

COMPETITION AHEAD? THE LEGAL LANDSCAPE FOR REVERSE PAYMENT SETTLEMENTS AFTER *FEDERAL TRADE COMMISSION V. ACTAVIS, INC.*

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In 2006, pharmaceutical company Cephalon, holder of both an active ingredient patent and a narrow formulation patent for the sleep-disorder drug Provigil, faced competition from four generic manufacturers seeking to enter the market with generic competitors to Provigil.¹ Although the active ingredient patent provided protection (and successfully prevented generic entry on this compound past patent expiration in 2001), the formulation patent, issued after the active ingredient patent, appeared to be an easy target to design around.² The four generic companies planned to enter the market in June 2006.³ To avoid the litigation threat posed by the generic companies, Cephalon settled by paying them a total of more than \$200 million combined.⁴ In exchange the generic manufacturers agreed to delay entry into the market until April 2012.⁵ The Cephalon CEO stated that this deal provided “six more years of patent protection. That’s \$4 billion in sales that no one expected.”⁶

Settlements such as the agreement described above are known as either “reverse payment settlements” (“RPS”) or “pay-for-delay settlements.”⁷ These settlements establish a pecuniary relationship between brand-name and generic manufacturers in which the brand-name company pays the generic firm to delay entry into the market until a specific date.⁸ Reverse payment settlements may take several forms and in some cases may include

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1. Michael A. Carrier, *Provigil: A Case Study of Anticompetitive Behavior*, 3 HASTINGS SCI. & TECH. L. J. 441, 441–42 (2011).

2. *Id.* at 442.

3. *Id.* at 443.

4. *Id.* at 444.

5. *Id.*

6. John George, *Hurdles Ahead for Cephalon*, PHILA. BUS. J. (Mar. 20, 2006), <http://www.bizjournals.com/philadelphia/stories/2006/03/20/story1.html?page=all>.

7. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1553 (2006).

8. *Id.* at 1557.

terms with other legitimate uses, not related to the delay of generic entry.⁹ However, such settlements have been extensively litigated in the courts on antitrust grounds because they may allow invalid patents to restrict competition unfairly.¹⁰ By restricting competition, reverse payment settlements may often significantly increase consumer prices for pharmaceutical drugs.¹¹

In June 2013, the Supreme Court decided *Federal Trade Commission v. Actavis, Inc.*, holding that under the Hatch-Waxman statutory framework, the parties entering into reverse payment settlements may have antitrust liability if the payments are designed to delay competition between a brand-name and a generic pharmaceutical manufacturer.¹² Under this ruling, the Supreme Court ordered lower courts to apply a modified antitrust rule-of-reason standard to reverse payment settlements, independent of examinations of the validity of the relevant patents.¹³ Although reverse payment settlements are not presumptively unlawful under *Actavis*, “the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”¹⁴

In essence, the ruling mandates that lower courts should apply the modified rule-of-reason standard rationale of *Actavis*, independent of patent validity examinations in situations when a reverse payment settlement is challenged.¹⁵ The Court asserts that patent validity is “normally not necessary to litigate” antitrust liability,¹⁶ but the validity of a patent does seem to have some relevance to the antitrust question if secondary,¹⁷ potentially weaker

9. *Id.* at 1561–62.

10. *Id.* at 1557.

11. For a recent review of the effects of pay-for-delay settlements on the cost of twenty drugs to consumers, see U.S. PIRG & COMMUNITY CATALYST, TOP TWENTY PAY-FOR-DELAY DRUGS: HOW DRUG INDUSTRY PAYOFFS DELAY GENERICS, INFLATE PRICES AND HURT CONSUMERS (July 2013) (stating that up to 142 brand-name drugs have been delayed since 2005 and detailing the effects of these delays on consumers).

12. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2225–26 (2013).

13. *Id.* at 2237.

14. *Id.*

15. *Id.* at 2238.

16. *Id.* at 2226.

17. Typically, secondary patents “provide regulatory protection to ancillary aspects of drug innovation—such as particular drug formulations and compositions—beyond the core, traditional protection, a patent on a novel active ingredient.” C. Scott Hemphill & Bhaven N. Sampat, *Drug Patents at the Supreme Court*, 339 SCI. 1386, 1386 (2013).

patents are less likely to be valid and thus more likely to be challenged in a patent litigation action.¹⁸

Although this ruling provides some guidelines to lower courts, brand-name pharmaceutical companies, and generic pharmaceutical companies in terms of the potential presence of antitrust liability, the holding of this case is limited and does not provide a concrete legal standard. It is thus likely that district courts and courts of appeal will interpret the holding of *Actavis* in different ways, producing another circuit split. As litigation regarding pay-for-delay settlements took nearly fifteen years to reach the Supreme Court,¹⁹ it may take a similarly long time for this potential inconsistency to be resolved across jurisdictions. However, the ruling provides restrictions on unfair competition concerning brand-name and generic pharmaceutical manufacturers. These restrictions may benefit consumers by addressing situations where reverse payment settlements actually do hinder competition, as not every settlement may be anticompetitive. On the other hand, analyzing the net competitive effects of a particular settlement also requires consideration of the benefits of avoiding litigation.

This Note reviews the relevant background relating to the Hatch-Waxman Act and antitrust liability in the context of the *Actavis* decision itself.²⁰ Accordingly, Section I.A reviews the Hatch-Waxman Act, as well as policy rationales for the development of the Act, while Section I.B discusses reverse payment settlements and how they are a result of the Hatch-Waxman framework. Section I.C addresses potential sources for antitrust liability in reverse payment settlements under Hatch-Waxman, including a review of how these standards applied to the settlement at issue in *Actavis*. Section I.D reviews *Actavis*'s path to the Supreme Court in the context of the antitrust principles authorizing the Federal Trade Commission ("FTC") to sue in this case. Finally, Part II reviews and analyzes the Supreme Court's majority and dissenting opinions.²¹

18. *See id.* at 1387.

19. *Schering-Plough*, the first major case to be heard on reverse payment settlements before a circuit court, began as a 2001–2002 Federal Trade Commission inquiry into the settlement between Schering-Plough, Upsher-Smith Laboratories, and American Home Products, in 1997. *Schering Plough Corp. et al.*, F.T.C. no. 9297 (Jun. 27, 2002). The first major wave of reverse payment settlements occurred between 1993 and 2000, and was halted by increased FTC antitrust enforcement activity. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009); C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey* 3–4 (Columbia Law School, Working Paper, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=969492.

20. *See infra* Part I.

21. *See infra* Part II.

Since the Supreme Court issued its decision in *Actavis*, the FTC and private litigants have brought forth several pay-for-delay cases in federal courts.²² These cases raise a number of issues regarding the valuation of a payment and types of payments permissible under *Actavis* that were not considered in the Supreme Court's decision. Part III reviews these cases and other likely applications of the *Actavis* doctrine in reverse payment settlements.

In addition, the FTC has indicated its intention to aggressively pursue pay-for-delay settlements that it believes may potentially violate antitrust laws.²³ As such, any regulatory scheme involving the FTC would need to account both for the expertise of that agency in these types of settlements, as well as the need for strong guidance in agency decisions.²⁴ Congress also currently is considering two pending bills focusing on pay-for-delay settlements.²⁵ Although a bill asserting the presumptive illegality of these arrangements may not achieve all of the public policy goals for RPSs, a bill removing some incentives for generics to sue brand-name companies in situations where the patent is probably valid may aid in eliminating sham litigation in RPSs. Part IV discusses these provisions in further detail, along with potential mechanisms by which Congress could enhance the framework of Hatch-Waxman to avoid reverse payment settlements without impeding legitimate settlements.

I. DEVELOPMENT OF *ACTAVIS* TO THE SUPREME COURT: THE HATCH-WAXMAN ACT, REVERSE PAYMENT SETTLEMENTS, AND SOURCES OF ANTITRUST LIABILITY

Reverse payment settlements arise from the complex pharmaceutical regulatory framework laid out by the Hatch-Waxman Act. First, Section I.A looks at the origins of the Hatch-Waxman Act, as well as policy rationales for the development of the Act, and Section I.B reveals how reverse payment settlements are logical results of loopholes in the Hatch-Waxman framework. Using the litigation in *Actavis* as an example, Section I.C describes how antitrust liability may arise in reverse payment settlements under Hatch-

22. See *infra* Part III.

23. See *infra* Part IV.

24. See *infra* Part IV.

25. Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013); Fair and Immediate Release of Generic Drugs Act ("FAIR Generics Act"), S. 504, 113th Cong. (2013).

Waxman. Finally, Section I.D provides the contextual history of *Actavis's* path to the Supreme Court, using the principles described in this Part.

A. THE HATCH-WAXMAN ACT: REGULATING INTERACTIONS BETWEEN BRAND-NAME AND GENERIC MANUFACTURERS AND POLICY RATIONALES

The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) aims to regulate disputes between manufacturers of generic and brand-name pharmaceuticals in the United States and also to promote competition between brand-name and generic manufacturers to benefit the consumer.²⁶ The Hatch-Waxman Act provides the framework in which manufacturers of pharmaceuticals must operate to obtain approval for marketing compounds within the United States.²⁷ First, brand-name pharmaceutical inventors must submit a New Drug Application to the federal Food and Drug Administration (“FDA”) and then subsequently complete a testing process to demonstrate the safety and effectiveness of the proposed pharmaceutical prior to marketing it in the United States.²⁸

After the FDA has given approval for the brand-name drug in question, generic manufacturers seeking to obtain approval for marketing of a generic compound may file an Abbreviated New Drug Application (“ANDA”) to the FDA.²⁹ In this application, the FDA requires that generic drug manufacturers provide certification that the generic is biologically equivalent to the brand-name drug and that the generic contains the same active ingredients as the brand-name drug,³⁰ as well as a “Paragraph IV” certification that either the generic product does not infringe on the brand-name drug or that the patent(s) on the brand-name drug are invalid or unenforceable.³¹

Importantly, the Hatch-Waxman Act also provides protocol for patent disputes arising from FDA approvals. The brand-name pharmaceutical manufacturer is required to provide a list of relevant patents and their

26. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), *amended by* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (collectively, the “Hatch-Waxman Act”).

27. *Id.*

28. 21 U.S.C. § 355(b)(1) (2012).

29. *Id.* § 355(j)(2)(A)(i)–(iv).

30. *Id.*

31. “Paragraph IV” refers to the relevant section of the Hatch-Waxman Act. *Id.* § 355(j)(2)(A)(vii)(IV).

expiration dates in the New Drug Application.³² Conversely, generic manufacturers are required to certify in their ANDA applications that their drugs do not infringe said brand-name patents.³³ This certification process often leads to patent infringement and patent invalidity disputes.³⁴ The Hatch-Waxman Act also specifies a timing regime for generic approval, pending resolution of any validity or infringement litigation pursuant to the ANDA application.³⁵

Finally, the Hatch-Waxman Act provides a major incentive for generic manufacturers to be the first-to-file an ANDA application. Through the “Paragraph IV” route, first-to-file generic manufacturers receive a 180-day exclusive right to market their drugs over other generic manufacturers.³⁶ This exclusivity right in effect establishes a duopoly between the brand-name and the first-to-file generic manufacturer, and it can often be extremely lucrative for the generic manufacturer.³⁷ The framework of the Hatch-Waxman Act enforces the public policy goals of the statute, as discussed in the next Section.

1. *Legislative History and Policy Underlying the Hatch-Waxman Act*

Henry Waxman, one of the original sponsors of the Act, stated that the Act was “intended to protect consumers against excessive drug costs by enhancing competition between brand-name and generic drug

32. *Id.* § 355(b)(1).

33. *Id.* § 355(j)(2)(A)(vii)(IV). This certification can be provided in one of several ways: by certifying that the brand-name manufacturer has not asserted valid patents, by certifying that relevant patents have already expired, or by certifying that any relevant patent the brand-name manufacturer has listed “is invalid or will not be infringed by the manufacture, use or sale” of the pharmaceutical compound described in the generic manufacturer’s ANDA. *Id.*

34. *See, e.g.,* Caraco Pharm. Lab., Ltd. v. Forest Labs., Inc., 527 F.3d 1278 (resolving a patent validity dispute); Bayer AG v. Pharm. Research Corp., 212 F.3d 1241 (holding that the patent at issue was not infringed by the generic company’s ANDA).

35. 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

36. *Id.* § 355(j)(5)(B)(iv).

37. *See* Hemphill, *supra* note 7, at 1588–94. The vast majority of a generic company’s profits on a generic drug come during the exclusivity period before other generics enter the market to force down prices. *Id.* In analyzing a broad range of pharmaceutical patent litigation decisions from 1984 to 2012, Jacobo-Rubio and coworkers have determined that brand-name firms value deterrence of generic entry to the market at \$3.9 billion, while generic companies value their right to enter at \$748.6 million, thereby outlining some of the motivation behind settlements for each side. Ruben Jacobo-Rubio et al., *The Private Value of Entry and Deterrence in the US Pharmaceutical Industry* (Dep’t of Econ., Univ. of Ga., Working Paper, 2014), available at http://ruben1.myweb.uga.edu/value-entry-deterrence_Jan-11-2014.pdf.

manufacturers.”³⁸ The 2003 Medicare Amendments to the Hatch-Waxman Act confirmed this procompetitive policy.³⁹

The drafters of the Hatch-Waxman Act also likely envisioned patent disputes arising under the Act as a method of encouraging private parties (generic manufacturers) to sue brand-name companies to invalidate sham patents, thereby encouraging competition.⁴⁰ However, under the Hatch-Waxman regime, generics are incentivized to sue brand-name manufacturers even if the generic company thinks it likely that the brand-name company will prevail in litigation, because the potential benefit of invalidating a patent (and thus gaining entry to the market prior to patent expiration) is so high.⁴¹ Remarkably, the Intellectual Property Owners Association has cited studies indicating that for more than ninety percent of branded drug sales, a generic challenger balancing upside gain under the Hatch-Waxman Act against downside risk from litigation costs can justify a litigation challenge to a brand-name patent if it believes it has a very low chance of success.⁴² As such, the structure of the Hatch-Waxman Act provides generic manufacturers a low-risk path to enter the market by suing their competitors. Although the brand-name patents may not withstand scrutiny and thus may be invalidated, thereby enhancing competition and benefitting consumers, the Patent and Trademark Office’s (“PTO”) current review mechanisms and resources cannot adequately verify the validity of all patents upon issuance, therein forcing expensive litigation to invalidate weak patents.⁴³

B. REVERSE PAYMENT SETTLEMENTS: ONE RESULT OF THE HATCH-WAXMAN FRAMEWORK

In the process of litigating a patent validity or infringement action under the Hatch-Waxman Act, in certain situations the parties may be incentivized to settle the dispute. One common way in which generic and brand-name

38. Brief for Rep. Henry A. Waxman as Amicus Curiae Supporting Petitioner at 11, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416).

39. *Id.* at 14.

40. Brief for the Intellectual Property Owners Association as Amicus Curiae Supporting Respondents at 25, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416).

41. *Id.* at 14.

42. *Id.* at 14–15. The brief argues that “for more than 90% of branded drug sales (measured in dollars), a generic challenger balancing upside gain under Hatch-Waxman against downside risk limited to litigation costs can justify the challenge if it believes it has at least a 1.3% chance of success.” *Id.* at 15 (citing Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI ANTITRUST CHRON., no. 2, Sept. 2012, available at <http://bit.ly/VMMTTS>).

43. See *infra* Section IV.A.

manufacturers have settled such actions is with an RPS, in which the brand-name innovator provides a monetary payment to the generic manufacturer, and the generic company agrees to end the litigation.⁴⁴ RPSs typically include a promise by the generic company not to market the generic compound against the brand-name product for a certain period of time.⁴⁵ The pay-to-delay mechanism in effect extends the right of a patent owner to exclude others from the market by paying competitors to remove themselves for a period of time. Oftentimes, these settlements block several competitors from competing, as the brand-name company will pay most or all generic companies that filed ANDAs within a certain period of time.⁴⁶ However, generic companies are disincentivized from suing if another generic company has already become the first-to-file because the 180-day exclusivity period is no longer available to subsequent challengers. Therefore, these settlements create Hatch-Waxman loopholes that may frustrate the policy purposes of the Act.

Early RPSs followed a model in which brand-name companies paid generic companies cash payments to delay their entry into a particular market, but subsequent settlements (since the mid-2000s or so) have typically been much more complicated.⁴⁷

The *Actavis* case clearly demonstrates the application of the Hatch-Waxman framework to produce an RPS that includes both cash payments and other forms of consideration, namely co-marketing agreements between brand-name and generic companies.⁴⁸ Brand-name pharmaceutical manufacturer Solvay Pharmaceuticals filed a New Drug Application with the

44. Peter Todaro et al., *A Post-Actavis Approach to Reverse Payment Settlements*, LAW360 (Jul. 31, 2013, 3:00 PM), <http://www.law360.com/articles/459510/a-post-actavis-approach-to-reverse-payment-settlements>.

45. *Id.* The period of time typically depends on the negotiation between the parties. Because only the first-to-file generic company may receive the 180-day exclusivity benefit, these agreements effectively discourage other generic companies from seeking to enter the market. *See id.*

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

47. *See, e.g.,* Hemphill, *An Aggregate Approach*, *supra* note 19; Hemphill, *Drug Patent Settlements*, *supra* note 19, at 1–49. Common terms in modern reverse payment settlement agreements include additional contract terms, agreements regulating other pharmaceutical products, or the lack of cash used as consideration. Other provisions may include an intellectual property license, supply and distribution agreements, or co-promotion of brand-name products. One particular type of agreement under current investigation in several pending actions is the no authorized generic (“No-AG”) agreement, in which the brand name company agrees to not market its own generic brand against a generic manufacturer’s product. Hemphill, *Drug Patent Settlements*, *supra* note 19, at 13–21.

48. *Actavis*, 133 S. Ct. at 2229.

FDA for the compound AndroGel, a testosterone-based drug, in 1999.⁴⁹ The FDA subsequently approved the marketing of the compound in 2000.⁵⁰ Pursuant to the requirements of the Hatch-Waxman Act, Solvay disclosed a relevant patent to the FDA in 2003.⁵¹ Generic manufacturer Actavis submitted an ANDA application for a compound related to AndroGel later that year, as did Paddock Laboratories.⁵² Both generic companies certified under Paragraph IV of the Hatch-Waxman Act that their compounds did not infringe Solvay's patent because "Solvay's listed patent was invalid."⁵³ To complicate the matter, Par Pharmaceuticals—another generic manufacturer—made an agreement with Paddock Laboratories to share litigation costs in exchange for a split of profits, should Paddock's application be approved by the FDA.⁵⁴

In 2003, Solvay filed suit against Actavis and Paddock under Paragraph IV of the Hatch-Waxman Act.⁵⁵ The FDA then approved Actavis's first-to-file generic application for AndroGel after a thirty-month stay in early 2006.⁵⁶ Later in 2006, all parties settled the dispute using a reverse payment settlement.⁵⁷ Actavis (and other generic manufacturers) agreed to not market its generic compound until August 31, 2015 (sixty-five months before the AndroGel patent's expiration), and in exchange Solvay agreed to pay tens of millions of dollars to each participating generic manufacturer, at least \$243 million in total.⁵⁸ Finally, Solvay agreed with all generic companies to co-promote brand-name AndroGel to urologists, while splitting any profits obtained from this business endeavor.⁵⁹

Courts generally encourage settlements in litigation actions to promote judicial efficiency.⁶⁰ However, reverse payment settlements may have the effect of raising costs for consumers, reflected in pharmaceutical prices

49. *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1304 (11th Cir. 2012).

50. *Id.*

51. *Actavis*, 133 S. Ct. at 2229.

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.*; *see also* *Watson Pharms., Inc.*, 677 F.3d 1298, 1304 (11th Cir. 2012).

56. Solvay did not bring suit against Par, however. *Actavis*, 133 S. Ct. at 2229.

57. *Id.*

58. *Id.*

59. Solvay agreed to pay Actavis between \$19 million and \$30 million a year for nine years, while \$60 million was paid to Par and \$12 million was paid to Paddock. *Id.*

60. *Id.*; *see also* Scott A. Stempel et al., *Eleventh Circuit Rejects FTC Challenge to Reverse Payment Settlement*, MORGAN, LEWIS & BOCKIUS, (May 9, 2012), http://www.morganlewis.com//pubs/Antitrust_LF_11thCircuitRejectsFTCChallenge_09may12.pdf.

61. *See, e.g.*, Randall R. Rader, *The State of Patent Litigation*, 21 FED. CIR. B.J. 331, 345 (2011).

higher than what consumers would pay if generics could enter the market and decrease prices overall. U.S. PIRG, a federation of citizen-funded organizations advocating in the public interest, has estimated that from 2005 through 2011, these settlements have cost consumers over \$98 billion.⁶¹ The FTC and other commentators estimated that consumers and the federal government pay an extra \$3.5 billion to \$12 billion per year cumulatively for pharmaceuticals as a result of reverse payment settlements.⁶² These figures highlight the importance of settlements in the overall economics of pharmaceutical development in the United States, as well as the high probability of consumer harm.

As most recent settlements are not simply an exchange of cash between a brand-name company and a generic manufacturer, determining the antitrust liability in a particular settlement can be a complicated endeavor, and settlements cannot simply be dismissed as anticompetitive.⁶³ Many analyses of the overall benefits of RPSs focus on the use of resources saved from settlements or obtained from settlements towards the development of new compounds. Brand-name pharmaceutical companies play an important role in innovative discovery. Pharmaceutical research is itself serendipitous—it is extremely difficult to predict which experiments or compounds will be successful in laboratory tests, much less in clinical trials. Accordingly, it is extremely difficult to quantify the potential value in terms of research results from adding additional funds to a pharmaceutical development pipeline. Compounding this difficulty is the composition of the modern development pipeline for pharmaceutical compounds, which does not only consist of large pharmaceutical companies, but also potential in-licensing partners as well,

61. U.S. PIRG has analyzed twenty of the estimated 142 drugs impacted by pay-for-delay settlements up to July 2013 and estimated that companies made an extra \$98 billion on these brand-name drugs alone before generic drugs entered the market. U.S. PIRG & COMMUNITY CATALYST, *supra* note 11.

62. The FTC estimates consumers pay an extra \$3.5 billion per year for pharmaceuticals due to reverse payment settlements. Jon Leibowitz, Chairman, FTC, “Pay-for-Delay” Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution), at 8 (Jun. 23, 2009), *available at* <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>. But note that in 2011, consumers spent a total of \$245 billion on pharmaceuticals. Brief for Petitioner at 7, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416). Other commentators have estimated higher costs for consumers—up to \$12 billion per year. *Protection Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the H. Subcomm. on Commerce, Trade, and Consumer Protection*, 111th Cong. 7 (2009) (statement of C. Scott Hemphill, Assoc. Prof., Columbia Law School).

63. *See, e.g.*, Hemphill, *An Aggregate Approach*, *supra* note 19; Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, ANTI-TRUST, Summer 2003, at 70.

such as small biotechnology companies and universities in research funds. Through financial support of these in-licensing partners, large pharmaceutical companies support a major portion of the research pipeline today.⁶⁴

Patents are particularly important in pharmacological innovation for several reasons. First, the development of a pharmaceutical compound for consumer use requires an immense investment on the part of the brand-name company.⁶⁵ These compounds typically also require significant investments of time in discovery and development, and the regulatory process to obtain approval is not short either.⁶⁶ Finally, once invented and developed, generic companies generally find it facile to copy the compound and develop generic compounds without the investments required by the brand-name company.⁶⁷ The patent right thus plays an essential role in incentivizing brand-name companies to undertake drug discovery in the first place.

After the enactment of the Hatch-Waxman Act in 1984, the number of “patents per drug roughly doubled for the cohort of drugs approved between 2000 and 2002 compared with drugs approved between 1985 and 1987.”⁶⁸ This change demonstrates, at least in part, that brand-name manufacturers pursued “secondary” patents—patents protecting aspects of pharmaceutical innovation besides the active ingredient itself—as part of their strategy to extend the overall period of time that a particular compound could be protected from competition.⁶⁹

Studies have shown that generic companies target these secondary patents far more frequently in ANDA certifications than the active ingredient patents, likely because generic companies have been much more successful in patent litigations focusing on secondary patents.⁷⁰ Brand-name manufacturers have won almost all disputes on active ingredients but have lost most litigations on secondary patents; moreover, eighty-nine percent of settlements with enough public information to analyze were centered on secondary patents.⁷¹ One can infer from this data that active ingredient patents are more likely than secondary patents to be found valid and

64. For a general discussion of the evolving pharmaceutical landscape, see Iain M. Cockburn, *The Changing Structure of the Pharmaceutical Industry*, 23 HEALTH AFF. 10 (Jan. 2004).

65. Brief for the Intellectual Property Owners Association as Amicus Curiae Supporting Respondents at 7, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416).

66. *Id.*

67. *Id.*

68. Hemphill & Sampat, *supra* note 17, at 1386.

69. *Id.*

70. *Id.* at 1386–87.

71. *Id.* at 1387.

infringed if litigation proceeded to its conclusion, and thus brand-name companies may be incentivized to settle suits on secondary patents because of their relative weakness.⁷²

One major question arising from this data is whether RPSs actually aid innovation, despite manufacturers' arguments that settlements add money to the drug discovery pipeline and thus are procompetitive.⁷³ Opponents of these settlements argue that settling a dispute in this manner is analogous to price fixing and other prohibited exclusionary behavior.⁷⁴ In addition, banning or limiting reverse payment settlements may serve to encourage brand-name manufacturers to focus on developing new compounds, thereby benefiting the consumer base at large, rather than insulating from competition the compounds that have already been developed and marketed.⁷⁵ Overall, it seems likely that eliminating the pay-for-delay settlement framework could prevent brand-name manufacturers from unfairly extending the lifespan of their exclusivity on a compound, particularly if they are using invalid patents as the basis of this exclusivity.

A great deal of the literature on reverse payment settlements has focused on whether such settlements should be legal, including several Notes in past editions of the *Berkeley Technology Law Journal's* Annual Review.⁷⁶ The legality of these settlements depends on the application of provisions of antitrust law; these provisions are reviewed below.

C. POTENTIAL SOURCES FOR LIABILITY UNDER ANTITRUST PROVISIONS: HOW DID *ACTAVIS* REACH THE SUPREME COURT?

Notably, although the reverse payment settlement in the *Actavis* case only included private parties, the FTC brought the suit that eventually reached the Supreme Court.⁷⁷ This Section explores the antitrust law that permits both

72. *Id.*

73. See Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Respondents at 19–20, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416). These companies argue that the preserved profits fund additional research into new compounds, thereby acting as procompetitive settlements. See *infra* Section I.C for a further discussion of procompetitive and anticompetitive effects of reverse payment settlements.

74. Brief for Petitioner at 51, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416).

75. Hemphill & Sampat, *supra* note 17, at 1386.

76. For some examples of Berkeley Technology Law Journal Annual Review Notes published on this topic, see, for example, Jeff Thomas, Note, Schering-Plough and In re Tamoxifen: *Lanful Reverse Payments in the Hatch-Waxman Context*, 22 BERKELEY TECH. L.J. 13 (2007); Larissa Burford, Note, In re Cardizem & Valley Drug Co.: *The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform*, 19 BERKELEY TECH. L.J. 365 (2004); Julia Rosenthal, Note, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317 (2002).

77. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

the FTC and private parties to bring challenges against potentially collusive activities such as reverse payment settlements.

In 1890, Congress passed the Sherman Act to prohibit “restraint[s] of trade or commerce among the several States.”⁷⁸ In 1914, Congress approved the Clayton Act, which permits consumers to sue business entities under its provisions to prohibit acquisitions whose effects “may be substantially to lessen competition or to tend to create a monopoly.”⁷⁹

The Federal Trade Commission may also become involved in monitoring and litigating against unfair settlements. The FTC, an independent governmental agency established in 1914 by the Federal Trade Commission Act,⁸⁰ promotes consumer protection and the prevention of anticompetitive business practices.⁸¹ The FTC Act empowered the FTC to investigate and stop certain behaviors that violate the Sherman and Clayton Acts.⁸²

Currently, the FTC plays a large role in monitoring and, in some cases, litigating against parties involved in reverse payment settlements under its authority from the Medicare Prescription Drug & Improvement Act, which requires pharmaceutical companies to file documentation of RPSs with the FTC and the Department of Justice within ten days of execution.⁸³ This Act applies to all settlements executed after January 7, 2004 between brand-name and generic companies involving an ANDA, as well as RPSs between two generic companies.⁸⁴

Private parties and the FTC are both authorized to bring suits against putatively illegal collusive settlements under the Sherman Act.⁸⁵ The rationale in all of these litigations is that the FTC is protecting consumers-at-large from illegal splitting of monopoly profits. Most relevant to *Actavis*, the FTC has challenged these arrangements as illegal or presumptively unlawful since the late 1990s under its authority to challenge activities in violation of Section

78. Sherman Antitrust Act, 15 U.S.C. §§ 1–7 (2012).

79. 15 U.S.C. § 18.

80. 15 U.S.C. §§ 41–58.

81. *About the FTC*, FTC, <http://www.ftc.gov/about.shtm> (last visited Oct. 25, 2013).

82. *See* *FTC v. Brown Shoe Co.*, 384 U.S. 316, 322 (1966) (“[The FTC can] arrest trade restraints in their incipiency without proof that they amount to an outright violation of § 3 of the Clayton Act or other provisions of the antitrust laws.”). Although the FTC brought the *Actavis* suit, the Department of Justice’s Antitrust Division may bring similar suits under the provisions of the Sherman and Clayton Acts. 15 U.S.C. § 15(a) (2012).

83. Federal Trade Commission Act (“FTC Act”), Ch. 311, §5, 38 Stat. 717 (codified at 15 U.S.C. §45(a) (2012)); *see also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003).

84. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003).

85. Sherman Antitrust Act, 15 U.S.C. §§ 1–7 (2012).

1 of the Sherman Act.⁸⁶ In the early 2000s, companies ceased using settlements as a tool to end litigation proceedings or to deal with other disputes between companies due to the FTC's active enforcement, but between 2005 and 2013 (after *Schering-Plough* but before *Actavis*), many courts favored settling disputes between the brand-name and generic manufacturers rather than promoting litigation.⁸⁷

1. *Conflicting Policy Doctrines of Patent Law and Antitrust Law*

Reverse payment settlements raise important questions relating to the intersection of patent law and antitrust law. The underlying principles of patent law foster innovation by providing patentees with a right to exclude others from practicing an invention within a certain time frame.⁸⁸ Patentees thus have the right to enjoy a limited monopoly (here, on a pharmaceutical compound or class of compounds).⁸⁹ Conversely, antitrust law in its most general sense functions to protect consumer welfare by preventing unfair monopolies.⁹⁰

The major divergence between antitrust and patent law lies in what each doctrine means when using the term “exclusivity.” Antitrust law seeks to police actions that may take place outside of a reasonable competitive sphere, while patents inherently promote exclusivity.⁹¹ Although there have been many efforts to harmonize the relationship between patent and antitrust law policy rationales,⁹² there are still several areas of the law where these rationales conflict—including in the reverse payment framework described in *Actavis*. Courts must determine whether reverse payments fall under the category of “legitimate competition,” or whether they overstep the reasonable bounds of the patent exclusivity right.⁹³

2. *Procompetitive and Anticompetitive Effects of Reverse Payment Settlements*

A large concern in antitrust analysis of reverse payment settlements is whether these settlements are inherently beneficial or harmful to consumer

86. FTC Act, Ch. 311, §5, 38 Stat. 717 (codified at 15 U.S.C. § 45(a) (2012)).

87. *See* *Watson Pharms., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332–37 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304, 1308 (11th Cir. 2003).

88. Robin Feldman, *Patent and Antitrust: Differing Shades of Meaning*, 13 VA. J.L. & TECH. 1, 4 (2008).

89. *Id.*

90. *Id.*

91. Feldman, *supra* note 88, at 1.

92. *See id.*

93. *Id.*

welfare. Unfortunately, this question is not always straightforward and may depend on the specifics of the deal in question. Judicial efficiency may favor patent settlements.⁹⁴ In addition, in some settlements, a generic company may enter the market prior to patent expiration, thereby providing a cost savings to consumers.⁹⁵ Settlements may encourage the clarification of patent rights between parties involved in disputes.⁹⁶ Therefore, in some cases there may be a reasonable argument that a patent settlement is procompetitive.

However, many parties have raised concerns about potential anticompetitive features of these settlements. For example, these settlements may lead to increased costs for consumers if the generic company delays entry into the market.⁹⁷ In situations where a patent is invalid, settlements may prevent legitimate generic entry into the market.⁹⁸ Also, a settlement may be viewed as the sharing of monopoly profits from a strictly economic viewpoint.⁹⁹

D. STANDARDS OF ANTITRUST REVIEW FOR REVERSE PAYMENT SETTLEMENTS AND APPLICATION TO THE *ACTAVIS* LITIGATION

Courts and agencies have considered and utilized three separate standards of antitrust review for reverse payment settlements: the rule-of-reason standard, the per se standard, and the quick-look standard.¹⁰⁰ These standards require different levels of inquiry to determine whether an antitrust violation has occurred.¹⁰¹ As the default standard for analysis of antitrust claims based on restriction of competition, the rule-of-reason analysis requires three conceptual steps that generally lend themselves to complex analysis.¹⁰² First, the plaintiff must demonstrate an “*actual* adverse effect on competition as a whole in the relevant market.”¹⁰³ The market relevant under

94. FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 25 (2002).

95. *Id.*

96. *Id.*

97. Hemphill, *supra* note 7, at 1557.

98. *Id.*

99. Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1722 (2003).

100. HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 15.3 (2013).

101. *Id.*

102. *Id.*; *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir. 1995).

103. *K.M.B.*, 61 F.3d at 127 (quoting *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir. 1993), *cert. denied*, 114 S. Ct. 388 (1993)).

reverse payment settlements is the market for pharmaceutical compounds.¹⁰⁴ The analysis requires an examination of whether harm is not only possible, but likely and significant in the given situation.¹⁰⁵ If the plaintiff successfully demonstrates this effect, the defendant must then demonstrate the procompetitive effects of the settlement in question.¹⁰⁶ Finally, the plaintiff must provide less restrictive alternatives to the settlement if the defendant can successfully show the procompetitive effects of the settlement.¹⁰⁷

The quick-look standard utilizes a “truncated rule-of-reason” approach in which a court is permitted to conduct a more cursory analysis than that required by the rule of reason.¹⁰⁸ As the court is permitted to assume certain portions of the analysis under this standard, it may only be applied when the settlement in question “[is] not per se unlawful but [is] sufficiently anticompetitive on [its] face that [it] do[es] not require a full-blown rule of reason inquiry.”¹⁰⁹

The per se standard may be applied in situations with a “predictable and pernicious anticompetitive effect” as an exception to the rule-of-reason doctrine.¹¹⁰ These situations may be classified as per se illegal “without elaborate inquiry as to the precise harm.”¹¹¹ This standard should be applied in situations where enough experience has accumulated showing that a rule-of-reason analysis would not permit the practice in question.¹¹²

1. *Application to Actavis: District Court and Eleventh Circuit Analysis in FTC v. Watson Pharmaceuticals*

The Federal Trade Commission filed suit against all parties to the AndroGel reverse payment settlement in the Northern District of Georgia in 2009, asserting that all parties violated Section 5 of the Federal Trade

104. *Id.*

105. Geoffrey D. Oliver, *Of Tenors, Real Estate Brokers and Golf Clubs: A Quick Look at Truncated Rule of Reason Analysis*, ANTI-TRUST 40, 40 (Spring 2010).

106. *Id.*

107. *Id.*

108. *Id.*

109. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 763 (1999) (quoting *Cal. Dental Ass’n v. FTC*, 128 F.3d 720, 727 (9th Cir. 1997)).

110. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *see also N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (“[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal . . .”).

111. *N. Pac. Ry. Co.*, 356 U.S. at 5.

112. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332–37 (Fed. Cir. 2008). For further examples of situations in which quick-look analysis may be appropriate versus per se analysis, *see, e.g., Oliver, supra* note 105.

Commission Act in enacting the reverse payment settlement.¹¹³ Specifically, the FTC argued that Solvay settled with the most likely litigants in a patent infringement dispute to maintain its monopoly unlawfully.¹¹⁴ The district court dismissed the FTC's complaint, stating that the settlement was permissible based on the monopoly power Solvay held as the patent holder.¹¹⁵ The FTC subsequently appealed the decision to the Eleventh Circuit.¹¹⁶

The Eleventh Circuit affirmed the decision of the district court and dismissed the FTC's complaint, stating that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."¹¹⁷ The court did recognize that generally antitrust laws prohibit payment schemes in which one company effectively pays another to delay entry of competitors into a market, but it held that the presence of a patent in this case allowed the patent holder the "lawful right to exclude others from the market."¹¹⁸ However, because the settlement allowed generic competition before the patent's date of expiration, the court determined that the settlement was within the "scope of the patent" and thus not eligible for antitrust analysis.¹¹⁹

2. *Circuit Split: Rationale for Supreme Court Certiorari?*

The Supreme Court granted certiorari on this matter on December 7, 2012, to resolve the circuit split on the lawfulness of reverse payment settlements that had developed over the preceding nine years.¹²⁰ Table 1 below provides relevant details on the previous reverse payment settlement litigation in several jurisdictions.

Along with the Eleventh Circuit, the Second Circuit and the Federal Circuit agreed that "reverse payment settlements do not violate the antitrust laws unless the exclusionary effects of the settlement exceed the scope of the

113. See *supra* Section I.B; 15 U.S.C. § 45; see also *In re Androgel Antitrust Litig.* (No. II), 687 F. Supp. 2d 1371, 1375–76 (N.D. Ga. 2010).

114. *In re Androgel Antitrust Litig.* (No. II), 687 F. Supp. 2d at 1376.

115. *Id.* at 1382.

116. *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1298 (11th Cir. 2012).

117. *Id.* at 1312.

118. *Id.* at 1307.

119. *Id.*

120. *FTC v. Watson Pharms., Inc., cert. granted sub nom, FTC v. Actavis, Inc.*, 133 S. Ct. 787 (2012).

patent at issue.”¹²¹ However, courts may invalidate settlements under the “scope of the patent” test if the PTO granted a patent where the patentee committed fraud, if the patent litigation was a sham, or if the settlement extended beyond the scope of the patent.¹²² Brand-name and generic pharmaceutical companies preferred this standard, as it gave maximum deference to potential settlements between these entities.

Conversely, the Sixth Circuit and Third Circuit established stricter standards of analysis for settlements in which antitrust liability may be scrutinized, although these circuits framed their decisions slightly differently. The Sixth Circuit held in *In re Cardizem Antitrust Litigation* that reverse payment settlements violated antitrust laws per se.¹²³ The Third Circuit, in *In re K-Dur Antitrust Litigation*, rejected the “scope of the patent” test on a set of facts very similar to a case heard in the Eleventh Circuit in 2005 (*Schering-Plough*).¹²⁴ The Third Circuit held that reverse payment settlements were presumptively anticompetitive and that courts should use the quick-look standard of antitrust analysis when determining antitrust liability.¹²⁵ In this analysis, the fact finder must treat reverse payments to a generic company “who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”¹²⁶ The patentee could demonstrate the settlement was permissible under antitrust laws by either showing that the payment was not for delayed entry or that the payment generated competitive benefits not possible without the settlement.¹²⁷ Notably, the Third Circuit’s view on potential antitrust liability showed remarkable consistency with the FTC’s views on settlement antitrust liability.

121. Todaro et al., *supra* note 44. See *Watson Pharms., Inc.*, 677 F.3d at 1308; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d at 1332–37; *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 212–13; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005).

122. *Watson Pharms.*, 677 F.3d at 1312.

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

124. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012); *Schering-Plough Corp.*, 402 F.3d at 1056.

125. *In re K-Dur Antitrust Litig.*, 686 F.3d at 218.

126. *Id.*

127. *Id.*

2014]

REVERSE PAYMENT SETTLEMENTS

511

**Table 1: Reverse Payment Settlement Cases of Significance, 2003–2013,
as of March 9, 2014**

Case	Year	Location	Holding	Most Recent Disposition
FTC v. Actavis, Inc. ¹²⁸	2013	Supreme Court	Rule-of-reason antitrust analysis required	Remanded for further review
FTC v. Watson Pharms. ¹²⁹	2012	Eleventh Cir.	“Scope of the Patent” Test	Remanded from Supreme Court
In re K-Dur ¹³⁰	2012	Third Cir.	RPSs are presumptively anticompetitive, quick-look analysis for antitrust liability	Under consideration for certiorari
In re Cipro ¹³¹	2008	Federal Cir.	“Scope of the Patent” Test	N/A
In re Tamoxifen ¹³²	2006	Second Cir.	“Scope of the Patent” Test	N/A
Schering-Plough Corp. v. FTC ¹³³	2005	Eleventh Cir.	RPSs should not be inherently suspect; “natural by-product” of Hatch-Waxman regime	N/A
In re Cardizem ¹³⁴	2003	Sixth Cir.	RPS violate antitrust laws per se	N/A

II. THE SUPREME COURT’S RULING IN *FTC V. ACTAVIS*: COURTS MUST APPLY THE “MODIFIED RULE-OF-REASON” STANDARD TO ANALYZE REVERSE PAYMENT SETTLEMENTS

In a 5-3 decision,¹³⁵ the Supreme Court in *Actavis* held that the Eleventh Circuit “should have allowed the FTC’s lawsuit to proceed” because reverse payment settlements “can sometimes violate the antitrust laws.”¹³⁶ The Court stated that both patent law policy and “procompetitive antitrust policies” must be considered to determine the “scope of the patent monopoly” and

128. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

129. *FTC v. Watson Pharms.*, 677 F.3d 1298 (11th Cir. 2012).

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

131. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

132. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

133. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

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

135. Justice Alito recused himself from the decision; no explanation was given for his absence. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2223 (2013).

136. *Actavis*, 133 S. Ct. at 2225.

antitrust liability.¹³⁷ As such, the Court mandated the analysis of reverse payment settlements by lower courts using a modified version of the antitrust “rule of reason.”¹³⁸ However, the Court also rejected the FTC’s position that reverse payment settlements are presumptively unlawful.¹³⁹

This Part reviews the rationale of the majority and dissenting opinions, in particular focusing on the guiding principles outlined for the application of the rule of reason in reverse payment settlement cases. The dissenting opinion elected to uphold the “scope of the patent” test, and this discussion outlines the rationale for this position.

A. MAJORITY OPINION: “SCOPE OF THE PATENT” TEST REJECTED;
ANTITRUST RULE-OF-REASON ANALYSIS REQUIRED

Justice Breyer, writing for the majority in *Actavis*, considered five factors in determining that the Federal Trade Commission should have had an opportunity to prove its case.¹⁴⁰ First, the Court argued that patent settlements may have “genuine adverse effects on competition” if the patentee can simply set price levels for a compound for extended periods of time.¹⁴¹ Second, in some cases the consequences of these payments may be anticompetitive and “unjustified,” for example where the payment does not offset the cost of litigation.¹⁴² Third, “where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.”¹⁴³ Fourth, the Court held that “it is normally not necessary to litigate patent validity to answer the antitrust question” because “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.”¹⁴⁴ Therefore, the Court reasoned, it may not be necessary to litigate patent validity to determine antitrust validity, as the payment itself “constitutes the relevant anticompetitive harm.”¹⁴⁵ Finally, recognizing that a settlement may still be the preferred method of dealing with the risk of

137. *Id.* at 2231.

138. *Id.* at 2236.

139. *Id.* at 2237.

140. *Id.* at 2234–38.

141. *Id.* at 2234.

142. *Id.* at 2235–36; *see also* Steven Shavell, *The Social Versus the Private Incentive to Bring Suit in a Costly Legal System*, 11 J. LEGAL STUD. 333, 333–339 (1982) (arguing that litigation is socially desirable only when deterrence benefits from litigation exceed the cost of litigation).

143. *Actavis*, 133 S. Ct. at 2236.

144. *Id.*

145. *Id.*

competition, the majority opinion stated that parties in litigation can still settle without employing a reverse payment settlement.¹⁴⁶

Although the Court laid out the rationale for considering antitrust liability extensively, it simply ordered lower courts to use the antitrust rule of reason to analyze antitrust liability without providing a complete framework for evaluating these settlements.¹⁴⁷ In so doing, the plaintiff in a case must demonstrate that a settlement's anticompetitive effects outweigh the procompetitive effects. This analysis will require a case-by-case look at the circumstances and terms of each settlement. The Court provided some guidance towards an analysis using traditional antitrust factors, but it highlighted that "large" payment sums should be analyzed more carefully, as a large payment may "provide a workable surrogate for a patent's weakness."¹⁴⁸ In addition, the Court explained that if the scale of the settlement is too large compared to the cost of potential future litigation, or if other reasonable justification is not available, a court may determine that a reverse payment settlement is anticompetitive.¹⁴⁹

B. DISSENT: "SCOPE OF THE PATENT" TEST SHOULD BE THE STANDARD

The dissent, authored by Chief Justice Roberts, argued that the Solvay settlement did not violate antitrust laws because the "conduct . . . did not exceed the scope of its patent."¹⁵⁰ Closely following the logic put forward in the Second, Eleventh, and Federal Circuits, the dissent stated that since there had not been allegations of fraud or sham litigation,¹⁵¹ Solvay's payments to generic companies did not violate antitrust law because the payments were made to force the other companies to respect Solvay's patent.¹⁵²

The dissent additionally focused on the majority's assumption that a payment by the brand-name manufacturer demonstrated that the patent holder doubted the validity of the patent.¹⁵³ The dissent offered other potential rationales, including that the patent holder may simply be risk-

146. *Id.* at 2237.

147. *Id.* at 2237–38.

148. *Id.* at 2236–37.

149. *Id.* at 2237–38.

150. *Id.* at 2238 (Roberts, C.J., dissenting).

151. In the antitrust context, the Supreme Court has provided guidance as to the test for "sham litigation." Sham suits must be "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60 (1993).

152. *Actavis*, 133 S. Ct. at 2239 (Roberts, C.J., dissenting).

153. *Id.* at 2244–45.

averse or unwilling to engage in litigation on the issue.¹⁵⁴ It concluded that the true motivation of parties involved in the reverse payment settlement could be hard to determine.¹⁵⁵

Finally, the dissent argued that under the majority's rationale, *all* patent settlements, not just those in the pharmaceutical industry subject to the Hatch-Waxman Act, would be subject to the rule of reason.¹⁵⁶ Additionally, it argued, the majority rationale would discourage settlements in patent litigation, thereby decreasing judicial efficiency and increasing litigation costs and burdens to the court system in general.¹⁵⁷

III. THE LEGAL LANDSCAPE AFTER *ACTAVIS*

Although the Supreme Court did not establish a standard of presumptive illegality in *Actavis*, it did establish that the legality of reverse payment settlements is definitely in question. However, considering the Court's decision left the actual application of the rule-of-reason antitrust standard to lower courts, it seems possible that circuits may split on application of the standard similarly to how they split on what level of antitrust scrutiny to apply. Section III.A explores the legal outcomes possible under the rule-of-reason rationale under *Actavis*, while also considering that one major effect of this ruling may be that patent litigation in these cases will continue, without settlements, regardless of cost or efficiency.

Additionally, several questions have been left open following the ruling in this case. First, both the majority and the dissent seem to agree that "reasonable" settlements are permissible, yet neither opinion specifies what a "reasonable" settlement would be.¹⁵⁸ It is likely that litigants will seek to push the boundaries of this doctrine, if only to see what the limits are. Second, the ruling does not specify how to approach cases in which monetary compensation is not the consideration offered in a settlement. Section III.B explores this concept more thoroughly, in the context of pending decisions on previously executed reverse payment settlements.

154. *Id.* at 2243–45.

155. *Id.*

156. *Id.* at 2245.

157. *Id.* at 2243.

158. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

A. POTENTIAL OUTCOMES IN ANTTITRUST LIABILITY CASES AFTER
ACTAVIS

The *Actavis* decision outlined situations in which settlements are definitely permissible and at risk. For example, parties may negotiate a date for the generic compound to enter the market prior to a patent's expiration.¹⁵⁹ In addition, brand-name companies may compensate generic companies in cash in certain limited situations like litigation costs.¹⁶⁰ However, "unexplained large reverse payment[s]" raise doubts as to the legality of the settlement, as such payments suggest that the patent holder must have doubts about the validity of the patent to have settled.¹⁶¹

One way of considering the potential effects of a settlement is to analyze what happens in situations where parties have settled. For example, if parties settle a litigation action over a valid patent that the generic company has actually infringed, the generic company gets an undeserved win, but the consumer may also win if the date of entry is set before patent expiration. Conversely, if the parties settle litigation when the patent is invalid and thus the generic is not infringing, the brand-name manufacturer received unfair exclusivity for a longer period of time.

Understandably, generic companies need to be able to bring patent challenges to reach the market, and the Hatch-Waxman regime facilitates these challenges. It may be logical to argue that the right to bring challenges inherently should include a right to settle in an effort to bring drugs to the market sooner. In a litigation scenario, if the patent challenger loses, entry is delayed until the patent expires, which may be bad for overall consumer welfare, but it is good for the patentee, since he will continue to enjoy profits presumably at the same level until the patent expires. If the patent challenger wins, the company may enter the market, benefitting the company and consumers (following the 180-day exclusivity period).¹⁶²

In both scenarios, a settlement may reflect the expectations of the parties. Another way of framing this idea is that the patent holder is accepting lower damages overall in a settlement from the generic company. If the patent challenger and the patentee settle, in many cases generic entry could occur before the end of the patent period. Thus, if it becomes more difficult to settle under the *Actavis* rule, generic companies will have no "easier" way out of litigation while still obtaining some potential benefits and will be

159. *Id.* at 2237.

160. *Id.* at 2235.

161. *Id.* at 2236.

162. *See supra* note 45.

incentivized to continue to pay litigation costs or to not pursue litigation in the first place. Generic companies will face greater risks in pursuing potentially costly settlements, particularly given their relatively finite resources. This change may limit the effectiveness of the Hatch-Waxman regime in removing deadweight patents.

Actavis also relies heavily on the logic from *California Dental Association v. FTC*, in which the Supreme Court held that the quick-look antitrust analysis was inappropriate where a professional association imposed restrictions on the types and qualities of permissible advertising for dentists.¹⁶³ In *California Dental* the Court reasoned that, as it held in *Actavis*, the likelihood of noncompetitive effects of the discount and advertising restrictions imposed in the case were not obvious and indeed could have been procompetitive.¹⁶⁴ This approach requires future courts considering similar situations to identify the basis of anticompetitive effects, even if theoretically, and then determine whether these effects actually were anticompetitive.¹⁶⁵ The rule-of-reason analysis proposed in *Actavis* echoes the cautious approach displayed in *California Dental*, and courts will likely look to the language and reasoning in *California Dental Association* when analyzing reverse payment settlements in the future.

B. PENDING CASES WITH *ACTAVIS* IMPLICATIONS¹⁶⁶

Given the number of reverse payment settlement deals executed since 2005, it is no surprise that litigation is pending in a number of these cases. In fact, particularly after *Actavis*, it is likely that even more lawsuits will be filed to stop reverse payment settlements under the rule-of-reason analysis. This Part analyzes these cases, their relevant issues, and likely outcomes under the *Actavis* doctrine. Table 2 provides an overview of pending litigation, both brought by the FTC and by private parties. The table reviews the parties involved in the litigation, the location of the suit, and the type of suit (whether instigated by the FTC or between private parties). In addition, the table provides information about the date of the settlement and the date of initial suit in the case, the volume of sales before a generic came onto the market, and the size of the settlement executed between the private parties at issue. Finally, the grounds for antitrust challenge are provided, as is the current state of the litigation.

163. *Cal. Dental Assn. v. FTC*, 526 U.S. 756, 756 (1999).

164. *Id.* at 771–72.

165. *Id.* at 774–76.

166. Thanks to Seth Silber for helpful discussions regarding this Section (and the Note in general).

2014]

REVERSE PAYMENT SETTLEMENTS

517

Much as before the *Actavis* decision, it seems likely that plaintiffs and defendants will elect to forum shop based on the expertise of the jurisdiction in question and the likelihood of receiving the desired verdict. Thus far, most cases have been brought in trial courts in the Third Circuit,¹⁶⁷ where, as before, many plaintiffs brought reverse payment settlement cases due to the favorable case law on the books.¹⁶⁸ Conversely, defendants will likely still focus their efforts on having their cases heard in the Second, Eleventh, and Federal Circuits because of the makeup of the panels and prior case law regarding RPSs.¹⁶⁹

167. *See infra* Table 2.

168. *See supra* Section I.D.2; *see also* Peter Levitas, *Post-Actavis, The Pay-For-Delay Debate Is Far From Over*, LAW360 (Dec. 18, 2013, 10:38 PM), <http://www.law360.com/articles/495157/post-actavis-pay-for-delay-debate-is-far-from-over>.

169. *Id.*

Table 2: Major Currently Pending and Recently Resolved RPS Cases, as of March 9, 2014

Case	Drug (Function)	Location	Parties	FTC/ Private Suit?	Settlement Date; Suit Date	Sales Before Generic	Settlement Size	Grounds for Antitrust Challenge	Current State of Litigation
<i>In re</i> Cephalon ¹⁷⁰	Provigil (sleep disorder)	E.D. Pa.	FTC, Cephalon, Teva	FTC/ Private	2005 ¹⁷¹ ; 2008 ¹⁷²	\$1.1 billion/ year ¹⁷³	> \$200 million ¹⁷⁴	FTC suit - anticompetitive ¹⁷⁵	Disgorgement under examination ¹⁷⁶
<i>In re</i> Androgel (<i>Actavis</i>) ¹⁷⁷	Androgel (testosterone replacement)	Eleventh Circuit	FTC, Par, AbbVie (Solvay), Actavis, Paddock	FTC/ Private	2006 ¹⁷⁸ ; 2009 ¹⁷⁹	\$1.3 billion/year ¹⁸⁰	≈ \$100 million ¹⁸¹	FTC suit - anticompetitive ¹⁸²	Supreme Court remanded to 11th Cir. ¹⁸³

170. See generally *In re* Cephalon Antitrust Litig., No. 2:08-cv-2141 (E.D. Pa. 2008). The Federal Trade Commission is attempting to add Teva to the suit. See Alex Lawson, *Teva Says FTC Can't Draw It Into Pay-For-Delay Case*, LAW360 (Jan. 8, 2014, 7:16 PM), <http://www.law360.com/articles/499717/teva-says-ftc-can-t-draw-it-into-pay-for-delay-case>.

171. Complaint at 2, *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21 (D.D.C. 2008) (No. 08-0244).

172. See generally *id.*

173. *U.S. Pharmaceutical Sales – 2011*, DRUGS.COM (Nov. 2013), <http://www.drugs.com/stats/top100/2011/sales> (last visited Jan. 16, 2014).

174. Carrier, *supra* note 1, at 444.

175. *In re* Cephalon Antitrust Litig., No. 2:08-cv-2141 (E.D. Pa. 2008).

176. Jonathan L. Lewis, *Give it Back! Disgorgement – Another FTC Arrow Against Reverse-Payment Settlements that Delay Generic Entry*, ANTITRUST ADVOCATE (Dec. 3, 2013), <http://www.antitrustadvocate.com/2013/12/03/give-it-back-disgorgement-another-ftc-arrow-against-reverse-payment-settlements-that-delay-generic-entry/>.

177. See generally *In re* Androgel Antitrust Litig. (No. II), No. 1:09-md-02084 (N.D. Ga. 2013).

178. *In re* Androgel Antitrust Litig. (No. II), 687 F. Supp. 2d 1371, 1375 (N.D. Ga. 2010).

179. *Id.* at 1375–76.

Case	Drug (Function)	Location	Parties	FTC/ Private Suit?	Settlement Date; Suit Date	Sales Before Generic	Settlement Size	Grounds for Antitrust Challenge	Current State of Litigation
<i>In re</i> Lipitor ¹⁸⁴	Lipitor (cholesterol reduction)	D.N.J.	End-payors (class action), Ranbaxy, Pfizer	Private	2008 ¹⁸⁵ ; 2011 ¹⁸⁶	\$7.4 billion/year ¹⁸⁷	Side deal; see below ¹⁸⁸	Side-deal ¹⁸⁹	Discovery ¹⁹⁰
<i>In re</i> Effexor ¹⁹¹	Effexor (depression)	D.N.J.	Wyeth/Pfizer	Private	2005 ¹⁹² ; 2011 ¹⁹³	\$2.4 billion/year ¹⁹⁴	No-AG agreement ¹⁹⁵	No-AG ¹⁹⁶	Stayed pending <i>K-Dur</i> cert ¹⁹⁷

180. U.S. Pharmaceutical Sales – 2012, DRUGS.COM (Nov. 2013), <http://www.drugs.com/stats/top100/2012/sales> (last visited Jan. 16, 2014).

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

182. *In re* Androgel Antitrust Litig. (No. II), No. 1:09-md-02084 (N.D. Ga. 2013).

183. *Actavis*, 133 S. Ct. at 2238. The case is currently being litigated in the Northern District of Georgia.

184. *In re* Lipitor Antitrust Litig., No. 3:12-cv-2389 (PGS), 2013 WL 4780496 (D.N.J. Sept. 5, 2013).

185. *Id.* at *19.

186. *Id.* at *42.

187. U.S. PIRG & COMMUNITY CATALYST, *supra* note 11.

188. Pfizer forgave Ranbaxy debt and a marketing agreement for generic Lipitor. *In re Lipitor*, 2013 WL 4780496, at *20.

189. *Id.*

190. *See generally id.*

191. *See generally In re* Effexor Antitrust Litig., No. 11-cv-5479 (D.N.J. 2011). Effexor may also be used for treatment of anxiety and panic disorder. *Id.*

192. *Id.*

193. *Id.*

194. U.S. PIRG & COMMUNITY CATALYST, *supra* note 11.

195. *In re Effexor*, No. 11-cv-5479 (D.N.J. 2011).

196. *Id.*

197. *Id.*

Case	Drug (Function)	Location	Parties	FTC/ Private Suit?	Settlement Date; Suit Date	Sales Before Generic	Settlement Size	Grounds for Antitrust Challenge	Current State of Litigation
<i>In re Lamictal</i> ¹⁹⁸	Lamictal (epilepsy)	D.N.J.	GlaxoSmithKline, Teva	Private	2005 ¹⁹⁹ ; 2012 ²⁰⁰	\$1.5 billion/year ²⁰¹	No-AG agreement ²⁰²	No-AG ²⁰³	Case dismissed ²⁰⁴
<i>In re Nexium</i> ²⁰⁵	Nexium (heartburn)	D. Mass.	AstraZeneca, Ranbaxy	Private	2008 ²⁰⁶ ; 2013 ²⁰⁷	\$5.6 billion/year ²⁰⁸	1) Nexium supply; 2) Generics of Plendil, Prilosec ²⁰⁹	No-AG ²¹⁰	Discovery ²¹¹

198. *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995(WHW), 2014 WL 282755 (D.N.J. Jan. 24, 2014). The Third Circuit remanded *In re Lamictal* to D.N.J. for reexamination in light of *Actavis*. *Id.* at *3.

199. *Id.* at *1.

200. *Id.* at *2.

201. U.S. PIRG & COMMUNITY CATALYST, *supra* note 11.

202. *In re Lamictal*, 2014 WL 282755, at *1–2.

203. *Id.*

204. *Id.* at *1.

205. *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY, 2013 WL 4832176 (D. Mass. Sept. 11, 2013).

206. *Id.* at *6.

207. *Id.* at *2.

208. U.S. PIRG & COMMUNITY CATALYST, *supra* note 11.

209. *In re Nexium*, 2013 WL 4832176.

210. *Id.* at *6–9.

211. *See generally id.*

Case	Drug (Function)	Location	Parties	FTC/ Private Suit?	Settlement Date; Suit Date	Sales Before Generic	Settlement Size	Grounds for Antitrust Challenge	Current State of Litigation
Loestrin 24 ²¹²	Loestrin (oral contraceptive)	E.D. Pa.	Class actions; Warner Chilcott PLC, Actavis, Lupin Pharms.	Private	2010 ²¹³ ; 2013 ²¹⁴	\$633 million ²¹⁵	License, side deal ²¹⁶	Side deal ²¹⁷	Centralized six class actions ²¹⁸
Niaspan ²¹⁹	Niaspan (niacin)	D.R.I. ²²⁰ ; E.D. Pa. ²²¹	City of Providence, Painters Dist. Council, AbbVie, Teva	Private	2005 ²²² ; 2013 ²²³	\$889 million ²²⁴	Supply and promotion ²²⁵	Restrictions on trade ²²⁶	Respond to complaint ²²⁷

212. United Food and Commercial Workers Local 1776 & Participating Emp'rs Health and Welfare Fund v. Warner Chilcott Pub. Ltd. Co., No. 2:13-cv-01807, 2013 WL 2256456 (E.D. Pa. May 23, 2013).

213. *Warner Chilcott*, 2013 WL 2256456, ¶95 (E.D. Pa. May 23, 2013).

214. *Id.*

215. *Estimated Dates of Possible First-Time Generics/Rx-to-OTC Market Entry*, MEDCO, <http://www.krtv.com/files/genericdates.pdf> (last visited May 19, 2014).

216. *Warner Chilcott*, 2013 WL 2256456, ¶97-98 (E.D. Pa. May 23, 2013).

217. *Id.*

218. Gavin Broady, *JPML Ships Loestrin Pay-For-Delay Suits to Rhode Island*, LAW360 (Oct. 3, 2013, 7:10 PM), <http://www.law360.com/articles/478010/jpml-ships-loestrin-pay-for-delay-suits-to-rhode-island>.

219. City of Providence v. AbbVie Inc. et al, No. 1:13-cv-00292 (D.R.I. Apr. 30, 2013); *see also* Elizabeth T. Brown, *Crop of Pay-For-Delay Suits Centered on Extended-Release Niacin Filed*, WESTLAW INTELL. PROP. DAILY BRIEFING, 2013 WL 71844265 (May 3, 2013). Niaspan uses the vitamin niacin to reduce cholesterol. *Id.*

220. *Id.*

221. Painters Dist. Council No. 30 Health & Welfare Fund v. AbbVie Inc. et al., No. 2:13-cv-02343 (E.D. Pa. Apr. 30, 2013).

222. *Id.*

223. *Id.*

Case	Drug (Function)	Location	Parties	FTC/ Private Suit?	Settlement Date; Suit Date	Sales Before Generic	Settlement Size	Grounds for Antitrust Challenge	Current State of Litigation
United Food & Commercial Workers Local 1776 v. Medici's Pharm. Corp. ²²⁸	Solodyn (acne drug)	E.D. Pa.	United Food & Commercial Workers, Medici's, Teva, Mylan, Sandoz	Private	2008 ²²⁹ ; 2013 ²³⁰	\$760 million/year ²³¹	\$55 million ²³²	No-AG, direct payments, product hopping ²³³	Response to complaint ²³⁴
Miami-Luken, Inc. v. Boehringer ²³⁵	Aggrenox (Stroke)	E.D. Pa.	Miami-Luken, Inc.; Boehringer, Barr Pharms.	Private	2008 ²³⁶ ; 2013 ²³⁷	\$366 million ²³⁸	\$120 million; side deal ²³⁹	Payment, side deal ²⁴⁰	Filed suit ²⁴¹

224. *Estimated Dates of Possible First-Time Generics/Rx-to-OTC Market Entry*, MEDCO, <http://www.krtv.com/files/genericdates.pdf> (last visited May 19, 2014).

225. *City of Providence v. AbbVie Inc. et al*, No. 1:13-cv-00292 (D.R.I. Apr. 30, 2013).

226. *Id.*

227. *Id.*

228. *United Food and Commercial Workers Local 1776 & Participating Emp'rs Health and Welfare Fund v. Medici's Pharm. Corp. et al.*, No. 2:13-cv-04235 (E.D. Pa. Jul. 23, 2013).

229. *Id.*

230. *Id.*

231. *2011 U.S. Sales* (Nov. 2013), DRUGS.COM, <http://www.drugs.com/stats/top100/2011/sales> (last accessed Dec. 21, 2013).

232. *Medici's Pharm. Corp.*, No. 2:13-cv-04235 (E.D. Pa. Jul. 23, 2013).

233. *Id.*

234. *Id.*

235. *Miami-Luken, Inc. v. Boehringer Ingelheim Pharma GMBH & Co. KG et al.*, No. 2:13-cv-06543 (E.D. Pa. Nov. 8, 2013).

236. Michael Lipkin, *Boehringer Sued Over \$120M Pay-For-Delay On Stroke Drug*, LAW360 (Nov. 12, 2013, 8:27 PM), <http://www.law360.com/articles/488020/boehringer-sued-over-120m-pay-for-delay-on-stroke-drug>.

237. *Id.*

Case	Drug (Function)	Location	Parties	FTC/ Private Suit?	Settlement Date; Suit Date	Sales Before Generic	Settlement Size	Grounds for Antitrust Challenge	Current State of Litigation
Int'l Union of Painters & Allied Trades v. Teva ²⁴²	Aggrenox (Stroke)	D. Minn.	Int'l Union of Painters & Allied Trades; Boehringer, Barr Pharms.	Private	2008 ²⁴³ ; 2014 ²⁴⁴	\$366 million ²⁴⁵	\$120 million; side deal ²⁴⁶	Payment, side deal ²⁴⁷	Filed suit ²⁴⁸
Am. Sales Co., LLC v. Boehringer ²⁴⁹	Aggrenox (Stroke)	D. Conn.	Am. Sales Co., LLC; Boehringer, Barr Pharms.	Private	2008 ²⁵⁰ ; 2014 ²⁵¹	\$366 million ²⁵²	\$120 million; side deal ²⁵³	Payment, side deal ²⁵⁴	Filed suit ²⁵⁵

238. *Id.*

239. *Id.*

240. *Id.*

241. *Id.*

242. Int'l Union of Painters and Allied Trades, Dist. Council 21 v. Teva Pharms. USA Inc. et al., No. 0:14-cv-00050 (D. Minn. Jan. 6, 2014).

243. Dan Prochilo, *Boehringer, Teva Sued Again Over Deal to Delay Generic*, LAW360 (Jan. 6, 2014, 4:12 PM), http://www.law360.com/lifesciences/articles/498915?nl_pk=127accd7-c358-49d8-9691-276f2bf3ab31&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences.

244. *Id.*

245. *Id.*

246. *Id.*

247. *Id.*

248. *Id.*

249. Am. Sales Co., LLC v. Boehringer Ingelheim Pharma GMBH & Co. KG et al., No. 3:14-cv-00003 (D. Conn. Jan. 2, 2014).

250. Jeff Overley, *Boehringer, Teva Sued Over \$120M Pay-For-Delay Deal*, LAW360 (Jan. 3, 2014, 7:10 PM), <http://www.law360.com/articles/498398/boehringer-teva-sued-over-120m-pay-for-delay-deal>.

251. *Id.*

252. *Id.*

253. *Id.*

254. *Id.*

1. *Pending FTC Litigation Against Reverse Payment Settlements*

As explained in Section I.C, *supra*, both the FTC and private plaintiffs may bring suits against parties to reverse payment settlements. For cases involving the FTC as enforcer, one must consider the FTC's agenda after winning the case—what result does the FTC want? In addition, the available resources of the FTC to implement any desired actions must be analyzed as well. Since the FTC's resources are limited, the FTC will only bring suits against potential violators in certain cases. Currently, the FTC has brought suit in two reverse payment settlement cases: *In re Androgel Antitrust Litigation*²⁵⁶ (the remand of the *FTC v. Actavis* Supreme Court case) and *In re Cephalon Antitrust Litigation*²⁵⁷ (the case described in the introduction of this Note).

a) *In re Androgel Antitrust Litigation (No. II)*

The Eleventh Circuit is currently reviewing the merits of the remanded *FTC v. Actavis* case in light of the *Actavis* decision. However, a Georgia federal judge has indicated that he would reverse his decision in the original case, thereby overturning his dismissal of the reverse payment settlement claims if the Eleventh Circuit decides to remand the case.²⁵⁸

b) *In re Cephalon Antitrust Litigation*

The FTC is also pursuing action in *In re Cephalon Antitrust Litigation*, a case centered on a reverse payment settlement for the sleep-disorder medication Provigil.²⁵⁹ The FTC has prioritized litigation based on the over \$200 million settlement between Cephalon and generic companies Teva, Ranbaxy, Mylan, and Barr.²⁶⁰

There, Cephalon had obtained patent protection on the active compound in its drug Provigil until 2001 and had obtained a secondary formulation

256. *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-md-02084 (N.D. Ga. 2013).

257. *FTC v. Cephalon, Inc.*, No. 2:08-cv-02141 (E.D. Pa. 2013).

258. Melissa Lipman, *AndroGel Judge Says It's Time to Revive Class Fight*, LAW360 (Oct. 24, 2013, 6:34 PM), http://www.law360.com/ip/articles/483004?nl_pk=25ea4785-aa48-4f5f-969c-81f045fa96b8&utm_source=newsletter&utm_medium=email&utm_campaign=ip.

259. For a description of the facts of the case, see the introductory comments to this Note.

260. Carrier, *supra* note 1, at 444. *In re Cephalon Antitrust Litigation* also raises the additional potentially anticompetitive action of “product hopping,” the consideration of which falls outside the scope of this Note. See *In re Cephalon Antitrust Litig.*, No. 2:08-cv-2141 (E.D. Pa. 2008).

patent lasting until October 2014.²⁶¹ Generic companies could not avoid the active ingredient patent, but they could devise formulations that would not infringe the secondary patent.²⁶² As such, the four generic companies listed above submitted ANDAs in December 2002.²⁶³

Cephalon and the generic companies alike had anticipated significantly decreased revenue for Cephalon following generic entry in the Provigil market. One Cephalon vice president estimated that prices would decrease seventy-five to ninety percent within one year, lowering the overall revenues for the product by \$400 million that year alone.²⁶⁴ Although Cephalon sought to extend its market share by creating a successor product called Nuvigil, which provided longer drug effects but had a similar composition to that of Provigil, the FDA did not approve the new compound in time to successfully block anticipated generic entry to the market in early 2006.²⁶⁵ Cephalon thus settled with the generic companies to prevent generic market entry until April 2012.²⁶⁶

In 2012, the FTC sued all parties involved in the settlement, alleging antitrust violations under Section 5(a) of the Federal Trade Commission Act; litigation in this proceeding is currently ongoing, despite the fact that generic versions of Provigil have been launched.²⁶⁷ Cephalon argued that the case should be dismissed in September 2013 pleadings, citing the current presence of generic versions on market as a primary reason for dismissal.²⁶⁸ But the FTC subsequently argued that there still existed appropriate remedies, especially considering that Cephalon received the benefit of the extra six years of generic market entry protection; “monetary equitable relief is particularly important to deny a proven violator its ill-gotten gains and to deter future violations.”²⁶⁹

261. Complaint ¶¶ 32–34, *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21 (D.D.C. 2008) (No. 08-0244).

262. *Id.* at ¶¶ 41–45.

263. *Id.* at ¶ 38.

264. Note that Teva made similar estimates that generic versions would obtain ninety percent of all prescriptions within a month of market entry, dropping prices to ten percent of the brand-name price within one year. *Id.* at ¶ 26.

265. *Id.* ¶ 3.

266. *Id.*

267. Melissa Lipman, *FTC Eyes Disgorgement in Cephalon Pay-For-Delay Fight*, LAW360 (Nov. 19, 2013, 5:11 PM), <http://www.law360.com/articles/489918/ftc-eyes-disgorgement-in-cephalon-pay-for-delay-fight>.

268. *Id.*

269. *Id.*

2. *Private Plaintiff Lawsuits*

In lawsuits with private plaintiffs, oftentimes the litigation targets will be determined by the cases private plaintiffs find potentially lucrative. A number of factors may play into whether a party chooses to raise a suit under the new *Actavis* regime. First, the relevance of the patent merits and the extent to which the brand-name party has paid the generic company to delay entry into the market will be assessed; of particular interest is the size of the payment. In addition, courts must consider the difference between the entry date and the date of patent expiration, as well as the overall size of the market for the drug in question. Private plaintiffs thus will be more likely to sue, particularly if the market for the patented compound is large.

Going forward, district courts will need to assess specific issues regarding the type of payment used in settlements. Three main issues have been raised in the pending cases, including no-authorized-generic (“No-AG”) deals, forgiveness on liability from unrelated litigation, and side deals. No-AG deals have been very common in recent settlements.²⁷⁰ The problem, in the context of *Actavis*, is that a non-compete agreement can be viewed as a significant payment to the generic company. Because *Actavis* did not specifically address this particular type of deal, the lower courts will have to analyze deals on a case-by-case basis, paying careful attention to the facts and deals in each case. In addition, some cases might involve part of the consideration coming in the form of forgiveness for liability from unrelated litigation.²⁷¹ *Actavis* did not clearly proscribe this action as a payment (or payments of any form, in fact), although it seems likely that future courts will view unrelated litigation cost forgiveness skeptically under the rule-of-reason standard. Finally, side deals have made an appearance in a number of settlements, including the deal at issue in *Actavis* (although the Court did not address this portion of the deal in the opinion). In *Actavis*, Solvay agreed to co-promote a compound with its generic competitors.²⁷² Whether this agreement constitutes a “payment” is not settled in case law, as few examples have arisen since the *Actavis* decision in June 2013.

a) No-Authorized-Generic Deals (No-AG)

One particular settlement term under current investigation in several pending actions is the No-AG agreement, in which the brand-name company

270. See *supra* Table 2.

271. *In re Effexor Antitrust Litig.*, No. 11-cv-5479 (D.N.J. 2011).

272. *FTC v. Actavis*, 133 S. Ct. 2223, 2229 (2013).

agrees to not market its own generic brand against a generic manufacturer's product. This settlement provision became common following the FTC's renewed focus on reverse payment settlements around 2006.²⁷³ However, *Actavis* did not speak specifically to the permissibility of this settlement term, and litigating parties have subsequently petitioned the courts to determine their legality.²⁷⁴

A number of pending cases address this settlement provision, with wide-ranging results. The District of Massachusetts has ruled that No-AG agreements are implicated under *Actavis*, while the District of New Jersey recently dismissed a complaint in a No-AG case under *Actavis*. A third case, *In re Effexor*, will be a case to watch on this controversial issue.

i) *In re Nexium (Esomeprazole) Antitrust Litigation*

In the District of Massachusetts, *In re Nexium (Esomeprazole) Antitrust Litigation* has provided a first interpretation of *Actavis*'s ruling at the district court level.²⁷⁵ Here, the district court allowed the reverse payment settlement suit to proceed forward under *Actavis*'s modified rule-of-reason standard, indicating that settlements without monetary compensation are still implicated under *Actavis*.²⁷⁶

Brand-name pharmaceutical company AstraZeneca manufactures Nexium, a compound designed to treat acid reflux.²⁷⁷ AstraZeneca and generic company Ranbaxy (along with other generic manufacturers) had settled a patent litigation suit with an RPS in 2008.²⁷⁸ Ranbaxy agreed to delay the launch of its generic version of Nexium, and AstraZeneca granted Ranbaxy an exclusive license to supply AstraZeneca with Nexium.²⁷⁹ In addition, AstraZeneca gave Ranbaxy the right to serve as an authorized generic distributor for two other pharmaceutical compounds.²⁸⁰ Finally, under the settlement AstraZeneca was not permitted to market its own

273. Hemphill, *Drug Patent Settlements Between Rivals*, *supra* note 19, at 17.

274. See *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995 (WHW), 2014 WL 282755 (D.N.J. Jan. 24, 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY, 2013 WL 4832176 (D. Mass. Sept. 11, 2013); *In re Effexor Antitrust Litig.*, No. 11-cv-5479 (D.N.J. 2011).

275. *In re Nexium*, 2013 WL 4832176.

276. See *id.* at *86–88.

277. *Id.* at *2.

278. *Id.* at *16.

279. *Id.* at *18.

280. *Id.*

authorized generic (AG) version of Nexium during a 180-day exclusivity period.²⁸¹

A class action suit was brought against the parties in 2012 in the District of Massachusetts.²⁸² The major issue in this pending case is whether No-AG agreements are a form of compensation implicated under the ruling in *Actavis*. In September 2013, the presiding judge ruled that the case could proceed, holding that “the Direct Purchasers have pled facts sufficient at the motion-to-dismiss stage to establish violations of sections 1 and 2 of the Sherman Act under the rule of reason.”²⁸³ The court determined that the settlement was sufficiently great in value and sufficiently unrelated to settlement of the particular patent in question to trigger antitrust liability, finding that AstraZeneca agreed to pay Ranbaxy consideration valued at over \$1 billion through the provisions in the agreement.²⁸⁴ Also, the settlement with Ranbaxy in particular would have prevented generic entry, even though Ranbaxy was not marketing its generic product until 2014.²⁸⁵ Ranbaxy and the other generic firms also likely would have chosen to enter the market “at risk” based on their past behavior, and finally, no evidence was presented showing procompetitive benefits from the settlement.²⁸⁶ Under the logic in *In re Nexium Antitrust Litigation*, No-AG deals appear to be very risky forms of compensation, and pharmaceutical companies considering a reverse payment settlement would be wise to follow this case closely.

ii) *In re Lamictal Direct Purchaser Antitrust Litigation*

On January 24, 2014, the District of New Jersey dismissed the direct purchaser complaint in *In re Lamictal* for failure to state a claim upon which relief could be granted.²⁸⁷ The court based the decision on an assessment that

281. As with *Actavis*, this case involved brand-name interactions with several generic companies. The litigation in this proceeding also addressed Teva and Dr. Reddy’s; however, the interpretation of *Actavis* in this decision focused on the reverse payment settlement between AstraZeneca and Ranbaxy. *Id.* at *18–22.

282. Dan Prochilo, *Dukes Prevents Class Cert. In Nexium MDL, AstraZeneca Says*, LAW360 (Sept. 17, 2013, 2:40 PM), <http://www.law360.com/competition/articles/473186/dukes-prevents-class-cert-in-nexium-mdl-astrazeneca-says>.

283. *In re Nexium*, 2013 WL 4832176, at *46.

284. *Id.* at *17–18. AstraZeneca also forgave contingent liabilities faced by Teva and Dr. Reddy’s in relation to drugs other than those at issue in the patent litigation. *Id.* at *21–22.

285. *Id.* at *17.

286. *Id.*

287. *In re Lamictal Direct Purchaser Antitrust Litig.*, No 12-cv-995 (WHW), 2014 WL 282755, at *1 (D.N.J. Jan. 24, 2014).

Actavis only applies to settlements that “contain an unjustified reserve payment of money.”²⁸⁸

GlaxoSmithKline (“GSK”) produces Lamictal (lamotrigine), a compound used to treat epilepsy and bipolar disorder.²⁸⁹ In 2002, Teva Pharmaceuticals and subsidiaries filed ANDAs with the FDA, and in response GSK sued Teva for patent infringement.²⁹⁰ GSK and Teva settled the suit in 2005, permitting Teva to enter the market by June 1, 2005 on the chewable formulation and later for tablets.²⁹¹ Most important, GSK and Teva agreed on a No-AG agreement in which GSK would not produce its own generic version of Lamictal products during Teva’s exclusivity period.²⁹²

The court found that “*Actavis* scrutiny only applies to patent settlements that contain reverse payments” and further that the only reverse payments implicated under *Actavis* consist solely of cash.²⁹³ The opinion cites *Actavis* itself for this assertion, noting that Justice Breyer discussed monetary amounts at several places within the opinion.²⁹⁴ Judge Walls also cites *Actavis*’s dissent for support of this position, asserting that Chief Justice Roberts assumed RPS referred only to money.²⁹⁵

Finally, the decision distinguishes *In re Lamictal* from the recent cases *In re Lipitor* and *In re Nexium*, where both cases proceeded forward for further examination of potential antitrust liability under *Actavis*.²⁹⁶ In *In re Lipitor*, the District of New Jersey permitted amendments to a complaint because “nothing in *Actavis* strictly requires that the payment be in the form of money.”²⁹⁷ However, the court ruled that Judge Roberts’s dissent did not support the manufacturers’ position, because their request more closely mirrored a “request for further briefing.”²⁹⁸ The court distinguished *In re Nexium* on the basis that the settlement in that action involved a No-AG agreement and a cash payment, as opposed to just a No-AG agreement.²⁹⁹ It

288. *Id.* at *11.

289. *Id.* at *1.

290. *Id.*

291. *Id.*

292. *Id.* at *2.

293. *Id.* at *6–7.

294. *Id.* at *7 (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2222, 2227, 2233 (2013)).

295. *Id.* at *8.

296. See *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY, 2013 WL 4832176 (D. Mass. Sept. 11, 2013); *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389 (PGS), 2013 WL 4780496 (D.N.J. Sept. 5, 2013).

297. *In re Lipitor*, 2013 WL 4780496, at *26.

298. *In re Lamictal*, 2014 WL 282755, at *9.

299. *Id.*

reasoned that the payments in *In re Nexium* were either “outsized” or “entirely disconnected” from the Nexium patent dispute, according to the logic of *Actavis*, whereas in *In re Lamictal*, all of the settlement terms were directly related to the Lamictal patent dispute.³⁰⁰

iii) *In re Effexor Antitrust Litigation*

As in the previously discussed cases, particularly *In re Nexium*, discussed *supra* at Section III.B.2.a.i, the predominant issue in *In re Effexor Antitrust Litigation* is the presence of a No-AG provision as a major part of a reverse payment settlement.³⁰¹ However, unlike in *In re Nexium*, the district court here has not ruled as of March 9, 2014. *In re Effexor* will be an important case to watch and compare to *Nexium* to better assess the potential permutations of the *Actavis* doctrine when looking at similar issues.

b) Side Deals

Side deals, also commonly found in recent pharmaceutical patent settlements, are settlement terms in which a brand-name and a generic company agree to a joint transaction not directly related to the ending of litigation through the settlement. Co-promotion of a compound is a common form for a side deal. In *Actavis*, the co-promotion to urologists settlement term functioned as a side deal.³⁰² *In re Lipitor*³⁰³ and *Loestrin 24*³⁰⁴ are two other district court cases currently examining side deals.

The legality of these deals is unclear as of yet, and settling parties using these provisions should be prepared for litigation. If a side deal is a legitimate transaction occurring at the same time as a settlement, however, it may be permissible under the rule-of-reason standard of *Actavis*.

c) Unrelated Litigation Costs: *In re Effexor Antitrust Litigation*

The holding in *Actavis* did not address unrelated litigation costs; this issue has been raised in the current *In re Effexor Antitrust Litigation* proceedings.³⁰⁵ Although the district court’s position in *In re Effexor* on unrelated litigation

300. *Id.*

301. Complaint ¶¶ 176, 180, 182, *In re Effexor Antitrust Litig.*, No. 11-cv-5479 (D.N.J. 2011).

302. *FTC v. Actavis, Inc.*, 133 S. Ct. at 2229.

303. *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389 (PGS) (D.N.J. Sept. 5, 2013).

304. Complaint at ¶¶ 5–12, *United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund v. Warner Chilcott Pub. Ltd. Co.*, 2013 WL 2256456 (E.D. Pa. Apr. 5, 2013) (No. 2:13-cv-01807).

305. *In re Effexor Antitrust Litig.*, No. 11-cv-5479 (D.N.J. 2011).

costs is thus far unclear, it seems likely that in situations where such costs are sufficiently large and thus an indicator of potentially anticompetitive activity, a court will find that litigation costs may be indicative of a reverse payment settlement in violation of antitrust laws. However, the Court indicated in *Actavis* that litigation costs of an appropriate size are not necessarily indicative of an anticompetitive settlement.³⁰⁶

IV. LOOKING FORWARD: ADDRESSING *ACTAVIS* POTENTIAL FUTURE PROBLEMS AND SOLUTIONS

Judging from the number of pending cases and settlements that have been made in the past few years, it seems likely that the rule-of-reason doctrine from *Actavis* with regard to RPS has not yet settled. As such, it is prudent to consider potential options beyond the court system to promote the values espoused in the case. Section IV.A considers possible improvements to the patent examination system itself that may reduce the number of invalid secondary patents that face litigation through the Hatch-Waxman regime. Next, the potential of using the FTC or other third parties to the settlements in the regulatory process is explored in Section IV.B. Section IV.C explores the international ramifications of the *Actavis* decisions and similar provisions in markets where pharmaceutical companies may operate. Two U.S. congressional initiatives currently under consideration are examined in Section IV.D. Finally, Section IV.E evaluates an amendment to the Hatch-Waxman Act designed to potentially mitigate some of the effects of reverse payment settlements, and it proceeds to make general recommendations on the viability of reverse payment settlements going forward.

A. BETTER PROSECUTION OF PATENTS AT THE PTO: ELIMINATE WEAK “SECONDARY” PATENTS

There is significant evidence in the scientific literature that brand-name companies are extending their periods of exclusivity rights on certain compounds using secondary patents, typically by patenting the method of use for a compound or other procedural aspects beyond the active compound itself.³⁰⁷ Typically, these patents are most likely to be challenged

306. *Actavis*, 133 S. Ct. at 2236–37.

307. For discussion on this issue, see, e.g., Hemphill & Sampat, *supra* note 17; Sherry M. Knowles, *Fixing the Legal Framework for Pharmaceutical Research*, 327 SCI. 1083 (2010); Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLoS ONE e49470 (2012).

by generic pharmaceutical companies within the framework of the Hatch-Waxman Act.³⁰⁸ As discussed previously, secondary patents are invalidated at a much higher rate than active ingredient patents in Hatch-Waxman litigation.³⁰⁹ These patents are also the most likely to be the patents at issue in RPSs; the vast majority of reverse payment settlements are the result of litigation challenges to secondary patents.³¹⁰ One of the policy goals of the Hatch-Waxman Act is to encourage generic challenges to invalid patents,³¹¹ but litigation is costly and time consuming, and eliminating invalid patents could be done more efficiently at an earlier stage.

Numerous commentators have discussed their belief that the current patent system creates too many “bad” patents.³¹² A reasonable goal to pursue would be to eliminate more of these secondary patents at the prosecution stage, rather than relying on the judicial system as a second quality-control check. One method to achieve this goal would require authorizing more patent agents and reforming the PTO examination system to increase the amount of time spent on examination of each patent, but this may not be the most practical method in the short term, due to available resources and investment from the government.³¹³ Currently, the PTO spends

308. Hemphill & Sampat, *supra* note 17, at 1386.

309. *See generally* Hemphill & Sampat, *supra* note 17.

310. According to this study, eighty-nine percent of reverse payment settlement litigation completed under Hatch-Waxman resulted from secondary patent challenges. *Id.* at 1387.

311. *See* Part I *infra*.

312. *See, e.g.*, Richard A. Posner, *Why There Are Too Many Patents in America*, THE ATLANTIC (July 12, 2012), available at <http://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/> (arguing that most industries have applied for and received more patents than necessary); Joshua L. Sohn, *Can't the PTO Get a Little Respect?*, 26 BERKELEY TECH. L.J. 1603, 1630–32 (2011) (exploring criticisms of the PTO's examination process, including the common criticism regarding “insufficiently rigorous” patent examinations, that examiners are insufficiently trained to properly evaluate patents and finally that examiners are incentivized in the current system to grant rather than reject patents); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 589–91 (1999).

313. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495 (2001). However, many scholars have argued that *increasing* the evaluation time of patents will lead to increased backlogs and is thus unfavorable; these scholars make other proposals regarding the feasibility of changing the process at all. *See, e.g.*, Jonathan S. Masur, *Costly Screens and Patent Examination*, 2 J. LEG. ANAL. 687 (arguing that the patent process serves to eliminate “unwanted participants” from the patent process, and removes socially harmful patents from the pool).

approximately eighteen hours evaluating each patent application.³¹⁴ So if improving the stringency of patent examination is not a viable solution, how do you identify “good” secondary patents and eliminate the “bad” ones?

It may be possible to change patent examination practices to enforce higher standards of validity on secondary patents. One strategy to deal with the examination of secondary patents has been approved in India, where Section 3d of the Indian patent regulations specifies that secondary patents are prohibited unless the applicant demonstrates increased “efficacy” of the new compound or formulation.³¹⁵ India’s approach has some conceptual relationship to the Hatch-Waxman approach, where litigation removes patents at the end of patent terms.³¹⁶ The Indian statute defines “efficacy” as related to therapeutic efficacy,³¹⁷ but widening the definition of “efficacy” to encompass other potential legitimate improvements to the drug may allow for patents that actually comprise an improvement to the drug in question, without allowing weak patents to be approved at the PTO.

B. A POTENTIAL REGULATORY ROLE FOR THE FTC OR THIRD PARTIES?

The court system may not be the most appropriate forum for the analysis of reverse payment settlements. As several authors have previously suggested, administrative agencies may have the proper scope, authority, and freedom to analyze settlements, particularly those involving details not available to the public or in the court’s record.³¹⁸ The FTC itself may be particularly well suited to this task, given its mandate, although establishing appropriate regulatory guidelines would be crucial.³¹⁹

The FTC has stated clearly and recently that it intends to continue to examine settlements, both old and new, for potential violations of antitrust

314. Lemley, *supra* note 313, at 1500 (estimating that patent examiners spend approximately eighteen hours reviewing each patent application, throughout the entire process).

315. Dr. Kenneth Shadlen, *Learning from India? A New Approach to Secondary Pharmaceutical Patents*, LONDON SCHOOL OF ECON. BLOGS (May 3, 2013), <http://blogs.lse.ac.uk/indiaatlse/2013/05/03/a-new-approach-to-pharmaceutical-patents/>.

316. *Id.*

317. *Id.*

318. See, e.g., Hemphill, *Paying for Delay*, *supra* note 7; Timothy A. Weil, Note, *Devising a Legislative Solution to the Reverse Payment Dilemma: How Congress Can Balance Competition, Innovation, and the Public Policy Favoring the Settlement of Disputes Without Litigation*, 55 ST. LOUIS U. L.J. 741 (2011); Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 602 (2005).

319. 15 U.S.C. § 45; see also *supra* note 318.

law under *Actavis*. Chairwoman Ramirez has recently announced that “the Commission will reexamine settlements previously filed with the Commission in light of the *Actavis* decision to determine whether they merit further investigation.”³²⁰ The *Actavis* and *Cephalon* cases are “near the top of the agency’s to-do list,” and “winning those two challenges” is “Mission 1,” according to Bureau of Competition Director Deborah Feinstein.³²¹ Feinstein also anticipates opening new pay-for-delay investigations based on examination of the Medicare Modernization Act filings as they are submitted by settling parties.³²² The FTC “want[s] to help shape the law . . . where [the FTC] think[s] it’s important for the court to basically treat the *Actavis* position a certain way, [the FTC is] going to help try to develop the law,” including in private cases.³²³

One potential concern with giving the FTC more latitude in these actions is that the FTC has indicated its intention to pursue potentially anticompetitive reverse payment settlements very aggressively,³²⁴ perhaps more aggressively than was intended by the Court in *Actavis*. Although Congress could authorize an increased mandate for the FTC in the regulation of settlements, doing so may lead to the elimination of all reverse payment settlements and heightened scrutiny on other types of settlements between brand-name and generic manufacturers.

Potentially, modifications could be made to either the current Medicare Act provision authorizing FTC scrutiny of settlements after their enactment or to allow the FTC to undertake an adjudicative review of settlements themselves. The current Medicare Act provision authorizes review ten days after the settlement has been enacted,³²⁵ but authorizing earlier review may not be an effective solution to the problem. Although an earlier review may give parties considering a settlement a better indication of the FTC’s position on the legality of the settlement, it may also encourage more litigation overall. Parties are incentivized to execute RPSs where possible and would likely take their settlements to district courts for judicial review, given the amount of

320. *Prepared Statement of the Federal Trade Commission on Pay-for-Delay Deals: Limiting Competition and Costing Consumer Before the United States Senate Comm. on the Judiciary, Subcomm. on Antitrust, Comp. Pol’y and Consumer Rights*, 113th Cong. 3 (Jul. 23, 2013).

321. Melissa Lipman, *Pay-For-Delay Remains Top Priority for Ramirez’s FTC*, LAW360 (Nov. 13, 2013, 9:53 PM), <http://www.law360.com/ip/articles/488528>.

322. *Id.*

323. *Id.*

324. *See supra* note 320.

325. Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

time and money invested into the settlements. If Congress instead authorized an adjudicative mechanism within the FTC, the FTC would need additional resources to support the numerous administrative law judges and proceedings that these adjudications would require. This proposal seems to be an inefficient use of administrative resources and might encourage the FTC to examine even more of these settlements in more depth than they already do.

Regardless, the use of a third party other than the court system for regulation would enhance efficiency and allow for more timely analysis of settlements. There are some indications that private entities, as indirect end users, may be authorized to file suit against parties involved in pay-for-delay settlements.³²⁶ However, the *Loestrin 24* case highlights efficiency problems with relying on class actions to challenge settlements.³²⁷ Class actions must be certified, and many, including *Loestrin 24*, must be consolidated from multidistrict litigation, taking time and resources.³²⁸ As such, this mechanism seems unlikely to provide consistency or clarity in the settlement process within a reasonable time.

C. IMPORTANCE OF OTHER JURISDICTIONS IN REVERSE PAYMENT SETTLEMENT LITIGATION

Going forward, pharmaceutical companies operating internationally will need to consider not only the *Actavis* ruling, but also rulings in other jurisdictions within which they intend to operate. June 2013 was a busy month for international rulings on reverse payment settlements. Besides the Supreme Court's ruling in *Actavis*, the European Commission ("EC") issued its first ruling in the Lundbeck case, in which it found that Lundbeck and several generic competitors had violated EC rules by executing a reverse payment settlement.³²⁹ The EC requires an analysis "by object," where

326. Aaron Edlin et al., *Activating Actavis*, ANTI-TRUST MAG. 16 (Fall 2013).

327. *United Food and Commercial Workers Local 1776 & Participating Emp'rs Health and Welfare Fund v. Warner Chilcott Pub. Ltd. Co.*, No. 2:13-cv-01807, 2013 WL 2256456 (E.D. Pa. May 23, 2013); see also Gavin Broady, *JPML Ships Loestrin Pay-For-Delay Suits to Rhode Island*, LAW360 (Oct. 3, 2013, 7:10 PM), <http://www.law360.com/articles/478010/jpml-ships-loestrin-pay-for-delay-suits-to-rhode-island>.

328. See *Warner Chilcott*, 2013 WL 2256456.

329. Press Release, European Commission, Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines (June 19, 2013), available at http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en; see also Jeff Sistrunk, *Lundbeck Fights \$125M Pay-For-Delay Fine in EU*, LAW360 (Sept. 3, 2013, 3:41 PM), <http://www.law360.com/ip/articles/469563/lundbeck-fights-125m-pay-for-delay-fine-in-eu>.

violators of Article 101 (the relevant EC anti-competition provision) have enacted an agreement that has “the object or effect of restricting competition in the European Union” and that any procompetitive results from the restriction cannot “outweigh the anticompetitive effects” identified by the examiner.³³⁰ This standard bears a strong resemblance to the per se standard of antitrust liability reviewed in Section I.D, *supra*, and it contrasts with the standard laid out in *Actavis* in that it does not require a careful weighing of factors as required under the rule-of-reason standard.³³¹ Some commentators have advocated dropping the “by object” standard and taking a line that approximates the standard used in *Actavis*, mostly to avoid confusion and lack of legal certainty regarding these arrangements.³³²

Oftentimes, the EC looks to the United States for guidance on competition-related issues in the pharmaceutical sector.³³³ It is thus likely that the full effects of *Actavis* have not been felt in Europe and that this issue will continue to be a major focus of competition law in Europe and other jurisdictions. Multinational companies may face liability in several countries for their potentially anticompetitive behavior.

D. POTENTIAL CONGRESSIONAL ACTION

Throughout the history of reverse payment settlements, numerous proposals have been made before Congress to modify or prohibit the use of these settlements in ending litigation between brand-name and generic manufacturers.³³⁴ Currently, Congress is considering two potential modifications to the current regulatory regime, which gives rise to reverse

330. Marleen Van Kerckhove, *Reverse Payment Settlement Cases: Under the Rule of Reason By Object? A Brief Reflection*, CPI ANTITRUST CHRON., no. 2, Sept. 2013, at 3.

331. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013); *see also* Press Release, European Commission, Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines (June 19, 2013), *available at* http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en.

332. *Id.*

333. *Id.* For example, in December 2013, the EC fined Johnson & Johnson and Novartis AG \$22.4 million for enacting an anticompetitive agreement to delay the entry of a generic version of Johnson & Johnson’s fentanyl (painkiller) patch in the Netherlands. Stewart Bishop, *J&J, Novartis Fined \$22.4M Over Pay-For-Delay Deal*, LAW360 (Dec. 10, 2013, 1:06 PM), <http://www.law360.com/articles/494572/j-j-novartis-fined-22-4m-over-pay-for-delay-deal>.

334. For a few examples, see Alan Klein, *Patent Settlement Agreements Remain a Focus in the U.S. Congress*, GENERICSWEB (Nov. 2011), http://www.genericsweb.com/index.php?object_id=1031; Jones Day, *Pending U.S. Legislation to Ban “Reverse Payment” Settlements Would Bring Fundamental Change (and Uncertainty) to Drug Patent Litigation* (Sept. 2010), http://www.jonesday.com/pending_us_legislation/.

payment settlements.³³⁵ The provisions of S. 214 would make these settlements presumptively illegal, while S. 504 proposes a modification to the exclusivity provisions of the Hatch-Waxman Act that would disincentivize generic companies from making reverse payment settlements.

1. *S. 214: Preserve Access to Affordable Generics Act*

In March 2013, the Senate began reconsidering legislation originally proposed in 2007: the Preserve Access to Affordable Generics Act (S. 214).³³⁶ The purpose of this legislation is to make pharmaceutical company pay-for-delay settlements presumptively illegal and to establish a framework for challenges to this presumption.³³⁷ The original version of this bill received a 10-8 vote in committee but died on the floor of the Senate during the 112th Congress.³³⁸

This legislation creates a new section of the Federal Trade Commission Act of 1914, 15 U.S.C. § 44 et seq., allowing the FTC to bring lawsuits with a presumption of illegality against parties involved in a reverse payment settlement.³³⁹ However, the current litigation would be applicable to any license involving an ANDA filer, even if the license came from discussions outside of litigation.³⁴⁰ In addition, courts may not use the presumption that absent a successful challenge to the patent, the generic manufacturer's product would not have entered the market until the expiration of the patent or the branded drug's "statutory exclusivity" period from the FDA.³⁴¹ The law would also disallow the presumption that RPSs are procompetitive because they allow generics onto the market prior to the expiration of the brand-name manufacturer's patent(s).³⁴² Under this rationale, simply allowing

335. Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013); Fair and Immediate Release of Generic Drugs Act ("FAIR Generics Act"), S. 504, 113th Cong. (2013).

336. Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007), repropoed as Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (2011).

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

338. *See supra* note 336. It is unclear why this bill was not enacted during the 112th Congress; some commentators postulated that the bill died as a result of vigorous lobbying by pharmaceutical companies against its enactment.

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

340. Jones Day, *supra* note 334.

341. Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013). Note that parties to the litigation may still prove this presumption affirmatively. *Id.* Also note that with regards to the presumption about the statutory exclusivity period, the FDA is still permitted to approve the generic compound during that time. *Id.*

342. *Id.*

market entry prior to patent expiration is not sufficient to justify use of RPSs that may be anticompetitive in other ways.

The consideration used to facilitate these settlements is a major focus of the proposed legislation. The settlement will not be considered unlawful if the consideration granted from the brand-name company to the generic company only consists of: (1) the right of the generic company to market its product prior to the expiration of any patent or other exclusivity right that would prevent this type of marketing, (2) a payment of “reasonable litigation expenses not to exceed” \$7.5 million, or (3) a “covenant not to sue on any claim that the [generic product] infringes a United States Patent.”³⁴³

S. 214 creates a “safe harbor” for certain licensing agreements in which the provisions are limited to the market entry date for the generic drug and the payment of attorney’s fees.³⁴⁴ Other terms, such as exclusivity or mutual releases, would make the agreements presumptively illegal.³⁴⁵ Finally, the agreement is presumptively illegal if the generic manufacturer “gives anything of value” and “agrees to limit or forgo research, development or sales” of its product “for any period of time.”³⁴⁶

Parties to litigation may rebut the presumption of illegality with regards to their settlement by using the seven factors outlined in the prospective legislation, with the understanding that parties to a settlement can prove with a standard of clear and convincing evidence that the procompetitive effects of the RPS outweigh anticompetitive effects.³⁴⁷ The court would first compare the length of time remaining until the end of patent exclusivity with the market entry date established in the settlement.³⁴⁸ Second, the court must hear evidence on the value of competition to consumers from the generic product.³⁴⁹ The form and consideration received by the generic company in the settlement must also be scrutinized.³⁵⁰ The potential results of the patent litigation must be weighed as part of the decision: the revenue the generic would have received had it won the patent litigation at issue must be determined, as well as any losses the brand-name company would have suffered had it lost the litigation.³⁵¹ Finally, the elapsed time between the

343. *Id.*

344. *Id.*

345. *Id.*

346. *Id.*

347. *Id.*

348. *Id.*

349. *Id.*

350. *Id.*

351. *Id.*

settlement date and the settlement of the patent infringement case should be determined, along with any other factor the fact finder may deem relevant to the analysis of the competitive effects of the settlement.³⁵²

2. *S. 504: Fair and Immediate Release of Generic Drugs Act*

Spring 2013 saw a second legislative proposal from the Senate: the Fair and Immediate Release of Generic Drugs Act (“FAIR Generics Act”).³⁵³ Although the bill seeks to ban RPSs, much as S. 214 does, it uses a different strategy to achieve its goals. In essence, the bill functions by reducing incentives for the companies to enter into a settlement by precluding the generic first-to-file company from exercising its 180-day exclusivity period under Hatch-Waxman if it has entered into a “disqualifying agreement.”³⁵⁴ As such, generic applicants would only be eligible for exclusivity if they have not made an impermissible settlement with a brand-name manufacturer.³⁵⁵

Another provision of the legislation limits the terms on which brand-name and generic manufacturers may settle.³⁵⁶ Exclusivity is not permitted for settlements where the generic first filer agrees to not seek FDA approval of its ANDA application at the earliest possible date or where the generic first filer elects to not start marketing its pharmaceutical compound as soon as it receives approval from the FDA.³⁵⁷ Should there be more than one date where a generic ANDA applicant may seek FDA approval or begin marketing its compound, “the ANDA applicant can seek approval or begin commercial marketing on the earlier of the latest date set forth in the agreement or 180 days *after* ‘another first applicant’ begins commercial marketing.”³⁵⁸

Finally, under this proposed legislation, 35 U.S.C. § 271(e) is amended to state:

(7) The exclusive remedy under this section for an infringement of a patent for which the Secretary of Health and Human Services has

352. *Id.*

353. Fair and Immediate Release of Generic Drugs Act (“FAIR Generics Act”), S. 504, 113th Cong. (2013); Kevin E. Noonan, *Senators Introduce Another Bill to Ban Reverse Payment Settlement Agreements*, PATENT DOCS (Mar. 14, 2013 11:59 PM), <http://www.patentdocs.org/2013/03/senators-introduce-another-bill-to-ban-reverse-payment-settlement-agreements.html>.

354. Fair and Immediate Release of Generic Drugs Act (“FAIR Generics Act”), S. 504, 113th Cong. (2013).

355. *Id.*

356. *Id.*

357. *Id.*

358. Noonan, *supra* note 353.

published information pursuant to subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act shall be an action brought under this subsection within the 45-day period described in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of the Federal Food, Drug, and Cosmetic Act.

Application of these provisions is limited to agreements subject to the amendments made by the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

It is the responsibility of the prevailing party in the litigation to notify the FDA.³⁵⁹

3. *Evaluation of Potential Congressional Legislation*

Congress will likely follow a “wait-and-see” approach while the first cases to be analyzed under the new regime proceed through the court system. Aside from the fact that this method will require less work from Congress, Congress would be wise to avoid the imposition of one-size-fits-all legislation into settlements that will differ according to the unique parties and patents involved, which confer distinct benefits. However, electing not to impose more definite requirements on these settlements likely will result in the development of different doctrines in different courts. Potentially a circuit split similar to the split leading to the *Actavis* certiorari could form, leading to a lack of consistency and predictability for parties involved in patent litigation under Paragraph IV of the Hatch-Waxman Act.

That being said, all eight justices rejected S. 214’s stance on the presumptive illegality of reverse payment settlements in *Actavis*.³⁶⁰ There are certainly examples of reverse payment settlements that are legal; the FDA typically determines that approximately half of the filed settlements each year are potentially anticompetitive.³⁶¹ In addition, although it may be rational to

359. Fair and Immediate Release of Generic Drugs Act (“FAIR Generics Act”), S. 504, 113th Cong. (2013).

360. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

361. FTC BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2011, *available at* <http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/1110mmaagree-2.pdf> (last visited Apr. 20, 2014); FTC BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2012, *available at* <http://www.ftc.gov/sites/default/files/documents/reports/>

put the burden of proving the legality of the settlement onto the parties actually transacting the settlement, the list of factors proposed in S. 214 to do so is extremely complex (even more so than those in *Actavis*'s rule-of-reason analysis). Courts may have a difficult time developing a coherent rationale for the application of these factors, and thus the outcome of litigation in a case relating to a reverse payment settlement will become very unpredictable.

Conversely, removing exclusivity incentives for settlements, as proposed in S. 504, may be a promising way to incentivize companies to consider alternatives to settlements.³⁶² Although one effect of this litigation would likely be to encourage more litigation of these settlements, this provision effectively supports a procompetitive rationale by removing a loophole for exclusivity from the Hatch-Waxman regime.

One potential problem arising from this legislation is that generic companies may be disincentivized to sue brand-name companies, knowing that they will not be able to settle if litigation becomes too expensive or time-consuming. As such, one of the main policy rationales behind the Hatch-Waxman Act—that generic companies may challenge the validity of certain brand-name patents, thereby removing “deadweight patents” from the marketplace—may not be adequately supported under this provision. The Hatch-Waxman framework encourages generics to sue even if the patent may actually be valid, because the potential rewards of winning the suit are so high for the generic company. Under this regime, generic companies will face greater risks in suing.

E. RECOMMENDATIONS AND SUGGESTED LEGISLATION

The goal in crafting legislation should be to discourage as many anticompetitive settlements as possible, while still encouraging generic companies to pursue ANDA applications where they believe the patents are invalid. But sham litigation has detrimental effects on judicial and overall market efficiency and should be avoided.³⁶³

Under *Actavis*, companies will likely consider their options more carefully before resorting to either litigation or settlements because of the potential consequences of a finding of an anticompetitive settlement in the courts.

agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf (last visited Apr. 20, 2014).

362. Fair and Immediate Release of Generic Drugs Act (“FAIR Generics Act”), S. 504, 113th Cong. (2013).

363. For a general review of the deleterious effects of sham litigation in the context of antitrust laws, see Thomas A. Balmer, *Sham Litigation and the Antitrust Laws*, 29 *BUFF. L. REV.* 39 (1980).

One potential solution to this dilemma may be to modify the exclusivity period a generic company receives, similar to the proposal in S. 504.³⁶⁴ Rather than eliminating the exclusivity period entirely, restricting the exclusivity period to ninety days through a modification to the Hatch-Waxman Act would move cheap drugs to the market more quickly, while also still providing generic companies a significant incentive to sue if a patent seems to be invalid. This limited approach would significantly decrease the motive to conduct sham litigation, as the potential financial reward to a generic company would decrease; litigation would only be reasonable to pursue if legitimate. In addition, if Congress shortened the exclusivity period, companies likely would consider shorter periods of delay in their lawful settlements and would likely discourage the formation of unlawful agreements because the amount of money to be split from the exclusivity period would be smaller.

Although the Supreme Court selected the rule-of-reason standard versus stricter standards, such as per se or quick-look, lower courts will face an analysis of the procompetitive and anticompetitive effects of these settlements for years to come. *Actavis* also mandates case-by-case analysis using the rule-of-reason standard. The PTO's current framework does not offer many potential quick fixes to the problem, as resources are too limited to effectively combat invalid patents at granting.³⁶⁵ Thus, congressional modification of the Hatch-Waxman Act, as proposed above, may be the most reasonable method to adjust the reverse payment settlement framework.

V. CONCLUSION

The Supreme Court's ruling in *FTC v. Actavis* indicated that reverse payment settlements may implicate antitrust liability for the parties entering into them if the settlements are intended to delay competition between brand-name and generic companies under Hatch-Waxman.³⁶⁶ It explained that lower courts should make this determination by using a modified antitrust rule-of-reason standard to analyze these settlements.³⁶⁷ Although the Court did not establish a presumptively unlawful standard for these settlements, different circuits will likely interpret the decision in different

364. Fair and Immediate Release of Generic Drugs Act ("FAIR Generics Act"), S. 504, 113th Cong. (2013).

365. *See supra* Section IV.A.

366. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2223 (2013).

367. *Id.* at 2237.

ways, as is already being demonstrated in the recent *In re Nexium*³⁶⁸ and *In re Lamictal*³⁶⁹ decisions. These interpretations may not be resolved without further litigation, perhaps before the Supreme Court. Accordingly, efforts to curtail settlements that may be anticompetitive may be focused at the PTO, where better prosecution of patents could limit the number of putatively invalid patents in litigation proceedings. The FTC will likely continue a strong focus on curbing reverse payment settlements, particularly those it deems to be anticompetitive. Congressional action will likely be slow while the court system spends the next several years parsing the ramifications of the *Actavis* decision.

In the meantime, settling parties should use the broad guidelines provided in *Actavis* to tailor their settlements. Under the *Actavis* standard, “the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”³⁷⁰ Lower courts will apply the modified rule-of-reason standard when a reverse payment settlement is challenged.³⁷¹

368. *In re Nexium* (Esomeprazole) Antitrust Litig., No. 12-md-02409-WGY, 2013 WL 4832176 (D. Mass. Sept. 11, 2013).

369. *In re Lamictal* Direct Purchaser Antitrust Litig., No 12-cv-995 (WHW), 2014 WL 282755 (D.N.J. Jan. 24, 2014).

370. *Actavis*, 133 S. Ct. at 2223.

371. *Id.* at 2238.