

^{189.} See FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 458–59 (1986) ("[W]e have been slow... to extend *per se* analysis to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious."); United States v. Topco Assocs., Inc., 405 U.S. 596, 607–08 (1972) ("It is only after considerable experience with certain business relationships that courts classify them as *per se* violations").

^{190.} See In re Cardizem, 332 F.3d at 907–08 (holding that a reverse payment settlement agreement was "at its core, a horizontal agreement to eliminate competition in the market," and was therefore a "classic example of a *per se* illegal restraint of trade"); Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 811 (D.C. Cir. 2001) (holding that a pay-for-delay agreement between generic and brand name pharmaceutical manufacturers fell in the category of *per se* illegality because it could be viewed as an effort to "preserve monopolistic conditions").

^{191.} See McNeil v. Nat'l Football League, 790 F. Supp. 871, 896–97 (D. Minn. 1992) (applying a rule of reason analysis, as opposed to finding *per se* illegal a series of rules governing football teams' first refusal and compensation rights following the expiration of player contracts, despite having considered *per se* illegality in such instances in earlier decisions). *But cf.* Ariz. v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 349, 357 (1982) (holding that a maximum fee arrangement among medical service providers was *per se* illegal, despite having never addressed the antitrust implications of a similar arrangement in the medical arena).

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ed entry into the market would impede on a brand-name's patent.¹⁹² Moreover, although some patent law scholars believe that paragraph IV litigation is a signal of patent invalidity,¹⁹³ Professor William Landes and Judge Richard Posner have presented data that contradicts the FTC's arguments for patent weakness, including a "remarkable increase" in patent validity holdings since the beginning of the Federal Circuit.¹⁹⁴ Prior to the Federal Circuit's inception, courts held patents valid in approximately forty-five percent of cases; but the Federal Circuit, which has been starkly in favor of finding patent validity, has increased that number to the sixty-five to seventy percent range.¹⁹⁵ In many instances, then, it is evident that much paragraph IV litigation has ended and could end in a brand-name's patent being held valid. If the Court had declared a standard that presumed illegality of reverse payment settlements, brand-names would be unfairly limited in their capacity to dictate the settlement terms of unfair challenges to their rightly-held patents before litigation. Furthermore, they would thereby improperly diminish the judicial resources that should appropriately be at their disposal.

2. The Court Properly Found That Reverse Payment Settlements Can Be Analyzed Using Antitrust Law

In addition to finding that pay-for-delay is not a *per se* illegal practice, the Court also correctly held that antitrust challenges to pay-for-delay settlements are very much justiciable, and that the legality of such settlements can be judged based on antitrust principles. Typical private antitrust actions for damages require the plaintiff to demonstrate that the defendant's restraints on trade caused the plaintiff injury in fact, or, if seeking injunctive relief, that the defendant's actions threatened the plaintiff with loss or damage by a violation of the antitrust laws.¹⁹⁶ When the FTC brings a claim against generic and brand-name drug manufacturers for anti-competitive collusion, the government must show that the agreement in question had an injurious impact on consumers participating in the pharmaceutical indus-

^{192.} GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION, supra note 83, at 13, 20.

^{193.} See, e.g., John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1998) (analyzing how patents fare in court).

^{194.} Steven W. Day, Note, *Leaving Room for Innovation: Rejecting the FTC's Stance Against Reverse Payments in* Schering-Plough v. FTC, 57 CASE W. RES. L. REV. 223, 248 (2006) (citing WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 338–39 (2003)).

^{195.} See WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 338 tbl.12.1 (2003); see also Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 25–30 (1989) (examining the Federal Circuit's pro-patent stance).

^{196. 15} U.S.C. §§ 12, 26 (2012).

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try.¹⁹⁷ In their challenges to reverse payment settlements, including *Actavis*, the FTC has alleged that massive public economic injury, to the tune of \$3.5 billion, results from the pay-for-delay framework.¹⁹⁸ The FTC argues that this framework not only denies consumers access to competitive pricing on pharmaceuticals, but also forces consumers to pay the brandname's costs included in the reverse payment settlement amounts transferred to generics in the form of increased brand-name drug prices.¹⁹⁹

Despite the FTC's demonstration of injury-in-fact to consumers, the Eleventh Circuit held—prior to *Actavis*—that although antitrust laws would ordinarily prohibit pay-for-delay arrangements,²⁰⁰ reverse payment settlements in the patent arena present "atypical cases" because one of the parties owns a patent, giving them the legal right to a monopoly.²⁰¹ This presumption of patent validity, combined with the heavy weight of public policy in favor of settlement, led the Eleventh Circuit to conclude that courts could not force parties to continue litigating in order to avoid a possible violation of antitrust principles.²⁰²

As the Court in *Actavis* recognized, the Eleventh Circuit's determination of the non-justiciability of the FTC's claim turned on an erroneous presumption that the brand-name company's patent is always valid.²⁰³ Although some federal courts have refused to consider patent validity when scrutinizing reverse payment settlements²⁰⁴ because patents are presumed

^{197.} Marlee P. Kutcher, Comment, Waiting Is the Hardest Part: Why the Supreme Court Should Adopt the Third Circuit's Analysis of Pay-for-Delay Settlement Agreements, 44 LOY. U. CHI. L.J. 1093, 1151 (2013).

^{198.} See id. at 2.

^{199.} See PAY-FOR-DELAY, supra note 77, at 2 (finding that pay-for-delay arrangements cost Americans \$3.5 billion per year); see also FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2012, A REPORT BY THE BUREAU OF COMPETITION 1–2 (2013) [hereinafter AGREEMENTS FILED WITH THE FTC], available at http://www.ftc.gov/os/2013/01/130117mmareport.pdf (finding that the number of reverse payment settlements rose from twenty-eight in 2011 to forty in 2012, and involved brandname pharmaceutical products with combined annual U.S. sales of \$8.3 billion).

^{200.} Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003).

^{201.} FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1307 (11th Cir. 2012), *rev'd sub nom*. FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

^{202.} Actavis, Inc., 133 S. Ct. at 2230 (citing Watson Pharm. Inc., 677 F.3d at 1313–14). 203. Id. at 2231.

^{204.} 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."), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212 (2d Cir. 2005) (holding that the validity of the patent need not be considered in the analysis of whether the settlement agreement violates antitrust law), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013):

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valid by law,²⁰⁵ such refusal is in error given two propositions. First, the refusal to consider patent validity in adjudging reverse payment settlements ignores the aforementioned FTC findings that the majority of generic challenges to brand-name patents reveal the brand-name patent's weakness,²⁰⁶ which can thereby often make the brand-name's claim of patent infringement frivolous. Second, refusal to consider patent validity ignores the fact that "[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office,"²⁰⁷ and not an infallible proclamation, as demonstrated by the FTC's study.²⁰⁸

B. The Court Should Have Adopted the Third Circuit's Quick Look Rule of Reason Analysis

As previously discussed, the Third Circuit announced in In re K-Dur that it would break from the Second, Eleventh, and Federal Circuits' prosettlement scope of the patent test, which mandates an irrefutable presumption of the brand-name's existing patent validity and is grounded in the principle that patent holders can do what they please within the scope of the patent's monopoly protections.²⁰⁹ Instead of adopting this lenient framework, the Third Circuit implemented a "quick look rule of reason analysis," in which a finder of fact must treat "any payment from a patent holder to a generic patent challenger as part of an agreement that delays the generic's market entry as prima facie evidence of an unreasonable restraint of trade."210 The quick look rule of reason analysis falls between the lenient scope of the patent test and the harsh per se rule of illegality for "predictable and pernicious" restraints.²¹¹ Fundamentally, the quick look rule of reason test differs from the scope of the patent test in that the former specifies a rebuttable presumption of reverse payment settlement illegality, while the latter specifies a rebuttable presumption of legality.

FTC v. Actavis marked the first time the Supreme Court heard a payfor-delay case, both despite and because of the fact that the legality of re-

^{205. 35} U.S.C. § 282 (2006).

^{206.} See GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION, *supra* note 83, at viii (finding that generic drug companies prevailed in seventy-three percent of cases wherein they challenged a brand-name's patent validity); *see also* PAY-FOR-DELAY, *supra* note 77, at 3 (same).

^{207.} In re K-Dur Antitrust Litig., 686 F.3d 197, 215 (3d Cir. 2012) (quoting Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969)), cert. granted and judgment vacated sub nom. Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013) (mem.).

^{208.} PAY-FOR-DELAY, supra note 77, at 3.

^{209.} *In re K-Dur*, 686 F.3d at 209; *see also supra* Part II.C (explaining the Third Circuit's implementation of a new "quick look rule of reason" analysis for pay-for-delay agreements and how it differs from other federal circuits' "scope of the patent" test).

^{210.} In re K-Dur, 686 F.3d at 218.

^{211.} See supra Parts II.B.1–2.

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verse payment settlements had been litigated in federal courts for decades.²¹² Given that the Court granted the FTC's petition for certiorari precisely to resolve the issue that different standards are used by the courts in reverse payment settlement cases,²¹³ it is perplexing that the Court did not in fact annunciate a workable set of criteria for courts to use in future cases. The Court ultimately declared that the FTC's challenge to the Actavis-Solvay settlement was justiciable, and that a typical antitrust rule of reason test could be used; however, in declining to adopt either the scope of the patent test or the quick look rule of reason analysis, the Court avoided the most essential issue of the case. Ruling on the overall legality of reverse payment settlement claims, without explaining in detail the test that should be employed to adjudicate such claims, is remarkably problematic. Consequently, this failure on the part of the Court has already resulted in confusion among federal courts faced with pay-for-delay challenges.²¹⁴

1. The Court Correctly Declined to Adopt the Scope of the Patent Test

The Court in *Actavis* should have announced a definitive standard and, in doing so, should have adopted the Third Circuit's quick look rule of reason analysis over the scope of the patent test.²¹⁵ As discussed in Part IV.A, the scope of the patent test's almost unrebuttable presumption of patent validity ignores the reality that generic challengers often prevail in paragraph IV litigation.²¹⁶ This further undermines the appropriateness of using the scope of the patent test and its presumption of patent validity in pay-for-delay cases. Reverse payment settlements thereby enable a brand-name patent holder—that knows its patent is weak—to buy its way out of competition and into a greater period of monopoly than it would rightly have if its patent were invalid.²¹⁷

^{212.} See supra Parts I & II.B (noting that the U.S. Supreme Court decided to hear Actavis to resolve the competing standards used by federal courts in judging reverse payment settlements, and discussing those varying standards).

^{213.} FTC v. Actavis, Inc., 133 S. Ct. 2223, 2230 (2013).

^{214.} *See* Cernak & Morron, *supra* note 182 (noting that the U.S. District Courts for the Districts of Massachusetts and New Jersey have struggled to apply the Court's "ambiguous guidance" set forth in *Actavis*).

^{215.} See supra Parts II.C.2–3.

^{216.} See GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION, *supra* note 83, at viii (finding that in paragraph IV litigation, generic challengers prevailed seventy-three percent of the time); *see also* Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 380, 385 (2000) (finding that between 1983 and 1999, the alleged infringer (the generic) prevailed in forty-two percent of paragraph IV cases that reached trial).

^{217.} In re K-Dur Antitrust Litig., 686 F.3d 197, 215 (3d Cir. 2012).

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Moreover, the scope of the patent test does not properly address whether a generic's patent indeed infringes on a brand-name's patent. In some paragraph IV cases, generics filing an ANDA purport, and can objectively show, that their desired patent does not infringe because it conveys the rights to something fundamentally different from what the brand-name holds.²¹⁸ In other cases, generic challengers can rightfully assert that their patents will not infringe because a brand-name's patent will have expired by the time that the generic version of the drug is marketable.²¹⁹ Yet, in both of these scenarios, where it is clear that there is no infringement and the brand-name's patent validity is not even in question, brand-name manufacturers pursue patent infringement suits against generic drug companies, which yield exorbitant settlement agreements for generics and perpetuate the pay-for-delay framework.²²⁰ Because the scope of the patent test presumes patent validity and solely examines whether a patent holder's settlement action exceeds the scope of its monopoly, it cannot effectively be used to judge settlement situations where the issue of validity was irrelevant because the generic simply would not infringe. If the applicable test focuses on brand-name patent validity, injured challengers cannot possibly win an antitrust claim against a reverse payment settlement wherein the patent's validity was never even at issue. The quick look rule of reason analysis, however, provides a proper framework for adjudging reverse payment settlements because, rather than focusing on the validity of the patent in question, it focuses on the context, the terms of the settlement, and the "economic realities" of pay-for-delay that cost consumers billions.²²¹

2. The Court Should Have Affirmatively Adopted the Quick Look Rule of Reason Analysis

In contrast to the scope of the patent test, the quick look rule of reason analysis provides a balance between respecting brand-name patent-holders' rights and allowing generic manufacturers to enter the market when they are confident that their drug will not infringe. In finding a pay-for-delay provi-

^{218.} See, e.g., In re Cardizem CD Antitrust Litig., 332 F.3d 896, 902 (6th Cir. 2003). In *Cardizem*, brand-name manufacturer Hoecsht Marion Roussel, Inc. ("HMRI") held the patent for the "dissolution profile" (the amount of a drug to be released into a person's system in a given period) of zero to forty-five percent of the active ingredient in the prescription hypertension drug Cardizem CD. *Id.* In its ANDA to market a generic version of the drug, generic manufacturer Andrx Pharmaceuticals specified that its formula had a dissolution profile of not less than fifty-five percent. *Id.* Despite the disparate dissolution profiles, HMRI "nonetheless" continued to pursue patent infringement litigation against Andrx. *Id.*

^{219.} E.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 193 (E.D.N.Y. 2003).

^{220.} *See supra* Parts II.A–B (discussing the high prices that brand-names will pay to generics to delay generic market entry through paragraph IV litigation reverse payment settlements).

^{221.} See infra Part IV.B.2.

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sion in a generic-brand name settlement to be rebuttable prima facie evidence of an antitrust violation,²²² the quick look rule of reason analysis targets the harmful collusion that is the fundamental problem with these settlements. At the crux of anti-competitive issues with reverse payment settlements is that generic drug manufacturers are monetarily incentivized to delay entry and disincentivized to pursue litigation, even when they are confident that they will not infringe on a brand-name's patent. Nothing in the Third Circuit's quick look rule of reason analysis limits parties' ability to reach settlements or negotiate generic drug entry dates without compensation for delay.²²³ Instead, only settlements in which a brand-name pays a generic to stay out of a particular market will require the manufacturers to rebut a presumption of illegality.²²⁴ Notably, FTC data suggests that this rule will only affect a small minority of pharmaceutical settlements; nearly seventy-five percent of Hatch-Waxman Act infringement suits that settled from 2004 to 2009 (152 out of 218 final settlement agreements) did so without reverse payments.²²⁵

In his dissenting opinion in *Actavis*, Chief Justice Roberts predicated his support for the scope of the patent test in part on the fact that judicial preference for settlement should be given the highest priority.²²⁶ The scope of the patent test is certainly much more pro-settlement than the quick look rule of reason analysis because it essentially declares reverse payment settlements unreviewable.²²⁷ Indeed, in considering whether to find pay-fordelay arrangements valid or invalid, many federal courts have given great weight to the economic advantages of settlement over expensive patent litigation.²²⁸ Although encouraging cooperative settlement is certainly an im-

^{222.} See supra Part II.B.3.

^{223.} In re K-Dur Antitrust Litig., 686 F.3d 197, 217–18 (3d Cir. 2012), cert. granted and judgment vacated sub nom. Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013) (mem.).

^{224.} Id. at 218.

^{225.} AGREEMENTS FILED WITH THE FTC, *supra* note 199, at 2; PAY-FOR-DELAY, *supra* note 77, at 4–5.

^{226.} FTC v. Actavis, Inc., 133 S. Ct. 2223, 2243 (2013) (Roberts, C.J., dissenting).

^{227.} See supra Part II.C.

^{228.} See FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1314 (11th Cir. 2012) (arguing that "[o]ur legal system can ill afford" to "undo much of the benefit of settling patent litigation, and discourage settlements"), *rev'd sub nom.* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); Erheart v. Verizon Wireless, 609 F.3d 590, 595 (3d Cir. 2010) ("Settlement agreements are to be encouraged because they promote the amicable resolution of disputes and lighten the increasing load of litigation faced by the federal courts."); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1072, 1075 (11th Cir. 2005) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.... There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation."); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 202 (2d Cir. 2005) (citing the "longstanding" principle that "'courts are bound to encourage' the settlement of litigation"), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

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portant goal, it should not override the public policy objective of litigating patent challenges to "protect consumers from unjustified monopolies" or the maintenance of needlessly artificial anti-competitive drug prices.²²⁹

The fact that one test would result in more settlements is insufficient to establish its cost-effective merits over the test that results in more litigation. This is because the pro-settlement test would, more often than not, result in an unnecessarily higher cost to consumers through inflated drug prices that come about as the result of brand-name manufacturers attempting to recoup their payment losses following pay-for-delay arrangements.²³⁰ The reality is many reverse payment settlements are collusive, horizontal restraints on trade,²³¹ and judicial preference for settlement should not be the deciding factor in the debate about pay-for-delay standards. The quick look rule of reason analysis takes into account the common sense understanding that an agreement wherein one company pays another company to delay entry into a particular market is a strong indication of anti-competitive intent. The test, however, still provides manufacturers with the opportunity to defend themselves and ensures that settlement will remain the prevalent form of resolution in cases where delay is negotiated without compensation.²³²

C. The Court Should Have Recommended That Judicial Settlement Approval Be Required in Future Reverse Payment Cases

While the quick look rule of reason analysis would provide the appropriate level of scrutiny for reverse payment settlements, using this standard to analyze settlements that have already occurred does not necessarily address the ubiquity of such agreements, which have significant financial implications for consumers.²³³ Even if pre-existing reverse payment settlements are eventually challenged in court and deemed unlawful, the damage will have already been done. Consumers will have had the excessive costs of settlement agreements pushed onto them in the form of higher prices and will have experienced delayed access to cheaper generic versions of their

^{229.} In re K-Dur, 686 F.3d at 217.

^{230.} PAY-FOR-DELAY, *supra* note 77, at 8, 10; *see also* C. Scott Hemphill, *Paying-for-Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1594 (2006) ("Saved litigation expense is thought to offset the allocative harm from the [reverse payment] settlement. But although litigation expense is large in absolute terms, perhaps tens of millions of dollars, its size is dwarfed by the hundreds of millions or billions of dollars reallocated when parties enter a pay-for-delay settlement.").

^{231.} *See* Hemphill, *supra* note 230, at 1572 ("The FTC's concern [with pay-for-delay] is straightforward. Privately optimal agreements that impose large negative effects upon nonparties frequently raise antitrust concerns."); *see supra* Parts II.B.1–3.

^{232.} In re K-Dur, 686 F.3d at 217.

^{233.} *See* Hemphill, *supra* note 230, at 1594 (noting that pay-for-delay results in consumers paying hundreds of millions of dollars in "reallocated" costs).

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medications, costing the public even more.²³⁴ The goal, therefore, should be to curb these settlements by discincentivizing generic companies from settling when they know their patent does not infringe. Additionally, brand-names should be disincentivized from challenging generics' patents when they knowingly hold a weak patent or know that their sought-after patent will not be infringed. The most effective means of accomplishing this task lies in judicial approval of settlement amounts.

Judicial settlement approval is a controversial solution that typically appears only in class action or Fair Labor Standards Act ("FLSA") litigation contexts.²³⁵ Generally, courts favor settlement approval requirements in situations where parties are of unequal size or have vastly different levels of sophistication as a way to prevent knowledgeable parties from taking advantage of those that are ignorant.²³⁶ The situation in Actavis and other pay-for-delay cases is of course different from employment lawsuitsgeneric and brand-name drug manufacturers are not of significantly different means and posture, and both parties are aware of the consequences if a brand-name's challenge to a generic's ANDA goes to trial. Yet, it is perhaps this awareness that makes judicial approval of settlement so necessary. Because a generic manufacturer is cognizant of what its adversary stands to lose, it is encouraged to engage in risk-seeking behavior by filing an ANDA and is incentivized to settle if the offered price is on par with or higher than what the generic would gain upon market entry.²³⁷ Additionally, because the first generic manufacturer to file an ANDA receives 180 days of exclusivity under Hatch-Waxman, generics manufacturers are induced to speed up their testing processes and file abbreviated applications, even when they are not entirely certain that their ANDA patents would not infringe.²³⁸ This period of exclusivity and a successful challenge of a major drug patent can

^{234.} See supra Parts I & II.A (explaining that the primary negative consequence of pay-fordelay arrangements is that, in addition to consumers losing access to significantly cheaper medicines for longer periods of time, to recoup the losses from their hefty settlement payouts, brandname drug manufacturers push their expenditures onto consumers in the form of higher drug prices).

^{235.} *See, e.g.*, Lynn's Food Stores, Inc. v. United States, 679 F.2d 1350 (11th Cir. 1982) (holding that judicial settlement approval is necessary for lawful settlement of FLSA claims brought by then-current employees); Pollar v. Judson Steel Corp., No. C-82-6833-MHP, 1984 WL 968 (N.D. Cal. Mar. 30, 1984) (holding that defendant in a class action suit was prohibited from proceeding with its settlement plan until further order of the court and court approval).

^{236.} *See, e.g.*, Brooklyn Sav. Bank v. O'Neil, 324 U.S. 697, 709–10 (1945) (expressing the importance of ensuring that the deterrent effect of a particular FLSA provision did not allow corrupt employers to take advantage of an employee by settling FLSA claims privately for a paltry amount).

^{237.} Hemphill, *supra* note 230, at 1579.

^{238.} Id. at 1578-79.

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provide generics with a "valuable bounty" of several hundred million dollars.²³⁹

Conversely, the pay-for-delay framework encourages brand-name manufacturers to be inherently risk-averse. They stand to lose their monopoly on the market share of a particular drug if a generic prevails in its ANDA application. It is therefore much more advantageous for them to settle patent litigation-including payment for a generic's delayed entry into the market—even if it comes at a high price.²⁴⁰ For instance, in their article quantifying the litigation risk calculations of both brand-name and generic drug manufacturers, Xiang Yu and Anjan Chatterji show that making reverse payment is a rational decision for a risk-averse brand-name manufacturer when there is high probability that a court will find its patent invalid during paragraph IV litigation, which would result in loss of its drug monopoly.²⁴¹ When the amount that a brand-name would lose is greater than the value of its projected litigation costs less the damages it could be awarded if the brand-name's predictions are wrong and a court finds its patent valid, there is an ostensible logical basis for a brand-name's incentive to settle, even at a high cost.²⁴² Judges and juries are fallible, however, and neither brand-names nor generics can always accurately predict their findings about patent validity over the course of litigation; thus, even when a brand-name is confident in its patent's validity, it is willing to make reverse payment offers to secure patent monopolies because of their lucrative potential.²⁴³ The uncertainty of litigation outcomes thereby encourages brandname companies to settle as long as there is even the slightest chance of losing the patent at trial.²⁴⁴

The brand-name manufacturer, secure in its patent monopoly, is often unable to feel the monetary loss resulting from its reverse payments because it can recoup its settlement payout by charging consumers higher prices for medicines.²⁴⁵ The FTC estimates that reverse payment settlements cost

^{239.} *See, e.g.*, Comment of Apotex Corp. in Support of Citizen Petition Docket No. 2004p-0075/CP1, to Div. of Dockets Mgmt., FDA 4 (Mar. 24, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf (discussing generic manufacturer Apotex's reported earnings of between \$150 million and \$200 million from the exclusivity period of its generic version of Paxil, an antidepressant).

^{240.} Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation*, 10 Nw. J. TECH. & INTELL. PROP. 19, 29 (2011).

^{241.} Id. at 29-30.

^{242.} Id.

^{243.} Id. at 29.

^{244.} Id.; Einer Elhauge & Alex Krueger, Solving the Patent Settlement Puzzle, 91 TEX. L. REV. 283, 301 (2012).

^{245.} Cook, *supra* note 122, at 428; Elhauge & Krueger, *supra* note 244, at 301–03; Hemphill, *supra* note 230, at 1582.

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consumers \$3.5 billion annually, a figure that reflects both the costs pushed on consumers by brand-names trying to earn back settlement payments, and the higher prices that consumers pay for medicines because of delayed access to generic products.²⁴⁶

In contrast, a generic is only incentivized to continue in litigating its patent challenge when the brand-name is willing to pay significantly less than the generic would receive in profits after its drug enters the market.²⁴⁷ Even when the generic is confident in its challenge and the non-infringement of its ANDA, a brand-name's high settlement offer is a definite win, as opposed to the mere prospect of profit from marketability that comes with continued litigation.²⁴⁸ Therefore, as antitrust scholar C. Scott Hemphill has noted,²⁴⁹ pay-for-delay arrangements are logical for both brand-name and generic manufacturers involved in paragraph IV litigation when the monetary incentive to settle is significantly greater than the amount that each thinks it would gain if litigation proceeded.²⁵⁰ Moreover, pay-for-delay arrangements become even more likely because of the "wide gap" that exists between a brand-name's risk tolerance and a generic's will-ingness to litigate, given the economic payoff for each party that results from pay-for-delay.²⁵¹

In order to break out of the problematic and costly reverse payment settlement framework, both brand-names and generics must be induced to pursue litigation over settlement or enter settlement agreements that do not involve excessive compensation for market delay. The most effective mechanism for accomplishing this goal is through required judicial settlement approval, which would ensure that settlements exceeding litigation costs would not be permitted. If a court finds that a brand-name has offered an excessive payment to delay a generic's entry into a particular market, the court can bar the settlement, which would compel the parties to renegotiate their agreement. In turn, generics would likely be encouraged to proceed with litigation when they are confident that their ANDA patent does not infringe because the potential gains resulting from ANDA approval would be greater than the gains resulting from settlement. Finally, brand-names would be discouraged from challenging generics' ANDAs for patents that the brand-name knows is weak or where the brand-name knows that the generic's patent would not infringe. Brand-names would also be incentivized to develop drugs and secure airtight, valid patents to minimize the risk of

^{246.} PAY-FOR-DELAY, supra note 77, at 2.

^{247.} Yu & Chatterji, supra note 240, at 24.

^{248.} Id.

^{249.} Hemphill, supra note 230, at 1594.

^{250.} Id. at 1591–92.

^{251.} Yu & Chatterji, supra note 240, at 34.

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generic ANDA challenges alleging brand-name patent invalidity. Settlement approval would therefore continue to serve Hatch-Waxman's goals of maintaining drug development and innovation while keeping drug prices low for consumers.

The mechanism of judicial settlement approval is directly in line with legislative efforts to end the exorbitant pay-for-delay framework dating as far back as 2002, after the U.S. Senate unanimously passed the Drug Competition Act of 2001.²⁵² The Drug Competition Act required all settlements between generic and brand-name manufacturers involving agreements over the "manufacture, marketing, or sale of the brand-name drug . . . [or] of the generic drug" to be disclosed to the FTC or the U.S. Department of Justice.²⁵³ More recently, however, members of Congress engaged in aggressive attempts to enact stringent legislation to curb the pay-for-delay phenomenon.

In the 109th, 110th, and 111th Congresses, Senator Herb Kohl of Wisconsin, along with several co-sponsors, supported the Preserve Access to Affordable Generics Act,²⁵⁴ which would make it illegal for any brandname and generic manufacturer to enter into an agreement where "(1) an ANDA filer [generic manufacturer] receives anything of value; and (2) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time."²⁵⁵ Kohl's version of the bill in the 111th Congress was the only version to include two exceptions to the harsh rule. First, any payments not exceeding \$7.5 million, which are intended to reimburse the generic ANDA filer for "reasonable litigation expenses," would be exempt from the bill.²⁵⁶ Second, the bill provided an opportunity for settling parties to rebut the presumption of the unlawful and anti-competitive nature of their settlement.²⁵⁷ In the House of Representatives, Representative Henry Waxman-the very congressman for whom Hatch-Waxman is partially named-introduced a bill in the 110th Congress that would prohibit reverse payment settlements outright.²⁵⁸ While none of these bills have been passed, the unwavering legislative endeavors to address reverse payment settlements demonstrate that the ubiquity of such settlements is a serious problem that requires a preventative fix.

^{252.} S. 754, 107th Cong. (as reported by S. Comm. on the Judiciary, June 20, 2002).

^{253.} Id. § 5(2)(2).

^{254.} See S. 369, 111th Cong. (as introduced in Senate, Feb. 3, 2009); S. 316, 110th Cong. (as introduced in Senate, Jan. 17, 2007); S. 3582, 109th Cong. (as introduced in Senate, June 27, 2006).

^{255.} See, e.g., S. 316, 110th Cong. § 3.

^{256.} S. 369, 111th Cong. § 3.

^{257.} Id.

^{258.} H.R. 1432, 110th Cong. (as introduced by Rep. Waxman, Mar. 9, 2007).

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Of course, patent litigation is not inexpensive, either. In fact, because it is particularly complex, it is also particularly costly: typically, a patent case that proceeds to trial costs each side \$1.5 million in legal fees alone.²⁵⁹ One study found that the total cost of litigation in an ANDA challenge is approximately \$10 million per suit.²⁶⁰ Therefore, if settlement approval led to increased litigation, the litigation costs incurred by brand-name and generic manufacturers could be publicly reflected in the form of increased drug prices in anticipation of litigation. Furthermore, although seemingly counterintuitive, brand-names could potentially charge higher prices for drugs as a-seemingly counterintuitive-means of recouping losses sustained upon generic market entry.²⁶¹ In a 2007 working paper for the American Enterprise Institute-Brookings Joint Center for Regulatory Studies, scholars Darius Lakdawalla, Tomas Philipson, and Richard Wang speculated that the increased costs and loss of market output that brand-names would face if pay-for-delay were abolished would create a short-term consumer welfare loss of approximately \$400,000 per month for each brandname drug facing generic entry.²⁶²

Nevertheless, as discussed in Part IV.B.2, the cost of litigation is not reason enough to forgo the policy of judicial settlement approval. Pay-fordelay creates an artificially inflated drug market wherein generic medications that should rightly be available to the public are delayed, forcing consumers to pay higher drug prices so that brand-name manufacturers can make profits by engaging in collusive behavior. The fundamental problem with the pay-for-delay arrangement is that it can represent an unnatural restraint on trade, which violates federal antitrust laws. Thus, this potentially unlawful practice will only be curbed through a policy change that disincentivizes both generic and brand-name manufacturers from entering into reverse payment settlements in the first place.

V. CONCLUSION

In deciding *FTC v. Actavis*, the U.S. Supreme Court was presented with a seminal opportunity to determine which of the competing standards being applied to pay-for-delay settlement arrangements in the various fed-

^{259.} Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes* 6 n.18 (Univ. of Cal. at Berkeley Sch. of Law Pub. Law & Legal Theory, Research Paper No. 113, 2003), *available at* http://ssrn.com/abstrat=380841.

^{260.} Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011).

^{261.} Yu & Chatterji, *supra* note 240, at 35; Darius Lakdawalla, Tomas Philipson & Richard Wang, *Intellectual Property and Marketing* 20–24 (Reg. Markets Ctr., Working Paper No. 07-20, 2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1089045.

^{262.} Lakdawalla, Philipson & Wang, supra note 261, at 2-3.

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eral courts was the correct approach.²⁶³ While the Court rightly held that antitrust laws are indeed applicable to pay-for-delay arrangements,²⁶⁴ the Court's avoidance of the issue at the crux of the case-that is, which standard should ultimately be used in adjudicating pay-for-delay settlement provisions-did not adequately address the fundamental problem of pay-fordelay that plagues federal courts, the FTC, and purchasers of pharmaceuticals alleging antitrust injury. ²⁶⁵ The Court should have annunciated the Third Circuit's quick look rule of reason analysis as the standard for courts to use in the future, as this test most effectively balances the need for antitrust scrutiny of settlements appearing to be prima facie restraints on trade, with the need to continue encouraging both generic and brand-name drug manufacturers to develop new medicines.²⁶⁶ Finally, the Court should have recommended, as a policy consideration, that judicial settlement approval be required for reverse payment settlement litigation going forward.²⁶⁷ This policy would serve to disincentivize generics and brand-names from entering into exorbitant settlements that vastly exceed litigation costs, encourage generics to pursue ANDA litigation when they know a brand-name's patent is weak or theirs would not infringe, and encourage brand-names to fight for their right to a patent when they know that infringement would be imminent with the generic's ANDA approval.

^{263.} See supra Part I.

^{264.} See supra Part IV.A.

^{265.} See supra Part IV.A.

^{266.} See supra Part IV.B.

^{267.} See supra Part IV.C.