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Cover Page Footnote

* University of Notre Dame Law School, J.D. Candidate 2015. I would like to thank my parents, Lisa and Will, and brother, Collin, for their continual love and support.

A PRESCRIPTION FOR THE FUTURE: REVERSE-PAYMENT SETTLEMENTS IN THE WAKE OF *FTC v. ACTAVIS PHARMACEUTICALS*

AUDRA J. PASSINAULT*

INTRODUCTION

The pharmaceutical industry is a large and important part of the overall health care system in the United States. Drug innovation and improvement lead to safer and more effective pharmaceuticals able to treat a variety of diseases and ailments. But the quest by pharmaceutical companies to develop the next successful drug is an expensive venture: pharmaceutical companies spend more on research and development, relative to sales revenue, than almost any other industry in the United States.¹ However, this innovation and investment is rewarded when the drug is granted a patent by the United States government, giving the developing company a legal monopoly over the production—and profit—of that drug.² Yet these patents held by brand-name pharmaceutical companies are not impervious to challenge. Often generic drug manufacturers do challenge patents held by brand-name companies, hoping to be let in on the market of a profitable new pharmaceutical. One strategy brand pharmaceutical companies have traditionally employed to deal with a drug patent challenge is to settle this threatened patent litigation by paying generic manufacturers large sums of money to drop patent lawsuits with the effect of delaying the generic drugs from entering the market. These arrangements between the brand and generic pharmaceutical companies are known as “pay-for-delay settlements” or “reverse payments” and have been largely successful in delaying the entry of the lower-priced generic products to the market.³

These reverse-payment settlements have rightly caused regulatory agencies and consumers to question the legality of the arrangements, as they cost private consumers—and the government—billions of dollars

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1. CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 9–10 (2006), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf> (estimating the cost of developing a new drug at \$800 million).

2. Murat C. Mungan, *Reverse Payments, Perverse Incentives*, 27 HARV. J.L. & TECH. 1 (2013).

3. Jonathan Stempel, *Supreme Court to Hear “Pay-for-Delay” Drug Case*, REUTERS (Dec. 7, 2012), <http://www.reuters.com/article/2012/12/07/us-usa-court-drugs-payfordelay-idUSBRE8B617T20121207>.

every year.⁴ The Federal Trade Commission (“FTC”) began a campaign against these pharmaceutical settlements,⁵ believing that the practice of brand-name companies paying off the generic drug companies amounted to behavior violating antitrust laws.⁶ The FTC led the charge against the reverse-payment settlements, and litigation started to be heard in courts across the nation.⁷ Yet, due to the complicated nature of the law and conflicting public policy goals involved in these cases, a circuit split developed between the courts, with the Eleventh Circuit confirming the validity of the payment settlements, and the Third Circuit declaring the payments presumptively anticompetitive and unlawful.⁸ Each court laid out in its respective opinion the jurisprudence and logic behind its decision, and the pharmaceutical world waited for the Supreme Court to resolve the dispute.

Eventually, in 2012, the Supreme Court heard the case *FTC v. Watson Pharmaceuticals*⁹ and resolved the circuit split. In the 5–3 decision¹⁰ the Court refused to adopt the idea that the settlements are facially anticompetitive but did not specifically endorse the arguments put forward by either the Eleventh Circuit or the Third Circuit. Instead, the Supreme Court chose an open, case-by-case approach and stated that the lower courts must analyze the potential anticompetitive effects of each settlement put before them.¹¹ This decision by the Supreme Court has wide-ranging impact on not only the pharmaceutical industry but also antitrust law, patent law, and health care policy goals in general.

4. *Id.* (“According to the FTC, 127 reverse-payment arrangements were struck between 2005 and 2011, at an annual cost to consumers of \$3.5 billion. [I]n November 2011, the nonpartisan Congressional Budget Office said a U.S. Senate bill to ban reverse payments would save the government \$4.79 billion and lower U.S. spending on prescription drugs by \$11 billion over a decade.”).

5. The FTC often pursues actions against the pharmaceutical companies together with the state attorney general. 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 *Lox. U. CHI. L.J.* 1093 (2013).

6. *Id.*

7. *Id.* Notably, landmark cases in the Third and Eleventh Circuits such as *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) and *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

8. Kutcher, *supra* note 5.

9. *Watson Pharmaceuticals* was bought out and is now Actavis Pharmaceuticals.

10. Justice Samuel Alito did not take part in the decision, “presumably because of his earlier involvement with the issue when he was a judge of the Third Circuit Court.” Lyle Denniston, *Opinion Recap: “Pay to delay” in Deep Trouble*, SCOTUSBLOG (June 17, 2013, 4:21 PM), <http://www.scotusblog.com/2013/06/opinion-recap-pay-to-delay-in-deep-trouble/>.

11. Mark Botti & Jessica Hoke, *Redefining the Border Between Intellectual Property and Antitrust: Implications of FTC v. Actavis*, BLOOMBERG LAW (July 19, 2013), <http://about.bloomberglaw.com/practitioner-contributions/redefining-the-border-between-intellectual-property-and-antitrust/> (“In addressing the intersection between patent law and antitrust, the Court found that the ‘exclusionary potential of the patent’ could not ‘immunize the agreement from antitrust attack.’ Rather, courts must consider both patent law and antitrust policies to determine the scope of the protection afforded by the patent.”).

This Note will proceed to discuss this issue in five parts: Part I will discuss the background of the legal issues presented by reverse-payment settlements and the history of the pharmaceutical system; Part II will briefly explain the history of the Third and Eleventh Circuit reverse-payment jurisprudence and highlight the origin of the circuit split; Part III will discuss the circuit split journey to the Supreme Court and the Court's eventual holding; Part IV will examine how the Supreme Court's holding affects the prescription drug landscape going forward, including the ethical and policy ramifications of continuing to allow reverse-payment settlements; and Part V will summarize and conclude the Note.

I. THE PHARMACEUTICAL DRUG INDUSTRY AND THE BIRTH OF REVERSE-PAYMENT SETTLEMENTS

The true question of whether the reverse-payment arrangements are desirable, or legal, rests on determining if these payments by the brand company to the generic company are anticompetitive even though the brand company holds the patent.¹² But in order for anyone to answer this question thoughtfully and completely, it is imperative to first understand the general background of the pharmaceutical drug landscape, how reverse-payment settlements came into use, and how the pharmaceutical patent system currently functions.

The requirements that a pharmaceutical company must meet before being allowed to distribute a new drug to the public are codified in the Federal Food, Drug, and Cosmetic Act.¹³ According to this Act, a pharmaceutical company must first receive approval of its Abbreviated New Drug Application ("ANDA") from the United States Food and Drug Administration ("FDA"), which requires that the application and drug meet a series of specific requirements.¹⁴ Securing the approval of this application from the FDA is neither a simple nor inexpensive process: the average new drug development takes 10 to 15 years and costs between \$800 million and \$1 billion.¹⁵ Perhaps the most costly and

12. Kutcher, *supra* note 5; see generally *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (analyzing the intersection of antitrust and patent law to resolve the reverse-payment problem).

13. Specifically, 21 U.S.C. § 355(a) (2006).

14. § 355(b). The requirements for approval are as follows:

(A) reports of investigations . . . show[ing] whether or not such drug is safe for . . . [and] effective in use; (B) a full list of . . . components; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components . . . ; (F) specimens of the labeling proposed to be used for such drug".

See also Hearing Procedure for Refusal or Withdrawal of Approval of New Drug Applications and for Issuance, Amendment, or Repeal of Antibiotic Drug Regulations 34 Fed. Reg. 14,596, 14,596-98 (Sept. 19, 1969).

15. FRONTIERS IN BIOCHIP TECHNOLOGY 192 (Wan-Li Xing & Jing Cheng eds., 2006). For every 5,000-10,000 compounds that enter the research and development pipeline, only one will receive approval. Additionally, it can take up to fifteen years to develop one new medicine from the earliest stages of discovery to the time it is available for treating

time-consuming parts of the application approval process for the brand-name pharmaceutical company to complete are the drug-safety and effectiveness studies performed in human clinical trials. The cost of a single human clinical trial is estimated at \$100 million and takes an average of five years.¹⁶

Prior to 1984, this approval process was not any less stringent for generic drug companies looking to manufacture a less-expensive version of the brand-name pharmaceutical. Generic drug companies were also required by the FDA to complete the expensive safety and effectiveness studies on the drug that the brand pharmaceutical companies had already done before the brand had secured the original FDA approval.¹⁷ This duplicative process required of the generic drug companies was further complicated by the fact that even beginning these tests on a drug currently covered by a brand patent constituted infringement. Therefore, to avoid patent infringement, the generic drug companies were required to wait until the original patent term held by the brand pharmaceutical company expired before even beginning their own tests.¹⁸ This delay imposed by the lengthy, duplicative process had the effect of creating “the practical extension of the monopoly position of the patent holder beyond the expiration of the patent” by creating “a lapse of several years between expiration of the patent term and availability of a generic version to consumers.”¹⁹ Generic drug companies, government agencies, and consumers all viewed this imposed delay as unfair and sought a way to change the system.

After significant lobbying effort by the generic drug companies to change what they saw as an inherently unfair process, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act.²⁰ In this Act, Congress recognized that “[t]he FDA rules on generic drug approval for drugs . . . have had serious anti-competitive effects.”²¹ The creation of the Hatch-

patients. *Id.* at 192. The cost grows to between \$1 billion and \$4 billion dollars when adjusted for these current failure rates. See Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012, 7:41 AM), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/>.

16. Herper, *supra* note 15; see also Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. MED. 362 (2001), available at http://www.medscape.com/viewarticle/405869_4 (describing how, on average, each drug must successfully complete at least three clinical trials).

17. Kutcher, *supra* note 5.

18. *Id.*

19. *Id.* at 1098–99 (quoting H.R. REP. NO. 98-857, at 14 (1984) (providing the legislative intent of the Hatch–Waxman Act)).

20. H.R. REP. NO. 98-857; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. The Act receives its name, the Hatch–Waxman Act, from its sponsors, Senator Orrin Hatch and Representative Henry Waxman.

21. H.R. REP. NO. 98-857. In addition to Congress being urged to act in recognizing and combating the anticompetitive effects, there were two other justifications put forward: “(2) The requirements of duplicative tests on humans unnecessarily endangered human health; and (3) the approval process diluted the resources of the FDA.” John C. O’Quinn, *Protecting Private Intellectual Property from Government Intrusion: Revisiting*

Waxman Act, Congress hoped, would create “incentive[s] for increased [research] expenditures” and therefore decrease drug prices by allowing for greater generic drug entry into the pharmaceutical market.²² The Act sought to make this goal a reality by amending the requirements for generic drug companies to place their products on the market, including the removal of the provision that the generic manufacturers must duplicate the brand drug’s clinical data studies on safety and effectiveness. Instead, generic drug manufacturers “may rely on the FDA’s prior findings on safety and efficacy if it can show that the generic drug is ‘bioequivalent’ to the patented drug.”²³ These amendments to the historical drug development process threatened to erode the profits of the brand-name pharmaceutical companies by giving generic drug manufacturers greater and easier access to the prescription drug market—the brand-name drug companies could no longer rely on the law to protect their market share.

The brand-name pharmaceutical companies began to look to the new regulations of the Hatch-Waxman Act to find a way to protect their profits. In this Act, the companies were able to find an opening to start using reverse-payment settlements. The specific language found in the Hatch-Waxman Act that gives rise to the opportunity for reverse-payment settlements is the requirement that the generic drug companies still file an ANDA with the FDA announcing their intent to manufacture a generic version of an existing brand-name drug. In this ANDA, the generic company must certify to the FDA that the new generic version of the drug will not infringe on the existing patent of the brand drug, or, if the generic drug *will* infringe on the brand patent, that the relevant parts of the brand patent are invalid.²⁴ The first generic firm to file a successful ANDA is “entitled, upon FDA approval, to a 180-day exclusive right to market a generic version in competition with the brand-name firm, effectively creating a duopoly during that period.”²⁵ Thus, there exists a great incentive for generic pharmaceutical companies to quickly file a challenge to the patent of the brand-name drug. After filing this generic ANDA with the FDA, the generic drug company has 20 days to notify the existing brand patent holder of their intent and support their claims of non-infringement or invalidity; the brand-name drug patent holder then in turn can challenge these declarations

SmithKline and the Case for Just Compensation, 29 PEPP. L. REV. 435, 457 (2002). Before its passage, only thirty-five percent of the best-selling drugs had generic equivalents. See Kutcher, *supra* note 5, at 1103.

22. H.R. REP. NO. 98-857, at 15; see also Kutcher, *supra* note 5.

23. Kutcher, *supra* note 5, at 1100 (citation omitted). The generic drug manufacturer must prove that: (1) the active ingredient of the patented drug and generic drug are the same; (2) the generic drug has the same “route of administration,” dosage form, and strength as the pioneer drug; and (3) the pioneer drug and generic drug have the same labeling. *Id.* at 1100–01. See also 21 U.S.C. § 355(j)(1)–(2)(A)(iv) (2006); *Guidance for Industry Bioequivalence Recommendations for Specific Products*, U.S. FOOD AND DRUG ADMIN. (2010) (providing a list of procedures and guidelines used to determine bioequivalency).

24. Kutcher, *supra* note 5, at 1101 (citing 21 U.S.C. § 355(j)(2)(A)).

25. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 634 (2009).

made by the generic drug company by suing them and having a court step in to resolve the infringement dispute.²⁶

Patent infringement litigation—like all litigation—is expensive, time-consuming, and uncertain in its outcome.²⁷ These factors provide strong motivation for the brand-name drug companies that hold the patents to search for alternative ways to resolve the dispute with the generic drug companies interested in entering the market. Due to the high cost of litigation on both sides, it is often the case that the generic drug manufacturer stands to receive more money through settlement than through successful litigation; the Hatch-Waxman Act, perhaps inadvertently, “offers great incentives for generics to file first, but not necessarily to aggressively pursue patent litigation.”²⁸ The reverse-payment settlement is one such example. After the generic company files their ANDA and notifies the brand-name manufacturer, the generic drug company is paid by the brand-name drug company to forego the patent challenge and to delay the drug’s entry into the market until the brand patent naturally (or almost) expires, thereby allowing the brand-name drug manufacturer to maintain its monopoly over production and profit.²⁹ These arrangements, unsurprisingly, have raised concern among many citizens and industry regulators as to the legality of the

26. The brand-name drug company that holds the patent for the drug has 45 days to file this patent infringement suit. If the brand-name drug company that holds the patent chooses not to sue during this time frame, the FDA may approve the ANDA on an accelerated time schedule. Kutcher, *supra* note 5, at 1101–02; *see also* 21 U.S.C. § 355(j)(5)(B)(iii).

27. Kutcher, *supra* note 5; *see also IP Litigation Costs*, WIPO MAGAZINE (Feb. 2010), available at http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2010/wipo_pub_121_2010_01.pdf (finding that the average cost through the end of suit for patent litigation was between \$3 to \$10 million); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 757 (2002) (noting there are both direct and indirect costs of patent litigation).

28. Kutcher, *supra* note 5, at 1102 (quoting Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39 (2009) (Carrier’s view is that because both the brand-name pharmaceutical company and generic drug company have the same interest to settle (thereby delaying the generic drug’s entrance into the market), these types of settlement arrangements make the antitrust harm more severe)). Not only does a brand-name pharmaceutical have billions to lose from generic competition, “generic entry hurts the brand-name firm more than it helps the generic firm. [Generic] entry lowers total producer profits by introducing price competition, particularly once other generic firms are free to enter after the 180-day period ends.” Hemphill, *supra* note 25, at 637 (noting that settling parties also offer a fundamental defense “permitting settlement increases the brand-name firm’s profit, and hence its expected reward for developing innovative drugs, the marketing of which provides great benefits to consumers.”).

29. A 2002 study conducted by the FTC found that “[d]uring the time period of the study, there were twenty final settlements of ANDA-related (Abbreviated New Drug Application) patent litigation. Fourteen of the twenty, at the time they were executed, had the potential to *delay the start* of the first generic applicant’s 180-day exclusivity.” FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION*, at vii (2002) (emphasis added). Further, the study found that “the range of brand (to generic) payments was \$1.75 million to \$132.5 million.” *Id.* at 31. Because a generic drug company already filed an ANDA, no other generic drug companies could challenge the brand drug during the 180-day period; therefore, “buying off the first filer is an effective means to remove the most potent entry threat.” Hemphill, *supra* note 25, at 635.

payments with many claiming they violate antitrust and patent laws.³⁰ In response to this concern of illegality and anti-competitiveness, circuit courts began to hear cases brought before them challenging reverse-payment settlements. However, circuit courts ended up issuing conflicting holdings.

II. EARLY REVERSE SETTLEMENT JURISPRUDENCE AND THE CIRCUIT SPLIT

Antitrust law, or competition law, is a unique set of regulations that promotes and maintains market competition by regulating anticompetitive conduct by companies. This theory of law and economics was born in the United States in 1890 when Congress passed the first antitrust law, the Sherman Antitrust Act.³¹ The Sherman Act was passed as a “comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade.”³² As such, antitrust law “maintains certain basic rules of competition as a way to preserve low prices, efficient production, and robust innovation.”³³ To interpret the appropriate application of antitrust laws, courts often employ the “rule of reason” analysis, holding that only actions and contracts that are found to unreasonably restrain trade are subject to court action and intervention.³⁴ Under this rule of reason analysis, courts believe it is very important to consider the circumstances under which the allegedly anticompetitive action is performed.³⁵

However, there are some actions taken by companies that courts recognize as *per se* illegal, regardless of circumstances, because “they result in ‘predictable and pernicious anticompetitive effects’ on competition and ‘lack any redeeming virtue.’”³⁶ In the past, courts have found activities *per se* illegal when the activity in question “facially appears to be one that would always or almost always tend to restrict

30. Congress attempted to curb the provisions of the Act from being abused by amending the Hatch-Waxman Act in 2003, with limited success. See 21 U.S.C. § 355(j)(5)(B). C. Scott Hemphill condemned the process, stating that without doubt “the consumer-disregarding effect of pay-for-delay settlements requires their condemnation as a violation of antitrust law. . . . [It] is a restraint on trade in violation of section 1 of the Sherman Act, and may also be condemned as illegal monopolization.” Hemphill, *supra* note 25, at 636 (citation omitted).

31. *The Antitrust Laws*, FED. TRADE COMM’N, <http://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> (last visited Mar. 26, 2014).

32. *Id.* Congress followed up the creation of the Sherman Act by passing the Federal Trade Commission Act, creating the FTC, and the Clayton Act, both in 1914.

33. Hemphill, *supra* note 25, at 630 (quoting MICHAEL D. WHINSTON, LECTURES ON ANTITRUST ECONOMICS 1 (2006)).

34. See *Standard Oil Co. v. United States*, 221 U.S. 1 (1911) (developing the rule of reason analysis).

35. *Id.* Some characteristics and circumstances that are often considered are “specific characteristics of the relevant business, the impact of the restraint on the condition of the business, and the history, nature, and effect of the restraint. . . .” Kutcher, *supra* note 5, at 1105.

36. Kutcher, *supra* note 5, at 1105 (quoting *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) and *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993)).

competition or decrease output.”³⁷ And once a court determines an activity is *per se* illegal, no surrounding circumstances are considered.³⁸

But antitrust law is not the only set of regulations that courts must consider when making decisions concerning reverse-payback settlements in the pharmaceutical industry—patent law issues must also be analyzed, as pharmaceutical development falls into the realm of intellectual property. The intellectual property system, at first glance, seems to be in tension with antitrust law which “fosters innovation through competition,” whereas patent law and intellectual property “promote[] innovation through ‘government-sanctioned monopolies.’”³⁹ The Patent Act itself states that “every patent shall . . . grant to the patentee . . . the right to exclude others from making, using, or selling the invention throughout the United States,”⁴⁰ which seems to run contrary to the goals promoted by antitrust law.

The spheres of antitrust law and patent law coexist harmoniously in that there is a stipulation in patent law stating that “a valid patent does not give the patent holder any exemption from the Sherman Act’s provisions, which ‘imposes strict limitations on the concerted activities in which patent owners may lawfully engage.’”⁴¹ Whether pharmaceutical companies engaging in reverse-payment settlement arrangements violate this stipulation of patent law, making the action a potential violation of the Sherman Act, is the question courts were tasked with answering.

The landmark case first holding that reverse-payment settlements do not violate antitrust laws or illegally restrain trade⁴² was heard in 2004 in the Second Circuit: *In re Tamoxifen Citrate Antitrust Litigation*.⁴³

37. *Broad. Music, Inc. v. CBS, Inc.*, 441 U.S. 1, 19–20 (1979); *see, e.g.*, *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984) (identifying horizontal price fixing as preventing competition); *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (identifying output limitations, market allocation, and group boycotts as evidence of competition restrictions).

38. Kutcher, *supra* note 5, at 1105–06 (“Classic examples of behavior subject to the *per se* rule include price fixing, group boycotts, and horizontal restraints of trade restricting prices or territories.”).

39. *Id.* at 1107 (quoting Joel Graham, *The Legality of Hatch-Waxman Pharmaceutical Settlements: Is the Terazosin Test the Proper Prescription?*, 84 WASH. U. L. REV. 429, 441 (2006)). “The U.S. Constitution grants Congress the power to enact patent legislation to advance scientific progress.” *Id.* (citing U.S. CONST. art. I, § 8, cl. 8).

40. 35 U.S.C. § 154(a)(1) (2006).

41. Kutcher, *supra* note 5, at 1107 (quoting *United States v. Singer Mfg. Co.*, 374 U.S. 174, 197 (1963)).

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

43. 466 F.3d 187 (2d Cir. 2006). There had been cases previously that were scattered in their holdings and logic. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (reasoning that the court must consider the exclusionary scope of the patent to determine whether an antitrust violation occurred); *In re Cardizem*, 332 F.3d at 915 (determining that the agreement was a horizontal market allocation device, and thus *per se* illegal); *Andrx Pharms.*, 256 F.3d at 819 (applying antitrust scrutiny

The resulting holding of the Second Circuit originated the “scope of the patent” test, which states that reverse-payment settlements are not facially anticompetitive as long as they do not restrict the generic drug’s eventual introduction to the market after a brand-name manufacturer’s patent rights expire.⁴⁴ Following the unfavorable *Tamoxifen* ruling, the FTC petitioned for certiorari from the Supreme Court, but was ultimately unsuccessful. This jurisprudence developed by the Second Circuit in *Tamoxifen* was later affirmed in proceeding cases, and eventually adopted by the Eleventh Circuit as well.⁴⁵

The Eleventh Circuit adopted the Second Circuit’s “scope of the patent test” when deciding *Schering-Plough Corp. v. FTC*⁴⁶ in 2005. The FTC challenged settlements that “Schering-Plough reached with two generic manufacturers that filed applications to make versions of the drug K-Dur, a potassium chloride supplement used to treat side effects from blood pressure medication.”⁴⁷ And so, in agreement with the Second Circuit’s *Tamoxifen* holding, the Eleventh Circuit held that the reverse-payment settlements were permissible “because they didn’t exceed the scope of Schering’s patent.”⁴⁸ This case did not die with the Eleventh Circuit’s holding, however. Additional antitrust litigation suits were filed by several pharmacies and a class of consumers on the basis that, because the generics were even somewhat delayed in their entrance to the market, they as retailers and consumers were being forced to pay higher brand-name prices. Although the case was originally tossed out of court, the parties made a subsequent successful appeal to the Third Circuit.⁴⁹ The Third Circuit heard the *Schering-Plough* settlement litigation in the case of *In re K-Dur Antitrust Litigation*.⁵⁰

The holding⁵¹ of *In re K-Dur* in the Third Circuit was unexpected by the pharmaceutical drug community and had far reaching implications for the future of reverse-payment litigation. The Third Circuit reviewed the same settlement arrangement that the Eleventh Circuit had considered in *Schering-Plough* but reached the opposite conclusion.⁵² The Third Circuit court held that:

to find that the agreement constituted prima facie evidence of an unreasonable restraint of trade).

44. See *Tamoxifen*, 466 F.3d at 213; see also Alison Frankel, *3rd Circuit Shocker: Pay-for-Delay Drug Settlements are Illegal*, REUTERS (July 17, 2012, 4:28 PM), <http://blogs.reuters.com/alison-frankel/2012/07/17/3rd-circuit-shocker-pay-for-delay-drug-settlements-are-illegal/>.

45. See Frankel, *supra* note 44.

46. 402 F.3d 1056 (11th Cir. 2005).

47. Frankel, *supra* note 44 (“The FTC claimed the settlements were an illegal restraint of trade that improperly preserved Schering’s monopoly on the drug.”).

48. *Id.*

49. *Id.*

50. 686 F.3d 197, 214–18 (3d Cir. 2012).

51. Written by Third Circuit Judge Dolores Sloviter for a panel that also included Judge Thomas Vanaskie and District Court Judge Lawrence Stengel, sitting by designation.

52. Kutcher, *supra* note 5, at 1123–27.

After consideration of the arguments of counsel, the conflicting decisions in the other circuits . . . and our own reading, we cannot agree with those courts that apply the scope of the patent test. In our view, that test improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.⁵³

The Third Circuit held that the reverse-payment settlements should be subject to a higher level of scrutiny under antitrust laws, siding with the FTC.⁵⁴ The reasoning behind this opinion was that reverse-payment deals permit even weak brand-name patents to confer monopoly rights, as any generic drug with a legitimate challenge would simply be paid off to drop the challenge, which is contrary to public policy.⁵⁵ Instead of placing a high level of emphasis on the potential costs to pharmaceutical companies if these settlements were outlawed, the Third Circuit focused more heavily on the cost of reverse-payment settlements to consumers.⁵⁶

In its holding, the Third Circuit went a step beyond merely invalidating the “scope of the patent” test⁵⁷ used in the Second and Eleventh Circuits. The Third Circuit proposed a new antitrust test for district courts to use when they were confronted with issues of reverse-payment settlements and broke this new test down into three considerations for lower courts to follow:

1. The court need not review the merits of the underlying patent infringement suit,⁵⁸

53. *In re K-Dur*, 686 F.3d at 214. This holding was perhaps bolstered by the Obama Administration proposing a ban on anticompetitive settlements in the 2009 annual budget proposal and stating their support of the FTC’s mission, “[t]he Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand-name and generic drug manufacturers intended to keep generic drugs off the market.” OFFICE OF MGMT. & BUDGET, A NEW ERA OF RESPONSIBILITY: RENEWING AMERICA’S PROMISE 28 (2009), available at http://www.whitehouse.gov/sites/default/files/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf.

54. See *In re K-Dur*, 686 F.3d at 214–18.

55. See *id.* at 216–17 (“Reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid. . . . [W]hile such a rule might be good policy from the perspective of name brand and generic pharmaceutical producers, it is bad policy from the perspective of the consumer, precisely the constituency Congress was seeking to protect.”); Kutcher, *supra* note 5, at 1125 (“In reality, allowing reverse-payment settlements does not reward patent holders based on the strength of their patents, but rather, on the ‘strength of [their] wallets.’” (quoting *K-Dur*, 686 F.3d at 217)).

56. See Kutcher, *supra* note 5, at 1121–27 (comparing *In re K-Dur*, 686 F.3d at 208 (focusing on the cost of reverse payments to the public), with *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (emphasizing the public policy in favor of settlements)).

57. The Third Circuit saw this scope of the patent test as creating an “almost un rebuttable presumption of patent validity.” *In re K-Dur*, 686 F.3d at 214.

58. The court and the FTC generally agree that an analysis of the validity of the underlying patent is unnecessary. The FTC has made clear that an analysis of patent validity would be inappropriate stating that:

2. The patent holder may attempt to rebut plaintiff's prima facie case of an unreasonable restraint of trade by demonstrating that there was no reverse payment because the settlement amount was consideration for something other than a delay in market entry, and/or

3. The patent holder may argue that the reverse-payment offers a competitive benefit that could not have been achieved without a reverse payment.⁵⁹

As shown in the Third Circuit's breakout of how cases should be decided going forward, this circuit's judiciary believed that courts should begin with the principle that reverse-payment settlements are an unreasonable restraint on trade and then shift the burden of proof onto the pharmaceutical companies, forcing the brand-name drug manufacturer to prove that the settlement, which delays the generic drug's entrance into the market, serves a secondary or competitive purpose.⁶⁰ The court decided against applying the "scope of the patent" test developed and applied in other circuits, "holding that it both fails to subject reverse payment settlements to antitrust scrutiny and ignores the policies underlying the Hatch-Waxman Act."⁶¹ Having reviewed the same Eleventh Circuit *Schering-Plough* settlement, the Third Circuit's holding in *In re K-Dur* directly contradicted the previous holding by the Eleventh Circuit, creating a circuit split that many saw as ripe for Supreme Court review.⁶²

[a]n after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

In re Schering-Plough Corp., 136 F.T.C. 956, 997 (2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005); *see also* Kutcher, *supra* note 5.

59. Kutcher, *supra* note 5, at 1126–27.

60. *Id.* at 1138.

61. *Id.* at 1124

The court explained that the scope of the patent test created an 'almost un rebuttable presumption of patent validity,' which presupposed the issue in the patent suit. The Third Circuit observed that when a court presumes that patent validity extends to the patent holder's ability to exclude competitors from the market, it forgets that the presumption of patent validity is a procedural device, rather than a substantive conclusion. 'The presumption, like all legal presumptions, is a procedural device, not substantive law.'

Id. (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983)). Perhaps most tellingly, the court cited an FTC study showing that generic challengers prevailed seventy-three percent of the time in Hatch-Waxman challenges. *See* Kutcher, *supra* note 5; *In re K-Dur*, 686 F.3d at 215 (citing FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION*, at 16 (2002)); Kimberly A. Moore, *Judges, Juries, and Patent Cases - An Empirical Peek inside the Black Box*, 99 MICH. L. REV. 365, 385 (2000) (reporting that alleged infringers prevailed in forty-two percent of patent cases that reached trial from 1983 to 1999).

62. Including FTC Chairman Jon Leibowitz, who expressed the need for Supreme Court review in his address at the Sixth Annual Georgetown Law Global Antitrust

III. REVERSE-PAYMENT SETTLEMENTS IN THE SUPREME COURT

The reverse-payment settlement case that was eventually heard and resolved in the Supreme Court, *FTC v. Watson Pharmaceuticals*,⁶³ originated in the Eleventh Circuit. Respondent, Solvay Pharmaceuticals, had received a patent in 2003 for its approved brand-name drug, AndroGel, used for treating low testosterone levels in men.⁶⁴ Later that same year, two generic drug companies, Watson Pharmaceuticals (now Actavis) and Paddock, filed patents for generic drugs closely modeled after AndroGel.⁶⁵ To block this generic drug from coming to the market, greatly decreasing the potential profits of Solvay, Solvay filed a patent infringement suit against Actavis and Paddock. After three years of preliminary patent litigation, the FDA cleared the way for Actavis' generic version of AndroGel to enter the market.⁶⁶

Despite having obtained FDA approval to continue with the development, creation, and distribution of its generic drug, Actavis decided to enter into a reverse-payment settlement with Solvay Pharmaceuticals in 2006.⁶⁷ Under the terms of this settlement agreement, Actavis was "granted a license to launch their generic AndroGel products starting in August 2015—five years before the [Solvay] patent was set to expire."⁶⁸ In return for Actavis agreeing to delay their entry into the pharmaceutical market, "Solvay agreed to pay . . . \$10 million per year for six years . . . [and] share a portion of its AndroGel profits with [Actavis]."⁶⁹

As required by law, these payments and settlement provisions were reported to the FTC, which is how the regulatory agency became alerted to the existence of the highly lucrative reverse-payment arrangement between Solvay and Actavis. After being notified of the settlement and reviewing the agreed-upon arrangements, the FTC filed an anti-

Enforcement Symposium. Jon Leibowitz, Chairman, Federal Trade Comm'n, Remarks at the Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium (Sept. 19, 2012), available at <http://www.ftc.gov/public-statements/2012/09/remarks-ftc-chairman-jon-leibowitz-prepared-delivery>; Edward Wyatt, *Justices to Take Up Generic Drug Case*, N.Y. TIMES, Dec. 7, 2012, at B1, available at http://www.nytimes.com/2012/12/08/business/justices-to-take-up-generic-drug-case.html?_r=0 (discussing the Supreme Court's decision to hear the pay-for-delay case and its importance to the industry and U.S. consumers).

63. 677 F.3d 1298 (11th Cir. 2012), cert. granted, 133 S. Ct. 787 (2012), and rev'd and remanded sub nom. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

64. Solvay Pharmaceuticals, Inc., DRUGS.COM, <http://www.drugs.com/manufacturer/solvay-pharmaceuticals-inc-132.html> (last visited Mar. 26, 2014). This patent Solvay had for AndroGel would last until 2020. David Tellekson & Melanie L. Mayer, *United States: Supreme Court Rules on "Reverse Payment" Settlements in Federal Trade Commission v. Actavis, Inc.*, MONDAQ, (June 18, 2013), <http://www.mondaq.com/unitedstates/x/245708/trials+appeals+compensation/Supreme+Court+Rules+On+Reverse+Payment+Settlements+In+Federal+Trade+Commission+v+Actavis+Inc>.

65. Denniston, *supra* note 10.

66. *Id.*

67. *Id.*

68. Tellekson & Mayer, *supra* note 64. Actavis also agreed to promote branded AndroGel to urologists and work with Par/Paddock to provide back-up manufacturing capabilities for the branded AndroGel product.

69. *Id.* Solvay projected these payments would total between \$19 million and \$30 million per year.

trust lawsuit against Solvay and Actavis.⁷⁰ In the complaint, the FTC alleged that “the settlement agreements were unlawful agreements not to compete.”⁷¹ Additionally, the FTC claimed that Solvay and Actavis entered into these agreements in order to “defer generic competition for the branded AndroGel product by postponing the entry date of the generic drugs, which maintained Solvay’s monopoly and allowed the parties to share those monopoly profits at the expense of consumers.”⁷² Arguments and motions were heard in the Georgia district court beginning in 2004.

Despite the FTC’s stated grounds for a claim, the district court granted Solvay’s motion to dismiss the complaint, citing the fact that the court believed the higher Eleventh Circuit precedent “immunized reverse payment settlement agreements from antitrust attack unless a settlement imposes an exclusion greater than that contained in the patent at issue.”⁷³ The FTC, in their complaint filed against Solvay, failed to allege that the settlement agreement between Solvay and Actavis exceeded the scope of the AndroGel patent.⁷⁴ The FTC appealed the Georgia district court’s decision to the Eleventh Circuit appeals court, but the Eleventh Circuit affirmed the lower court’s dismissal because the settlement between the companies passed the “scope of the patent” test.⁷⁵ This was not the end of the case, as it provided an opportunity for the issue of reverse-payment settlements to be heard in the Supreme Court. *FTC v. Actavis, Inc.* was granted certiorari to be heard by the Supreme Court for a resolution of the circuit split.

At the conclusion of oral arguments, the Supreme Court handed down a 5-3 decision reversing the Eleventh Circuit ruling that antitrust laws would only apply to patent holders if they acted outside the scope of their patent monopoly.⁷⁶ The Court majority opinion, written by Justice Stephen G. Breyer, held that the question if the patent violated antitrust laws must be decided by measuring the anticompetitive effect on patent law policy and also by measuring against “procompetitive”

70. *Id.*

71. *Id.* This, the FTC claimed, was in violation of antitrust laws and Section 5(a) of the Federal Trade Commission Act.

72. *Id.* (“The FTC’s claim was based on the FTC’s allegation that Solvay would have lost the underlying patent litigation and the [AndroGel] patent would therefore not have barred the generic manufacturers from bringing their generic AndroGel products to market.”).

73. *Id.* (citing *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010)).

74. Tellekson, *supra* note 64 (“Indeed, the settlement agreements provided that the generic manufacturers could market generic AndroGel five years before the . . . patent was set to expire.”).

75. *Id.* (quoting *FTC v. Watson Pharms.*, 677 F.3d 1298 (11th Cir. 2012)). The settlement passed the test in that the FTC had not alleged that the patent infringement litigation was sham litigation, that the AndroGel patent was obtained by fraud, or that any anticompetitive effects of the settlement agreements were outside the scope of the exclusionary potential of the patent.

76. Denniston, *supra* note 10 (The Supreme Court overturned the result of the 11th Circuit ruling. The Court “did not rule for the FTC on the legality of this arrangement, but rather returned the case to set up an actual trial at which the FTC will have to prove its claims of illegality.”).

antitrust law policies.⁷⁷ In the view of the Supreme Court majority, reverse-payment settlements “can sometimes violate the antitrust laws.”⁷⁸ In its holding, the Court refused to take the hardline stance advocated by the FTC (presuming all reverse-payments are unlawful) and also refused to take the position the dissent and pharmaceutical company backed (that such agreements are not subject to antitrust scrutiny unless they involve sham litigation or a patent obtained through fraud).⁷⁹ Justice Breyer’s majority opinion “criticized the Eleventh Circuit’s (and the dissent’s) promotion of the patent laws’ goal of encouraging innovation over the competing antitrust laws’ intent to promote unrestricted competition.”⁸⁰

The Supreme Court majority, instead of completely siding with either side of the argument, developed a middle ground approach similar to the holding of the Third Circuit. The Court held that when a reverse-payment settlement agreement is legally challenged, the reviewing court must evaluate the agreement under a “rule of reason” analysis.⁸¹ The rule of reason analysis developed by the Supreme Court majority, common in antitrust litigation, is a test in which “the complaining party must prove that the anticompetitive effects resulting from the allegedly wrongful conduct outweigh any pro-competitive benefits associated with the same conduct.”⁸² This is a new style of antitrust lawsuit that the Court is promoting in their decision, with Justice Breyer, writing for the majority, making it clear that “the mere fact that the generic was being held off only during the remaining period of a patent’s validity was not enough to make such a payoff immune to antitrust lawsuit.”⁸³

77. *Id.*

78. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2225 (2013).

79. *Reverse Payment Settlements in Jeopardy Following Supreme Court Ruling in FTC v. Actavis*, FISH & RICHARDSON (June 19, 2013), <http://www.fr.com/FTC-Actavis-Reverse-Payment-Settlement/>.

80. *Id.* See Kutcher, *supra* note 5, at 1124 (citations omitted) (The Court looked to previously offered “empirical and legal support for the public interest in judicial testing and eliminating weak patents.”); *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 100–01 (1993) (noting both the public policy in resolving questions of patent validity and the danger of granting monopoly privileges to the holders of invalid patents). Additionally, “patent laws embody a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.” Kutcher, *supra* note 5, at 1124 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989)). Indeed, the Supreme Court has noted that a patent “affords no immunity for a monopoly not fairly or plainly within the grant.” *Id.* (quoting *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942)). And finally, the Court agrees with the Third Circuit finding that “It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.” *Id.* (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

81. FISH & RICHARDSON, *supra* note 79.

82. *Id.* The rule of reason analysis is notorious among antitrust practitioners (and litigants) for its fact-intensive nature and overall complexity, both of which increase litigation costs.

83. Denniston, *supra* note 10.

With this holding, the majority decided to invalidate the jurisprudence laid out by the Eleventh Circuit below because it saw that “the Eleventh Circuit’s decision ‘throws the baby out with the bath water’ by sacrificing the pro-competition policies underlying the antitrust laws because of the difficulties associated with conducting a rule-of-reason analysis.”⁸⁴ The majority opinion provided five rationales for this conclusion reached in the decision:

- (1) reverse-payment settlements risk “significant” anticompetitive effects;
- (2) those anticompetitive effects can be unjustified;
- (3) based on the magnitude of some payments, the party making the payments likely has power to quell competition;
- (4) the administrative burden associated with resolving these cases is less onerous than feared, because “it is normally not necessary to litigate patent validity to answer the antitrust question”; and
- (5) possible antitrust liability for “large, unjustified” reverse payments does not discourage parties from entering into legitimate settlements of litigation.⁸⁵

It can be seen through the application of these five rationales and the broader holding of the Supreme Court that it saw the Second, Eleventh, and Federal Circuits improperly interpreted the presumption of patent validity.⁸⁶ *FTC v. Actavis, Inc.* was reversed and remanded to the Eleventh Circuit to be reconsidered by the court in light of the new Supreme Court jurisprudence.⁸⁷

84. *Id.* (quoting *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013)).

85. *Id.*

86. Kutcher, *supra* note 5; see *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (“In the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (“Unless and until the patent is shown to have been procured by fraud, or a suit of its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.”); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (finding reverse payments legal because they did not exceed the patents); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308, 1311 (11th Cir. 2003) (instructing the district court to consider the scope of the patent and whether the agreements exceeded the scope).

87. Many scholars in the pharmaceutical development community, including Kutcher in her article, advocated this eventual outcome reached by the Supreme Court. She writes: “[T]he Supreme Court should further outline specific factors for lower federal courts to consider when evaluating the antitrust defendants’ rebuttal” and “[b]ecause fully analyzing patent validity would be overly burdensome and potentially unreliable, allowing antitrust defendants to present evidence of the patent’s validity offers a suitable middle-ground approach.” Kutcher, *supra* note 5, at 1145, 1148. Kutcher was not alone in this view; see Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 76 (2009) (proposing these rebuttal options for antitrust defendants). This approach is what the Supreme Court used when developing its opinion. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

IV. POLICY CONSIDERATIONS AND THE NEW REVERSE PAYMENT LANDSCAPE

There are many ethical and policy considerations that set the scene for the Supreme Court decision that, while not completely outlawing reverse payment settlements, is seen as more favorable to the settlement challengers. After all, it is true that reverse-payment settlements merely transfer “wealth from consumers to drug makers, in the form of continued high pharmaceutical prices, with brand-name firms sharing a portion of that transfer with the generic firm.”⁸⁸ Additionally, high pharmaceutical drug costs force consumers and insurance providers to “adjust purchasing decisions, which also contributes to consumer welfare loss.”⁸⁹

These higher pharmaceutical costs are not a harmless facet of the health care industry, and with the ruling in *FTC v. Actavis*, the Supreme Court recognized this fact. David Balto, a former Federal Trade Commission policy director, described *Actavis* as “the health care reform case of 2013” and said that “[t]here’s no other case that can have as much impact on reducing health care costs.”⁹⁰ The Congressional Budget Office estimates that generic drugs save consumers an estimated “\$8 to \$10 billion a year at retail pharmacies”⁹¹ and with greater availability of generics, savings would be even higher. According to the FDA, prescription drug “consumers who are able to replace all their brand-name drugs with generics can save up to 52% on their daily drug costs.”⁹²

These potential savings would have a great impact on the lives of Americans. Overall, Americans spent \$325.8 billion on prescription

88. Kutcher, *supra* note 5, at 1131 (quoting Hemphill, *supra* note 25, at 636).

89. Hemphill, *supra* note 25, at 636. Hemphill goes on to explain that [i]n an ordinary market, setting a price above marginal cost produces an allocative distortion and accompanying welfare loss for consumers, because consumers who value the good above its marginal cost, but below the prevailing price, are deflected to less desired substitutes. To the extent that public and private insurance secures the purchase of a drug, this distortion is reduced, though it is not eliminated (as insurance is incomplete). Moreover, the higher price produces new distortions (and hence inefficiency) in the decision-making process of the insurance provider, through decisions to charge higher premiums and not to reimburse drugs whose value exceeds their marginal cost. In a similar manner, the existence of incomplete insurance affects the assessment of the size of the transfer.

Id. at 636 n.21; see also Raymond Gibbons, M.D., Jeffrey Korsmo & Roshelle Plutowski, *Payment Changes Necessary to Catalyze Higher-Quality, Lower Care Cost*, 25 NOTRE DAME J.L. ETHICS & PUB. POL’Y 393 (2011).

90. Brett Norman, *Supreme Court Takes Up Case on Generic Drugs*, POLITICOPRO (Dec. 10, 2012, 4:29 AM), <http://www.politico.com/story/2012/12/supreme-court-generic-drugs-pay-for-delay-84810.html?hp=r6>.

91. *Generic Drugs: Same Medicine, Lower Cost*, U.S. FOOD & DRUG ADMIN., (Feb. 2013) at 2, <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM340458.pdf>.

92. Timothy P. Colligan, *Generic Drugs: A Smart Way to Reduce Healthcare Costs*, OPTIMAHEALTH, <http://www.optimahealth.com/wellnesspayoff/sitesources/Generic-Drugs-Colligan.pdf> (last visited March 26, 2014).

drugs in 2012⁹³ and, according to the IMS Institute for Healthcare Informatics' director of research, Michael Kleinrock, many Americans are skipping out on their prescriptions because they are struggling to afford all of their medical costs and are therefore being forced to ration their health care.⁹⁴ But this rationing does not seem to be reflected in the profits of large pharmaceutical companies: the eleven largest drug companies' profits have been climbing over the past eight years, with those companies earning approximately \$85 billion in 2012.⁹⁵ There is a disconnect in the pharmaceutical drug industry between manufacturer and customer, and many see *Actavis* as a case that may play a part in shifting the tide.

Preventing large companies from taking advantage of consumers through the creation of anticompetitive arrangements is precisely what antitrust laws were designed to prevent. The Sherman Act, the landmark antitrust act, was created with the purpose to "preserve[] the fundamental rules of competition to protect and encourage lower prices, spark innovation, and maintain efficient industry production."⁹⁶ By the Supreme Court acknowledging that reverse-payment settlements sometimes harm consumers, they have further opened the dialogue on ethical health care spending and consumer access.

The impact of the Supreme Court decision is enhanced due to the fact that reverse-payment settlements⁹⁷ made by brand pharmaceutical companies to generic pharmaceutical companies are not a rare occurrence with minimal impact.⁹⁸ It is true that the Hatch-Waxman Act has increased generic drug entry into the market. Generic drugs now com-

93. Tara Culp-Ressler, *Prescription Drug Spending Drops As Struggling Americans Are Forced To Cut Back On Health Care*, THINKPROGRESS (May 10, 2013, 6:08 PM), <http://thinkprogress.org/health/2013/05/10/1993841/prescription-drug-spending-drops/>.

94. *Id.* ("IMS found affordability of health care remains a big problem for many Americans, with growing out-of-pocket costs forcing people to go without needed doctor visits, medicines and other treatments. One out of every five Americans has asked their doctor to prescribe a cheaper medication in order to lower their prescription costs . . .").

95. *Id.*

96. Kutcher, *supra* note 5, at 1104; *see also* The Sherman Antitrust Act, 15 U.S.C. § 1 (2006) ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.").

97. *See* Hemphill, *supra* note 25, at 632 ("Whereas early settlements simply traded cash for delay, modern settlements show sophistication in the means by which payment and delay are provided. One example is the use of side deals, consummated at the same time as settlement of the patent litigation, in which the generic firm contributes unrelated value, such as a separate patent license, ostensibly in exchange for payment.").

98. *See* Kevin D. McDonald et al., *United States: Antitrust Alert: New FTC Pharma Patent Litigation Report Finds Increase in "Reverse Payment" Settlements Based on Expanded Definition of "Payments"*, MONDAQ, <http://www.mondaq.com/unitedstates/x/221012/Antitrust+vCompetition/Antitrust+Alert+New+FTC+Pharma+Patent+Litigation+Report+Finds+Increase+In+Reverse+Payment+Settlements+Based+On+Expanded+vDefinition+Of+Payments>.

The FTC's current definition of "payment"—meaning "some form of compensation" or any "valuable thing"—could include every type of consideration available in a patent-litigation settlement, such as allowing an early entry date, a low royalty to the patent-holder, a beneficial field of use restriction, or a compromise on a damages claim—as well as paying cash or providing an exclusive license.

prise 47% of the total number of drugs prescribed, up 19% since the passage of the Hatch-Waxman Act in 1984.⁹⁹

Despite this increase, prior to the *Actavis* ruling, the number of generic drugs available to the consumer was often being artificially suppressed through the employment of reverse-payment settlements: “In Fiscal Year (FY) 2012, the number of potentially anticompetitive patent dispute settlements between branded and generic drug companies increased significantly compared with FY 2011, jumping from 28 to 40.”¹⁰⁰ FTC Chairman Jon Leibowitz weighed in on this, stating, “[s]adly, this year’s report makes it clear that the problem of pay-for-delay is getting worse, not better.”¹⁰¹ Chairman Leibowitz went on to say that “[m]ore and more brand and generic drug companies are engaging in these sweetheart deals, and consumers continue to pay the price. Until this issue is resolved, we will all suffer the consequences of delayed generic entry—higher prices for consumers, businesses, and the U.S. taxpayer.”¹⁰²

The cost savings from brand-name pharmaceuticals to generic drugs is astounding; generic drugs typically cost 85% less than brand-name drugs.¹⁰³ Not only does this increased cost affect the individual, but it also affects the government and businesses. The FTC found that “[b]y delaying the entry of cheaper generics, pay-for-delay deals cost Americans \$3.5 billion annually and will add to the federal deficit.” This was echoed by a report from the Congressional Budget Office that estimated “legislation restricting these agreements would reduce the debt by almost \$5 billion over the next decade.”¹⁰⁴ High and increasing prescription drug expenditures create “an unsustainable burden on America’s economy, with far-reaching consequences,” according to a Commonwealth Fund report.¹⁰⁵ This economic burden trickles down to American businesses providing health insurance plans, making them “less competitive internationally” and restricting “resources to invest in

99. GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION, *supra* note 29.

100. Press Release, Federal Trade Commission, FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market (Jan. 17, 2013), <http://www.ftc.gov/news-events/press-releases/2013/01/ftc-study-fy-2012-branded-drug-firms-significantly-increased>.

101. *Id.*

102. *Id.* (“Generic drugs are the key to making medicines affordable for millions of American consumers, and help hold down costs for taxpayer-funded health programs such as Medicare and Medicaid.”).

103. *Id.*

104. *Id.*; see also C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1553 (2006) (explaining the antitrust implications of reverse-payment settlements); Marcy L. Lobanoff, Comment, *Anti-Competitive Agreements Cloaked as “Settlements” Thwart the Purpose of the Hatch-Waxman Act*, 50 EMORY L.J. 1331, 1338 (2001) (“[P]ioneer brand-name drug companies are paying generic drug companies, which challenge the brand-name drug patents, not to compete or to delay litigation.”).

105. *What is Driving U.S. Health Care Spending? America’s Unsustainable Health Care Cost Growth*, BIPARTISAN POLICY CENTER, at 4 (Sept. 2012), <http://bipartisanpolicy.org/sites/default/files/BPC%20Health%20Care%20Cost%20Drivers%20Brief%20Sept%202012.pdf>; see also Clark C. Havighurst & Barak D. Richmand, *Who Pays? Who Benefits? Unfairness in American Health Care*, 25 NOTRE DAME J.L. ETHICS & PUB. POL’Y 493 (2011).

innovation and new technologies.”¹⁰⁶ On an individual level, the increased cost of employer-provided health insurance, due largely in part to high prescription drug cost and utilization, “contributes to the stagnation of middle class wages, because salary increases are replaced by an employer’s subsidies toward health care benefits.”¹⁰⁷ With these facts and figures as a reality in the United States, it is no wonder *Actavis* is quoted as a case with great potential impact.

Yet critics of the holding, including the dissent in the case,¹⁰⁸ raise considerations that should not be ignored. It is easy to see how many in the broader intellectual property world would be concerned, for as this Supreme Court analysis is used in the lower courts, its holding will likely grow to reach beyond reverse-payment settlements in the pharmaceuticals industry.¹⁰⁹ The majority attempted to address this concern by writing that “most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation.”¹¹⁰ Chief Justice Roberts, writing in the dissent, says this containment is “unlikely” and “fear[s] the Court’s attempt to limit its holding to the context of patent settlements under Hatch-Waxman will not long hold.”¹¹¹ This worries many in the patent law field, and with good reason. Patent law, as previously stated, serves an important and worthy purpose in balancing antitrust laws, and courts should pause before subjecting standard clauses in patent licensing agreements to greater scrutiny. As the majority stressed in the *Actavis* holding, lower courts should work to truly determine the desired balance between any potentially anticompetitive actions with potential benefits.

The second objection to the holding made in the dissent speaks to the structure of the justice system and principles of judicial economy. The dissent wrote that not only would the majority holding fail to be contained to the pharmaceutical drug industry, it “would [also] do grave harm to the entire concept that it is a good thing for lawsuits—especially expensive ones like patent fights—to be settled without trials.”¹¹² Even among reverse-payment settlements, not all such payments between pharmaceutical companies are improper or made in bad faith; a pharmaceutical company with a strong drug patent, but with “knowledge that there is always a chance it may be struck down

106. *U.S. Healthcare Costs: Report on Healthcare Spending*, MEDICAL MUTUAL, at 2, https://www.medmutual.com/~/_/media/Files/Miscellaneous%20MedMutualcom%20PDFs/U%20S%20%20Healthcare%20Costs%20Report_rvsd%20092413.ashx (last visited March 26, 2014).

107. *Id.*

108. Chief Justice Roberts filed dissenting opinion in which Justices Scalia and Thomas joined. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2238–47 (2013) (Roberts, J., dissenting).

109. Botti & Hoke, *supra* note 11 (“Both the majority and the dissent relied and shed new light on older antitrust decisions involving patents, making clear that the *Actavis* decision would apply to patent pools, cross-licensing arrangements, and more routine patent licensing decisions.”).

110. *Actavis*, 133 S. Ct. at 2227.

111. *Id.* at 2243.

112. Denniston, *supra* note 10.

and . . . that even winning a patent case costs lots of money, may be willing to make a modest payment to gain several years of peace and profits.”¹¹³

It is important to remember when considering reverse settlement payments, that the majority opinion did not hold that all such settlements are *per se* illegal. The Court merely confirmed that such arrangements are subject to antitrust laws and instructed the lower courts “to test whether [the settlements] are or are not harmful to competition.”¹¹⁴ A settlement is deemed harmful to competition, according to the majority, when the payments are “large and unjustified.”¹¹⁵ Although some criticize this bar to be too amorphous and undefined,¹¹⁶ the uncertainty inherent in judicial balancing tests will undoubtedly make pharmaceutical companies think twice before engaging in a bad-faith reverse-payment settlement to protect a weak patent. The progress that has come from this opinion is undeniable, and groups are already using this holding as a springboard for further prescription drug and ethical health care dialogue.¹¹⁷

V. CONCLUSION

It remains to be seen if the Supreme Court holding in *FTC v. Actavis, Inc.* has any effect on decreasing the numbers of reverse-payment settlements. Further, it would be even longer until anyone could estimate the impact the decreased number of reverse-payment settlements would have on the price and utilization of prescription drugs. But it is undeniable that the pharmaceutical industry is a large player in the overall health care system in the United States, and that this health care system can always improve. With nearly 70% of Americans utilizing at least one prescription drug,¹¹⁸ it should be no surprise that this issue was front and center in the judiciary when *FTC v. Actavis, Inc.* made its way to the Supreme Court in 2012.

It is important for domestic health care policy to encourage drug innovation and improvement with an emphasis on the development of safer and more effective pharmaceuticals with a range of treatment objectives. Although it is a reality that the goal of developing a new

113. Alan Morrison, *Commentary: Subjecting Reverse Payments in Patent Cases to Antitrust Scrutiny: Sounds Like a Good Idea, But Can It Work?*, SCOTUSBLOG (July 25, 2013, 10:23 AM), <http://www.scotusblog.com/2013/07/commentary-subjecting-reverse-payments-in-patent-cases-to-antitrust-scrutiny-sounds-like-a-good-idea-but-can-it-work/>.

114. Denniston, *supra* note 10.

115. Morrison, *supra* note 113.

116. *Id.*

117. *Id.* Some are proposing that this holding is somewhat vague and does not have a concrete path to practice. One solution would be for Congress to enact a statute that would create antitrust immunity if the district court approved the settlement as fair and reasonable, rather like the way that class actions are settled.

118. Mayo Clinic, *Nearly 7 in 10 Americans Are on Prescription Drugs*, SCIENCE DAILY (June 19, 2013), <http://www.sciencedaily.com/releases/2013/06/130619132352.htm>. Antibiotics, antidepressants and painkilling opioids are most commonly prescribed. Additionally, twenty percent of patients are on five or more prescription medications. Drugs were prescribed to both men and women across all age groups. *Id.*

successful drug is an expensive venture for pharmaceutical companies, these investments are rewarded with company profits in the billions of dollars. The goal of patent law is to encourage research, development, and innovation, and when a pharmaceutical company manages to develop a new drug, no one doubts that this innovation should be rewarded with a patent. This patent will help the pharmaceutical company recuperate the money invested in research, development, testing, and distribution; it will reward the company for its innovative idea; and it will provide an incentive for other companies to also develop new drugs.

But the reward of being granted a patent is not absolute, nor without caveat. Patents held may be challenged, and those holding the patents are still bound to respect antitrust laws spelled out in the Sherman Act. The question of whether reverse-payment settlements violate antitrust laws was decided by the Supreme Court in *FTC v. Actavis, Inc.*, healing a circuit split on the issue. The Court refused to adopt the idea that the settlements are facially anticompetitive, instead choosing an open, case-by-case approach, instructing lower courts to analyze the potential anticompetitive effects of each settlement put before them. This decision by the Supreme Court is lauded by many for its wide-ranging impact on not only the pharmaceutical industry, but also antitrust law, patent law, and health care policy goals in general.

Even without enough distance between the Supreme Court decision and today to be able to analyze the shift in prescription drug reverse-payment settlements, there are still concrete changes that have begun to manifest in the industry. As a practical matter, “[m]anufacturers of pharmaceuticals, both branded and generic, must carefully consider whether patent disputes can continue to be resolved by reverse payment settlement agreements, given the likelihood that such settlements will trigger costly litigation challenging their validity.”¹¹⁹ The FTC, now with the backing of the Supreme Court’s validation, has the power to rigorously examine under a regulatory microscope “[t]he terms of reverse payment settlement agreements, including settlement payments and collaborative research and development agreements”¹²⁰ among the pharmaceutical parties.

FTC Chairwoman Edith Ramirez summarizes the Supreme Court opinion best, stating that the decision “is a significant victory for American consumers, American taxpayers, and free markets With this finding, the Court has taken a big step toward addressing a problem that has cost Americans \$3.5 billion a year in higher drug prices.”¹²¹ As Chairwoman Ramirez states, this decision by the Supreme Court cannot be viewed only in the context of antitrust and patent law. It is important to remember that this decision has a great impact on the health

119. FISH & RICHARDSON, *supra* note 79.

120. *Id.*

121. Press Release Federal Trade Commission, Statement of FTC Chairwoman Edith Ramirez on the U.S. Supreme Court’s Decision in *FTC v. Actavis, Inc.* (June 17, 2013), <http://www.ftc.gov/news-events/press-releases/2013/06/statement-ftc-chairwoman-edith-ramirez-us-supreme-courts-decision>.

care realities of millions of Americans, and on the American economy. Thanks to the *Actavis* decision, regulatory agencies are now in a stronger position¹²² to challenge these settlements and work to protect the basic principles of a free market; for although patents should be a reward bestowed upon those who invest in innovation, they should not be an impenetrable shield against valid claims of anticompetitive activity.

122. Press Release, Federal Trade Commission, FTC: Recent Supreme Court Decision Puts Agency in Stronger Position to Protect Consumers From Anticompetitive Pay-for-Delay Drug Settlements (July 23, 2013), <http://www.ftc.gov/news-events/press-releases/2013/07/ftc-recent-supreme-court-decision-puts-agency-stronger-position>.