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FTC v. Actavis: Analysis of the Court's Decision and How it Affects Drug Prices for Those Who Need Them the Most

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FTC v. Actavis: Analysis of the Court’s Decision and How it Affects Drug Prices for Those Who Need Them the Most

*Kyle Virtue**

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I. Introduction

Rising healthcare costs have had a devastating impact on many American families in recent years.¹ One of the main drivers of this national problem is the price consumers must pay for prescription drugs.² Although rising prescription drug costs place a heavy burden on all individuals, they are most harmful to those who cannot afford health insurance or those dependent on prescription drugs due to chronic illness.³ Of particular concern are the poor and the elderly, who are more prone to chronic conditions that require long-term care.⁴ Without more affordable options, these groups do not have access to many of the therapies they need in order to sustain a healthy life, including the newer, more expensive prescription drugs.⁵

1. See AMERICA'S HEALTH INS. PLANS, BOARD OF DIRECTORS STATEMENT: BRINGING DOWN HEALTHCARE COSTS 1 (2013), available at <http://www.ahip.org/BoardofDirectorsStatements/> (stating that soaring healthcare costs force “[w]orking families and seniors [to] face difficult choices between the basic necessities of living and needed health care”).

2. See Dennis Cauchon, *Drug Prices Jump Again While Other Health Costs Decline*, USA TODAY (Feb. 13, 2013, 8:09PM), <http://www.usatoday.com/story/news/nation/2013/02/13/price-of-a-prescription-rising-again/1918099/> (citing data from the Bureau of Economic Analysis that shows drug prices increased at twice the rate of inflation in 2012).

3. See Ron Claiborne & Jessica Hopper, *Price of Brand-Name Drugs Soars*, ABC NEWS (Aug. 25, 2010), <http://abcnews.go.com/WN/cost-brand-drugs-soars-hurting-elderly-americans-fixed/story?id=11478210> (noting that those who cannot afford health insurance are likely on fixed incomes and must bear the full cost of medical expenses out-of-pocket).

4. See Soonim Huh, et al., *Prescription Drug Coverage and Effects of Drug Expenditures Among Elderly Medicare Beneficiaries*, 43 HEALTH SERV. RES. 810, 811 (June 2008), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC_2442248/pdf/hesr0043-0810.pdf (“Rapid growth of prescription drug expenditures is likely to disproportionately influence the elderly because they are more dependent upon them than any other group, due to high prevalence of chronic conditions that require long-term medications.”).

5. See The Commonwealth Fund, *Prescription Drug Nonadherence: Elderly Adults*, THE COMMONWEALTH FUND (Oct. 24, 2013), <http://www.commonwealthfund.org/Perfor>

One of the ways Americans have been able to minimize their healthcare spending is through substituting less expensive generic medications for more expensive patented branded pharmaceuticals.⁶ However, spending on prescription drugs remains high, suggesting that generic substitution has not met its full potential.⁷ One reason for this problem is arguably an active effort by drug manufacturers to keep generic drugs from entering the market,⁸ leading to an artificial maintenance of high drug prices for tens of millions of Americans.⁹ Drug manufacturers have been able to accomplish this through the use of reverse payment or “pay-for-delay” settlement agreements.

Reverse payment settlement agreements arise where a generic manufacturer attempts to enter the market by producing a generic version of a brand name drug.¹⁰ The manufacturer of the branded version files a lawsuit for patent infringement, and the generic manufacturer defends the suit on the ground that the patent is invalid or the generic drug does not infringe the patent.¹¹ Instead of litigating the patent dispute, the generic and brand-name manufacturer strike a settlement agreement whereby the generic manufacturer agrees not to bring a competing drug to market for an agreed-upon period of time.¹² In return, the brand-name drug manufacturer

mance-Snapshots/Unmet-Needs-for-Health-Care/Prescription-Drug-Nonadherence--Elderly-Adults.aspx (“More than one-quarter of seniors reported that they did not fill or adhere to a prescription for cost-related reasons in 2003.”).

6. See David A. Mott & Richard R. Cline, *Exploring Generic Drug Use Behavior: The Role of Prescribers and Pharmacists in the Opportunity for Generic Drug Use and Generic Substitution*, 40 MEDICAL CARE 662, 663 (2002), available at <http://www.jstor.org/stable/3767620> (noting that spending on drugs can be reduced through the use of prescription drugs due to the high cost differential between generic and brand-name drugs).

7. See Press Release, RAND Corporation, Financial Burden of Prescription Drugs is Dropping, But Costs Remain a Challenge For Many Families (Feb. 8, 2012), available at <http://www.rand.org/news/press/2012/02/08/index1.html> (stating that generics have help decrease healthcare expenditures for Americans but prescription costs remain a challenge for low-income individuals).

8. See U.S. PUBLIC INTEREST RESEARCH GROUP, TOP-TWENTY PAY-FOR-DELAY DRUGS, U.S. PIRG), available at http://uspig.org/sites/pirg/files/reports/Top_Twenty_Pay_For_DelayDrugs_USPIRG.pdf [hereinafter U.S. PUBLIC INTEREST RESEARCH GROUP] (stating that pay-for-delay settlements has held back the introduction of many generic drugs).

9. See generally Mott & Cline, *supra* note 6 (giving a brief overview of the negative impact reverse payment settlement agreements can have on consumers through delayed generic entry of key drugs).

10. 2 WILLIAM C. HOLMES, INTELL. PROP. AND ANTITRUST LAW § 38:3 (2013).

11. See *id.* (stating that reverse payment settlement agreements arise out of patent infringement suits).

12. See *id.* (stating that compensation is paid to the infringer “in return for the

compensates the generic manufacturer, typically by a large monetary payment.¹³ Although these agreements can avoid costly litigation, they can also substantially harm competition and consumers. That is true where the agreement delays the entry of a generic drug but the court would have found the patent invalid or not infringed. Therefore, had litigation continued, the generic would have been permitted to enter the market earlier than permitted by the reverse payment agreement.¹⁴ Thus, reverse payment agreements can provide a way for brand-name manufacturers with invalid or non-infringed patents to stave off competition in the drug market, potentially allowing the brand-name manufacturer to continue to charge supracompetitive prices by leaving consumers without a cheaper generic alternative.¹⁵ Because of their potential adverse effect on consumer healthcare expenditures, the Federal Trade Commission (FTC) has made ending reverse payment agreements one of its top priorities since the late 1990's.¹⁶

If reverse payment settlement agreements have the potential to harm consumers and competition, why haven't the courts eliminated these agreements altogether? While reverse payment agreements may run against the antitrust policy of maximizing competition in the marketplace, holders of valid, infringed patents see these payments as a way to exercise their right under the patent laws to exclude others from infringing their patents and to reduce litigation costs.¹⁷ If the patent is valid and a generic

infringer's agreement to refrain from producing or selling its allegedly infringing product for an agreed period ending on or before expiration of the patentee's patent").

13. See *supra* notes 10–12 and accompanying text (discussing the basic structure of a reverse payment agreement).

14. See discussion *infra* Parts II.B., III.

15. See *Pay-for-Delay Deals: Limiting Competition and Costing Consumers: Hearing Before the Subcomm. on Antitrust, Comp. Pol'y, and Consumer Rights*, 113th Cong. 2 (2013) (statement of George Slover, Consumers Union), available at http://consumersunion.org/wpcontent/uploads/2013/12/generic_drug_pay_for_delay_statement_0813.pdf (stating that reverse payment settlements have been used to eliminate generic entry, “thereby prolonging the period during which [brand-name drug makers] can charge monopoly prices to consumers who need the drug and have no alternative”).

16. See *Pay-For-Delay Deals: Limiting Competition and Costing Consumers: Hearing Before the Subcomm. on Antitrust, Comp. Pol'y, and Consumer Rights*, 113th Cong. 1 (2013) (statement of the Federal Trade Commission), available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pay-delay-deals-limiting-competition-and-costing/130723payfordelay.pdf.

17. See Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 766–69 (2002) (discussing the fact that both antitrust law and patent law share the same objective of increasing consumer welfare but their paths in achieving this goal often diverge and conflict).

manufacturer infringes on that patent, the patent holder should be able to settle a patent infringement in lieu of undergoing time-consuming, costly, and unpredictable patent litigation. Antitrust proponents, however, believe that patent holders are using such settlements as a device to unlawfully exclude competition based on an invalid or non-infringed patent.¹⁸

Given the widely divergent views held on the appropriate legal framework for analyzing reverse payment agreements, such agreements have been one of the most discussed antitrust topics over the past two decades.¹⁹ The topic came to the forefront in the summer of 2013, when the Supreme Court decided *FTC v. Actavis*.²⁰ In *Actavis*, the Court was asked to settle a circuit split about the antitrust standard that courts should apply in determining the lawfulness of these types of agreements; that is, given their potential anticompetitive effects, the appropriate depth of scrutiny for determining the effect on competition of the agreements and thus their lawfulness under the antitrust laws.²¹ Because reverse payment agreements have the potential to restrain competition, the Court held that they should be subjected to the “rule of reason” analysis.²² Prior to the Court’s decision, most circuit courts of appeals used the more name-brand-manufacturer-friendly “scope-of-the-patent test,” whereby the settlement would be unlawful only if the exclusion under the agreement exceeded the right of exclusion provided by the patent laws.²³ This would be the case in only very limited situations and thus critics argued that reverse payment settlement agreements were effectively per se legal, causing substantial consumer harm.²⁴

18. See HOLMES, *supra* note 10 (noting that patent holders believe that engaging in these agreements falls within their right to exclude others from producing infringing products while antitrust proponents believe these agreements go beyond the intended scope of patent laws).

19. See Kenneth Glazer & Jenée Desmond-Harris, *Reverse Payments: Hard Cases Even Under Good Law*, 24 ANTITRUST 14, 14 (Spring 2010) (noting that “reverse payments remain one of the most contentious areas of antitrust”).

20. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237–38 (2013) (holding that reverse payment settlement agreements should be analyzed under rule of reason and tasked the lower courts with developing “the present rule-of-reason antitrust litigation”).

21. See discussion *infra* Part VII (discussing the details and implications of *Actavis* at length).

22. See *Actavis*, 133 S. Ct. 2223 at 2226 (2013) (declining to hold that reverse payments are presumptively unlawful and therefore they should be analyzed under “rule of reason” analysis).

23. See discussion *infra* Part VI.B (discussing the different antitrust standards lower courts applied to reverse payment settlement agreements before *Actavis* was decided).

24. See discussion *infra* Part VI.B.

Although the *Actavis* decision has been touted as a victory for consumers and the FTC because reverse payment agreements will be subjected to a more stringent antitrust standard than before, the general consensus is that this ruling provided more questions than answers. Among the questions most discussed is whether the Court intends for lower courts to apply “full-blown” rule of reason analysis to these types of agreements.²⁵ Although this topic will be discussed in the following sections, the most important issue raised by *Actavis* for the purposes of this Note is how the ruling will affect the cost of healthcare for consumers, especially the poor and elderly, and the likelihood that legislation will be enacted in order to adequately protect these groups.

Part II of this Note provides background to the concept of reverse payment settlements, focusing on legislation passed in the mid-1980s that inadvertently gave rise to these types of agreements. Part III examines the impact reverse payment agreements have on competition, noting that these agreements can have both anticompetitive and procompetitive effects. Part IV addresses how anticompetitive reverse payments affect consumers, particularly the poor and the elderly. Part V summarizes recent congressional bills introduced to eliminate reverse payment settlement agreements. Part VI provides an overview of how lower courts addressed the legality of reverse payment before *Actavis* was decided. Part VII discusses the *Actavis* decision and the major questions the Court created, including the exact standard the Court expects lower courts to apply and what constitutes a “large and unjustified” reverse payment as that phrase was used by the Court. Part VIII discusses the possible implications of *Actavis* on consumer welfare as well as the likelihood that congressional action will take place to further reduce the prevalence of reverse payment agreements. Part VIII also argues that recent changes in the national healthcare landscape could also reduce the burden prescription drug costs have on poor and elderly Americans. This Note concludes that the *Actavis* decision should allow Americans greater access to needed prescription drugs.

25. See *infra* Part VII.A–C (providing an extensive discussion of the standard adopted by the Court in reverse payment cases and the most likely way lower courts will apply that standard).

II. Background: Reverse Payment Settlement Agreements and the Hatch-Waxman Act

A. Overview of the Hatch-Waxman Act

Competition in the pharmaceutical industry is difficult to maintain, which is why patent protection is very important in ensuring new drugs are brought to market.²⁶ Pioneer drug companies are exposed to major risks when deciding to develop new drug therapies because development requires high sunk costs and extensive regulatory compliance.²⁷ Competition could prevent brand-name drug manufacturers from recouping the R&D and regulatory costs associated with inventing a new drug and bringing it to market, eliminating the incentive for manufacturers to develop new drugs necessary to increase public welfare.²⁸

Despite the importance of patent protection in this industry, Congress found that competition in the pharmaceutical industry was wholly inadequate. After 1962, congressional testimony revealed that there were 150 brand-name drugs off patent for which there was no generic counterpart.²⁹ For generic manufacturers, the time and money required to bring a new drug to market was simply too great to induce the effort.³⁰ Through the Drug Price Competition and Patent Restoration Act of 1984,³¹ also known as the Hatch-Waxman Act, Congress sought to increase the entry of low-cost generics by reducing the regulatory burdens required of generic manufacturers in bringing a generic drug to market.³² Since its

26. See Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 251 (2012) (noting that patent protection is important in the pharmaceutical industry because it is “one of the most cost- and time-intensive areas of technological innovation . . .”).

27. See *id.*

28. See *id.* (stating the importance of patent protection in the drug industry because, “[i]dentifying a compound with possible therapeutic benefits is only the first of many slow and incredibly expensive steps, and the cost of discovering, testing, and marketing new drugs is extremely high and continues to rise”).

29. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999) (stating that no generics were entering the market because “generic companies simply would not spend the time and money doing the clinical trials to get to market, . . .”).

30. See *id.* at 194 (stating that, “[t]he robust generic drug industry owes its very existence to the Act, . . .”).

31. Drug Price Competition and Patent Restoration Act, 21 U.S.C. § 355 (2012).

32. See Morris, *supra* note 26, at 248 (“The Hatch-Waxman Act therefore promotes generic market entry by relieving almost all of the regulatory burdens for generic

enactment, the Hatch-Waxman Act has had a significant impact on competition in the pharmaceutical industry.³³ Today, almost every top-selling drug faces generic competition whereas there were only generic equivalents available for 35% of brand-name drugs prior to Hatch-Waxman.³⁴ Further, 70% of prescriptions today are filled by generics whereas generics only comprised 15% of the pre-Hatch-Waxman prescription drug market.³⁵ The result has been millions of dollars in cost savings for Medicaid and Medicare—and commercial health plans and consumers—due to generic substitution programs.³⁶

The Hatch-Waxman Act increased competition by streamlining the process for generic drug approval, consequently creating an incentive for generic manufacturers to enter the market.³⁷ Prior to this Act, generic drug manufacturers, like branded-drug manufacturers, had to submit and obtain approval of a New Drug Application (NDA) before the FDA approved their drug.³⁸ Filing a NDA is an extremely costly and time-consuming process.³⁹ Generic drug manufacturers were forced to submit clinical data verifying a drug's safety and efficacy even though a brand name manufacturer had already undergone the NDA approval process using identical data for a bioequivalent drug.⁴⁰

Under the Hatch-Waxman Act, generic drug manufacturers are able to skip this process by filing an Abbreviated New Drug Application (ANDA),

manufacturers, as well as by helping generic manufacturers challenge the validity of brand-name pharmaceutical patents that might be hindering such market entry.”).

33. See Glazer & Desmond-Harris, *supra* note 19, at 14 (“The emergence of a successful generic drug industry has often been attributed to the Act . . .”).

34. Martha M. Rumore, *The Hatch-Waxman Act-25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACYTIMES (Aug. 15, 2009), <http://www.pharmacytimes.com/publications/supplement/2009/GenericSupplement0809/Generic-HatchWaxman-0809#sthash.kK1xbMSX.dpuf>.

35. *Id.*

36. See Aaron S. Kesselheim, et al., *Extensions Of Intellectual Property Rights And Delayed Adoption Of Generic Drugs: Effects On Medicaid Spending*, 15 HEALTH AFFAIRS 1637, 1638 (2006), available at <http://content.healthaffairs.org/content/25/6/1637.full#ref-8> (“Several reports have detailed millions of dollars in cost savings achievable through generic-substitution policies employed by government and private payers.”).

37. See Glazer & Desmond-Harris, *supra* note 19, at 15 (stating that the approval process was significantly streamlined because the Act allowed “generic manufacturers to circumvent the lengthy and expensive NDA filing by filing instead an Abbreviated New Drug Application (ANDA)”).

38. *See id.*

39. *See id.*

40. *Id.*

which allows the generic drug manufacturer to use the safety and efficacy data gathered and submitted by the brand-name manufacturer to complete its original NDA.⁴¹ The generic drug manufacturer need only supplement the original NDA with data showing that the generic drug is the “bioequivalent” of the already-approved brand-name drug.⁴² If approved, an ANDA filer is given a 180-day exclusivity period in which no other generic manufacturer can have an ANDA approved that covers the same drug.⁴³ This exclusivity period can be very profitable for the “first filer.” It creates a generic drug “bottleneck,” excluding other generics from the market, thus allowing the first filer to charge a higher price than it otherwise would be able to do if other generics were allowed to enter the market.⁴⁴

In order to maintain the balance between innovation and competition, the Hatch-Waxman Act provides safeguards to protect the brand-name manufacturer from infringement of its patent. For example, Congress recognized that it takes a long time for the FDA to approve a drug after a patent holder files the NDA for that drug.⁴⁵ During this time period, the patent holder is losing months off the patent’s life. The Hatch-Waxman Act adds back one half of the patent life lost during this time period to the exclusionary period of the patent.⁴⁶ Also, the generic drug manufacturer seeking approval through an ANDA must submit a certification 1) that the drug is not covered by an existing patent, 2) that if there is a patent that the patent has expired, 3) providing information regarding the expiration date of such existing patent, and 4) that if there is an existing patent, the patent is invalid or will not be infringed upon by the generic drug manufacturer.⁴⁷ Once this “Paragraph IV” certification is filed, patent holders of brand-name drugs may bring a patent-infringement claim against an ANDA filer within forty-five days of the first filer’s ANDA filing if they believe the

41. *Id.*

42. *Id.*

43. Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(5)(b)(IV)(iv) (2012).

44. If other generics were allowed to enter the market during the exclusivity period, the sole generic would be forced to lower its price to a competitive level, or else lose consumers to the other generics willing to charge a lower price. Without competition, there is no incentive for the generic to lower its price because consumers do not have a competitor to turn to. See Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 373 (2010).

45. See Morris, *supra* note 26, at 260.

46. See *Id.* (“[T]he Hatch-Waxman Act provides for restoration of patent term equal to one-half of the time period from the start of human clinical trials to NDA approval and all of the time spent during the NDA approval process itself.”).

47. 21 U.S.C. § 355(j)(2)(A)(vii) (2012).

generic drug infringes on their patent.⁴⁸ This is colloquially called “Paragraph IV litigation.” If a patent holder challenges the ANDA, the approval of the ANDA is automatically stayed for thirty months.⁴⁹

B. The Development of Reverse Payment Settlement Agreements

To understand how reverse payments can affect competition and consumer drug prices, an explanation of how reverse payments develop is necessary.⁵⁰ As part of the “procompetitive thrust” of the Hatch-Waxman Act, the Act facilitates and encourages challenges to a patent’s validity.⁵¹ Aside from the valuable 180-day exclusivity period afforded to the first filer, the generic challenger is also free to challenge an existing patent by creating a patent-infringing generic with little risk. This is because, at best, the subsequent challenge by the patent holder can be characterized as an “artificial” patent infringement suit, as the generic manufacturer has neither marketed nor sold an infringing drug before the suit is filed.⁵² Because the generic manufacturer has not yet infringed on the patent holder’s patent, the generic manufacturer is not at risk of being held liable for damages when challenging a patent.⁵³

The brand-name manufacturer must accept this challenge because the structure of the Hatch-Waxman Act almost requires the brand-name manufacturer to bring a patent infringement suit against the generic, or else lose its patent. If the brand-name manufacturer does not file suit, the generic drug will enter the market immediately once its ANDA is

48. 21 U.S.C. § 355(c)(3)(C) (2012).

49. *Id.* This “thirty-month” provision is particularly important in the context of reverse payment settlements because it encourages patent holders to file suit and enjoy the thirty-month stay rather than immediately lose the exclusivity of their patent.

50. The mechanics of reverse payment settlements can be difficult to grasp. For a better understanding of this concept, see *infra* Part VI.B and for recent examples, see *infra* Part VII.

51. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2225–26 (2013) (noting that the Hatch-Waxman Act facilitates patent challenges and requires parties in a Paragraph IV dispute to report the settlement agreement to the government).

52. See Robin P. Sumner & Melissa J. Hatch, *A Turducken Task: How Actavis Invites Relitigation of Patent Merits in Reverse Payment Cases*, 29 No. 10 WESTLAW J. PHARM. 12 at *4 n.13 (Nov. 26, 2013) (noting that a generic challenger is not liable for damages because it has not actually marketed an infringing product).

53. See *id.*

approved,⁵⁴ and the branded manufacturer will typically lose a substantial volume of business.

The result is that the Hatch-Waxman Act achieved its goal of increasing the number of patent challenges. But it also increased the number of patent infringement suits filed.⁵⁵ These patent infringement suits often end in a settlement between the parties.⁵⁶ The structure of these settlements is quite unique because the patent holder pays off the patent-infringing generic manufacturer in return for the generic manufacturer's promise not to enter the market.⁵⁷ The opposite direction in which these payments flow is the reason they are called "reverse payment settlements."⁵⁸

The antitrust concerns in reverse payments are two-fold. First, under a reverse payment agreement, the brand-name manufacturer is able to maintain monopoly power with a patent that may have been found invalid or not infringed had litigation continued. Second, the generic manufacturer, instead of bringing a competitive drug to market, essentially shares the branded manufacturer's profits resulting from its supracompetitive prices.⁵⁹ These agreements not only have the effect of taking the first filer's generic out of the market, but they also prevent other generics from trying to enter the market before the parties have settled.⁶⁰ As a result, consumers are not

54. *See id.*

55. *See* Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 443 (2008) (noting that one of the intentions behind the Hatch-Waxman Act was to increase challenges to brand name drug companies' patents before the expiration of such patents).

56. *See* Dickey et al., *supra* note 44, at 367, 373–74 ("From 1992 to 2000, nearly forty percent of litigations against the first ANDA filer resulted in a settlement.").

57. *See id.* at 374 (listing a number of forms that reverse payment settlements typically take). If, on the other hand, the patent would have been found valid and infringed upon had litigation continued, the reverse payment would have no adverse effect on competition. *See also infra* Part III.

58. These agreements take place in reverse because the patent holder bringing suit against an alleged infringer (the generic manufacturer) pays the infringer rather than the infringer paying the patent holder for their potentially infringing conduct. *See* HOLMES, *supra* note 10.

59. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234 (2013) (stating that reverse payment settlements have the effect of setting "prices at patentee-set levels, potentially producing the full patent-related . . . monopoly return while dividing that return between the challenged patentee and the patent challenger").

60. Several provisions of the Hatch-Waxman Act make this the case. First, subsequent generic challengers have no incentive to bring additional challenges to a weak patent because they cannot benefit from the 180-day exclusivity period. Because competing

able to benefit from the cost savings they would have realized had the generic entered the market and taken business from the brand-name manufacturer.⁶¹ The generic's entrance into the market would reduce the branded manufacturer's market power, likely forcing it to reduce its price to compete with the lower-priced generic drug.

III. *The Impact of Reverse Payments on Competition*

As noted above, reverse payment settlement agreements can have procompetitive effects by reducing litigation costs and allowing generics to enter the market sooner than they otherwise would.⁶² But these agreements also carry the major risk of stifling competition. The key indicators of the effect a particular reverse payment will have on competition are the strength of the underlying patent and whether, if the patent is valid, the generic drug infringes it. If a patent is strong and infringed, a reverse payment agreement that forces the generic manufacturer to delay entry into the future but allows the generic to enter before the expiration of the patent will not be anticompetitive or harm consumers.⁶³ Without such an agreement, the generic would not be able to enter the market until the expiration of the patent. But under the agreement, the generic would be allowed to enter into the market sooner than otherwise—a procompetitive result.⁶⁴ However, if the underlying patent is weak and likely to be found

generics are not likely to challenge the patent, they will wait until both parties have settled their patent infringement claim before filing their own ANDA with the FDA. And like the first filer they must wait approximately thirty months before the FDA gives its approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). *See id.* at 2235.

61. *See* Glazer & Desmond-Harris, *supra* note 19, at 15 (stating that reverse payments allow the generic manufacturer and brand-name manufacturer to split monopoly profits, profits that would have trickled down to consumers in the form of cost savings had the generic been allowed to enter the market).

62. *See supra* notes 10–17 and accompanying text (stating that reverse payments can have both procompetitive and anticompetitive effects).

63. *See* Dickey et al., *supra* note 44, at 376–77 (“If the patent is quite strong, and likely to be found valid and infringed, then even a settlement with an agreed-upon entry date well into the future, but before the patent’s expiration, may bring generic drugs to market sooner than the expected outcome from continued litigation.”).

64. I believe this is a point many often ignore when they criticize the Supreme Court’s decision in *Actavis*. Although reverse payments may result in higher prices for consumers, many actually reduce drug prices by enabling generics to enter the market sooner. *See, e.g.,* Alex Galvan, *A Second Opinion on Pharmaceutical Reverse Payment Settlements: Why Actavis Missed the Mark*, 30 GA. ST. U. L. REV. 561, 586 (2014) (stating that the Court should have applied quick-look analysis to reverse payments because they eliminate

invalid or if the generic drug were non-infringing, a delayed entry would be anticompetitive. The fact that reverse payment agreements can be procompetitive or anticompetitive has led to extensive debate and inconsistent court decisions over the last twenty years as to where these agreements fit in antitrust law.⁶⁵

IV. *The Impact of Reverse Payments on Consumers*

Although reverse payment settlements have the potential to be procompetitive, it appears that the net result of these types of agreements is a substantial loss to consumers. The Federal Trade Commission (FTC) found that reverse payment agreements cost American consumers an estimated \$3.5 billion per year in savings because brand-name drugs are ten times more expensive than their generic counterparts.⁶⁶ Consumers are prevented from enjoying these low-cost generics because reverse payment agreements delay generic market entry by approximately seventeen months.⁶⁷ Therefore, if a consumer is forced to spend \$300 per month for a prescription drug when a marketable generic is available for \$30, a delay due to a reverse payment agreement of seventeen months would cost a single consumer \$4,950 over the delay period.⁶⁸ A drug cost increase of

competition “and the consumer is left to pay the (high) price”).

65. *See id.* at 384 (“While the potential for patent settlements to be procompetitive is generally recognized by economists, antitrust agencies, and the courts, ‘reverse payment’ settlements have generated extensive debate in recent years.”).

66. *See* FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (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>. This figure seems to rest on assumptions not fully explained in the FTC’s report. Most importantly, the report might be making the assumption that *all* reverse payment agreements will cost consumers. It does not fully explain instances where, had litigation continued, the patent would have been found valid and infringed upon. In these cases, a settlement between the parties would result in the generic entering the market sooner than it otherwise would have. *See supra* Part III. However, the report does state that “generics prevailed in 73% of the patent litigation ultimately resolved by a court decision between 1992 and June 2002,” indicating the challenged patents are often invalid. *See* FED. TRADE COMM’N at 3.

67. *See* FED. TRADE COMM’N, *supra* note 66, at 4.

68. These figures are based on a hypothetical generic drug costing \$300 per month used by the FTC staff in the making of this report. However, the report cited by the FTC highlights twenty popular brand name drugs affected by reverse payments. It shows that a brand name drug costing \$300 per month is not unusual and the cost of its generic counterpart on average is ten times less than the brand name counterpart, but can be as much as thirty-three times cheaper. *See id.*

almost \$5,000 would be difficult for many Americans to stomach; particularly considering that in 2012 over half of elderly Medicare recipients had annual incomes lower than \$22,500.⁶⁹

Even more concerning is the fact that these reverse payments are particularly harmful to historically underrepresented Americans, specifically the poor and the elderly. These groups are most affected by inflated drug prices because they are least able to afford medication and the most at-risk for chronic medical conditions.⁷⁰ Further, Americans who are elderly or uninsured are much more likely to forgo needed prescriptions due to cost and unavailability.⁷¹ In fact, according to the AARP, “having a generic option is often the difference between having access to a healthcare treatment and not having any treatment option at all.”⁷² The harsh reality is that many Americans need generic drugs in order to stay alive.⁷³ To further exacerbate the problem, the need for prescription drugs is steadily increasing and spending on national healthcare has quadrupled in the last decade and a half.⁷⁴

Reverse payment settlements have also proven to be a major burden on the national healthcare system. A study conducted by the U.S. Public Interest Research Group (U.S. PIRG) found that reverse payments affect the

69. See *10 Years Later: A Look at the Medicare Prescription Drug Program: Hearing Before the Senate Special Commission on Aging*, 113th Cong. 10 (2013) (statement by Robert G. Romasco, AARP President), available at http://www.aging.senate.gov/imo/media/doc/04_Romasco_5_22_131.pdf.

70. See Brief for AARP, et al. as Amici Curiae Supporting Petitioners, at *1, *FTC v. Watson Pharmaceuticals, Inc., et al.*, 133 S. Ct. 787 (2013) (No. 12-416) (“Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has experienced an increasing rate of prescription drug use.”).

71. See Ellyn R. Boukus & Emily R. Carrier, *Americans’ Access to Prescription Drugs Stabilizes, 2007-2010*, HEALTH SYSTEM CHANGE (2011), available at <http://hschange.com/CONTENT/1264/1264.pdf> (“In 2010, those with incomes below 200% of poverty—\$44,100 for a family of four—were 3.4 times more likely to report drug access problems as those earning 400% of poverty or more . . .”).

72. Brief for AARP, *supra* note 70, at *5.

73. See Alicia I. Hogges-Thomas, *An American Drug Problem: Reclaiming Consumers’ Rights Under the Hatch-Waxman Act*, 37 VT. L. REV. 737, 737 (2013) (“There are Americans who need their prescription drugs to stay alive.”).

74. See Brief for AARP, *supra* note 70, at *2. One could argue that an increase in spending on healthcare can be attributed to the dramatic development of medical technology that has reduced the negative effects of some diseases. However, American spending on healthcare continues to be much higher than what is spent in other developed countries. And this high cost has not translated to longer life expectancy compared to countries like Canada and many European countries. Thomas F. Cotter, *Patents, Antitrust, and the High Cost of Healthcare*, 13 ANTITRUST SOURCE 1, 1 (April 2014).

availability of drugs used to remedy a wide range of chronic medical conditions, from cancer and heart disease to bacterial infections and depression.⁷⁵ In total, reverse payment agreements have adversely affected 142 brand-name drugs since 2005.⁷⁶ Further, brand-name drug sales of these drugs during the time period in which generics were not allowed to enter the market has been estimated at \$98 billion.⁷⁷ Among those drugs most affected are drugs commonly prescribed to elderly patients including Cardizem (a calcium channel blocker), Effexor (an antidepressant), Lipitor (a lipid lowering agent), K-Dur (a potassium replacement therapy), and Sinemet (an anti-Parkinson's therapy).⁷⁸ The Congressional Budget Office found that if generics were allowed to enter the market sooner, they would save Medicare billions of dollars per year.⁷⁹

V. Congressional Action Proposed to Stop Reverse Payment Settlements

Over the last five years, several bills that have been introduced in Congress aimed at eliminating reverse payment agreements, but all have stalled in the legislative process.⁸⁰ Despite this lack of success, two bills

75. *Pay-for-Delay Deals: Limiting Competition and Costing Consumers: Hearing Before the Subcomm. on Antitrust, Competition, Policy and Consumer Rights*, 113th Cong. 4 (2013) (statement of Mike Russo, Federal Program Director for U.S. PIRG), available at <http://www.judiciary.senate.gov/imo/media/doc/7-23-13RussoTestimony.pdf>.

76. See U.S. PUBLIC INTEREST RESEARCH GROUP, *supra* note 8.

77. See *Id.* (“Combined, these brand-name drug companies have made an estimated \$98 billion in total sales of these drugs while the generic versions were delayed.”).

78. Data gathered by comparing the most popular drugs affected by reverse payment settlement agreements and the most common drugs prescribed to elderly patients. See *id.*; see also *Drugs Commonly Prescribed to Elderly*, HOMEMEDS.ORG (last visited Feb. 30, 2014), available at <http://www.homemeds.org/images/medialibrary/0620A6A37F028F33FEDC05FC1272963D.pdf>.

79. See *10 years later: A Look at the Medicare Prescription Drug Program: Hearing Before The Senate Special Comm. on Aging*, 113th Cong. 10 (2013) (statement of Max Richtman, National Committee to Preserve Social Security and Medicare), available at <http://www.ncpssm.org/PublicPolicy/LettersTestimony/Documents/ArticleID/1158/10-Years-Later-A-Look-at-the-Medicare-Prescription-Drug-Program> (stating that if the FTC were able to prevent reverse payment settlements from occurring, it would save Medicare \$11 billion over the next 10 years).

80. See Hogges-Thomas, *supra* note 73, at 738 (citing four bills that have been introduced but stalled: America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 2563 (2009); Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009) (died in committee and reintroduced as S. 27 on January 25, 2011); Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2012)).

were reintroduced in 2013 in an attempt to remedy the anticompetitive harm reverse payments can cause, either by eliminating reverse payments altogether or amending certain key provisions in the Hatch-Waxman Act.⁸¹ To date, no new bills have been introduced in 2014.

Sen. Amy Klobuchar introduced the Preserve Access to Affordable Generics Act (PAAG Act) in February 2013, which aims to “prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.”⁸² The bill notes that generic drugs are substantially less expensive than brand-name drugs and that the Hatch-Waxman Act has facilitated the prevention of entry by low-cost generic drugs.⁸³ The PAAG Act would create a rebuttable presumption that all reverse payment agreements “have anticompetitive effects and [are] unlawful.”⁸⁴ Courts can consider several enumerated factors when determining whether the parties have successfully rebutted this presumption, including the remaining lifetime of the patent involved and the value to consumers of competition in the relevant drug market.⁸⁵

In March of 2013, Sen. Al Franken introduced another bill addressing reverse payments, the Fair and Immediate Release of Generic Drugs Act (FAIR Generics Act).⁸⁶ This bill proposes a slightly more patent-friendly solution to reverse payments than the PAAG Act; if passed, it will revise the “first-filer” definition by only awarding the 180-day exclusivity period to any ANDA applicant that has not entered into a “disqualifying agreement.”⁸⁷ The bill defines a disqualifying agreement as an agreement where the applicant agrees with a brand-name manufacturer not to seek approval of its application or market its drug before the life of the patent in question expires.⁸⁸ The bill also attempts to provide more clarity regarding litigation risk for generic manufacturers and brand name companies by requiring brand name companies to decide whether to file an infringement action within the 45-day window provided in the Hatch-Waxman Act.⁸⁹

81. Both bills introduced are bills that have previously failed somewhere along the legislative process. *See* Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013); *see also* FAIR Generics Act, S. 504, 113th Cong. (2013).

82. Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013).

83. *Id.* at §2(a)(4)–(6).

84. *Id.* at §28(a)(2).

85. *Id.* at §28(b).

86. FAIR Generics Act, S. 504, 113th Cong. (2013).

87. *Id.* at §3(a)(1)(vii)(II).

88. *Id.* at §3(a)(1)(vii)(II).

89. *Id.* at §3(b)(7).

*VI. Analysis of Reverse payments Pre-Actavis**A. Antitrust Standards: A Primer*

Reverse payment agreements may have procompetitive and anticompetitive effects depending on the specific facts. For this reason, the most controversial aspect of reverse payments is the depth of antitrust scrutiny that courts should apply to determine their effect on competition. Consumers should be concerned about the court's decision on this issue, because the antitrust standard courts end up applying affects the number of reverse payments permitted to squeeze by antitrust condemnation.

The FTC has challenged reverse payment agreements under section 5 of the Federal Trade Commission Act, which prohibits “unfair methods of competition in or affecting commerce.”⁹⁰ Unfair methods of competition under section 5 include agreements that would violate section 1 of the Sherman Act, which prohibits agreements that unreasonably restrain competition.⁹¹ In determining whether an agreement unreasonably restrains competition, courts and the FTC generally apply one of three standards: 1) the per se rule, 2) “quick-look” analysis, or 3) rule of reason analysis.⁹² The standard of review the court applies depends on the nature of the conduct in question and how likely it is that the type of conduct under challenge has anticompetitive effects.⁹³ If it is a type of conduct that is so inherently anticompetitive “as to warrant perfunctory antitrust condemnation without inquiry into [its] actual market impact or possible competitive justification,” it will be deemed per se illegal.⁹⁴ Because the per se rule establishes a conclusive presumption of unlawfulness regardless of the conduct's actual effect and thus does not permit the defendant to rebut

90. Unfair Methods of Competition Unlawful; Prevention by Commission, 15 U.S.C. § 45 (2012).

91. See Robert E. Entwisle & Daniel K. Storino, *United States: The Uncertain Reach Of Section 5 Of The Federal Trade Commission Act*, MONDAQ (Apr. 8, 2014), <http://www.mondaq.com/unitedstates/x/305416/Trade+Regulation+Practices/The+Uncertain+Reach+Of+Section+5+Of+The+Federal+Trade+Commission+Act> (“Although not expressly authorized to enforce the Sherman Act, the FTC reaches such conduct through Section 5, . . .”).

92. See generally WILLIAM HOLMES & MELISSA MANGIARACINA, *ANTITRUST LAW HANDBOOK* § 2:9 (2012-2013 ed. 2012) (providing a thorough discussion of the various antitrust standards and the specific circumstances when each is used).

93. See *Agnew v. NCAA*, 683 F.3d 328, 335 (7th Cir. 2012) (stating that the category of analysis courts use is determined by its potential competitive effects).

94. HOLMES & MANGIARACINA, *supra* note 92, at § 2:10.

the presumption of illegality, it applies only in rare circumstances.⁹⁵ Agreements that have been deemed *per se* unlawful include horizontal price fixing and market allocation agreements.⁹⁶

If the conduct is not inherently anticompetitive but instead has both anticompetitive and procompetitive effects, it will be analyzed under the more flexible “rule of reason” standard.⁹⁷ Under full-blown rule of reason analysis, the court weighs the conduct’s procompetitive and anticompetitive effects and asks whether the procompetitive effects, *i.e.*, increased efficiencies or consumer benefits, outweigh the decrease in competition that result from such conduct.⁹⁸

Between the *per se* rule and rule of reason analysis lies a “continuum” of standards that borrow approaches from both *per se* and rule of reason analysis for conduct that does not fit in either of the two extremes.⁹⁹ For example, the “quick look” or truncated rule of reason is used where the defendant’s conduct is not *per se* illegal, yet the conduct’s apparent anticompetitive effects makes it unnecessary to go through full-blown rule of reason analysis.¹⁰⁰ For the quick-look rule to apply, “the conduct at issue and context in which it arises must have likely anticompetitive effects that are so intuitively obvious as to be clear without a detailed market analysis,

95. *Id.* at § 2:9.

96. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 209 (3d Cir. 2012) (“Examples of agreements that have been held unlawful pursuant to the *per se* rule include horizontal price fixing, output limitations, market allocation, and group boycotts.”).

97. *See HOLMES & MANGIARACINA, supra* note 92, at § 2:10.

98. *See Nat’l Soc’y of Prof’l Engrs v. United States*, 435 U.S. 679, 691 (1978) (“[T]he inquiry mandated by the Rule of Reason is whether the challenged agreement is one that promotes competition or one that suppresses competition.”). In rule of reason analysis, courts typically employ a burden-shifting framework. The plaintiffs bear an initial burden to demonstrate the defendants’ challenged behavior had an actual adverse effect on competition in the relevant market. If the plaintiffs satisfy their initial burden, the burden shifts to the defendants to offer evidence of the procompetitive effects of their agreement, and if the defendants can provide such proof, the burden shifts back to the plaintiffs to prove that any legitimate competitive benefits offered by defendants could have been achieved through less restrictive means. *See Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 829–30 (2010). Ultimately, the factfinder will weigh the effects and determine which effect predominates. If, on balance, the conduct has significant anticompetitive effects, it violates section 1 of the Sherman Act or, if the action is brought by the FTC, section 5 of the Federal Trade Commission Act. *Id.*

99. *See HOLMES & MANGIARACINA, supra* note 92, at § 2:9 (discussing other standards that are used when conduct is “difficult to place under either the *per se* or the rule of reason banner”).

100. *Id.* at § 2:10.

i.e., from just a ‘quick look.’”¹⁰¹ Under the quick-look rule, the plaintiff need not prove that the conduct has actual anticompetitive effects—they are presumed. But the defendants are permitted to offer procompetitive justifications for their conduct. If they do, the court must balance the effects; but if not, the conduct is condemned without the plaintiffs having to define the relevant market or establish the defendant’s market power.¹⁰²

B. Antitrust Standards Applied to Reverse Payment Settlement Agreements

Before the Supreme Court’s decision in *Actavis*, circuits applied varying standards to reverse payment settlements. *In re Cardizem CD Antitrust Litigation*,¹⁰³ a case from the Sixth Circuit, involved an agreement between Hoescht Marion Roussel Inc., the manufacturer of the prescription drug Cardizem CD (Cardizem), and Andrx Pharmaceuticals (Andrx), a company that would produce the generic version of that drug.¹⁰⁴ Pursuant to a reverse settlement agreement, Cardizem would pay Andrx \$10 million per year and in exchange, Andrx would refrain from marketing their drug even after it had received FDA approval.¹⁰⁵ The Sixth Circuit determined that at its core, the reverse payment agreement was a horizontal restraint on trade and was thus *per se* unlawful.¹⁰⁶ Therefore, the court held that the *per se* rule should apply.¹⁰⁷

The Second and Eleventh Circuits, however, rejected the *per se* rule and instead held that a reverse payment is valid as long as competition is restrained only within the exclusionary scope of the patent.¹⁰⁸ That is, the

101. *Id.*

102. *See id.* (stating that most circuit court of appeals employ a burden shifting framework like that typically used in rule of reason analysis).

103. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003) (holding that the reverse payment agreement in question was “a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws”).

104. *Id.* at 899.

105. *Id.*

106. *Id.* at 908.

107. *See id.* at 900 (“The Agreement . . . is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws.”).

108. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (adopting the question presented in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) of whether the “exclusionary effects of the agreement” exceed the “scope of the patent’s protection”).

reverse payment would not be illegal if the agreement not to enter the market ended before the brand-name manufacturer's patent expired.¹⁰⁹ These courts noted that to expose these types of reverse payment agreements to antitrust scrutiny would chill settlement.¹¹⁰ It also runs in the face of the principle that a patent holder has a right to exclusion that is largely immune from antitrust liability.¹¹¹ These courts instead held that a patent is presumptively lawful absent sham or baseless litigation if the exclusion does not exceed the scope of the exclusion permitted under the patent laws.¹¹²

The Third Circuit disagreed with the scope-of-the-patent test because it institutes an almost irrebuttable presumption that the patent is valid.¹¹³ In *In re K-Dur Antitrust Litigation*,¹¹⁴ the court decided that such a presumption is unfounded, as many patents issued by the Patent and Trade Office are later found to be invalid or not infringed in paragraph IV litigation.¹¹⁵ Further, there are strong public policy grounds for allowing first filers to challenge weak patents; patents should be a limited exception to the general rule that ideas and innovation should be able to flow freely throughout an industry.¹¹⁶ Given these public policy concerns, the Third

109. See *Tamoxifen*, 466 F.3d at 213 (holding that a reverse payment is presumptively lawful absent sham or baseless litigation if the exclusion does not exceed the scope of the exclusion permitted under the patent laws), *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (same), and *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1305 (11th Cir. 2003) (same).

110. See *Schering-Plough Corp.*, 402 F.3d at 1064 (citing *Valley Drug Co.*, 344 F.3d at 1309) (stating if the agreement is no more broad than the exclusionary scope of the patent, there is no need for these agreements to undergo antitrust scrutiny).

111. See *Valley Drug Co.*, 344 F.3d at 1307 (stating that patent immunity can only be pierced if "the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office").

112. See *Tamoxifen*, 466 F.3d at 208–09 ("In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.").

113. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d Cir. 2012) ("[W]e take issue with the scope of the patent test's almost un rebuttable presumption of patent validity.").

114. See *id.* at 218 (holding that the scope of the patent test is inappropriate and directed the lower courts to apply quick look analysis to reverse payment cases).

115. See *id.* at 215 ("Many patents issued by the PTO are later found to be invalid or not infringed, and a 2002 study conducted by the FTC concluded that, in Hatch–Waxman challenges made under paragraph IV, the generic challenger prevailed seventy-three percent of the time.").

116. See *id.* ("This practical analysis is supported by a long line of Supreme Court cases

Circuit rejected the scope-of-the-patent test because it fails “to protect consumers from unjustified monopolies by brand name drug manufacturers.”¹¹⁷ Instead, the court held that the quick look standard applied, whereby the reverse payment could be used as *prima facie* evidence of an unreasonable restraint on competition.¹¹⁸

VII. FTC v. Actavis

Given the split among the circuits, the Supreme Court granted certiorari in *FTC v. Actavis*, a reverse payment settlement agreement decision from the Eleventh Circuit with facts similar to those in other reverse payment settlement cases. In 1999, Solvay Pharmaceuticals (Solvay) filed an NDA with the FDA for a new brand-name drug called AndroGel.¹¹⁹ Later that year, petitioner Actavis (known as Watson Pharmaceuticals at the time) filed an ANDA with the FDA to begin manufacturing a generic version of AndroGel.¹²⁰ Actavis, along with Paddock Laboratories (Paddock), another generic manufacturer, certified under Paragraph IV that Solvay’s patent was invalid.¹²¹ Solvay then initiated Paragraph IV patent infringement litigation against Actavis, Paddock, and the generic manufacturer Par (a pharmaceutical company working with Paddock).¹²²

Actavis’s drug was approved and was granted the 180-day first-filer exclusivity period.¹²³ However, in 2006 all parties settled the patent litigation. Under the settlement, Actavis agreed not to bring its generic drug to market until sixty-five months before Solvay’s patent expired.¹²⁴ Therefore, their agreement was within the exclusionary scope of Solvay’s patent. Actavis also agreed to market AndroGel to urologists during the agreement period.¹²⁵ In return, Solvay agreed to pay millions of dollars to

recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas.”).

117. *Id.* at 217.

118. *Id.* at 218.

119. *See* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013).

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.*

124. *See* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013).

125. *Id.*

the respondent generic manufacturers, including an annual payment of \$19 to \$30 million a year to Actavis for nine years.¹²⁶ The FTC subsequently filed a lawsuit against Solvay, Actavis, Paddock, and Par under §5 of the FTC Act for agreeing to share Solvay's monopoly profits and abandoning their patent challenges.¹²⁷

Prior to the Supreme Court's grant of certiorari, the Eleventh Circuit dismissed the FTC's complaint. Applying the scope-of-the-patent test, it held that the reverse payment was valid because the agreement not to enter Solvay's market expired before the life of the patent.¹²⁸ The FTC urged the Court to apply the quick-look standard.¹²⁹ They recognized that there are "possible legitimate justifications for the payment" but reverse payments are similar to conduct that has received per se treatment.¹³⁰ Respondents, on the other hand, urged the Court to uphold the scope of the patent test citing the longstanding principle that a "patentee is exempt from the antitrust laws so long as the patentee does not use its patent to reach 'beyond the limits of the patent monopoly.'" ¹³¹ The Court decided that the quick-look rule was not appropriate, as reverse payments do not clearly have anticompetitive effects.¹³²

The Supreme Court also rejected the scope of the patent test, determining that reverse payments "can sometimes violate antitrust laws."¹³³ For this reason, the Eleventh Circuit should have allowed the FTC's complaint to proceed.¹³⁴ The Court resolved the contentious circuit split by rejecting the quick look approach, the per se rule, and the scope of

126. *Id.*

127. *Id.* at 2229–30.

128. *Id.* at 2227.

129. See Brief for Petitioner at 33, *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012) (No. 10-12729), available at <http://sblog.s3.amazonaws.com/wp-content/uploads/2013/01/12416tsUnitedStates.pdf>.

130. *Id.* at 33.

131. Brief for Respondent at 15, *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012) (No. 10-12729) (citing *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)), available at <http://sblog.s3.amazonaws.com/wp-content/uploads/2012/11/12-416-Brief-for-Solvay-Pharmaceuticals.pdf>.

132. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013) (stating that reverse payments do not meet the requisite criterion which would allow the Court to adopt a presumptive standard in favor of rule of reason).

133. *Id.* at 2227.

134. *Id.*

the patent test, holding that reverse payments should be analyzed under rule of reason.¹³⁵

A. The Court's Guidance to Analyzing Reverse Payments (Or Lack Thereof)

The Court made several general observations justifying its holding in *Actavis* that reverse payment settlements should be assessed under the rule of reason standard and also attempted to shed some light on how the lower courts should apply it.¹³⁶ First, the Court recognized that reverse payments can be anticompetitive because they sometimes allow patent holders to enjoy market exclusivity even if their patents are invalid or not infringed by the generic entrant.¹³⁷ Second, the anticompetitive effects of these settlements at least sometimes outweigh their potential benefits of reducing litigation costs and decreasing uncertainty.¹³⁸ Third, the Court claimed that the size of the reverse payment can be a strong indicator of the market power of the brand name manufacturer, and thus its ability to cause anticompetitive harm.¹³⁹ Fourth, the Court stated that applying the rule of reason to reverse payments is feasible because it will often not be necessary to test the patent's validity.¹⁴⁰ This statement is in response to the dissent's main concern that assessing the patent's validity, and whether the generic infringes in each case, will be complex and lead to uncertainty.¹⁴¹ Lastly, the Court noted some alternatives the parties could use to settle the infringement suit in lieu of reverse payments, including allowing the generic drug manufacturer to simply enter the market before the expiration of the patent.¹⁴² The Court recognized that cash settlements might be more

135. *See id.* at 2237 (rejecting the FTC's argument that reverse payments should be analyzed under the quick look rule instead of rule of reason because reverse payments are not clearly unlawful).

136. *See id.* at 2234 (“[F]ive sets of considerations lead us to conclude that the FTC should have been given the opportunity to prove its antitrust claim.”).

137. *Id.*

138. *See id.*

139. *See* discussion *infra* Part VII.B. The Court states that “the ‘size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power’—namely, the power to charge prices higher than the competitive level.” *See* FTC v. Actavis, 133 S. Ct. 2223, 2236 (2013) (citing PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046, at 351 (3d ed. 2012)).

140. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013)

141. *Id.*

142. *Id.*

beneficial to the settling parties but noted that if the only reason a cash settlement is beneficial is because it allows the parties to split monopoly profits, the reverse payment agreement is unlawful.¹⁴³

B. How Should Lower Courts Apply Actavis?

Although the Court's decision to adopt the rule of reason can be considered a victory for consumers because all reverse payment agreements are now subject to antitrust scrutiny, the Court punted the issue of how to apply this standard to the lower courts.¹⁴⁴ As a result, the decision leaves many unanswered questions.¹⁴⁵ The first is whether the Court actually expects lower courts to adopt full-blown rule of reason analysis. Some argue that a number of the Court's observations suggest a framework more indicative of a quasi-rule of reason/quick look standard.¹⁴⁶ The Court decided that testing the validity of the underlying patent would not be necessary because the size of the reverse payment is a "strong indicator" of the severity of its economic effects.¹⁴⁷ In traditional rule of reason analysis, the plaintiff must initially prove that the conduct has anticompetitive effects either through direct evidence (i.e. supracompetitive prices or decreased output or quality) or circumstantial evidence (i.e. a showing that the defendant has sufficient market power to bring about anticompetitive harm).¹⁴⁸ In *Actavis*, the Court established an initial presumption that the conduct is anticompetitive due to the unreasonable size of the reverse

143. *Id.*

144. *See id.* at 2238 (2013) ("We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.").

145. *See* Peter Picht, *New Law on Reverse Payment Settlements-The Agenda for Courts and the Legislature After the Supreme Court's Actavis Ruling*, 16 TUL. J. TECH. & INTELL. PROP. 105, 119 (2013) (stating that although the Court held that rule of reason analysis was appropriate in reverse payment cases, "[t]he exact shape of the Supreme Court's new approach is much less clear").

146. *See* Joshua D. Wright, Commissioner, Fed. Trade Comm'n, Remarks at the Concurrences Journal Annual Dinner 10 (Sept. 26, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf (noting the "general proposition that *Actavis* appears to direct lower courts to apply the rule-of-reason with a relatively light touch in the reverse payment context").

147. *Id.*

148. *See supra* note 98 and accompanying text (discussing the balance shifting framework employed in rule of reason analysis).

payment, eliminating the need to prove market power or provide direct economic evidence.¹⁴⁹

Not requiring the lower courts to determine the strength of the patent would provide an enormous benefit in the form of efficiency and cost savings. First, by allowing the size of the payment to take the place of testing the patent's validity, the lower courts can avoid deciding the major patent law questions. Lower courts often complain about being forced to litigate a patent claim within an antitrust claim because of the administrative and conceptual difficulties associated such a task.¹⁵⁰ Further, litigating the validity and infringement issues imposes heavy burdens on the courts.¹⁵¹ Patent and antitrust are two areas of law where litigation takes an enormous amount of time.¹⁵² Both patent and antitrust litigation also heavily rely on expensive economic and industry experts. For example, the Eleventh Circuit stated in *FTC v. Watson Pharmaceuticals*¹⁵³ that the reverse payment litigation resulted in “mountains of evidence—when the lawsuit settled, more than 40 depositions had been taken and one side alone had produced more than 350,000 pages of documents.”¹⁵⁴ And even if the expert testimony is given and the facts are laid out, it is still often very difficult to determine the strength of the patent in part because some patent holders are unsure of the strength of their patent themselves.¹⁵⁵

Despite the potential benefits of relying on the size of the reverse payment, most practitioners and scholars have concluded that the Court was incorrect when it stated that the size of the settlement can replace litigating

149. See *supra* note 139 and accompanying text (stating that the Court in *Actavis* found that the size of the reverse payment could indicate the anticompetitive effect the settlement agreement would have on the pharmaceutical market).

150. See Sumner & Hatch, *supra* note 52, at *4 (“Lower courts have long recognized that the ‘turducken task’ of litigating the merits of a patent case within an antitrust case is conceptually and administratively difficult . . .”).

151. See Sumner & Hatch, *supra* note 52, at *4.

152. See Daniel A. Crane, *Optimizing Antitrust Enforcement*, 63 VAND. L. REV. 675, 692 (2010) (citing a Georgetown University study that found the average antitrust case takes three times longer than other civil federal cases from claim to judgment).

153. See *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1314 (11th Cir. 2012) *cert. granted*, 133 S. Ct. 787 (2012), and *rev'd and remanded sub nom. FTC v. Actavis*, 133 S. Ct. 2223 (2013) (holding that a reverse payment settlement agreement is valid absent sham as long as it meets the scope of the patent test).

154. See *id.* at 1314.

155. See Tania Khatibifar, Note, *The Need for A Patent-Centric Standard of Antitrust Review to Evaluate Reverse Payment Settlements*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1351, 1393 (2013) (“Evaluating the strength of a patent is difficult to pinpoint with precision and may be unknowable to the patentee itself, . . .”).

the patent's validity.¹⁵⁶ Determining the appropriateness of a reverse payment necessitates assessing the subjective opinion of the parties regarding their expected success in litigation and therefore their beliefs on the strength of the underlying patent.¹⁵⁷ Therefore, in assessing the anticompetitive effects of a reverse payment settlement, the central issue should be determining the validity of the patent and whether the generic would infringe.¹⁵⁸ In fact, FTC Commissioner Joshua Wright, in addressing the issues surrounding the *Actavis* decision, stated that "it would be surprising if courts summarily did away with the question of patent validity as part of their analysis altogether."¹⁵⁹

Presuming that a patent is invalid when a large reverse payment is involved also ignores the fact that reverse payments may be used even when the patent is valid. A patent holder may be extremely confident about its validity but may be willing to pay a large sum of money to eliminate the risk that, if put before a jury, the patent would be found invalid.¹⁶⁰ By ordering the lower courts to proceed through rule of reason analysis without testing the patent's validity, the Court takes a strong defense from the patent holder.¹⁶¹ Chief Justice Roberts highlights this point in his dissenting opinion:

156. See, e.g., Sumner & Hatch, *supra* note 52, at *2 (noting that "careful consideration also calls into question the high court's assurances that the parties will be able to avoid relitigating the patent case they were trying to settle"); see also *infra* note 159 and accompanying text, and Rahul Guha, et. al, *Evaluating Reverse Payment Settlements After Actavis*, LAW360 (June 19, 2013), available at <http://www.law360.com/articles/451286/evaluating-reversepayment-settlements-after-actavis> (arguing that "efforts by a plaintiff to avoid litigating the underlying merits of the patent litigation should prove unsuccessful").

157. See Sumner & Hatch, *supra* note 52, at *3 ("Any court considering whether a settlement delayed competition must determine the probabilistic entry date had the parties continued to litigate.").

158. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 228 (2d Cir. 2006) (Pooler, J., dissenting) ("[I]n assessing the reasonability of a Hatch–Waxman settlement, I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled . . .").

159. Wright, *supra* note 146, at 12.

160. See Jeffrey M. Cross et al., *The Supreme Court Adopts the Rule of Reason In Antitrust Challenges to Reverse-Payment Patent Settlements: Now what?*, 21 WESTLAW J. ANTITRUST 6 (Oct. 16, 2013) ("[E]ven if a patent holder is 95 percent confident that the patent is valid, it might pay a good deal of money to rid itself of a 5 percent chance of a finding of invalidity.").

161. See Rahul Guha et al., *Evaluating Pay-For-Delay Deals after FTC v. Actavis*, LAW360 (June 29, 2013), available at http://www.pbwt.com/files/Uploads/Documents/Evaluating%20Pay-For-Delay%20Deals%20after%20FTC%20v%20Actavis_Law360_2013.pdf.

[T]he defendant (patent holder) will want to use the validity of his patent as a defense I therefore don't see how the majority can conclude that it won't normally be "necessary to litigate patent validity to answer the antitrust question," . . . unless it means to suggest that the defendant (patent holder) cannot raise his patent as a defense in an antitrust suit. But depriving him of such a defense—if that's what the majority means to do—defeats the point of the patent, which is to confer a lawful monopoly on its holder.¹⁶²

In some cases, reverse payments are the only rational choice. Patent infringement litigation is often unpredictable and the costs associated with going all the way through a patent litigation are much more than the costs the defendant endures in such litigation.¹⁶³ Analysis of reverse payments must account for these circumstances.

C. How Would You Calculate the Size of the Settlement?

If lower courts do in fact use the size of the settlement as a surrogate for the validity of the patent, the question then becomes at what amount a settlement will be deemed large and unjustified.¹⁶⁴ There have been several different approaches offered since *Actavis* was decided. In *Actavis*, the Court suggested the likelihood of a reverse payment's illegality could be determined by comparing its size to the expected litigation costs.¹⁶⁵ However, this approach suffers from a major shortcoming: it would be impossible to estimate the parties' litigation costs without first determining the likely outcome of patent litigation, which in turn includes assessing the validity of the patent.¹⁶⁶

162. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2244 (2013) (Roberts, C.J., dissenting).

163. See Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation*, 10 NW. J. TECH. & INTELL. PROP. 19, 19 (2011) (stating that due to the asymmetric information inherent in patent litigation reverse payments can be "a conscious business decision based on risk management").

164. See Sumner & Hatch, *supra* note 52, at *3 (noting that *Actavis* presented this question without providing an answer).

165. See *Actavis*, 133 S. Ct. at 2236, (noting that a reverse payment may not be anticompetitive if it "amount[s] to no more than a rough approximation of the litigation expenses saved through the settlement").

166. See *supra* notes 152–155 and accompanying text (discussing the reason why determining whether a payment is unreasonable includes assessing the validity of the patent).

A second possibility is to compare the size of the settlement to a fixed benchmark.¹⁶⁷ The dissent in *Actavis* points to one study that estimates the cost of reverse payment settlement litigation in the neighborhood of \$10 million.¹⁶⁸ Professor Herbert Hovenkamp believes this would be a useful benchmark to begin with, as this number is slightly higher than patent litigation generally.¹⁶⁹ Once this benchmark is established, the parties can then dispute whether there are extenuating circumstances to justify a higher or lower number.¹⁷⁰ Although not without its critics,¹⁷¹ this approach seems far more feasible than attempting to estimate the expected litigation costs in each case. If courts do decide to use the size of the reverse payment in lieu of testing the validity of the patent, the fixed benchmark is the logical approach, as long as courts account for circumstances specific to each case.

The most likely answer to the question of how lower courts will treat reverse payments post-*Actavis* is they will initially apply something more akin to full-blown rule of reason, using the size of the reverse payment as one of many factors in determining the potential adverse effect it has on competition and consumers. The initial burden will rest with the plaintiffs to show that the agreement has an adverse effect on competition. The plaintiff, whether it is the government or a private party, will have to show that the agreement delayed entry of the generic drug into the market past an expected entry date. Analyzing the strength of the patent, the size of the payment, and the expected litigation costs if litigation were to continue will prove the anticompetitive effect.

If the plaintiff is able to show that the payment has the potential of having an adverse effect on competition, the defendant drug manufacturers can offer evidence of the procompetitive effects of the agreement. As

167. See Wright, *supra* note 146, at 12.

168. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2244 (2013) (Roberts, C.J., dissenting) (citing MARC GOODMAN ET AL., MORGAN STANLEY, QUANTIFYING THE IMPACT FROM AUTHORIZED GENERICS 9 (2004)).

169. Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, 15 MINN. J.L. SCI. & TECH. 3, 27 (2014).

170. See *id.* at 27 (“A good approach would be to start with a presumptive number of about [\$10 million], letting the parties dispute whether special factors in their case justify a number that is higher or lower.”).

171. See Wright, *supra* note 146, at 13 (“[S]imply pulling a number out of the air to serve as a benchmark may not allow courts to understand the important dynamics at play in a specific case and would fly in the face of antitrust doctrine’s increasing preference for economic substance over formal distinctions.”); see also Barry C. Harris et al., *Activating Actavis: A More Complete Story*, 28 ANTITRUST 83, 83 (Spring 2014) (stating that using expected litigation costs as a benchmark is essentially adopting the “quick look” approach; the approach expressly rejected by the Court).

discussed above, the manufacturer could offer evidence that the payment was given in order to avoid costly litigation or the payment is indicative of the branded manufacturer's subjective opinion of the likelihood of winning its patent infringement suit after assessing the risk of litigation. The burden will then shift back to the plaintiff to show that there were less restrictive means of achieving those competitive benefits, including allowing the generic manufacturer to enter the market in lieu of a cash settlement. The dissent in *Actavis*, however, is skeptical of the early-entry solution, as it may reduce the chances the parties will decide to settle because they have less with which to bargain.¹⁷²

Although a lengthy rule of reason analysis may be required initially, lower courts may be able to adopt a more truncated rule of reason analysis given a period of "economic learning and experience"¹⁷³ This is the kind of experience the FTC would argue courts have already developed.¹⁷⁴ In *Polygram Holding, Inc. v. FTC*,¹⁷⁵ a case involving an ancillary restraint on competition between Polygram and Warner Communications, the D.C. Circuit endorsed the Commission's view that some conduct can be held presumptively unlawful if the anticompetitive effects are "obvious from the nature of the challenged conduct."¹⁷⁶ This same case-specific approach can be eventually applied to reverse payment agreements. Although the Court in *Actavis* has found that evidence is not yet strong enough to completely condemn reverse payment agreements, new economic evidence may arise allowing courts to find a presumption of illegality in certain cases.¹⁷⁷

172. See *Actavis*, 133 S. Ct. at 2247 (Roberts, C.J., dissenting) ("The majority assures us, with no support, that everything will be okay because the parties can settle by simply negotiating an earlier entry date for the generic drug manufacturer But it's a matter of common sense, confirmed by experience, that parties are more likely to settle when they have a broader set of valuable things to trade.").

173. *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 36 (D.C. Cir. 2005).

174. See *supra* Part VII (noting that the FTC argued that the Court should adopt the quick look approach, indicating that courts have already had two decades of experience dealing with the effects reverse payments have on competition).

175. See *Polygram Holding, Inc.*, 416 F.3d at 31 (finding that an ancillary restraint on competition engaged in by two record companies, although not per se illegal, was presumptively unlawful).

176. *Id.* at 36.

177. See Wright, *supra* note 146, at 14 ("Although it is clear the Supreme Court does not believe the existing evidence presented to it by the Commission and *amici* concerning the competitive effects of reverse payment agreements is sufficient to draw such conclusions today, new evidence may permit a properly tailored case-specific presumption in the future.").

VIII. Post-Actavis Implications on Drug Prices and Consumer Welfare

Actavis holds that the rule of reason applies to reverse payment settlement agreements, rejecting the in-effect “safe harbor” for agreements permitting the generic to enter prior to the patent’s expiration date.¹⁷⁸ Although the effect of this decision on future reverse payment litigation has been discussed at length, an important question still remains; will the Court’s decision have an appreciable impact on drug prices and thus reduce healthcare costs for consumers? Some argue that it will. On the day *Actavis* was decided, the New York Attorney General exclaimed that “[t]oday’s ruling is a victory for millions of Americans who depend on generic drugs to treat illness and pain.”¹⁷⁹ The AARP issued a press release stating that *Actavis* was a win for consumers because it should stop excessively extended patent monopolies that create costs which trickle through our national healthcare system and burden those who need to treat chronic illnesses.¹⁸⁰ As a testament to the importance of this decision, the National Legislative Association on Prescription Drugs sent a letter to the Supreme Court just before *Actavis* was decided, urging the Court to find reverse payments anticompetitive, as “‘few cases before the Supreme Court this session could have more direct impact on consumers’ pocketbooks’ than this one.”¹⁸¹

A. What Actavis Means for Consumers

The *Actavis* decision should result in a decrease in anticompetitive reverse payment agreements, which will increase consumer access to

178. See Wright, *supra* note 146, at 15.

179. Richard Wolf, *Supreme Court Hits Drug Companies’ Profit-sharing Deals*, USA TODAY, June 17, 2013, <http://www.usatoday.com/story/news/nation/2013/06/17/supreme-court-brand-generic-drug-profit-sharing-deals/2178489/>.

180. See Press Release, *AARP Reacts to Supreme Court Decision on Pay-for-Delay*, AARP (June 17, 2013), available at <http://www.aarp.org/about-aarp/press-center/info-06-2013/AARP-React-to-Supreme-Court-Decision-on-Pay-for-Delay.html> (summarizing a statement by an AARP senior Vice President who proclaimed that “[t]he Court’s decision recognizes that pay for delay arrangements may violate antitrust laws. Making sure prescription drugs are available and affordable for consumers is critical to our nation’s health care system”).

181. See Nat’l Leg. Assoc. on Prescription Drug Prices, *Nlarx Signs Letter To Supreme Court Seeking Action To Stop “Pay For Delay” Deals Hike Drug Costs, Reduce Access*, NLARX (June 16, 2013), http://www.reducedrugprices.org/read_nlarxnews.asp?news=6770 (quoting a previous statement made by the Boston Globe Editorial Board).

generic drugs. The decision provides the FTC with more room to aggressively challenge reverse payment settlements, and the FTC has indicated that it intends to do so.¹⁸² *Actavis* also creates more uncertainty in patent infringement litigation, possibly deterring such litigation from taking place.¹⁸³ However, there is a possibility that drug manufacturers could shift toward other, more discrete means of settlement in an attempt to avoid antitrust scrutiny.

The *Actavis* decision makes it easier for the FTC to bring an antitrust claim against drug manufacturers. Practitioner Amanda Reeves believes this to be true because the threshold for pleading a reverse payment case under rule of reason is relatively low, making it more difficult for defendants to prevail on a motion to dismiss.¹⁸⁴ In some circumstances, the FTC may even be able to survive a 12(b)(6) motion if the manufacturers offer evidence that their settlement is not anticompetitive. The *Actavis* Court noted that while although “a reverse payment [may reflect] traditional settlement considerations,” this possibility “does not justify dismissing the FTC’s complaint.”¹⁸⁵ This is particularly true where “the settlement includes both a payment that exceeds litigation costs *and* a provision for delayed entry.”¹⁸⁶

Reverse payments, and thus patent infringement litigation, may also become less prevalent because litigation may be perceived as riskier to the parties post-*Actavis*. Settling parties will face increased uncertainty in determining whether courts will find their agreement unlawful. Initially, parties will only be able to speculate as to how the size of the settlement will fit in to district courts’ rule of reason analysis and what specific mitigating factors defendants will be able to use to prove that their

182. See *Pay-For-Delay Deals: Limiting Competition and Costing Consumers: Hearing Before the Subcomm. on Antitrust, Comp. Pol’y, and Consumer Rights* 113th Cong. 3 (2013) (statement of the Federal Trade Commission), available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pay-delay-deals-limiting-competition-and-costing/130723payfordelay.pdf (stating that in light of *Actavis*, the Commission will continue to challenge pay-for-delay settlements and re-investigate settlements previously filed with the Commission).

183. See *infra* notes 184–187 and accompanying text.

184. See Amanda P. Reeves, *Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis*, 28 ANTITRUST 9, 13 (Fall 2013) (noting that “[r]ule of reason cases typically are very hard to defeat at a motion to dismiss stage”).

185. *FTC v. Actavis*, 133 S. Ct. 2223, 2236 (2013).

186. Reeves, *supra* note 184, at 13.

agreements are lawful.¹⁸⁷ There is also uncertainty about the likelihood that the FTC will investigate the settlement and attempt to block it before its inception.¹⁸⁸ Although the Court granted the FTC more power to challenge these settlements and the FTC has stated it intends to use this power, it is more likely that the FTC will challenge only those agreements that are clearly anticompetitive.¹⁸⁹ But now that every reverse payment agreement is open to challenge, drug manufacturers might be more hesitant to enter into these agreements in the first place.

Drug manufacturers may attempt to avoid the *Actavis* decision by using means of compensation other than cash. Although the *Actavis* decision provides guidelines on how lower courts should address monetary reverse payments, it does not give guidance on how courts should assess the legality of “non-monetary” reverse payments. In some situations, the brand name manufacturer does not provide monetary compensation to the generic.¹⁹⁰ Instead the parties may engage in an ancillary business transaction such as a cross-licensing or supply agreement.¹⁹¹ For example, in *In re Nexium Litigation*,¹⁹² a generic manufacturer, in exchange for an agreement to delay entry was provided an exclusive license to distribute the branded product instead of being paid in cash.¹⁹³ Lower courts are split as to whether *Actavis*' definition of “reverse payment” should be read to include any transfer of value between the parties. The *Nexium* court held that a payment need not be in money to constitute an antitrust violation under the *Actavis* Court's framework.¹⁹⁴ Instead, the court did “not see fit to read into

187. *Id.* at 14 (noting that litigants will face uncertainty as the courts and the FTC decided how to use the size of the payment in reverse payment analysis).

188. *See id.* (arguing that Patent IV settlements will be riskier for manufacturers because it is hard to determine “whether the FTC will sue to block a settlement, sending the parties into years of costly litigation and follow-on private class actions (which is harder to predict)”).

189. *See id.* (arguing that the FTC will reserve its power by going after only the most egregious reverse payments because they do not want to risk losing a challenge and creating bad law).

190. *See* Dickey et al., *supra* note 44, at 375 (listing a number of settlement agreements that include provisions other than cash payments).

191. *See id.*

192. *See In re Nexium (Esomeprazole) Antitrust Litig.*, CIV.A. 12-MD-02409, 2013 WL 4832176 (D. Mass. Sept. 11, 2013) (holding that the plaintiffs pled facts sufficient at the motion-to-dismiss stage to establish violations of the Sherman Act where the brand name entered into a “no-authorized generic” agreement with a generic manufacturer in lieu of a cash payment).

193. *Id.* at *6.

194. *Id.* at *15.

the opinion a strict limitation of its principles to monetary-based arrangements alone,” thus concluding drug manufacturers cannot avoid liability by payments in kind.¹⁹⁵ However, the court in *In re Lamictal Direct Purchaser Antitrust Litigation*¹⁹⁶ held that *Actavis* should be read to only apply reverse payment agreements where the consideration for delayed entry is monetary.¹⁹⁷ The *Lamictal* court reasoned that the Supreme Court deliberately distinguished reverse payments from “traditional” and “commonplace” forms of settlement.¹⁹⁸ The *Lamictal* court also stated that the definition of “reverse payment” used in *Actavis* was not meant to include every situation where the patent holder confers a financial benefit on the generic.¹⁹⁹

Although there will likely be considerable debate in the future as to how *Actavis* will be applied to non-monetary compensation agreements, anticompetitive reverse payment settlements that are not enshrined in an express agreement will inevitably make it more difficult for the FTC to prove anticompetitive conduct.²⁰⁰ The possibility of non-monetary reverse payments introduces the risk that drug manufacturers will find clever ways around the *Actavis* holding by “hiding” their settlement agreements in more benign arrangements.²⁰¹ It therefore seems likely that reverse payment agreements will continue to exist and be challenged by the FTC.

B. The Likelihood of Congressional Action

If the Court’s decision in *Actavis* is not enough to eliminate the negative impact of reverse payment agreements on consumers altogether, another option is congressional action. As discussed above, there have been

195. *Id.*

196. *See In re Lamictal Direct Purchaser Antitrust Litigation*, No. 12-cv-995, 2014 WL 282755, at *11 (D.N.J. Jan. 24, 2014).

197. *See id.* (holding that an agreement between two drug manufacturers whereby the patentee gave the generic the right to enter the market early along with a promise that they could do so without competition survives *Actavis* scrutiny because it did not involve a monetary payment).

198. *Id.* at *7.

199. *Id.*

200. *See Glazer & Desmond-Harris, supra* note 19, at 14 (“Proving a pay for delay when there is no express agreement is like trying to prove a conspiracy from circumstantial evidence: it’s possible to do but it’s never easy.”).

201. *See id.* (“This difficulty will exist even if all payments by branded to generic providers are banned, as more indirect means of payment will inevitably be devised to circumvent this prohibition.”).

several bills introduced by the both the 112th and 113th Congresses aimed at eliminating anticompetitive reverse payments.²⁰² Although congressional action is likely necessary to further limit the opportunity for parties to enter into anticompetitive agreements, any law passed must be careful not to upset the *Actavis* Court's determination that some reverse payments can have procompetitive effects, or at the very least do not have an adverse effect on competition.

For this reason, Sen. Klobuchar's PAAG Act will likely fail.²⁰³ The *Actavis* Court unequivocally stated that reverse payments should not be deemed presumptively illegal.²⁰⁴ The PAAG Act has been heavily criticized because it essentially deems all reverse payments per se unlawful. It would thus eliminate those reverse payment agreements that are conducted to compensate parties for litigation costs.²⁰⁵ Also, deeming reverse payments per se illegal runs contrary to the established antitrust principle that per se illegality should apply to conduct only when courts have had sufficient experience with a certain type of conduct and determined that it is almost always anticompetitive.²⁰⁶ And given that this bill has been introduced and rejected in the past, it seems unlikely to pass at present.²⁰⁷ This is especially true after the *Actavis* decision, as Congress is now more likely to see how the decision will play out in the lower courts before deciding that further legislation is necessary.²⁰⁸ Sen. Klobuchar has stated that she intends to go forward with the bill, but the Court's decision in *Actavis* essentially makes the key provisions of her bill moot.

202. See discussion *supra* Part V.

203. Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009) (died in committee and reintroduced as S. 27 on January 25, 2011).

204. See *FTC v. Actavis, Inc.*, 133 S. Ct. at 2237 (stating that the complexities of reverse payments, "lead us to conclude that the FTC must prove its case as in other rule-of-reason cases").

205. See Picht, *supra* note 145, at 129 (noting that the Court in *Actavis* stated reverse payments that are compensation for litigation costs are not anticompetitive).

206. See *id.* at 130 ("[I]t is a longstanding principle of U.S. antitrust law that per se rules should be established only if sufficient experience has proven that a particular type of conduct is almost always and to an overwhelming extent anticompetitive.").

207. See Peter Levitas, *Post-Actavis, Pay-for-Delay Debate is Far From Over*, LAW360 (Dec. 18, 2013, 10:38 PM), http://www.arnoldporter.com/resources/documents/Post%20Actavis%20Pay%20For%20Delay%20Debate%20Is%20Far%20From%20Over_Law360.pdf (arguing that after *Actavis*, "it will be difficult for this legislation to move forward").

208. See *id.* ("Members of Congress will likely be receptive to the argument that after *Actavis*, even more than previously, it makes sense to wait and see how this issue plays out in the courts.").

A more promising Congressional bill is Sen. Franken's proposed FAIR Generics Act.²⁰⁹ Research has shown that the anticompetitive effects of reverse payment settlements are increased when the settlement is with the first filer and the first filer does not relinquish its right to the 180-day exclusivity period.²¹⁰ Under the provisions of the FAIR Generics Act, *any* generic manufacturer that wins a patent challenge in the district court or is not sued by a brand-name drug manufacturer can share the first filer's 180-day exclusivity period.²¹¹ This would ultimately increase the number of generics allowed to enter. Some, including the Generic Pharmaceutical Association, argue that the FAIR Generics Act will result in countervailing anticompetitive effects.²¹² They fear that removing the 180-day exclusivity period will remove the incentive for generics to challenge weak patents thus eliminating the "checks and balances" built into the Hatch-Waxman Act.²¹³ This will allow weak or invalid patents to survive, ultimately reducing the number of generics entering the market where patent protection should not exist.

But a strong argument can be made that this bill has the potential to end the "unintended, structural flaw in" the Hatch-Waxman Act: "parked exclusivities" that block generic introduction.²¹⁴ It also has the potential to actually increase the incentive for generics to introduce new versions of drugs into the market. If the exclusivity period could be shared by a number of generic manufacturers, there is nothing stopping generic manufacturers

209. FAIR Generics Act, S. 504, 113th Cong. (2013).

210. See Dickey et al., *supra* note 44, at 371 (2010) (citing FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 3* (2002)).

211. Generics and Biosimilars Initiative, *FAIR Generics Act Could Remove 180-day Exclusivity*, GABI (Nov. 25, 2011), <http://gabionline.net/Policies-Legislation/FAIR-Generics-Act-could-remove-180-day-exclusivity> (hoping that "[t]his new incentive structure would end the pay-to-delay problem and bring less expensive generics to market sooner").

212. Claire Sheahan, *GPhA Supports Bill to Block Authorized Generic and Restore the Value of the 180-day Generic Exclusivity Period*, GPhA (Jan. 31, 2007), <http://www.gphaonline.org/gpha-media/press/gpha-supports-bill-to-block-authorized-generics-and-restore-the-value-of-the-180-day-generic-exclusivity-period> (arguing that allowing more generics to enter the market during the 180-day exclusivity period would decrease the incentive for generics to produce drugs and therefore decrease competition in the drug market).

213. *Id.*

214. See 157 Cong. Rec. S7, 616–17 (daily ed. Nov. 16, 2011) (statement of Sen. Bingaman) (arguing that this proposed bill will reduce instances where the first filer "parks" itself in the exclusivity period by not bringing a competing drug to market, therefore increasing generic competition in the pharmaceutical industry).

who are not first filers to also challenge potentially weak or invalid patents and thus enter the market sooner.²¹⁵ Therefore, passage of the FAIR Generics Act or a similar bill has the greatest potential of increasing generic entry into the market without holding all reverse payment settlements presumptively unlawful.

C. The Effect of the Affordable Care Act on the Adverse Effects of Reverse Payments

The Courts decision in *Actavis* will likely reduce the number of harmful reverse payment agreements drug manufacturers enter into. For those agreements that survive, poor and elderly consumers will be further insulated from inflated drug prices due to the enactment of the Affordable Care Act (ACA).²¹⁶ The ACA expands Medicaid coverage to an estimated 17 million additional low-income adults and children.²¹⁷ Congress also expects the expansion program to provide cost savings for states that choose to implement the expansion program in the form of reduced healthcare spending for the uninsured.²¹⁸

The implementation of the ACA also helps reduce prescription drug prices for the elderly. Several provisions of the ACA aim at reducing drug costs for seniors. Under the ACA, Medicare patients with a gap in drug coverage will receive a one-time \$250 rebate to help pay for prescription drugs.²¹⁹ Further, brand name drug companies will be forced to provide a 50% discount on drugs for seniors who face a gap in coverage.²²⁰ Expanded drug coverage should increase the level of drug use and the probability of

215. *See id.* (“The legislation also maximizes the incentive for all generic challengers to fight to bring products to market at the earliest possible time by holding generic settlers to the deferred entry date agreed to in their settlements.”).

216. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2012).

217. MICHELLE GREENHALGH, AMERICAN ACADEMY OF FAMILY PHYSICIANS, THE AFFORDABLE CARE ACT: MEDICAID EXPANSION & HEALTHCARE EXCHANGES 6 (2013), available at <http://www.aafp.org/dam/AAFP/documents/advocacy/coverage/aca/ES-MedicaidExpansion.pdf>.

218. *Id.*

219. Robert F. Rich et al., *The Patient Protection and Affordable Care Act of 2010: Implementation Challenges in the Context of Federalism*, 16 J. HEALTH CARE L. & POL’Y 77, 82 (2013).

220. *Id.* at 83.

receiving prescription drugs is expected to increase among elderly Americans.²²¹

With this dramatic increase in insurance coverage, fewer Americans will be paying for their prescription drugs out-of-pocket.²²² Therefore, while the health insurer must still pay near monopoly prices for patented drugs, consumers are only required to pay a price closer to its competitive market value through their co-pay.²²³ The result of the introduction of the ACA in relation to reverse payment settlements will be a shift in the “deadweight loss” created by monopoly pricing from the consumer to the private or public health insurer.²²⁴ So as anticompetitive reverse payments may continue to be a problem for Medicaid and Medicare, they should have less of a direct impact on newly insured poor and elderly consumers under the ACA.

IX. Conclusion

Congress intended the Hatch-Waxman Act “to make available more low cost generic drugs”²²⁵ Reverse payment settlement agreements frustrate this purpose, as they provide incentives for drug manufacturers to conspire rather than compete.²²⁶ Those reverse payment agreements that have an adverse effect on competition disproportionately burden older

221. See Soonim Huh et al., *supra* note 4, at 828 (“[A]fter controlling for possible selection bias, drug coverage significantly increases both the probability of receiving prescription drugs and the level of drug use.”).

222. See Margaret E. Blume-Kohout & Neeraj Sood, *Health Insurance Expansions and Pharmaceutical Markets*, 14 HARV. HEALTH AND POL’Y REV. 17, 17 (Spring 2013), available at <http://hhpronline.org/wp-content/uploads/2013/08/Sood1.pdf> (expecting “the quantity of prescription drugs sold [to] increase, as newly insured consumers are likely to have lower out-of-pocket costs . . .”).

223. See Anup Malani, *A Different Perspective on Reverse Payment Settlements*, BILL OF HEALTH (Jan. 26, 2013), <http://blogs.law.harvard.edu/billofhealth/2013/01/26/a-different-perspective-on-reverse-settlements/>.

224. *Id.*

225. H.R. REP. NO. 98-857, pt. 1, at 14 (June 21, 1984).

226. See *Barriers to Generic Entry: Hearing Before the Special Comm. on Aging*, 109th Cong. 11 (2006) (statement by the Federal Trade Commission), available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-generic-drug-entry/p052103barrierstogenericentrytestimonysenate07202006.pdf (“By increasing the likelihood of generic entry, however, the statute also increases the incentive for brand and generic manufacturers to conspire to share, rather than compete for, the expected profits generated by sales of both brand and generic drugs.”).

Americans and those who are uninsured.²²⁷ These populations bear the brunt of the negative effects because they are the most likely to live on fixed incomes and need prescription drugs to treat chronic medical conditions. *Actavis* was the Court's attempt to reestablish the purpose for which Hatch-Waxman was enacted by narrowing a loophole that runs contrary to its intent. Although it is too early to tell, *Actavis* should reduce the number of anticompetitive reverse payments, increasing the number of generics available to the people who need them the most. This decision, along with expanded Medicaid coverage under the ACA, promises to reduce the number of people in our population whose health is deteriorating despite the fact that there are helpful medications available.

227. *See id.* (stating that older Americans, typically those in greatest need of health care in our population and often living on fixed incomes, bear a disproportionate share of increased healthcare costs).