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Why Congress or the Supreme Court Must Take Action Opposing
Reverse Payment Settlements**

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Pay-for-Delay and Interstate Commerce: Why Congress or the Supreme Court Must Take Action Opposing Reverse Payment Settlements

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I. INTRODUCTION

A pay-for-delay drug settlement, also called a reverse payment settlement, occurs when a brand name pharmaceutical company agrees to pay the maker of a similar generic drug to delay the release

of the generic drug into the stream of commerce, thereby allowing the brand name pharmaceutical company to eliminate competition for an extended period of time.¹ These agreements allow both the brand name manufacturer and the generic manufacturer to profit immensely.² The brand name manufacturer's "prices stay high, and the brand and generic share the benefits of the brand's monopoly profits."³ These settlements cost the American public an estimated \$3.5 billion per year.⁴ Further, reverse payment settlements on average prevent generic drugs from entering the stream of commerce for an additional seventeen months.⁵ As a result, the public is missing out on generic drugs that could be up to ninety percent cheaper than the brand name version.⁶

This Comment intends to show that reverse payment settlements are unduly burdensome on interstate commerce, and thus it is within the purview of Congress to regulate these types of agreements. First, this Comment will explore the statutory framework through which pay-for-delay settlements became prominent. Next, this Comment discusses the history of pay-for-delay litigation and the underlying patent and antitrust laws that courts have focused on in making their decisions. After the necessary background is established, this Comment explores the commerce clause of the United States Constitution⁷ and argues that pay-for-delay settlements are unduly burdensome on interstate commerce, and therefore, either Congress should legalize the settlements through legislation or the Supreme Court

1. See FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1 (Jan. 2010), 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>.

2. *Id.*

3. *Id.*

4. *Id.* at 2.

5. *Id.*

6. FED. TRADE COMM'N, *supra* note 1, at 2. By keeping drug prices high, reverse payment settlements "protect at least \$20 billion in sales of brand-name pharmaceuticals from generic competition." *Id.*

7. U.S. CONST. art. 1, § 8, cl. 3. The text of the commerce clause states that "[t]he Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."

should find them unconstitutional.⁸ Finally, the possible benefits of such legislation are discussed.

II. THE HATCH-WAXMAN ACT

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, outlines the procedures that must be used by generic drug companies in order to gain Food & Drug Administration (FDA) approval and enter a new drug into the stream of commerce.⁹ Under the Hatch-Waxman Act, a generic manufacturer can file an “abbreviated new drug application”¹⁰ to attempt to enter their drug into the market prior to the expiration of brand name patents.¹¹ To gain early entry, the generic company must include in their application a certification stating that the brand name patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.”¹² If the first applicant for a new drug submits an application that contains all of the required materials, they can then receive a “180-day exclusivity period” during which other generic manufacturers of the same drug cannot market their product.¹³

8. Merck, a brand name drug manufacturer, filed a petition for certiorari on Friday, August 24, 2012, requesting that the Supreme Court review the conflict over these agreements in light of a recent Third Circuit decision. See Lyle Denniston, “*K-Dur*” Fight Reaches Court (UPDATED), SCOTUSBLOG (Aug. 24, 2012, 10:46 PM), <http://www.scotusblog.com/2012/08/k-dur-fight-reaches-court/>. Shortly thereafter, the Federal Trade Commission filed a petition for certiorari requesting that the Supreme Court review an Eleventh Circuit pay-for-delay decision. See Alison Frankel, *FTC Cert Petition Puts SCOTUS in Pay-for-Delay Pickle*, THOMSON REUTERS NEWS & INSIGHT (Oct. 8, 2012), <http://blogs.reuters.com/alison-frankel/2012/10/08/ftc-cert-petition-puts-scotus-in-pay-for-delay-pickle/>. The Supreme Court addressed the anticompetitive effects of pay-for-delay settlements in *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). This decision will be discussed later in this Comment.

9. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 (2006)).

10. 21 U.S.C. § 355(j).

11. FED. TRADE COMM’N, *supra* note 1, at 3.

12. 21 U.S.C. § 355(j)(2)(vii)(IV).

13. *Id.* § 355(j)(5)(B)(iv) (“If the application contains a certification described in subclause (IV) paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after the date . . . of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.”).

This 180-day exclusivity period paved the way for the emergence of reverse payment settlements.¹⁴ The exclusivity period gives generic drug manufacturers an incentive to file abbreviated new drug applications and challenge the validity of brand name patents in order to secure a very profitable period of time where their generic drug is the only one on the market.¹⁵ Once an application is submitted, the brand name pharmaceutical companies often “challenge the generic’s declaration, and litigation ensues between the brand-name and generic pharmaceutical manufacturers to determine whether the relevant patents are valid and infringed.”¹⁶ Rather than deal with the risks of litigation, brand name pharmaceutical companies and generic drug manufacturers then frequently agree to pay-for-delay settlements, thereby allowing the brand name company to remain the only supplier on the market and keep prices high, while also garnering for the generic manufacturer enormous profits from the settlements.¹⁷

III. UNITED STATES PATENT LAW

Patent law plays an integral role in the application of the Hatch-Waxman Act and the litigation that has occurred regarding reverse payment settlements. Under the U.S. Patent Act of 1952, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.”¹⁸ By patenting an invention, the inventor gains “the right to exclude others from profiting by the patented invention.”¹⁹ This exclusion includes the “making, using, offering for sale, or selling [of] the invention.”²⁰ The right to exclude is further protected by the ability to bring a cause of action for copyright infringement.²¹ Any unauthorized making, selling, or using of a

14. FED. TRADE COMM’N, *supra* note 1, at 3.

15. *Id.*

16. *Id.*

17. *Id.* (“Given the costs and potential uncertainty of patent litigation, brand-name and generic pharmaceutical companies sometimes settle their patent litigation before a final court decision.”).

18. 35 U.S.C. § 101 (2000).

19. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980). *See also United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) (“[T]he precise terms of the [patent] grant define the limits of a patentee’s monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise.”).

20. 35 U.S.C. § 154.

21. 35 U.S.C. § 271.

patented invention is an infringement on the patent that may result in injunctive or monetary relief for the inventor.²²

In the context of pharmaceutical companies, a drug is considered a patentable invention that grants the inventor the right to exclude.²³ Thus, under the typical reverse payment settlement scenario, a brand name pharmaceutical company attempts to preserve its right to exclude competition from profiting by the patented drug, while the generic manufacturer tries to circumvent the patent by either challenging its validity or arguing non-infringement.²⁴

IV. UNITED STATES ANTITRUST LAW

Additionally, much of the litigation regarding the pay-for-delay controversy has focused on antitrust law. Under the Sherman Antitrust Act, “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”²⁵ The Supreme Court has previously held that the standard for determining whether there is a violation of the Sherman Antitrust Act is whether the acts unreasonably restrain competition.²⁶ For example, horizontal price fixing, or the act of competing entities fixing prices at a specified level, has been found to be a per se unreasonable restraint on competition.²⁷

With regards to reverse payment settlement litigation, it is generally argued that the settlement creates an unreasonable restraint on competition by horizontal competitors forcing the generic drugs out of the market and essentially monopolizing the brand name version

22. *Id.*

23. *Id.* § 271(e)(2)(A).

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

25. 15 U.S.C. § 1 (2000).

26. *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 690 (1978) (“Unreasonableness under that test could be based either (1) on the nature or character of the contracts, or (2) on surrounding circumstances giving rise to the inference or presumption that they were intended to restrain trade and enhance prices.”). *See also State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (“Some types of restraints, however, have such predictable and anti-competitive effect, and such limited potential for precompetitive benefit, that they are deemed unlawful *per se*.”).

27. *See Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 348 (1982). The Court in *Arizona* held that setting uniform prices, setting price maximums, and setting price minimums are all per se violations of antitrust law. *Id.*

of the drug.²⁸ Judge Posner eloquently explained the typical scenario in *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*:

Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices—masks—for fixing prices, in violation of antitrust law.²⁹

V. THE TENSION BETWEEN PATENT LAW AND ANTITRUST LAW

The policy behind both patent law and antitrust law is founded in “the ultimate goal of stimulating competition and innovation.”³⁰ However, essentially opposite means are used by each of these bodies of law to achieve the same end. Antitrust law attempts to prevent business practices that unreasonably restrain trade and allow business entities to essentially monopolize markets, whereas patent law grants individuals the right to exclude others from profiting by their invention.³¹ In simpler terms, antitrust law lets external competition in while patent law keeps external competition out.³² Because these two areas of law seem to be at odds with each other, “the exclusionary power of a patent may seem incongruous with the goals of antitrust law, [and thus] a delicate balance must be drawn between the two regulatory schemes.”³³ Courts trying to sustain this “delicate balance” must be careful to recognize and protect the rights of the patent holder while also not “[extending] the patentee's monopoly beyond

28. *E.g.*, *Cardizem CD*, 332 F.3d at 908 (holding that a reverse payment settlement is essentially a horizontal agreement between drug manufacturers to reduce output and eliminate competition, thus rendering it an unreasonable restraint on trade).

29. *Asahi Glass Co. v. Pentec Pharm., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003).

30. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 201 (2d Cir. 2005).

31. *Id.* at 201-02.

32. *See id.*

33. *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1067 (11th Cir. 2005).

its statutory right to exclude.”³⁴ The interplay between these two seemingly conflicting bodies of law has been at the heart of the courts’ reasoning in every pay-for-delay case to date.³⁵

VI. RESEARCH AND DEVELOPMENT COSTS OF NEW DRUGS

Much of the motivation behind brand name drug manufacturers entering into these deals is likely to recoup some of the losses that are handed to them as a result of the massive costs of research and development of drug innovation.³⁶ In innovating new drugs, “[research and development] decisions have very long-term ramifications, and the impact of market or public policy changes may not be fully realized for many years.”³⁷ Pay-for-delay settlements fit perfectly into this trend, as the decision to enter into one of these settlements is essentially a business judgment of the drug manufacturer that is slowly causing a major shift in public policy.³⁸ In simpler terms, drug manufacturers enter into reverse payment settlements because they will allow them to keep prices high and make up for the costs lost from research and development, thereby shifting the burden of these costs onto consumers, in turn resulting in a strong public sentiment by the FTC and other groups that these settlements must be prevented.³⁹

To fully grasp the reasons behind the high costs of innovating new drugs, it is important to have a general overview of the drug development process. Generally, the process begins with the discovery phase, which “result[s] in the synthesis of compounds that are tested in assays and animal models.”⁴⁰ After discovery, human testing occurs in three phases.⁴¹ The first phase involves the testing of healthy individuals in order to gather data on “absorption, distribution, metabolic effects, excretion, and toxicity of the compound.”⁴² Phase two

34. *Id.*

35. *E.g., id.* at 1067.

36. See Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003), available at http://moglen.law.columbia.edu/twiki/pub/LawNetSoc/BahradSokhansanjFirstPaper/22JHealthEcon151_drug_development_costs_2003.pdf.

37. *Id.* at 152.

38. See *id.*

39. See *id.*

40. *Id.* at 155.

41. See DiMasi et al., *supra* note 36, at 155.

42. *Id.*

involves testing on usually hundreds of individuals with the targeted disease or condition in order to gather data on success rates and safety.⁴³ Phase three consists of large-scale testing on usually thousands of individuals in order to definitively determine the effectiveness of the drug and the possible side effects.⁴⁴ Once the testing is satisfactorily completed, the drug manufacturer can then use this data in submitting a New Drug Application.⁴⁵

Based on a 2000 study, the estimated average research and development cost per drug is \$802 million.⁴⁶ Furthermore, there is an obvious trend in the data suggesting that these numbers will continue to rise.⁴⁷ Between 1973 and 2000, “the average amount that surveyed firms reported spending on research and development of new molecular entities increased nearly sixfold in real terms.”⁴⁸ The rising costs can be attributed to six main reasons: an increase in drugs that fail human testing, longer human testing phases, more drugs “intended to treat chronic and degenerative diseases,” expensive technology involved in testing, the “commercialization of basic research,” and longer discovery periods.⁴⁹ Based on the lofty and continually rising estimates of research and development costs to drug manufacturers, it is clear that part of the motivation behind reverse payment settlements is to recoup these costs. This all leads back to the original dispute: is it fair for American citizens to shoulder the burden of these costs rather than the drug manufacturers?

VII. PAST LITIGATION FAVORING PAY-FOR-DELAY SETTLEMENTS

The vast majority of federal circuit courts have found pay-for-delay settlements to be “not presumptively anti-competitive.”⁵⁰ The

43. *Id.* at 156.

44. *Id.*

45. *Id.*

46. *See* DiMasi et al., *supra* note 36, at 180. In 1987, the same group estimated that the cost of research and development was \$231 million. *Id.* The cost today is likely even higher than the 2000 estimates due to this trend of increasing costs. *See id.*

47. *See* CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 21 (2006), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf>.

48. *Id.*

49. *Id.* at 22. It is important to also note that “faster FDA reviews, regulatory changes, and speedier methods of identifying potential R&D failures” have worked in the opposite direction to slow the rising costs. *Id.*

50. Frankel, *supra* note 8.

circuit courts have primarily decided the issue as a question of anti-trust and patent validity.⁵¹

In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, the Eleventh Circuit introduced the “scope of the patent” test into pay-for-delay litigation in upholding these types of agreements.⁵² *Valley Drug Co.* involved a successful drug developed by Abbott Laboratory, Hytrin, which is prescribed to combat hypertension and an enlarged prostate.⁵³ Geneva and Zenith, both generic drug manufacturers, filed abbreviated new drug applications in order to market their generic versions of Hytrin.⁵⁴ Patent infringement lawsuits soon followed.⁵⁵ However, prior to trial, Abbott came to an agreement with Zenith where Zenith would receive “\$3 million up front, \$3 million after three months, and \$6 million every three months thereafter until March 1, 2000” in exchange for Zenith not marketing their generic version of Hytrin for a specified period of time.⁵⁶ Additionally, Abbott entered into a similar agreement with Geneva, agreeing to pay them \$4.5 million per month to withhold their drug from the market.⁵⁷

While the court did recognize that the settlements had an exclusionary effect on the drug market, it held that Abbott’s patent granted them the right to exclude others from utilizing the drug until its expiration, and thus the reverse payment settlements were lawful.⁵⁸ This case is an excellent illustration of the massive dollar amounts involved in these agreements and the intermingling of various areas of law in analyzing their legality.

51. *Id.*

52. *See* *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003).

53. *Id.* at 1298.

54. *Id.*

55. *Id.*

56. *Id.* at 1300. Specifically, Zenith agreed not to market a generic version of the drug until Abbott’s patent expired, or until a different manufacturer introduced a generic version into the market. *Valley Drug*, 344 F.3d at 1300.

57. *Id.* Similar to the Zenith agreement, Geneva agreed not to market a generic version until a different manufacturer introduced a generic version, Abbott’s patent expired, or Geneva obtained a court judgment finding that the patent was invalid or that the Geneva’s generic did not infringe upon the patent. *Id.*

58. *Id.* at 1308. It is worth noting that one of Abbott’s patents at issue was found to be invalid prior to this court’s decision. However, this did not impact the court’s decision since “the reasonableness of agreements under the antitrust laws are [sic] to be judged at the time the agreements are entered into.” *Id.* at 1306.

The Eleventh Circuit came to a similar conclusion in *Schering-Plough Corp. v. Federal Trade Commission*, again utilizing the “scope of the patent” test.⁵⁹ In this case, Schering, a brand name manufacturer, marketed K-Dur 20, a drug used to treat high blood pressure and congestive heart disease.⁶⁰ Upsher-Smith laboratories sought to introduce Klor Con M20, a generic version of the drug.⁶¹ Schering subsequently sued for patent infringement.⁶² The day before the trial was set to begin, the companies entered into a complex settlement agreement whereby Upsher-Smith agreed not to market their generic product for a specified period of time and agreed to give Schering the licenses to five other Upsher products in exchange for millions of dollars in royalties.⁶³

The court reasoned that “[w]hat we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal.”⁶⁴ Thus, the anticompetitive effects of the settlements were permissible as a result of Schering's patent rights.⁶⁵

The Second Circuit further expanded on the “scope of the patent” test in *In re Tamoxifen Citrate Antitrust Litigation*.⁶⁶ Here, the court found that so long as the reverse payment settlement did not discourage the marketing of “non-infringing or unrelated products”

59. See *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1075 (11th Cir. 2005).

60. *Id.* at 1058.

61. *Id.*

62. *Id.* at 1059.

63. *Id.* at 1060.

64. *Schering-Plough Corp.*, 402 F.3d at 1076 (citations omitted).

65. Notwithstanding the court's holding, the court seems to have recognized that had the payments by Scherer to Upsher-Smith been made solely for the purposes of delaying the generic's entry into the market, rather than for the licenses, the settlement may have been illegal. *Id.* at 1071.

66. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 216 (2d Cir. 2005). This case involved Imperial Chemical Industries, a drug manufacturer that produced a breast cancer drug called Tamoxifen. *Id.* at 193. Four months after Imperial's patent was approved, Barr, a generic manufacturer, filed an abbreviated new drug application. *Id.* Imperial subsequently filed a patent infringement suit against Barr. *Id.* The district court found that the initial patent was invalid due to Imperial's non-disclosure of information regarding animal testing. *Id.* While an appeal was pending, the two parties entered into a reverse payment settlement whereby Barr agreed not to market its generic version until the patent expired in exchange for twenty-one million dollars and a non-exclusive license to sell Tamoxifen under Barr's label. *Tamoxifen Citrate*, 466 F.3d at 193-94.

or prevent other generic manufacturers from entering the market, there was no violation of antitrust laws.⁶⁷

The Federal Circuit also adopted the “scope of the patent” test in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.⁶⁸ The court concisely summed up the test in stating that a “settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention.”⁶⁹

As the various circuit courts have noted in their opinions upholding pay-for-delay settlements, a patentee’s right to exclude essentially shields them from antitrust scrutiny under the “scope of the patent” test.⁷⁰

VIII. PAST LITIGATION STRIKING DOWN PAY-FOR-DELAY SETTLEMENTS

In contrast to the majority of the United States Courts of Appeals, the Sixth Circuit in *In re Cardizem CD Antitrust Litigation* found that reverse payment settlements are a per se illegal restraint of trade.⁷¹ The drug at issue in this case was Cardizem CD, a drug produced by Hoechst Marion Roussel (HRM) that is used to treat angina and hypertension, as well as for prevention of heart attacks and strokes.⁷² Andrx filed an abbreviated new drug application seeking the valuable 180-day exclusivity period.⁷³ Shortly thereafter, HRM filed a patent infringement suit against Andrx, arguing that the generic version of Cardizem CD infringed upon HRM’s patent in the “dis-

67. *Id.* at 215.

68. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008). In this case, Bayer, a brand name manufacturer, owned a patent for the active ingredient in Cipro, a drug that fights bacterial illnesses. *Id.* at 1328. Barr filed an abbreviated new drug application, arguing that the patent was invalid based on the obviousness of the ingredient. *Id.* Bayer sued Barr for patent infringement, which resulted in a reverse payment settlement being entered into just before trial began. *Id.* The settlement paid Barr \$49.1 million in exchange for Barr not marketing the generic drug until after the patent expired. *Id.* at 1329. Further, “Bayer agreed to either supply Barr with Cipro for resale or make quarterly payments.” *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1329.

69. *Id.* at 1337.

70. *E.g., id.*

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

72. *Id.* at 901.

73. *Id.* at 902.

solution profile” of Cardizem CD.⁷⁴ During the course of this litigation, the FDA gave tentative approval to Andrx’s generic drug, thereby eliciting a reverse payment settlement between the parties just nine days later.⁷⁵ Under the agreement, Andrx agreed not to market their generic version of Cardizem CD until certain conditions were met in exchange for millions of dollars in payments from HRM.⁷⁶ Approximately two years after the settlement, the FDA approved Andrx’s revised abbreviated new drug application.⁷⁷ Shortly thereafter, Andrx began marketing its generic product, Cartia XT.⁷⁸ According to the court, “Cartia XT has sold for a much lower price than Cardizem CD and has captured a substantial portion of the market.”⁷⁹ The court held that there was “no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, 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.”⁸⁰ In making this determination, the court noted that the agreement not only delayed Andrx’s entry into the market, but it delayed other generic drug manufacturers from entering the market until Andrx’s 180-day exclusivity period had run, thereby stifling any possibility of competition.⁸¹

74. *Id.*

75. *Id.*

76. *In re Cardizem CD*, 332 F.3d at 902-03. The agreement specified that Andrx could not market a generic version of Cardizem CD until one of three conditions were met: the patent court determined that Andrx did not infringe on the “dissolution profile” patent owned by HRM, HRM and Andrx entered into a license agreement, or HRM entered into a license agreement with a third party. *Id.* The settlement paid Andrx \$40 million per year once they received FDA approval, and \$100 million a year after the patent litigation was either resolved in Andrx’s favor or dismissed by HRM. *Id.* at 903.

77. *Id.*

78. *Id.*

79. *In re Cardizem CD*, 332 F.3d at 903.

80. *Id.* at 907.

81. *Id.* The reverse payment settlement at issue in this case contained an agreement that Andrx would not “relinquish or transfer” the rights to their 180-day exclusivity period, thus ensuring that no other generic drug manufacturers could enter the market during this period. *Id.* In fact, Andrx brought suit against Biovail, another generic manufacturer that filed an abbreviated new drug application, seeking a clarification of its 180-day exclusivity rights and thus seeking to prevent Biovail’s drug from entering the market. *See Andrx Pharms. Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001). The D.C. Circuit Court reversed the district court’s motion to dismiss, holding that Biovail could allege an antitrust injury because Andrx’s agreement to retain their rights in the 180-day exclusivity period “could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions.” *See id.* at 811.

The court was careful to point out that profiting from the monopoly that arose from a patent was not unlawful, but rather it was the strengthening of that monopoly through payments that rendered it an unreasonable restraint on trade.⁸²

IX. THE LATEST DEVELOPMENTS

On July 16, 2012, the Third Circuit in *In re K-Dur Antitrust Litigation* found reverse payment settlements to be a violation of anti-trust laws.⁸³ This was the first time since *In re Cardizem CD Antitrust Litigation* in 2003 that a circuit court invalidated a pay-for-delay settlement.⁸⁴

In re K-Dur Antitrust Litigation involved the same set of facts as *Schering-Plough Corp. v. Federal Trade Commission*,⁸⁵ except that the lawsuit was brought on behalf of “a class of plaintiffs consisting of forty-four wholesalers and retailers who purchased K-Dur directly from Schering.”⁸⁶ In holding that reverse payment settlements were unlawful, the court expressly rejected the “scope of the patent” test.⁸⁷ The court reasoned that, when the “scope of the patent” test is applied, there is a presumption that the patent is valid and that the holder of the patent would have prevailed in the ensuing patent infringement litigation.⁸⁸ In reality, it is unknown whether the generic drugs actually infringed on the patent, and thus it becomes impossible to determine whether the pay-for-delay agreements were actually within the scope of the patent.⁸⁹ Practically speaking, “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.”⁹⁰ As a result, the consumer is hurt by higher brand name prices and a lack of generic alternatives—

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

83. *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

84. *See In re Cardizem CD*, 332 F.3d 896.

85. *See Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056 (11th Cir. 2005).

86. *In re K-Dur Antitrust Litig.*, 686 F.3d at 208.

87. *Id.* at 214.

88. *Id.*

89. *See id.* at 215. A 2002 study by the FTC showed that the generic drug manufacturers prevailed in 73% of Hatch-Waxman patent challenges that did not end in a pay-for-delay settlement. FED. TRADE COMM’N, *supra* note 1, at 3. This further calls into question whether pay-for-delay settlements are actually within the “scope of the patent.” *Id.*

90. *In re K-Dur Antitrust Litig.*, 686 F.3d at 215.

the exact opposite of what the Hatch-Waxman Act was intended to do.⁹¹ In place of the “scope of the patent” test, the Third Circuit articulated that:

[T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.⁹²

Because this decision differs drastically from the earlier precedents set by the Federal Circuits, the Supreme Court was forced to address some of these issues.⁹³

In *F.T.C. v. Actavis, Inc.*, the Supreme Court attempted to resolve a controversy involving Watson Pharmaceuticals, Paddock, and Solvay.⁹⁴ Solvay produced a form of testosterone gel, and agreed to pay twelve million dollars to Paddock and nineteen to thirty million dollars annually to Watson for nine years in exchange for Paddock and Watson delaying the release of their generic testosterone gel into the stream of commerce.⁹⁵ The FTC filed a complaint, alleging that Solvay violated antitrust law 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.’”⁹⁶ The district court dismissed the lawsuit, and the Eleventh Circuit affirmed the dismissal.⁹⁷

91. *Id.* at 217. The court notes that the Hatch-Waxman Act intended challenges of patents by generic manufacturers to result in increased competition and, in turn, lower priced generic drug options for the consumer. *Id.*

92. *Id.* at 218. The court foresaw that it would be rare for a reverse payment settlement to have a pro-competitive benefit. *See id.* One example the court offered is if a “modest” settlement allows a near-bankrupt generic drug manufacturer to stay in business and eventually market a generic drug, thereby increasing competition. *In re K-Dur Antitrust Litig.*, 686 F.3d at 218.

93. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013) (“Because different courts have reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlements, we granted the FTC’s petition.”). *See Frankel, supra* note 8.

94. *Actavis*, 133 S. Ct. 2223.

95. *Id.* at 2229.

96. *Id.* at 2230.

97. *Id.* at 2225.

The Supreme Court disagreed and held, in a five-to-three decision, that the FTC should have had the opportunity to prove their antitrust claim.⁹⁸ The Court articulated five main reasons for their decision. First, despite recognizing the value of promoting settlements, the Court found that reverse payment settlements have “potential for genuine adverse effects on competition.”⁹⁹ The Court noted that a reverse payment settlement, as discussed earlier, allows the brand name manufacturer and the generic manufacturer to profit, while the consumer loses. Second, the Court found that the anticompetitive settlements will not always be justified.¹⁰⁰ In some cases, the payments may be compensation for other services that the generic manufacturer has agreed to provide for the brand name manufacturer, including distribution of the patented item. However, these justifications will not always be present, and a plaintiff should be allowed an opportunity to prove its case.¹⁰¹ Third, the Court found that when there is a reverse payment settlement in place, the brand name manufacturer likely will have the power to charge prices higher than the competitive level, damaging consumers.¹⁰² Fourth, “an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed,” with an “unexplained large reverse payment itself . . . normally suggest[ing] that the patentee has serious doubts about the patent’s survival.”¹⁰³ Fifth, the Court noted that despite the risk of antitrust liability involved with a reverse payment settlement, parties can still settle their lawsuits for reasons other than “maintain[ing] and . . . shar[ing] patent-generated monopoly profits.”¹⁰⁴

In support of the Supreme Court’s view that Solvay’s claim should not have been dismissed, the Court held that district courts should follow the “Rule of Reason” test in reverse payment settlement cases.¹⁰⁵

98. *Id.*

99. *Actavis*, 133 S. Ct. at 2234 (citing *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 460-61 (2009)).

100. *Id.* at 2236.

101. *Id.*

102. *Id.* The Court cited studies showing that “reverse payment agreements are associated with the presence of higher-than-competitive profits—a strong indication of market power.” *Id.*

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

104. *Id.*

105. *Id.*

[T]he inquiry mandated by the Rule of Reason is whether the challenged agreement is one that promotes competition or one that suppresses competition. “The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.”¹⁰⁶

Thus, district courts must weigh all the circumstances and determine if the plaintiff has proven that a reverse payment settlement is destroying competition.¹⁰⁷

While the Supreme Court took a big step in finding that pay-for-delay settlements may come with anticompetitive effects, the Court failed to outlaw these settlements altogether. Furthermore, the Supreme Court did not address the commerce clause issues surrounding these settlements.¹⁰⁸

X. THE BURDEN OF PAY-FOR-DELAY SETTLEMENTS ON INTERSTATE COMMERCE

A. THE COMMERCE CLAUSE

The United States Constitution states that “[t]he Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.”¹⁰⁹ The Framers’ original intention of the commerce power was to control animosity between the states, such as “hostile state restrictions, retaliatory trade regulations, and protective tariffs on bank imports from other states.”¹¹⁰ By controlling retaliation and hostility between the states, the Framers hoped to create a more cohesive national economy, rather than just a collection of individual state markets.¹¹¹

106. *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 691 (1978) (citing *Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (1918)).

107. *See Actavis*, 133 S. Ct. at 2238. The plaintiff need not show that the settlement was unfair or unlawful, only whether it suppresses competition. The Court noted that these settlements need to be evaluated on a case-by-case basis and that there is a sliding scale in assessing reasonableness of a settlement. *Id.* at 2237-39.

108. *Id.*

109. U.S. CONST. art. I, § 8, cl. 3.

110. KATHLEEN M. SULLIVAN & GERALD GUNTHER, *CONSTITUTIONAL LAW* 82 (Robert C. Clark et al. eds., 17th ed. 2010).

111. *See id.*

Since its inception, interpretations of the commerce clause have varied greatly. The early courts often invalidated congressional action and deferred to the authority of the individual states, whereas courts after 1937 tended to give Congress great freedom in crafting laws that regulated national commerce.¹¹²

Modern interpretation of the commerce clause recognizes three general categories that can be regulated by Congress:

First, Congress may regulate the use of the channels of interstate commerce. Second, Congress is empowered to regulate and protect the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat may come only from intrastate activities. Finally, Congress' commerce authority includes the power to regulate those activities . . . that substantially affect interstate commerce.¹¹³

B. INTERSTATE COMMERCE AND DRUGS

The Supreme Court in *Gonzalez v. Raich* upheld the power of Congress to regulate the production of drugs because of their effects on the national drug market.¹¹⁴ California's Compassionate Use Act of 1996 created an exemption from prosecution for users and physicians who cultivate or possess marijuana for medicinal purposes.¹¹⁵ The respondents were ill and required the use of medicinal marijuana

112. *See id.* (noting that, at one point, "no law was struck down as exceeding the reach of the commerce power for nearly six decades").

113. *United States v. Lopez*, 514 U.S. 549, 558-59 (1995). Exemplifying congressional control of the channels of interstate commerce was *The Shreveport Rate Cases*, 234 U.S. 342 (1914), where the Court upheld congressional action regulating the rates of railroads. *Id.* Further illustrating the regulation of the instrumentalities of interstate commerce was *Perez v. United States*, 402 U.S. 146 (1971), where the Court upheld a federal law that criminalized threatening violence to collect on loans, also known as loan sharking. By outlawing these kinds of activities, Congress aimed to protect people and businesses that were losing money at the hands of organized crime. *See id.* at 155. Finally, an example of congressional regulation of activities substantially affecting interstate commerce was *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241 (1964), where the Court upheld a law that prevented a motel from refusing to rent rooms to African Americans. The Court reasoned that this activity discouraged a large portion of African Americans from traveling and thus substantially affected interstate commerce. *Id.* at 261.

114. *Gonzales v. Raich*, 545 U.S. 1 (2005).

115. *Id.* at 6.

per their doctors' recommendations, prompting them to cultivate their own personal supply.¹¹⁶ Notwithstanding that their cultivation was legal under California law, agents from the Federal Drug Enforcement Administration destroyed all respondents' medical marijuana plants pursuant to the Controlled Substances Act.¹¹⁷

The Court concluded that Congress did not overstep its bounds in regulating intrastate drug activity.¹¹⁸ The Court noted that the purpose of the Controlled Substances Act was to "control the supply and demand of controlled substances in both lawful and unlawful drug markets."¹¹⁹ The Court reasoned that personal cultivation of marijuana could result in that marijuana entering the market and thereby affect supply and demand.¹²⁰

Similar to the personal cultivation of marijuana, pay-for-delay settlements have the potential to greatly alter the market for prescription drugs.¹²¹ When a generic drug hits the market, after only one year it will gain ninety percent of the sales originally held by the brand name patent holder.¹²² Further, the generic drugs on average cost only fifteen percent of the price of the brand name drug.¹²³ Because consumers have alternatives to purchasing high price brand name drugs, the demand for the brand name drug falls.¹²⁴ When a pay-for-delay settlement occurs, the two drug manufacturers prevent the generic drug from entering the stream of commerce, thus affect-

116. *Id.* at 7.

117. *Id.* See also 21 U.S.C. § 801(6) (2006) ("Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.").

118. See *Gonzalez*, 545 U.S. at 19.

119. *Id.*

120. *Id.*

121. See FED. TRADE COMM'N, *supra* note 1, at 8.

122. *Id.*

123. *Id.* Recently, brand name manufacturers have begun offering consumers coupons that lower the price of their drugs in order to compete with the much more affordable generic drugs. Linda A. Johnson, *New Coupons Aim to Keep People Off Generic Drugs*, YAHOO! FINANCE (Aug. 20, 2012, 10:45 AM), <http://finance.yahoo.com/news/coupons-aim-keep-people-off-143732733.html>. These tactics by drug manufacturers reinforce the drastic effects that generic drugs have on the market. See *id.* ("On a big drug, every day that you can delay the sales drop is a happy day at the drug company.").

124. See FED. TRADE COMM'N, *supra* note 1, at 8.

ing supply and demand in the national market and causing prices to stay high.¹²⁵

Gonzalez offers a clear precedent that it is within the purview of Congress to regulate activities that affect the market conditions for legal and illegal drugs.¹²⁶ Thus, because pay-for-delay settlements greatly affect the market price, supply, and demand of various drugs, they are unduly burdensome on interstate commerce and should be regulated by Congress.

C. DRUG COMPANIES AS AN AGGREGATE CLASS

In *Wickard v. Filburn*, the Supreme Court defined the “aggregate approach” to interstate commerce, whereby certain classes of people or entities were deemed to have a substantial effect upon interstate commerce.¹²⁷ *Wickard* involved the Agricultural Adjustment Act of 1938, which established a quota that farmers were to follow in the production of wheat bushels.¹²⁸ The purpose of the quota was to prevent surplus or shortages that would affect the wheat market.¹²⁹ Further, the quota would keep supply at a normal level, allowing farmers to sell their products at higher prices.¹³⁰ According to the Court, in 1941, farmers who stayed within the quota of the Agricultural Adjustment Act sold their products for an average of \$1.16 per bushel, whereas the world market price was \$0.40 per bushel.¹³¹ The appellee exceeded his wheat quota and suffered a monetary penalty as a result.¹³² He subsequently challenged the validity of the Act, arguing that his acts were trivial and purely local, thus having no direct substantial effect on interstate commerce.¹³³

The Court found that the “appellee's own contribution to the demand for wheat may be trivial by itself [but] is not enough to remove him from the scope of federal regulation where, as here, his contribu-

125. See *id.* (“[P]atent settlements restricting generic entry finds that agreements with compensation on average prohibit generic entry for nearly 17 months longer than agreements without payments.”).

126. *Gonzales v. Raich*, 545 U.S. 1 (2005).

127. See *Wickard v. Filburn*, 317 U.S. 111 (1942).

128. *Id.* at 114.

129. *Id.* at 115.

130. *Id.* at 126.

131. *Id.*

132. *Wickard*, 317 U.S. at 115.

133. *Id.*

tion, taken together with that of many others similarly situated, is far from trivial.”¹³⁴ In simpler terms, under the “aggregate approach,” if Congress determines that the activities of a class of people, when combined, have an effect on interstate commerce, then Congress can regulate that class of people and the individuals within that class.¹³⁵ The Court based its rationale on the principle that “the power to regulate commerce includes the power to regulate the prices at which commodities in that commerce are dealt in and practices affecting such prices.”¹³⁶ Accordingly, because wheat farming as a whole had a substantial effect on interstate commerce, the individuals within that class, including the appellee, could be regulated regardless of the triviality or local character of their activity.¹³⁷

In the context of a reverse payment settlement, one such settlement may have a relatively small effect on interstate commerce; however, the drug companies as an aggregate class have come to terms on sixty-six settlements between 2004 and 2009, each involving millions of dollars in compensation and substantial delays.¹³⁸ Further illustrating the substantial effects of this aggregate class on interstate commerce are the estimated yearly costs to American consumers: thirty-five billion dollars.¹³⁹ Consequently, under the precedent set by *Wickard*, any pay-for-delay settlement, regardless of how significant the monetary amounts or the length of delay, can be regulated by Congress under the commerce clause.¹⁴⁰

134. *Id.* at 127-28.

135. *See id.* *See also* Katzenbach v. McClung, 379 U.S. 294 (1964). In *Katzenbach*, the owner of a barbecue restaurant allowed African Americans to carry out food but refused to allow them to dine-in. *Id.* at 297. This was in violation of Title II of the Civil Rights Act of 1964, prompting the owner to challenge the validity of the Act. *Id.* Here, the Court again used the “aggregate approach” in finding that the local discriminatory actions of the restaurant owner could be regulated because of the substantial effect that discrimination has on interstate commerce. *Id.* at 303. In fact, the Court compared the per capita spending of African Americans in highly discriminatory areas with other areas and found it to be much lower where discrimination was prevalent. *Id.* at 299.

136. *Wickard*, 317 U.S. at 128.

137. *Id.*

138. *See* FED. TRADE COMM’N, *supra* note 1, at 4.

139. *Id.* at 2.

140. *See Wickard*, 317 U.S. 111. Under the “aggregate theory,” each individual drug company that engages in a settlement contributes to the overall effect of reverse payment settlements on the market for drugs; consequently, each drug company could be regulated by congressional legislation under the commerce clause. *See id.*

D. CONGRESS, NOT DRUG COMPANIES, CAN REGULATE PRICES

Wickard clearly held that the commerce power grants Congress the right to regulate practices affecting the price of commodities in the stream of commerce.¹⁴¹ Reverse payment settlements prevent generic drugs from entering the stream of commerce, thereby preventing competition and allowing the brand name manufacturers to keep their prices high.¹⁴² As noted earlier, the average price of a generic drug is only fifteen percent of the brand name price prior to generic entry.¹⁴³ Based on these statistics, it is clear that reverse payment settlements drastically affect the price of drugs in the stream of commerce.¹⁴⁴ The right to regulate the prices of commodities in the stream of commerce is not reserved for private drug companies, but rather for Congress, through the commerce clause.¹⁴⁵ Accordingly, drug companies must not be allowed to engage in regulating practices that result in drastic effects to the drug market.¹⁴⁶

The congressional Act at issue in *Wickard*, the Agricultural Adjustment Act of 1938,¹⁴⁷ is an excellent illustration of Congress's reserved right to regulate the practices affecting the price of commodities in the stream of commerce.¹⁴⁸ Essentially, the government is engaging in a reverse payment settlement with American farmers. The government is providing agricultural subsidies for farmers in exchange for farmers not releasing crops past a certain set quota into the stream of commerce.¹⁴⁹ Consistent with Congress's right to regulate the prices of commodities, the "general purpose of the Agricultural Adjustment Act, insofar as it relates to wheat, is to control production in order to avoid the problems resulting from deficits or sur-

141. *Id.* at 128.

142. FED. TRADE COMM'N, *supra* note 1, at 3.

143. *Id.* at 8.

144. *Id.* at 3.

145. *See Wickard*, 317 U.S. 111.

146. *Id.*

147. 7 U.S.C. § 1346(a) (2012) ("Whenever farm marketing quotas are in effect with respect to any crop of cotton, the producer shall be subject to a penalty on the farm marketing excess at a rate per pound equal to 50 per centum of the parity price per pound.").

148. *See Wickard*, 317 U.S. at 114.

149. *See id.* at 131 ("It is hardly lack of due process for the Government to regulate that which it subsidizes.").

pluses.”¹⁵⁰ It follows, then, that the power to engage in quasi-reverse payment settlements that affect commodity markets falls within Congress’s power to regulate interstate commerce. Because the commerce clause grants Congress this power, it does not follow that drug companies share this congressional power.

Brand name drug manufacturers enter into reverse payment settlements in order to prevent competition and avoid over-saturation of the market that would result in decreased drug prices.¹⁵¹ Through these agreements, drug manufacturers are regulating the price of drugs.¹⁵² Because the power to regulate the price of commodities is reserved for Congress, reverse payment settlements are unduly burdensome on interstate commerce.¹⁵³

E. RECENT LIMITS ON THE COMMERCE POWER

Cases decided by the Supreme Court under the commerce clause since 1995 have tended to restrict the power of Congress to regulate interstate commerce. In *United States v. Lopez*, the Court, for the first time in fifty years, invalidated a law based on it exceeding the scope of the commerce power.¹⁵⁴ In *Lopez*,¹⁵⁵ the Court struck down the Gun-Free School Zones Act of 1990, which made it a crime for “any individual knowingly to possess a firearm at a place that the individual knows, or has reasonable cause to believe, is a school zone.”¹⁵⁶ The defendant was arrested after arriving at school with a .38 caliber handgun and five bullets in his possession.¹⁵⁷ The law was challenged as an unconstitutional exercise of congressional control over public schools.¹⁵⁸ The government argued that the law was simply an exercise of the commerce power because possession of guns in schools would have a substantial effect on interstate commerce.¹⁵⁹

150. *U.S. v. Stangland*, 242 F.2d 843, 845 (7th Cir. 1957). *See also Wickard*, 317 U.S. at 131 (noting that that individual supply needed to be regulated in order to avoid surpluses and shortages of wheat).

151. *See* FED. TRADE COMM’N, *supra* note 1, at 1.

152. *See id.*

153. *See Wickard*, 317 U.S. at 128.

154. *See U.S. v. Lopez*, 514 U.S. 549, 593 (1995).

155. *Id.* at 551.

156. *Id.* (citing Gun-Free School Zones Act of 1990, 18 U.S.C. § 922(q)(1)(A) (2012)).

157. *Id.* at 551.

158. *Id.*

159. *Lopez*, 514 U.S. at 563.

Specifically, they argued that guns in schools would cause insurance prices to rise as a result of increased violent acts.¹⁶⁰ Further, the government argued that violence in schools would negatively impact education, thereby creating a less productive workforce.¹⁶¹ The Court rejected the government's arguments for three main reasons: the conduct regulated was in no way an economic activity,¹⁶² there was no jurisdictional nexus ensuring that the conduct affected commerce,¹⁶³ and the law essentially granted Congress broad police powers that were reserved to the states.¹⁶⁴

Despite these recent limitations on the commerce power, pay-for-delay settlements are still within the purview of Congress's power to regulate interstate commerce. In *Lopez*, the Court broadly defined an economic activity as one that, if repeated, would substantially affect interstate commerce.¹⁶⁵ This definition is analogous to the "aggregate approach" as defined in *Wickard*.¹⁶⁶ An activity that is performed by a specific class of people is necessarily a repeated activity.¹⁶⁷ Further, both the "aggregate approach" and the *Lopez* defi-

160. *Id.* at 564 ("[T]he presence of guns in schools poses a substantial threat to the educational process by threatening the learning environment. A handicapped educational process, in turn, will result in a less productive citizenry.").

161. *Id.*

162. The Court found that "[t]he possession of a gun in a local school zone is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce." *Id.* at 567.

163. The Court notes that neither the statute itself nor its legislative history contained any language evidencing a connection between interstate commerce and regulation of guns in schools. *Id.* at 562. As a result, the statute lacked the requisite jurisdictional element connecting the possessed firearms with interstate commerce. *Lopez*, 514 U.S. at 562.

164. The Court recognized that upholding a law that has such a tenuous connection to interstate commerce would essentially turn Congress's commerce power into a broad police power that would interfere with the states' constitutional rights. *Id.* at 567. The Court used these same three factors to decide *United States v. Morrison* five years later. See *United States v. Morrison*, 529 U.S. 598 (2000). In *Morrison*, a female student at Virginia Tech was raped by two other students and sought a civil remedy under the Violence Against Women Act. *Id.* at 605. The Act provided civil relief for the victims of violent crimes motivated by gender. *Id.* In invalidating the law, the Court found that "[g]ender-motivated crimes of violence are not, in any sense of the phrase, economic activity." *Id.* at 613. Next, the Court held that civil remedies have no connection to interstate commerce and thus the statute lacks the requisite jurisdictional nexus. *Id.* at 609. Further, the Court recognized that there is a distinction between national and local activity and that violent crimes are local activity that must be policed by the states. *Morrison*, 529 U.S. at 617-18.

165. *Lopez*, 514 U.S. at 567.

166. See *Wickard v. Filburn*, 317 U.S. 111 (1942).

167. *Id.*

dition require that the repeated activity have a substantial effect on interstate commerce.¹⁶⁸

The statistics and the purpose behind pay-for-delay settlements make it clear that these agreements constitute economic activities as they are defined in *Lopez*.¹⁶⁹ Drug manufacturers enter into reverse payment settlements in order to “permit the sharing of monopoly rents between would-be competitors.”¹⁷⁰ By doing so, the brand name drug manufacturers are able to keep the generic drugs off the market, keep the prices on their drugs high, and maximize their profits.¹⁷¹ Furthermore, as noted earlier, reverse payment settlements are a common trend among drug manufacturers with sixty-six settlements being entered into between 2004 and 2009.¹⁷² These settlements substantially affect interstate commerce by preserving \$20 billion worth of sales made by brand name drug manufacturers and costing the American public \$3.5 billion annually.¹⁷³ Based on these numbers, it is clear that pay-for-delay settlements are an oft-repeated agreement among various drug manufacturers that substantially affect interstate commerce.¹⁷⁴ Thus, because every element of the *Lopez* definition is satisfied, pay-for-delay settlements are an economic activity.¹⁷⁵

Additionally, while pay-for-delay settlements do not explicitly address their connection to interstate commerce within the contract, this connection can be implied through the jurisdictional nexus.¹⁷⁶ Reverse payment settlements obviously involve drugs.¹⁷⁷ Drugs are not limited to a specific jurisdiction or a specific population; rather, the majority of the American public uses them in different capacities. Thus, the use of drugs spans every jurisdiction in the country,¹⁷⁸ creating a jurisdictional nexus between purchase of prescription drugs and interstate commerce.¹⁷⁹ Because pay-for-delay settlements affect

168. *Id.*; *Lopez*, 514 U.S. at 567.

169. *See Lopez*, 514 U.S. at 567.

170. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 216 (3d Cir. 2012).

171. *See id.* at 208.

172. FED. TRADE COMM’N, *supra* note 1, at 4.

173. *See id.* at 2.

174. *See Lopez*, 514 U.S. at 567.

175. *See id.*

176. *See id.* at 562.

177. *See* FED. TRADE COMM’N, *supra* note 1, at 1.

178. *See id.*

179. *See Lopez*, 514 U.S. at 562.

the availability and pricing of prescription drugs, this jurisdictional nexus necessarily implicates a connection between these agreements and interstate commerce.¹⁸⁰

Finally, legislation curtailing the power of drug companies to enter into pay-for-delay settlements would not create an overly broad police power in Congress.¹⁸¹ In *Lopez*, the Court declined to uphold the law because it required them to “pile inference upon inference in a manner that would bid fair to convert congressional authority under the commerce clause to a general police power of the sort retained by the States.”¹⁸² The connection between interstate commerce and reverse payment settlements is not so tenuous. Case law and statistical evidence previously alluded to point to these agreements being unduly burdensome on interstate commerce.¹⁸³ Because proposed legislation would be narrowly tailored to a specific activity that substantially affects interstate commerce, it would not be overly broad and would not give Congress a blank check to legislate any activity Congress desired.¹⁸⁴

Moreover, the activities that Congress aimed to regulate in both *Lopez* and *Morrison* involved violence prevention.¹⁸⁵ The *Morrison* Court noted that “[t]he regulation and punishment of intrastate violence that is not directed at the instrumentalities, channels, or goods involved in interstate commerce has always been the province of the States.”¹⁸⁶ These cases seem to indicate that the Court is not willing to rely on the commerce clause in order to uphold legislation concerning local violence that is not strongly connected to interstate commerce.¹⁸⁷ This contention is further supported by *Perez v. United States*, where the Court upheld a law forbidding loan sharking.¹⁸⁸ While the legislation in *Perez* aimed to prevent violence associated with loan sharking, the regulated activity was so closely connected to interstate commerce that the Court found it was within Congress’s

180. *See id.*

181. *See id.* at 567.

182. *Id.*

183. *See* FED. TRADE COMM’N, *supra* note 1, at 1.

184. *See, e.g., Lopez*, 514 U.S. at 567.

185. *See id.* (discussing gun possession in schools); *U.S. v. Morrison*, 529 U.S. 598 (2000) (discussing violence against women).

186. *Morrison*, 529 U.S. at 618.

187. *See id.*; *Lopez*, 514 U.S. at 567.

188. *Perez v. United States*, 402 U.S. 146 (1971); *see also supra* text accompanying note 73.

power to regulate.¹⁸⁹ Unlike these precedents, legislation against pay-for-delay settlements would not aim to prevent violent crimes.¹⁹⁰ Rather, legislation proposing to end these agreements would involve an economic activity that is strongly connected to interstate commerce, thus not interfering with the individual states' police power.¹⁹¹

Despite the limits that the Supreme Court defined in *Lopez* in 1995, legislation proposing to end pay-for-delay settlements would nonetheless survive commerce clause scrutiny.¹⁹² These settlements represent an economic activity that contains a jurisdictional nexus, and do not give Congress a plenary police power that is meant for the states.¹⁹³ Because none of the limits enumerated in *Lopez* are implicated, it is within the purview of Congress to pass legislation ending pay-for-delay settlements.¹⁹⁴

F. REVERSE PAYMENT SETTLEMENTS AND "OBAMACARE"

The most recent Supreme Court case interpreting Congress's power under the commerce clause, *National Federation of Independent Business v. Sebelius*, involved the Patient Protection and Affordable Care Act.¹⁹⁵ This piece of legislation was introduced by the Obama administration and was intended to "increase the number of Americans covered by health insurance and decrease the cost of health care."¹⁹⁶ The central part of the bill, called the "individual mandate,"¹⁹⁷ requires that individuals maintain "minimum essential" health care.¹⁹⁸ If people choose not to comply with the "individual mandate" and forego the directive to acquire health insurance cover-

189. *Id.*

190. *See Morrison*, 529 U.S. at 618; *Lopez*, 514 U.S. at 567; *Perez*, 402 U.S. 146.

191. *See Morrison*, 529 U.S. at 618; *Lopez*, 514 U.S. at 567; *Perez*, 402 U.S. 146.

192. *See U.S. v. Lopez*, 514 U.S. 549 (1995).

193. *See id.*

194. *See id.*

195. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012); Patient Protection & Affordable Care Act, 26 U.S.C. § 5000A (2012).

196. *Sebelius*, 132 S. Ct. at 2580.

197. *Id.* at 2578. The "individual mandate" of the bill does not apply to certain classes, such as prisoners and undocumented aliens. *Id.* at 2580; 26 U.S.C. § 5000A(d).

198. *Sebelius*, 132 S. Ct. at 2579. The opinion notes that many people will receive health insurance coverage from non-private sources such as Medicare, Medicaid, the CHIP program, or employee health insurance. *Id.*; 26 U.S.C. § 5000A(f). If people are not receiving healthcare from one of these sources, then the "individual mandate" requires them to purchase a minimum coverage private health plan. *Sebelius*, 132 S. Ct. at 2580.

age, then they are assessed a “penalty” which is calculated based on a percentage of household income.¹⁹⁹

The Government argued unsuccessfully to the Court that the “individual mandate” was a valid exercise of Congress’s power under the commerce clause.²⁰⁰ The Government argued that health care in America is plagued by a “cost-shifting” problem, where hospitals are required to provide services to many individuals who are unable to afford the services rendered.²⁰¹ As a result, “[t]o recoup the losses, hospitals pass on the cost to insurers through higher rates, and insurers, in turn, pass on the cost to policy holders in the form of higher premiums,”²⁰² causing a substantial and detrimental effect on interstate commerce.²⁰³

In denying the Government’s contentions, the Court, in a five-to-four decision, refused to extend Congress’s commerce power to inactivity.²⁰⁴ The Court found, that in order for Congress to regulate a certain activity, this activity must already exist.²⁰⁵ In simpler terms, Congress can regulate individuals intertwined in some way with interstate commerce, but Congress cannot force individuals to become intertwined with interstate commerce.²⁰⁶ Consistent with other recent limits on the commerce power, the Court held that allowing legislation of inactivity would give Congress a blank check to regulate eve-

199. 26 U.S.C. § 5000A. The bill calls this penalty a “shared responsibility payment.” *Id.* The payment is “subject to a floor based on a specified dollar amount and a ceiling based on the average annual premium the individual would have to pay for qualifying private health insurance.” *Sebelius*, 132 S. Ct. at 2580. For example, the Court states that in 2016, the “penalty will be 2.5 percent of an individual’s household income, but no less than \$695 and no more than the average yearly premium for [their] insurance” *Id.* See also 26 U.S.C. § 5000A(c).

200. *Sebelius*, 132 S. Ct. at 2585.

201. *Id.* at 2585.

202. *Id.*

203. *Id.* Specifically, the government argues that by requiring individuals to have health insurance, the “cost-shifting” problem will be avoided. *Id.*

204. *Sebelius*, 132 S. Ct. at 2591 (“The Commerce Clause is not a general license to regulate an individual from cradle to grave, simply because he will predictably engage in particular transactions.”). It should also be noted that the “individual mandate” was ultimately upheld under Congress’s taxing power. *Id.* at 2595.

205. *Id.* at 2586.

206. See *id.* at 2587.

ry aspect of people's lives, even if the activity regulated was only hypothetically connected to interstate commerce.²⁰⁷

While *Sebelius* sets a clear line in further limiting commerce clause power to active conduct, it is clear that pay-for-delay settlement legislation would not fall within this limitation.²⁰⁸ Pay-for-delay settlements are not hypothetical and are a major factor in the availability of generic drugs and their prices.²⁰⁹ Drug manufacturers have been actively engaging in these types of agreements for decades in order to keep out competition and maximize profits on the resulting monopoly.²¹⁰ This is distinct from the reasoning of the *Sebelius* Court, which refused to compel people to participate in an activity that had not yet occurred.²¹¹ Pay-for-delay settlements have already occurred and are a regular practice among drug manufacturers.²¹² Furthermore, when drug manufacturers decide to market a drug, the manufacturer has already made the decision to place the drug into the stream of commerce and become intertwined with interstate commerce. Therefore, legislation designed to end pay-for-delay settlements would not be compelling individuals to become active in commerce since the actors are already actively involved in commerce.²¹³ Because legislation would not be regulating inactivity, but rather a prevalent, existing practice, the limitations on the commerce clause articulated by the *Sebelius* Court would not be implicated, and it would be within Congress's power to regulate reverse payment settlements.²¹⁴

Additionally, many of the policy reasons cited for drafting the Patient Protection and Affordable Care Act are also prevalent in a pay-for-delay context.²¹⁵ The primary goals of this bill were to increase the number of people covered by health insurance and to decrease the costs of health insurance coverage so as to protect people from the enormous financial burdens associated with medical ser-

207. See *id.* The Court specifically distinguished *Wickard v. Filburn*, 317 U.S. 111 (1942), finding that Congress's legislation in *Wickard* was a valid exercise of the commerce clause power since the farmer was actively producing wheat. *Sebelius*, 132 S. Ct. at 2857.

208. See *id.* at 2591.

209. See FED. TRADE COMM'N, *supra* note 1, at 3.

210. See *id.* at 1.

211. See *Sebelius*, 132 S. Ct. at 2591.

212. FED. TRADE COMM'N, *supra* note 1, at 3.

213. See *Sebelius*, 132 S. Ct. at 2591.

214. See *id.*

215. See Patient Protection and Affordable Care Act, 26 U.S.C. § 5000A (2012).

vices.²¹⁶ Going hand-in-hand with this goal is an increase in the quantity of generic drugs on the market. By increasing the availability of generic drugs, the competition would necessarily cause prices to decrease.²¹⁷ Consequently, lower drug prices would lower the cost of health insurance premiums, thereby making it easier for people to afford coverage.²¹⁸ This would prevent more people from being forced to “cut their pills in half or skip needed medications altogether” as a result of high prescription drug prices.²¹⁹ Because Congress’s main goals in passing the Patient Protection and Affordable Care Act were to increase the number of people covered by health insurance and decrease the cost of health insurance, it logically follows that Congress should pass legislation ending pay-for-delay settlements since this legislation would help achieve the same goals.²²⁰

XI. BENEFITS OF ELIMINATING PAY-FOR-DELAY SETTLEMENTS

A 2009 report by the Obama Administration’s Office of Management and Budget stated that in its effort to reduce drug prices, “[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.”²²¹ This recognition by the president of the troublesome nature of these settlements is further evidence that pay-for-delay settlements are very problematic and come with a great cost to the American public.²²²

Congressional action that would render pay-for-delay settlements per se illegal would have many benefits to the American con-

216. *Sebelius*, 132 S. Ct. at 2580. “Everyone will eventually need health care at a time and to an extent they cannot predict.” *Id.* at 2585.

217. *See* FED. TRADE COMM’N, *supra* note 1, at 1.

218. *See* Jon Leibowitz, Chairman, Fed. Trade Comm’n, Address at the Center for American Progress: “Pay-for-Delay” Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumer’ [sic] Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution) at 3 (June 23, 2009), *available at* <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>.

219. *Id.* at 4.

220. *See id.*; 26 U.S.C. § 5000A.

221. OFFICE OF MANAGEMENT AND BUDGET, A NEW ERA OF RESPONSIBILITY: RENEWING AMERICA’S PROMISE 28 (2009), *available at* http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf.

222. *See id.*

sumer, healthcare, and the economy as a whole.²²³ Primarily, barring reverse payment settlements would result in much lower prescription drug prices for the American consumer.²²⁴ Studies and history show that “when multiple generics are on the market, the price for the generic version can drop more than 90 percent below the price of the branded product”²²⁵ Obviously, this would lead to great savings to the American consumer on prescription drugs.²²⁶ To put this in perspective, a month supply of the generic version of Zantec, a drug preventing ulcers, is available for \$3, whereas the brand name drug would cost \$111.²²⁷ Furthermore, pay-for-delay settlements delay entry of the generic drug into the stream of commerce by an average of seventeen months.²²⁸ In the Zantec example, seventeen months of paying the brand name price rather than the generic price would cost a consumer \$1,836.²²⁹ Estimates by the FTC indicate that a per se bar on pay-for-delay settlements would save consumers at least \$35 billion over a ten-year period and up to \$75 billion over this period.²³⁰

Additionally, ending reverse payment settlements would greatly buoy the American healthcare system. Because the federal government pays for a large portion of the country’s overall prescription drug costs, the FTC estimates that the federal government would save at least \$12 billion over a ten-year period and up to \$25 billion over this period.²³¹ These savings could then be used to fund and improve federal healthcare programs, such as Medicaid or Medicare. Furthermore, as noted earlier, a decrease in prescription drug prices would lead to a decrease in health care premiums, allowing more affordability and access to private insurance.²³²

Not only will a per se bar to pay-for-delay settlements aid the healthcare system, but it will help spur the economy as a whole by increasing innovation and competition. The Supreme Court once not-

223. See Leibowitz, *supra* note 218, at 10-11.

224. See *id.* at 8.

225. *Id.* at 3. Because the Hatch-Waxman Act requires that each reverse payment settlement is filed with the FTC, the FTC claims that they are in the best position to analyze the economics and statistics surrounding reverse payment settlements. *Id.* at 7.

226. *Id.* at 3.

227. Leibowitz, *supra* note 218, at 3.

228. *Id.* at 4.

229. See *id.* at 3.

230. *Id.* at 8.

231. *Id.*

232. See Leibowitz, *supra* note 218, at 3.

ed that “[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress”²³³ In the pay-for-delay context, a brand name drug manufacturer is most inclined to pay off its would-be competitors when they are aware of the weakness of their patent.²³⁴ Thus, the brand name manufacturer, without any real innovation, is reaping the maximum rewards for drugs that likely would not be afforded patent protection if challenged.²³⁵ Moreover, because of the precedent set by previous pay-for-delay settlements, generic manufacturers are encouraged to file patent challenges under the Hatch-Waxman Act solely to attempt to coax the brand name manufacturers into settlements for large monetary sums, rather than filing challenges based on actual medical innovation.²³⁶ By barring these agreements, manufacturers will be forced to have strong patents and actual innovation in order to withstand generic patent challenges.

Furthermore, the Hatch-Waxman Act was passed with the intention of increasing competition in the market by making it easier for generic drugs to challenge weak drug patents.²³⁷ However, pay-for-delay settlements have resulted in the exact opposite effect: weak drug patents circumventing the generic challenges, resulting in fewer generic drugs and less market competition.²³⁸ Legislation ending reverse payment settlements would allow the Hatch-Waxman Act to operate as Congress originally intended, increasing competition in the marketplace.²³⁹

XII. CONCLUSION

Lofty research and development costs, and the desire to maximize profits, lead many drug manufacturers to enter into reverse payment settlements with generic drug makers. While these settlements may seem like sound business judgments, they present a clash between antitrust law, patent law, and constitutional law principles.

233. *E.g.*, *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 402 (2007).

234. *See Leibowitz, supra* note 218, at 6.

235. *See id.*

236. *See id.* at 5 (“Instead of competing to be first to come to market, generic companies compete to be first to get paid off.”).

237. *See id.* at 3.

238. *See id.*

239. *See Leibowitz, supra* note 218, at 6.

Courts have traditionally focused their analysis on the interplay between antitrust and patent law. However, the blatant commerce clause implications of reverse payment settlements strongly point to the conclusion that they are in violation of constitutional law principles.

Statistics and case law discussing pay-for-delay settlements point to these agreements costing American consumers billions of dollars by forcing generic competition out and keeping prescription drug prices high.²⁴⁰ Because of the substantial, detrimental effect of these agreements on consumers' wallets, the healthcare system, and the nation's economy, it would be sound public policy for either Congress to pass legislation declaring reverse payment settlements per se illegal, or for the Supreme Court to outlaw these agreements as unduly burdensome on interstate commerce.

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240. FED. TRADE COMM'N, *supra* note 1, at 2.

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