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Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has Schering-Plough Created the Blueprint for Defensible Antitrust Violations?

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Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has *Schering-Plough* Created the Blueprint for Defensible Antitrust Violations?

I. Introduction

The Federal Trade Commission (FTC) has been battling pharmaceutical manufacturers for almost a decade over massive reverse payment settlements that the FTC found to unfairly restrict generic entry into the marketplace, and the Supreme Court's denial of certiorari in *FTC v. Schering-Plough*¹ has led to the recent resurgence of reverse payment settlements within the industry.² Patent infringement settlements typically involve payment from the infringer to the patent holder, but reverse payment settlements, sometimes referred to as pay for delay, exit, or exclusion payment settlements, result in payments from the patent holder to the infringer. Patents play a major role in the pharmaceutical industry, and the Hatch-Waxman Act regulates the entry of new generic drugs into the marketplace. Provisions within the Hatch-Waxman Act provide generic drug manufacturers special methods to challenge the patents of brand-name drugs to gain market access prior to the patent lapsing.³ To protect the patent monopoly, reverse payment settlements in the pharmaceutical industry result in the brand-name patent holder paying millions of dollars to the potential generic patent infringer.⁴ The FTC and consumer groups attack these

1. 126 S. Ct. 2929 (2006).

2. FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, at 3-4 (2005) [hereinafter FTC AGREEMENTS REPORT 2005], available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf> (noting that no known settlements involving both restrictions on generic entry and compensation to the generic manufacturer were entered into during the period between the FTC's announcement of its investigation into the practice in 1999 through 2004, but three emerged in 2005); see also FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, at 1-5 (2006) [hereinafter FTC AGREEMENTS REPORT 2006], available at <http://www.ftc.gov/reports/mmact/MMAreport2006.pdf> (noting that in 2006 there were fourteen final settlements between branded and generic manufacturers that involved restrictions on generic entry and compensation to the generic).

3. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28 & 35 U.S.C. (2000 & Supp. III 2003)).

4. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193-94 (2d Cir. 2006) (settlement agreement involved \$66.4 million payment from patent holder to generic company and generic's supplier); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1300 (11th Cir. 2003) (settlement agreements involved payments of up to \$2 million per month to one generic manufacturer and \$4.5 million per month to second generic manufacturer from patent

reverse payment settlements between branded and generic pharmaceutical companies as anticompetitive under antitrust laws.⁵ They contend that the result is artificially high costs for brand-name drugs due to the unlawful restriction of generic competition.⁶

Initial actions challenging reverse payment settlements proved highly successful. In the late 1990s, the FTC brought a series of actions against branded and generic manufacturers that entered into settlements which included significant reverse payment settlements.⁷ These actions resulted in several consent decrees dissolving the settlements and restricting both the branded and generic manufacturers from entering into any settlements without FTC approval.⁸ The Sixth Circuit followed the lead of the FTC in *In re Cardizem CD Antitrust Litigation*, an action brought by pharmaceutical purchasers challenging a reverse payment settlement agreement between branded and generic manufacturers.⁹ The Sixth Circuit upheld the district court's decision that the \$89.83 million reverse payment settlement between the manufacturers was "a naked, horizontal restraint of trade and, as such, *per se* illegal" under the Sherman Act.¹⁰

The *per se* rule applies to specific trade practices, holding them as illegal restraints of trade under antitrust laws, "regardless of whether it actually harms

holder); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 903 (6th Cir. 2003) (settlement agreement resulted in \$89.83 million payment from patent holder to generic); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519 (E.D.N.Y. 2005) (settlement agreement included \$49.1 million payment from patent holder to generic and approximately \$350 million payment for not supplying generics with supply of patent holder's drug to market as generic under separate supply settlement agreement).

5. See, e.g., *Tamoxifen*, 466 F.3d at 193-94; *Valley Drug*, 344 F.3d at 1300; *Cardizem*, 332 F.3d at 903; *In re Ciprofloxacin*, 363 F. Supp. 2d at 519.

6. See, e.g., *Tamoxifen*, 466 F.3d at 193-94; *Valley Drug*, 344 F.3d at 1300; *Cardizem*, 332 F.3d at 903; *In re Ciprofloxacin*, 363 F. Supp. 2d at 519.

7. See, e.g., *Bristol-Myers Squibb Co.*, No. C-4076, 2003 WL 21008622 (Fed. Trade Comm'n Apr. 14, 2003) (complaint & decision and order); *Schering-Plough Corp.*, No. 9297, 2001 WL 418903 (Fed. Trade Comm'n Apr. 2, 2001) (complaint); *Hoechst Marion Roussel, Inc.*, No. 9293, 2000 WL 1744889 (Fed. Trade Comm'n Nov. 28, 2000) (consent order); *Abbott Labs.*, No. C-3945, 2000 WL 681848 (Fed. Trade Comm'n May 22, 2000) (complaint & decision and order); *Abbott Labs.*, No. C-3946, 2000 WL 681849 (Fed. Trade Comm'n May 22, 2000) (complaint & decision and order).

8. See, e.g., *Bristol-Myers Squibb Co.*, 2000 WL 21008622 (complaint & decision and order); *Schering-Plough Corp.*, 2001 WL 418903 (complaint); *Hoechst Marion Roussel, Inc.*, 2000 WL 1744889 (consent order); *Abbott Labs.*, 2000 WL 681848 (complaint & decision and order); *Abbott Labs.*, 2000 WL 681849 (complaint & decision and order).

9. *Cardizem*, 332 F.3d 896.

10. *Id.* at 905-15. The Sherman Antitrust Act makes illegal actions of parties that would restrain trade or commerce and attempts by individuals or groups to establish a monopoly. 15 U.S.C. §§ 1-2 (2000).

anyone.”¹¹ Several recent court decisions, however, rejected this per se illegal approach to reverse payment settlements in the pharmaceutical industry.¹² In its place, some courts adopted the rule of reason to evaluate the antitrust aspects of settlements in the pharmaceutical industry.¹³ The rule of reason requires the court to analyze economic factors to determine if the action is an unreasonable restraint of trade and, thus, an antitrust violation.¹⁴ In *Schering-Plough Corp. v. FTC*, the Eleventh Circuit rejected both the per se and rule of reason antitrust analysis and instead adopted its own three-part standard for analyzing antitrust liability in the patent law arena.¹⁵ The Supreme Court’s denial of certiorari of the FTC’s petition in *Schering-Plough* now leaves this narrow, but important, area of law without a strong guiding principle.

As is often the case, academic arguments can be found on all sides of the issue. Reverse payment proponents point out that “[t]he general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.”¹⁶ The fact that, in litigation, patents are presumed to be valid is also used by proponents to bolster the argument that reverse payment settlements are not antitrust violations, as long as the settlement does not restrict generic entry beyond the patent term.¹⁷ Opponents contend that the willingness of pharmaceutical patent holders to pay millions of dollars to protect their monopoly indicates that the branded patent is invalid

11. BLACK’S LAW DICTIONARY 1178 (8th ed. 2004); *see also* N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) (holding that certain restraints of trade are per se illegal “because of their pernicious effect on competition and lack of any redeeming virtue”); 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION § 1509c (2d ed. 2003) (stating that per se illegality applies when the restraint of trade can “properly [be] classified as ‘naked’”).

12. *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 520 (E.D.N.Y. 2005).

13. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *In re Ciprofloxacin*, 363 F. Supp. 2d at 520; *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003).

14. BLACK’S LAW DICTIONARY, *supra* note 11, at 1360; *see also* 7 AREEDA & HOVENKAMP, *supra* note 11, § 1507f (stating that the “standard rule of reason methodology [] requires the plaintiff to allege and define some market in which competition is significantly restrained by the challenged behavior”).

15. 402 F.3d at 1065-66.

16. *Asahi Glass*, 289 F. Supp. 2d at 991.

17. *See, e.g.,* Brief in Opposition at 11-12, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2005 WL 2428345.

or not infringed by the generic competitor and thus, in such cases, the settlements must be challenged.¹⁸

Ultimate resolution of these issues will have to come from the Supreme Court, and many court observers anticipated such resolution via *Schering-Plough*.¹⁹ Unfortunately, as the Solicitor General of the United States stated in his amicus brief on behalf of the United States opposing the FTC's petition to the Court, "[w]hatever the correct standard for determining the antitrust treatment of patent settlements involving reverse payments, [*Schering-Plough* does] not present an appropriate occasion to address that question or to assess the validity of the FTC's approach."²⁰ This comment contends that the Supreme Court should specifically address the issue of reverse payment settlements between branded and generic pharmaceutical manufacturers and hold that reverse payment settlements which exceed a de minimus standard should be subject to patent examination to ensure the settlement does not protect an invalid or noninfringed patent and thus further an illegal monopoly. Further, this comment argues that the Preserve Access to Affordable Generics Act²¹ and the Protecting Consumer Access to Generic Drugs Act of 2007²² banning settlements in the pharmaceutical industry that transfer value from the patent holder to the generic manufacturer and result in delayed entry of the generic should not be enacted by Congress as introduced because conditions might exist in which a reverse payment settlement actually enhances pharmaceutical competition.

Part II of this comment explains the Hatch-Waxman procedures for generic entry into the pharmaceutical market and the conflicts that can arise between patent and antitrust law in the pharmaceutical industry under these unique conditions. Part III examines FTC actions against and litigation involving reverse payment settlements between branded and generic pharmaceutical

18. See, e.g., Brief in Opposition at 8-12, *Andrx Pharmaceuticals, Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779), 2003 WL 23146428.

19. See, e.g., James C. Burling, *Hatch-Waxman Patent Settlements: The Battle for a Benchmark*, ANTITRUST, Spring 2006, at 41; Neal R. Stoll & Shepard Goldfein, *Antitrust Trade and Practice*, N.Y. L.J., Apr. 19, 2005, at 3.

20. Brief for the United States as Amicus Curiae at 12, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2006 WL 1358441. The Court was presented with another opportunity to address these issues when *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), was appealed, but again, following the recommendation of the Solicitor General of the United States, Brief for the United States as Amicus Curiae at 20, *Joblove v. Barr Labs., Inc.*, 127 S. Ct. 3001 (2007) (No. 06-830), 2007 WL 1511527, the Court elected to deny certiorari. *Joblove v. Barr Labs., Inc.*, 127 S. Ct. 3001 (2007).

21. S. 316, 110th Cong. (2007), H.R. 1432, 110th Cong. (2007), S. 3582, 109th Cong. (2006).

22. H.R. 1902, 110th Cong. (2007).

manufacturers and the variety of results that have been obtained. Part IV explores the scholarly debate surrounding reverse payment settlements in the pharmaceutical industry. Finally, part V proposes that the Supreme Court determine its own standard for analyzing patent settlements specific to the pharmaceutical industry by rejecting the standard of the Eleventh Circuit. Instead, the Court should require that reverse payment settlements that exceed a de minimus standard be found in violation of antitrust principles if unable to withstand patent examination. This comment concludes in part VI.

II. How the Hatch-Waxman Act Shifted the Patent-Antitrust Balance in the Pharmaceutical Industry

The Drug Price Competition and Patent Term Restoration Act of 1984,²³ the Hatch-Waxman Act, dramatically altered the pharmaceutical industry in the United States. Prior to 1984, the Food, Drug, and Cosmetic Act mandated that generic drug manufacturers submit a new drug application (NDA) to the Food and Drug Administration (FDA) for approval to enter the market with full efficacy and safety studies and data, mirroring the requirements of pioneer manufacturers.²⁴ Such testing and trials were so expensive that few generics actually entered the market.²⁵ Section A is an exploration of the statutory changes to the Federal Food, Drug, and Cosmetic Act²⁶ and the Patent Act²⁷ implemented by the Hatch-Waxman Act as well as the impact of these amendments on the generic approval process. Section B examines the issues that arose between patent and antitrust law as a result of those changes and explores reverse payment settlements as “a natural by-product of Hatch-Waxman’s shift of the litigation risk from the generic manufacturer to the patent holder.”²⁸ Section C discusses the 2003 amendments to the Hatch-Waxman Act contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Reform Act)²⁹ and examines their impact on some of the patent-antitrust issues arising from reverse payment settlements.

23. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28 & 35 U.S.C. (2000 & Supp. III 2003)).

24. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§ 301-397 (2000)).

25. See *infra* notes 49-50 and accompanying text.

26. 21 U.S.C. §§ 301-397 (2000) (original version at ch. 675, 52 Stat. 1040 (1938)).

27. 35 U.S.C. §§ 1-376 (2000) (original version at ch. 950, 66 Stat. 792 (1952)).

28. *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro II)*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003).

29. Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended in scattered sections of 26 & 42 U.S.C. (Supp. III 2003)).

A. The Hatch-Waxman Act's Delicate Balance

The Hatch-Waxman Act “emerged from Congress’ efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”³⁰ The FDA approval process for new pharmaceuticals requires extensive animal testing and approval of an investigational new drug (IND) application prior to any human clinical trials to demonstrate the safety and efficacy of the new drug.³¹ This process, including all the clinical trials, takes place after patent application and significantly impacts the effective term of the patent.³² The basic term of a patent in the United States is twenty years from the date of application.³³ Prior to the Hatch-Waxman Act, studies indicated that “effective patent life [of pharmaceuticals] had fallen to less than seven years.”³⁴ The Hatch-Waxman Act provided for a unique patent term extension for pharmaceuticals, calculated based on the amount of time between the IND application and final FDA approval of the new drug application that allows up to a maximum patent life of fourteen years.³⁵ This extension of a patent’s life was drafted to “create incentives for increased research expenditures” by pioneer pharmaceutical manufacturers.³⁶ With this additional time, pharmaceutical patents today typically have an eleven to twelve year effective patent life.³⁷

In exchange for the patent term extension, pioneer pharmaceutical manufacturers were forced to accept an expedited generic drug approval process that resulted in a dramatic increase in generic competition.³⁸ Prior to the Hatch-Waxman Act, generic manufacturers had to wait until a pioneer drug’s patent term expired to begin the testing necessary for FDA approval,

30. *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting).

31. 21 U.S.C. § 355(b)(1) (2000); *see also* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 448-54 (1986).

32. Wheaton, *supra* note 31, at 451-54.

33. 35 U.S.C. § 154(a)(2) (2000).

34. Wheaton, *supra* note 31, at 452.

35. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) § 201(c), Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28 & 35 U.S.C. (2000 & Supp. III 2003)). IND application takes place after animal testing of the drug has been completed, and approval of the IND is necessary to begin human clinical trials. 21 U.S.C. § 355(i)(1)(A) (2000).

36. H.R. REP. NO. 98-857, pt. 2, at 6 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2690.

37. Reid F. Herlihy, Note, *The Federal Circuit's Interpretation of the Hatch-Waxman Act: Allowing Generics to Induce Infringement*, 15 FED. CIR. B.J. 119, 133 (2005).

38. *See infra* note 50 and accompanying text.

which resulted in an effective patent term extension for the pioneer drug.³⁹ The Hatch-Waxman Act amended the Patent Act by inserting a safe harbor provision for the experimental use of a patented pharmaceutical “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs”⁴⁰ This allows generic manufacturers to obtain a sample of the patented drug to experimentally verify that the active ingredients of the generic are chemically equivalent to the patented drug and that the generic is bioequivalent to the patented drug, as required by Hatch-Waxman’s new “abbreviated new drug application” (ANDA) for generics.⁴¹ Thus, under the Hatch-Waxman Act, generic manufacturers can now obtain FDA approval as soon as, or even before, the pioneer patent expires.⁴² However, patents for novel active pharmaceutical ingredients receive additional protection because the FDA may not accept a generic’s ANDA until four or five years after the novel ingredient’s patent approval date.⁴³

In addition to the patent safe harbor provision, the Hatch-Waxman Act’s ANDA procedures do not require manufacturers seeking FDA approval for a generic drug that is the same as and bioequivalent to an FDA approved drug to submit the same experimental safety and efficacy data as the NDA.⁴⁴ For pharmaceuticals developed during the 1990s, the estimated cost of this safety and efficacy experimentation for an average NDA was \$478 million (in year 2000 dollars).⁴⁵ Allowing a generic manufacturer to make use of the pioneer manufacturer’s efficacy and safety data, instead of having to go through the lengthy and expensive process of experimentally recreating that evidence for approval by the FDA, is a major incentive to bring generics to the market.⁴⁶

39. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990). The development time for generic drugs is typically three to five years. Sarah M. Yoho, Note, *Reformation of the Hatch-Waxman Act: An Unnecessary Resolution*, 27 NOVA L. REV. 527, 549 (2003).

40. Hatch-Waxman Act § 202 (codified as amended at 35 U.S.C. § 271(e)(1) (2000)).

41. *Id.* § 101 (codified as amended at 21 U.S.C. § 355(j)(2)(A)(ii)-(iv) (Supp. III 2003)). Bioequivalence is defined by the statute as the generic drug having no significant difference in the rate and extent of absorption as the patented drug. 21 U.S.C. § 355(j)(8)(B) (2000).

42. 21 U.S.C. § 355(j)(5).

43. *Id.* § 355(j)(5)(F)(ii). ANDAs containing paragraph I, II, and III certifications of a novel ingredient patent cannot be accepted by the FDA until five years after patent approval while ANDAs containing a paragraph IV certification of a novel ingredient patent can not be accepted by the FDA until four years after patent approval. *Id.* See *infra* notes 51-58 and accompanying text for a discussion of the paragraphs I-IV ANDA certifications.

44. See 21 U.S.C. §§ 355(b)(1), 355(j)(2)(A) (2000 & Supp. III 2003).

45. DAVID REIFFEN & MICHEL R. WARD, “BRANDED GENERICS” AS A STRATEGY TO LIMIT CANNIBALIZATION OF PHARMACEUTICAL MARKETS 7 (2005), http://www.ftc.gov/be/healthcare/wp/12_Reiffen_BrandedGenericsAsAStrategy.pdf.

46. See *id.*

Generic manufacturers, however, must still bear the cost of experimentally demonstrating bioequivalence to the pioneer drug. In addition, they must also “show sound manufacturing procedures and that [the] product has sufficient shelf stability.”⁴⁷ This requires “a production facility and an approved source of raw material supply [to] be in place prior to filing an ANDA.”⁴⁸ While these costs are significant, the ability to utilize a pioneer drug’s safety and efficacy data creates an economic environment conducive to generic entry.

Ultimately, the Hatch-Waxman Act led to a significant reduction in the cost of securing FDA approval for generic drugs.⁴⁹ This, in part, resulted in the expansion of the generic market from only nineteen percent of the pre-amendment pharmaceutical market to over forty-seven percent, and while in 1984 only thirty-six percent of the most frequently prescribed drugs with expired patents had a generic equivalent, now virtually all of these drugs have a generic competitor.⁵⁰

“Paragraph IV” certification under the Hatch-Waxman Act represents another factor encouraging generic entry.⁵¹ The FDA requires that pharmaceutical manufacturers list patents for approved drugs in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known in the industry as the “Orange Book.”⁵² All abbreviated new drug applications must contain a certification with respect to the Orange Book listed patents.⁵³ ANDA paragraph I through III certifications request approval of generic versions of pioneer drugs: (I) that did not file patent information in the Orange Book; (II) whose patents have expired; and (III) whose patents will expire on the specified approval request date.⁵⁴ Under paragraph IV, however, the generic manufacturer must certify that the patent listed for the pioneer drug in the Orange Book “is invalid or will not be infringed by the manufacture, use, or sale of the” generic version of the drug.⁵⁵ If a generic manufacturer makes a paragraph IV certification, the manufacturer must provide notice of the

47. *Id.* at 8.

48. *Id.*

49. *Id.*

50. Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 607 (2003).

51. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000).

52. Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 169 (2005).

53. *Id.*; see also § 355(j)(7)(A)(iii); 21 C.F.R. § 314.53 (2004).

54. 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(III). If the applicant certifies that the patent will expire on a specified date, that is the earliest date possible for the generic application. *Id.* § 355(j)(5)(B)(ii).

55. *Id.* § 355(j)(2)(A)(vii)(IV).

application to the patent holder.⁵⁶ The notice must include “a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”⁵⁷ The drug patent holder has forty-five days after receipt of the notice to file a patent infringement suit against the generic manufacturer or the generic drug will be eligible for FDA approval.⁵⁸

The paragraph IV ANDA patent infringement suit filed by the pioneer manufacturer is an artificial patent infringement suit created by the Hatch-Waxman Act since no actual infringement has taken place in submitting the ANDA.⁵⁹ Filing the patent infringement suit typically grants the patent holder an automatic thirty-month stay of generic approval, which prevents the marketing and sale of the generic drug.⁶⁰ Under the statute, this thirty-month stay may be reduced if a district court rules that the patent is invalid or not infringed, or if an appellate court overrules a district court finding of validity or infringement during the stay.⁶¹ This artificial patent infringement litigation, exclusive to the pharmaceutical industry, permits a generic manufacturer to challenge a listed pharmaceutical patent without having to go through the expense of actually manufacturing and marketing the product. This encourages generic manufacturers to challenge pioneer patents by allowing resolution of patent questions prior to the expenditure of these traditional start-up costs.⁶² Due to their much lower profit margins compared to branded manufacturers, a finding of patent infringement could be disastrous to generic manufacturers once start-up costs have been incurred.⁶³

As a further incentive to challenge listed patents, the Hatch-Waxman Act also provides a 180-day period of generic market exclusivity for the first generic manufacturer to file a paragraph IV ANDA for a listed patent.⁶⁴ This

56. 21 U.S.C. § 355(j)(2)(B) (Supp. III 2003).

57. *Id.* § 355(j)(2)(B)(iv)(II).

58. *Id.* § 355(j)(5)(B)(iii).

59. *See* Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) § 202, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. § 271(e)(2)(A) (2000)).

60. 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. III 2003). It is possible for the stay period to exceed thirty months when the ANDA application has been submitted during the fourth year after the new drug's FDA approval. In this instance, the earliest approval of the challenged ANDA application is set by the Hatch-Waxman Act at seven and one-half years after the new drug approval date. *Id.* § 355(j)(5)(F)(ii). In addition, the district court has the discretion to shorten or lengthen the stay period based upon the parties' actions during litigation. *Id.* § 355(j)(5)(B)(iii).

61. *Id.* § 355(j)(5)(B)(iii).

62. Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 78 (2003).

63. *Id.*

64. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)

market exclusivity results from the statutory ban on FDA approval of subsequent abbreviated new drug applications until the 180-day period runs.⁶⁵ As originally enacted, this 180-day market exclusivity period commenced with either the first commercial marketing of the generic version of the drug or a court finding that the patent is invalid or not infringed.⁶⁶ The 180-day market exclusivity period provides the generic manufacturer an opportunity to secure a significant portion of the generic market prior to additional generic entry. It “can translate into a significant profit for the generic manufacturer to whom it is awarded and is the big prize that generic manufacturers fight over.”⁶⁷

The Hatch-Waxman Act achieved its goal of increased generic entry into the market.⁶⁸ Unfortunately, as enacted, the Hatch-Waxman Act not only created incentives for branded manufacturers to invest in research and development of new drugs and facilitated generic entries into the pharmaceutical market; it also created incentives for anticompetitive behavior between branded and generic manufacturers. The ability of branded manufacturers to obtain multiple, successive thirty-month stays of generic entry by manipulating Orange Book patent listings; the ability of generic manufacturers to obtain, but not invoke, the 180-day market exclusivity period; and the ability to settle litigation without disclosing the settlement terms can all factor into anticompetitive behaviors by branded and generic manufacturers.

B. The Hatch-Waxman Act's Antitrust Implications

The automatic stays of generic entry, artificial infringement actions, and 180-day market exclusivity period for the paragraph IV first filer created by the Hatch-Waxman Act raise antitrust and patent issues in the pharmaceutical industry not typically found elsewhere.⁶⁹ Two questionable interconnected courses of behavior followed by branded and generic manufacturers are of particular interest to the FDA and FTC, courts, legal scholars, and consumers

§ 101, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000)).

65. *Id.*

66. Hatch-Waxman Act § 101 (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv) (2000)). As originally enacted, the branded and generic manufacturers could act in concert to prevent the 180-day exclusivity period from commencing, thus blocking all other generics from the market because the generics could not receive FDA approval until after the period had run.

67. Colman B. Ragan, *Saving the Lives of Drugs: Why Procedural Amendments in Hatch-Waxman Litigation and Certification of Markman Hearings for Interlocutory Appeal Will Help Lower Drug Prices*, 13 FED. CIR. B.J. 411, 413 (2004).

68. *See supra* note 50 and accompanying text.

69. Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1751 (2003).

when analyzing antitrust concerns in the pharmaceutical industry.⁷⁰ First, concern arises from the Orange Book patent listing practices of branded manufacturers and the subsequent thirty-month stay of generic approval that the patent holder can obtain against a paragraph IV ANDA filer. Prior to the 2003 amendments to the Hatch-Waxman Act, patent holders could manipulate the patent listing process to obtain multiple, consecutive thirty-month stays.⁷¹ Second, the Hatch-Waxman Act creates the potential for branded and generic manufacturers to settle patent infringement litigation, often involving reverse payments, which works to delay generic entry to the market in excess of actual patent protection were litigation to go forward.⁷² The ability of the branded manufacturer to obtain multiple thirty-month stays of generic entry places significant pressure on the generic manufacturer to settle the litigation and thus enhances the possibility that the settlement results in expanded patent powers for the branded manufacturer.

New drug application filers must include patent information for listing in the Orange Book when patents cover a drug or method of drug use which reasonably may result in a claim of patent infringement.⁷³ Supplements to the NDA that alter the strength or formulation, use, or method of administration of the drug require that the patent information of the NDA be updated as well.⁷⁴ In addition, if patents claiming the drug or uses of the drug are issued after the NDA was approved, the holder of the approved application is required to file that patent information with the FDA within thirty days for subsequent inclusion in the Orange Book.⁷⁵ All of these subsequently listed patents required generic manufacturers to make new ANDA paragraph IV listings.⁷⁶ “Consequently, one of the major frustrations of generic companies with the original Hatch-Waxman legislation [was] that it allowed innovative [pioneer] companies to obtain multiple [thirty]-month stays on FDA approval of generic drugs.”⁷⁷

The ability on the part of branded manufacturers to obtain multiple thirty-month stays results in anticompetitive behavior in the pharmaceutical industry

70. Derzko, *supra* note 52, at 175-203; M. Elaine Johnston & Matthew J. Galvin, *Antitrust Aspects of Settling Intellectual Property Litigation*, LICENSINGJ., Sept. 2006, at 12, 13; *see also* Hovenkamp, Janis & Lemley, *supra* note 69, at 1752-54.

71. Derzko, *supra* note 52, at 167-68; Hovenkamp, Janis & Lemley, *supra* note 69, at 1754.

72. Derzko, *supra* note 52, at 175-76; Hovenkamp, Janis & Lemley, *supra* note 69, at 1752-55; Johnston & Galvin, *supra* note 70, at 13.

73. 21 U.S.C. § 355(b)(1) (Supp. III 2003); *see also* Derzko, *supra* note 52, at 169, 176.

74. 21 C.F.R. § 314.53(d)(2) (2002); Derzko, *supra* note 52, at 170.

75. 21 U.S.C. § 355(c)(2) (2000); *see also* Derzko, *supra* note 52, at 176.

76. Derzko, *supra* note 52, at 176.

77. *Id.*

unavailable in other industries.⁷⁸ Such behavior could be implicated under section 5 of the FTC Act which makes unlawful “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce”⁷⁹ The FDA’s refusal to police such listings, however, exacerbated manipulation of the Orange Book listing process.⁸⁰ In addition, the Federal Circuit held that, prior to the Hatch-Waxman Act being amended, no private cause of action existed to de-list patents from the Orange Book; thus, generic manufacturers were powerless to fight the practice of manipulating the patent listing process to obtain multiple stays.⁸¹ The ability to invoke multiple stays without regulatory oversight also led to branded manufacturers broadly interpreting which patents needed to be listed and when they would be listed to maximize their ability to restrict generic entry into the market.⁸² These behaviors increased the incentive for generic manufacturers to settle patent infringement suits with pioneer manufacturers.⁸³

Anticompetitive settlements between branded and generic manufacturers have additional antitrust implications. Section 1 of the Sherman Act makes illegal “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce”⁸⁴ Section 2 states that “[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce . . . shall be deemed guilty of a felony”⁸⁵ But under patent law, a patent holder is granted the statutory power to monopolize or restrain trade: “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”⁸⁶ Thus, the question in analyzing branded-generic settlements

78. Hovenkamp, Janis & Lemley, *supra* note 69, at 1754.

79. 15 U.S.C. § 45(a)(1) (2000).

80. Derzko, *supra* note 52, at 171.

81. Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1332-33 (Fed. Cir. 2001); *see also* Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1079 (2004) [hereinafter Cotter, *Antitrust Implications*]; Derzko, *supra* note 52, at 178; Johnston & Galvin, *supra* note 70, at 14.

82. Derzko, *supra* note 52, at 176-84; Hovenkamp, Janis & Lemley, *supra* note 69, at 1754; Johnston & Galvin, *supra* note 70, at 14.

83. Cotter, *Antitrust Implications*, *supra* note 81, at 1079; Johnston & Galvin, *supra* note 70, at 13-14.

84. 15 U.S.C. § 1.

85. *Id.* § 2.

86. *Id.* § 45.

becomes one of determining when patent protections end and antitrust principles begin.

A settlement that keeps a generic drug off the market even though the branded drug has no patent or whose patent expired clearly falls outside of patent protection and constitute a violation of section 1 or 2 of the Sherman Act⁸⁷ or section 5 of the FTC Act.⁸⁸ In contrast, a settlement involving the restriction of generic entry when the patent was deemed valid or infringed by a court clearly falls under patent protection and does not violate antitrust laws.⁸⁹ Unfortunately, the incentives created by the Hatch-Waxman Act generate a number of patent infringement settlements involving reverse payments that fall squarely between these two extremes.⁹⁰

The Hatch-Waxman Act's regulatory scheme allows branded manufacturers and the paragraph IV first filers to settle patent litigation delaying generic entry in a manner beneficial to both, but costly to consumers.⁹¹ The Act grants the patent holder an automatic thirty-month stay of generic approval for simply filing a patent infringement suit against a paragraph IV abbreviated new drug applicant even if the patent is suspected to be weak, not infringed, or even improperly listed in the Orange Book.⁹² As it was originally enacted, the Hatch-Waxman Act allowed the ANDA paragraph IV first filer to retain the 180-day market exclusivity right even if the patent was upheld and the first filer's entry was delayed until patent expiration. Subsequent noninfringing generics would be blocked from entering the market until 180 days after patent expiration.⁹³ And since the FDA was unlikely to penalize an ANDA paragraph IV first filer that incorrectly asserted the invalidity or noninfringement of the branded manufacturer's patent, the ANDA applicant had significant incentive to file a paragraph IV certification knowing that their legal opinion of invalidity or noninfringement may be suspect.⁹⁴ In sum, the pre-amendment Hatch-Waxman Act created "the perverse incentive for Hatch-Waxman litigants to agree to anticompetitive deals."⁹⁵

Because branded-generic settlements take place under the patent umbrella, differences of opinion arise as to the proper application of antitrust principles

87. 35 U.S.C. § 271(a) (2000).

88. 15 U.S.C. §§ 1-2.

89. 35 U.S.C. § 271(a).

90. Thomas F. Cotter, Commentary, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 MINN. L. REV. 1789, 1792-93 (2003) [hereinafter Cotter, *Refining*].

91. Derzko, *supra* note 52, at 167-68.

92. Cotter, *Antitrust Implications*, *supra* note 81, at 1078-79.

93. *Id.* at 1077-78; Hovenkamp, Janis & Lemley, *supra* note 69, at 1755.

94. Cotter, *Antitrust Implications*, *supra* note 81, at 1078-79.

95. *Id.* at 1071.

to such settlements.⁹⁶ Per se and the rule of reason represent the two traditional methods of antitrust analysis for potentially anticompetitive activity.⁹⁷ Per se violations develop over time as courts rule that certain anticompetitive behaviors are so detrimental to consumers that a full-blown analysis of the case is not required to determine that antitrust laws have been violated.⁹⁸ Instead, the violation is presumed and the behavior is considered illegal.⁹⁹ Under a rule of reason analysis, anticompetitive behavior is examined to determine if it significantly restricts competition and represents an unjustified business practice; actions with both characteristics are typically harmful to consumers and are, thus, illegal.¹⁰⁰ In between the per se and rule of reason approaches is the “quick look” approach to antitrust analysis. The quick look approach “applies to those intermediate cases where the anticompetitive impact of a restraint is clear from a quick look, as in a *per se* case, but procompetitive justifications for it also exist.”¹⁰¹ A quick look approach would be appropriate if “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question have an anticompetitive effect,” but the activity did not fall within a defined per se class.¹⁰² Much of the friction among legal commentators, and even among courts, centers on which analysis should apply to reverse payment settlements in the pharmaceutical industry: per se, rule of reason analysis, quick look, or some other judicially determined analysis.

The FTC’s initial position was to apply the per se antitrust violation standard to reverse payment settlements that resulted in delayed generic entry.¹⁰³ The FTC began investigating anticompetitive behaviors in the pharmaceutical industry in the late 1990s and focused on the unique conditions created by the Hatch-Waxman Act that seemed ripe for anticompetitive abuse.¹⁰⁴ One

96. See generally Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617 (2006); Cotter, *Refining*, *supra* note 90; Hovenkamp, Janis & Lemley, *supra* note 69; Johnston & Galvin, *supra* note 70; Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004).

97. Fed. Trade Comm’n, *An Antitrust Primer*, <http://www.ftc.gov/bc/compguide/antitrust.htm> (last visited Aug. 26, 2007).

98. *Id.*

99. *Id.*

100. *Id.*

101. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1312 (S.D. Fla. 2005).

102. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999).

103. *Schering-Plough Corp.*, No. 9297, 2002 WL 1941700 (Fed. Trade Comm’n Aug. 9, 2002) (appeal brief of counsel supporting the complaint).

104. See *supra* note 2.

behavior examined was the practice of branded manufacturers obtaining multiple thirty-month stays of generic approval, encouraging settlement of litigation.¹⁰⁵ Also, the practice of the paragraph IV first filer retaining, but not invoking, the 180-day market exclusivity period presented a concern because such actions could be part of a branded-generic settlement in order to lock other generics out of the market.¹⁰⁶ The antitrust concerns were furthered by the secrecy of infringement settlements which precluded a full examination of the potential anticompetitive behaviors of the settling parties.¹⁰⁷ Congress responded to these concerns and included amendments to the Hatch-Waxman Act in the massive Medicare Reform Act of 2003.¹⁰⁸

C. Amending Hatch-Waxman

Title XI, Access to Affordable Pharmaceuticals, of the Medicare Reform Act of 2003 amended the Hatch-Waxman Act in an effort to address the concerns that had arisen within the pharmaceutical industry since 1984.¹⁰⁹ The amendments were intended to be a “legislative fix to the Hatch-Waxman strategic behavior problem” that resulted in anticompetitive behavior by branded and generic pharmaceutical manufacturers.¹¹⁰ Amendments address the thirty-month stay provision and the 180-day market exclusivity provision.¹¹¹ Also, new provisions allow for FTC review of some settlements between pharmaceutical manufacturers.¹¹² Further, the amendments permit an ANDA paragraph IV filer to seek a declaratory judgment of patent invalidity or noninfringement should the patent holder elect not to file a patent infringement suit.¹¹³ The amendments to the thirty-month stay, the 180-day market exclusivity provision, and FTC review of settlements closely mirrored the

105. Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, ANTITRUST, Summer 2002, at 53, 54-56; *see also supra* notes 69-83 and accompanying text.

106. Brodley & O'Rourke, *supra* note 105, at 54-56.

107. *Id.*

108. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended in scattered sections of 21 U.S.C. (Supp. III 2003)).

109. *Id.*; *see also* Derzko, *supra* note 52, at 212-49.

110. Derzko, *supra* note 52, at 221.

111. §§ 1101-1102, 117 Stat. at 2448-60 (codified as amended in 21 U.S.C. § 355(j)); *see also* Derzko, *supra* note 52, at 233.

112. § 1112, 117 Stat. at 2461-63; *see also* Derzko, *supra* note 52, at 246.

113. § 1101, 117 Stat. at 2448-57 (codified as amended in 21 U.S.C. § 355(j)); *see also* Derzko, *supra* note 52, at 233.

recommendations found in *Generic Drug Entry Prior to Patent Expiration: An FTC Study*.¹¹⁴

The amendments to the thirty-month stay provision mandate that the infringement action brought by the patent holder against any abbreviated new drug application paragraph IV filer be based on “information [that] was submitted . . . before the date on which the application . . . was submitted.”¹¹⁵ As a result, branded manufacturers can no longer obtain multiple thirty-month stays.¹¹⁶ Only patents listed in the Orange Book at the time of ANDA filing can be used to trigger the patent infringement suit and the thirty-month stay of generic approval.¹¹⁷ In addition, the amendments also clarify that a district court’s finding of patent invalidity or noninfringement ends the thirty-month stay period.¹¹⁸ Thus, as a result of the amendments, generics no longer have to wait for a final ruling on the issue if taken up on appeal.¹¹⁹ If the district court finds the patent valid or infringed, the thirty-month stay period can end on the date of an appellate decision reversing the district court or on the date the court enters a consent decree or settlement order.¹²⁰ Given the nature of patent litigation, however, it is unlikely that litigation will be completed within the thirty-month stay period, especially if the decision is taken up on appeal. Additionally, as a prophylactic measure, ANDA filers are now prohibited from amending or supplementing the original ANDA by adding a new drug to the application, thus preventing generic applicants from adding new drugs to a thirty-month stay that has already commenced.¹²¹

The Medicare Reform Act’s amendments also provide for the forfeiture of the 180-day market exclusivity period granted to the paragraph IV first filer under certain conditions.¹²² ANDA first filers forfeit the market exclusivity period due to: (1) a failure to market the generic within specified time periods; (2) the withdrawal of the application; (3) the amendment or withdrawal of the paragraph IV certification; (4) the failure to obtain tentative approval for the application; (5) entering into a settlement agreement with another generic or branded manufacturer which has been found by the FTC or a court to violate antitrust laws in a final decision that has not been or can not be appealed, except

114. FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

115. 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. III 2003).

116. Derzko, *supra* note 52, at 235.

117. *Id.*

118. 21 U.S.C. § 355(j)(5)(B)(iii)(I); Derzko, *supra* note 52, at 236.

119. 21 U.S.C. § 355(j)(5)(B)(iii)(I); Derzko, *supra* note 52, at 236.

120. 21 U.S.C. § 355(j)(5)(B)(iii)(II); Derzko, *supra* note 52, at 236.

121. 21 U.S.C. § 355(j)(2)(D)(i); Derzko, *supra* note 52, at 234.

122. 21 U.S.C. § 355(j)(5)(D)(ii); Derzko, *supra* note 52, at 243.

to the Supreme Court; and (6) the expiration of all patents addressed in the application.¹²³ Thus, the amendments effectively remove an incentive to enter into collusive settlements. The paragraph IV first filer can no longer obtain but not commence the 180-day market exclusivity period preventing other generics from obtaining FDA approval for an expansive period of time.¹²⁴

In addition, the amendments also require that certain agreements entered into by pharmaceutical companies be filed with the Assistant Attorney General and the FTC.¹²⁵ Filing requirements apply to agreements between pioneer and generic manufacturers that affect the listed brand-name drug in the ANDA, the generic drug that is the subject of the ANDA, or the 180-day market exclusivity period that is the subject of that ANDA or any other ANDA for the same listed brand-name drug.¹²⁶ In addition, agreements between generic manufacturers that affect the 180-day market exclusivity period of one of the ANDAs must also be filed with the Assistant Attorney General and the FTC.¹²⁷ This filing requirement will shed much needed light on settlement agreements in the pharmaceutical industry.¹²⁸

The amendments added additional language to the Hatch-Waxman Act that allows a generic manufacturer to seek the delisting of a patent in the Orange Book or a declaratory judgment of patent invalidity or noninfringement.¹²⁹ This necessity was brought on by a conflict between the Federal Circuit and the FDA. In holding that no independent cause of action existed for generic manufacturers to delist a patent from the Orange Book, the Federal Circuit placed the burden of delisting patents on the FDA holding that “an ANDA applicant can bring a delisting action against the FDA under the Administrative Procedure Act.”¹³⁰ Unfortunately, the FDA asserted that it did not have either the legal expertise or resources to police patent listings in the Orange Book.¹³¹ To resolve this dispute, section 1101(a)(2)(C)(ii)(I) of the Medicare Reform Act provides that an ANDA filer in a patent infringement suit may bring a counterclaim seeking to correct or delist patent information in the Orange Book.¹³² Unfortunately, section 1101(a)(2)(C)(ii)(II) specifically states that no

123. Derzko, *supra* note 52, at 243; *see also* 21 U.S.C. § 355(j)(5)(D)(i).

124. Derzko, *supra* note 52, at 244-45.

125. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461-63 (2003) (codified as amended in scattered sections of 21 U.S.C. (Supp. III 2003)); Derzko, *supra* note 52, at 246.

126. § 1112(a)(2), 117 Stat. at 2462; Derzko, *supra* note 52, at 246.

127. § 1112(b)(2), 117 Stat. at 2462; Derzko, *supra* note 52, at 246.

128. *See infra* Part V.

129. § 1101, 117 Stat. at 2448; Derzko, *supra* note 52, at 241-42.

130. Derzko, *supra* note 52, at 180.

131. *Id.* at 171.

132. *Id.* at 242.

other independent cause of action to delist patents is authorized.¹³³ Another benefit for generics is provided in section 1101(a)(2)(C)(i), however; if a patent holder does not assert a patent infringement claim against a paragraph IV ANDA filer, the ANDA filer can seek a declaratory judgment on patent validity or infringement by the ANDA.¹³⁴ It is hoped that “these provisions will help resolve patent disputes and clear the way to the introduction of new generic drugs by eliminating patents that are deemed by courts to be invalid or not infringed.”¹³⁵

It is still too early to determine the impact of the Medicare Reform Act on settlements in the pharmaceutical industry because the current crop of reverse payment settlement cases that progressed through the administrative and judicial systems in the past six years were all commenced prior to the Medicare Reform Act’s enactment. It is telling, however, that the seventeen settlements reported to the FTC in fiscal years 2005 and 2006 involving both a reverse payment of some kind and delayed generic entry were the first such settlements involving both characteristics known to the FTC since 1999 when it first began investigating reverse payment settlements.¹³⁶ And as the FTC states, “[i]t is worth noting that [sixteen] of the agreements . . . occurred after the 11th Circuit Court of Appeals’ decision in *Schering-Plough v. Federal Trade Commission*, reversing the Commission’s decision that two settlements involving a restriction on generic entry and compensation to the generics violated the Federal Trade Commission Act.”¹³⁷

III. The Administrative and Judicial Response to Reverse Payment Settlements in the Pharmaceutical Industry

When the FTC began to investigate reverse payment settlements in the late 1990s, it uncovered eight settlement agreements finalized between 1992 and 1999 that included both a reverse payment to the generic manufacturer and delayed market entry by the generic drug.¹³⁸ These settlements provided the basis for the reverse payment litigation that has made its way through the FTC and the courts since 1999.

133. *Id.*

134. *Id.* at 241.

135. *Id.*

136. FTC AGREEMENTS REPORT 2005, *supra* note 2, at 3-4; FTC AGREEMENTS REPORT 2006, *supra* note 2, at 1-5.

137. FTC AGREEMENTS REPORT 2006, *supra* note 2, at 1.

138. FTC AGREEMENTS REPORT 2005, *supra* note 2, at 3-4.

A. The Settlement Party Ends: The FTC's Investigation of Reverse Payment Settlements

1. Abbott Laboratories and Geneva Pharmaceuticals, Inc.

The FTC's 1999 announcement that it would investigate reverse payment settlements in the pharmaceutical industry essentially ended the practice until the *Schering-Plough* ruling was handed down in 2005.¹³⁹ One of the FTC's first actions resulted in a consent decree with Abbott Laboratories, the patent holder, and Geneva Pharmaceuticals, the ANDA paragraph IV first filer.¹⁴⁰ The FTC complaint alleged that the day after Geneva's generic received FDA approval, Abbott agreed to pay Geneva \$4.5 million per month to stay out of the market until a district court ruled on the patent litigation. Abbott also agreed to pay \$4.5 million per month into an escrow account on a winner-take-all basis if Abbott were to lose at the district level and appeal the ruling.¹⁴¹ Geneva agreed to refrain from marketing its generic throughout the appeals process and to retain control of its 180-day market exclusivity period, preventing other generics from receiving FDA approval.¹⁴²

According to the FTC complaint, Geneva refrained from marketing its generic after winning on a summary judgment motion while Abbott lost in the Federal Circuit and appealed to the Supreme Court.¹⁴³ Nevertheless, about a year and a half after signing the agreement, Abbott and Geneva became aware of the FTC's investigation into the reverse payment settlement and voluntarily ended it.¹⁴⁴ While the consent decrees signed by Abbott and Geneva do not admit guilt in these matters, the terms of the decrees imposed strict limitations on any future patent infringement settlements for either party.¹⁴⁵

2. Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp.

Shortly after issuing its complaint against Abbott and Geneva in March of 2000, the FTC issued a complaint against Hoechst Marion Roussel, Incorporated (Hoechst MRI), Carderm Capital L.P., a limited partnership

139. *Id.* at 4. The FTC lacks information on settlements entered into between June 1, 2002, when their generic drug study ended, and January 7, 2004, when the Medicare Reform Act's notice provision began. *Id.* at 3 n.4.

140. Abbott Labs., No. C-3945, 2000 WL 681848 (Fed. Trade Comm'n May 22, 2000) (complaint & decision and order).

141. *Id.* ¶¶ 26-27.

142. *Id.* ¶¶ 26-27.

143. *Id.* ¶¶ 31, 33.

144. *Id.*

145. *Id.*

controlled by Hoechst MRI that held the patents at issue, and Andrx Corporation, the ANDA paragraph IV first filer.¹⁴⁶ The complaint alleged that Hoechst MRI agreed to pay Andrx \$10 million per quarter once Andrx received FDA approval to market its generic.¹⁴⁷ The payments were to continue until a final judgment was rendered in the litigation, Andrx obtained a license from Hoechst MRI to market a generic, or Hoechst MRI decided to market its own generic or provide a license to another generic manufacturer.¹⁴⁸ Hoechst MRI also agreed to make an additional payment of \$60 million per year for the same time period should it lose the infringement suit.¹⁴⁹ In exchange, the complaint alleged that Andrx agreed not to market the generic covered by the paragraph IV ANDA or any other generic versions of the drug. Further, Andrx would retain its 180-day market exclusivity period, thus preventing FDA approval of any other generics.¹⁵⁰

Hoechst MRI and Andrx consented to similar terms as Abbott and Geneva, restricting their ability to participate in patent settlements.¹⁵¹ Unfortunately for Hoechst MRI and Andrx, this did not conclude the litigation. Purchasers of Cardizem CD, Hoechst MRI's branded drug, later filed an antitrust action against Hoechst MRI and Andrx in the Eastern District of Michigan which the Sixth Circuit ultimately heard in *In re Cardizem CD Antitrust Litigation*.¹⁵² As discussed in Part III.B.1, *infra*, the Sixth Circuit held that the settlement between Hoechst MRI and Andrx was a per se violation of the Sherman Act.¹⁵³

3. American Home Products

The FTC complaint against Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation (AHP) also moved beyond the administrative level and was decided by the Eleventh Circuit in *Schering-Plough Corp. v. FTC*.¹⁵⁴ AHP, however, opted not to pursue the action at the FTC administrative hearing level and instead agreed to a consent order with the FTC.¹⁵⁵ In its complaint against Schering-Plough, Upsher-Smith,

146. Hoechst Marion Roussel, Inc., No. 9293, 2000 WL 288452 (Fed. Trade Comm'n Mar. 16, 2000) (complaint & decision and order).

147. *Id.* ¶ 24.

148. *Id.* ¶ 23.

149. *Id.* ¶ 24.

150. *Id.* ¶ 23.

151. Hoechst Marion Roussel, Inc., No. 9293, 2000 WL 1744889 (Fed. Trade Comm'n Nov. 28, 2000) (consent order).

152. 332 F.3d 896 (6th Cir. 2003).

153. *Id.* at 900.

154. 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

155. FED. TRADE COMM'N, OVERVIEW OF FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS 7 (2005), <http://www.ftc.gov/bc/050802antitrustpharmprods.pdf>.

and AHP, the FTC alleged that Schering-Plough, the branded manufacturer, made anticompetitive reverse payments to Upsher-Smith and AHP, potential generic competitors.¹⁵⁶

ESI Lederle, Incorporated (ESI), a division of AHP, filed a paragraph IV ANDA challenging Schering's patent for its branded medication seeking approval as soon as Upsher-Smith's 180-day exclusivity period ran.¹⁵⁷ The FTC alleged that in exchange for delayed market entry of ESI's generic, Schering-Plough agreed to pay AHP and ESI up to \$15 million.¹⁵⁸ In April 2002, two months prior to the FTC's Administrative Law Judge's decision in favor of the manufacturers, AHP agreed to a consent order with the FTC and withdrew from the litigation.¹⁵⁹ The consent decree again placed severe restrictions on AHP's ability to settle patent infringement litigation.¹⁶⁰

4. *Bristol-Myers Squibb Company*

Bristol-Myers Squibb Company also agreed to significant restraints on its ability to settle patent litigation, as well as limitations on its Orange Book patent listing practices, when it signed a consent decree with the FTC in April 2003. The FTC's complaint against Bristol-Myers alleged that it had been engaging in anticompetitive conduct relating to its highly profitable brand-name drugs that had cost consumers hundreds of millions of dollars.¹⁶¹ Bristol-Myers agreed to cease manipulating Orange Book listings and filing false patent information for the purpose of obtaining multiple thirty-month stays.¹⁶² Bristol-Myers also agreed not to enter into reverse payment settlements that required the generic manufacturer to retain the 180-day market exclusivity period blocking other generics from the market.¹⁶³

As evidenced by these consent decrees, the FTC's position has long been that reverse payment settlements in the pharmaceutical industry that result in delayed generic entry are anticompetitive and violate antitrust laws. In its brief appealing the administrative law judge's ruling in favor of the defendants in *In re Schering-Plough Corp.*, the FTC initially articulated its belief that reverse

156. Schering-Plough Corp., No. 9297, 2001 WL 418903 (Fed. Trade Comm'n Apr. 2, 2001) (complaint).

157. *Id.* ¶¶ 51-52.

158. *Id.* ¶ 55.

159. Schering-Plough Corp., No. 9297, 2002 WL 512135 (Fed. Trade Comm'n Apr. 2, 2002) (decision and order as to American Home Products Corp.).

160. *Id.*

161. Bristol-Myers Squibb Co., No. C-4076, 2003 WL 21008622 (Fed. Trade Comm'n Apr. 14, 2003) (complaint & decision and order).

162. *Id.*

163. *Id.*

payment settlements are per se antitrust violations.¹⁶⁴ Nevertheless, in its opinion reversing the administrative law judge's decision in favor of the manufacturers, the FTC relied on a rule of reason analysis in finding the settlement agreements illegal.¹⁶⁵ A careful reading of the FTC's opinion, however, seems to indicate that it will apply a presumption of illegality to reverse payment settlements involving payments greatly exceeding potential litigation costs which would be so difficult to rebut, as to almost serve as a de facto per se standard.

B. The Settlement Party Begins Again? Reverse Payment Settlements Go to Court

While the FTC consistently opposes reverse payment settlements as anticompetitive, courts trend toward the opposite conclusion. Unfortunately, antitrust challenges to reverse payment settlements between branded and generic manufacturers have not led to consensus on the major issues in pharmaceutical patent-antitrust litigation.¹⁶⁶ The presumptive weight given to patent validity, the importance of ancillary agreements in which the branded manufacturer makes significant payments to the generic manufacturer for licenses to unproven products of questionable value, and the relevance of the policy favoring settlements all receive a variety of treatments by courts.¹⁶⁷ Also unresolved is "the legality of 'reverse payments' that exceed the anticipated profits of the generic product."¹⁶⁸ Given the current state of case law in this area, guidance from the Supreme Court is desperately needed.

1. In re Cardizem CD Antitrust Litigation

Initially, courts seemed to follow the FTC's lead, finding reverse payment settlements in the pharmaceutical industry per se antitrust violations. The plaintiffs in *In re Cardizem CD Antitrust Litigation*, direct purchasers of Hoechst Marion Roussel, Inc.'s branded drug, filed suit in the Eastern District of Michigan alleging that the reverse payment settlement discussed in Part III.A violated federal and state antitrust laws.¹⁶⁹ In granting a partial summary judgment in favor of the plaintiffs, the district court certified a question for

164. Schering-Plough Corp., No. 9297, 2002 WL 1941700 (Fed. Trade Comm'n Aug. 9, 2002) (appeal brief of counsel supporting the complaint).

165. Schering-Plough Corp., No. 9297, 2003 WL 22989651 (Fed. Trade Comm'n Dec. 8, 2003) (final order), *vacated*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

166. Johnston & Galvin, *supra* note 70, at 15.

167. *Id.*

168. *Id.*

169. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003).

interlocutory appeal on its finding that the settlement agreement was a per se violation of the Sherman Act and its corresponding state laws.¹⁷⁰ In making its ruling on the certified question, the Sixth Circuit focused on both the \$10 million per quarter payment from Hoechst MRI to Andrx Pharmaceuticals for Andrx to refrain from marketing its FDA approved generic and on Andrx's not invoking or relinquishing its 180-day market exclusivity period.¹⁷¹

The court determined that the effect of the settlement agreement "was, at its core, a horizontal agreement to eliminate competition . . . throughout the entire United States, a classic example of a *per se* illegal restraint of trade."¹⁷² The court found that the settlement expanded patent rights for Hoechst MRI, because Andrx was required to retain the 180-day exclusivity period preventing any other noninfringing generics from legally entering the market.¹⁷³ As the court stated, "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market."¹⁷⁴

2. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*

The United States District Court for the Southern District of Florida also found a reverse payment settlement between branded and generic manufacturers a per se violation of antitrust laws, but the Eleventh Circuit on appeal held that the per se application was inappropriate because valid patents permit anticompetitive behaviors.¹⁷⁵ The first settlement involved a reverse payment from Abbott Laboratories to Geneva Pharmaceuticals and restricted Geneva from marketing its FDA approved generic in exchange for \$4.5 million per month.¹⁷⁶ Geneva had actually filed two abbreviated new drug applications, one for the capsule form and one for tablet form, both containing paragraph IV certifications that Abbott's patent was invalid.¹⁷⁷ Abbott only filed a patent infringement suit against the tablet ANDA, thus allowing the capsule version to receive FDA approval as early as forty-five days after the application date.¹⁷⁸

170. *Id.*

171. *Id.* at 907.

172. *Id.* at 908.

173. *Id.* at 907.

174. *Id.* at 908 (footnote omitted).

175. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003).

176. *See supra* Part III.A.

177. *Valley Drug*, 344 F.3d at 1299.

178. *Id.* The patent holder must file the infringement suit within forty-five days after receiving notice of the ANDA paragraph IV filing in order to invoke the thirty-month stay of generic approval. 21 U.S.C. § 355(j)(5)(B)(iii) (2000).

Abbott was also faced with a paragraph IV ANDA from Zenith Goldline Pharmaceuticals.¹⁷⁹

Zenith filed its ANDA prior to Geneva, but Abbott listed two new patents it obtained in the Orange Book and asserted that Zenith would have to amend its ANDA to take the new patents into account.¹⁸⁰ Zenith filed a suit to force Abbott to delist the patents in question and Abbott counterclaimed for infringement.¹⁸¹ Zenith lost at the district level, and subsequently appealed to the Federal Circuit.¹⁸² Abbott and Zenith then entered into a settlement agreement whereby both dismissed their causes of action, Zenith acknowledged the validity of Abbott's patents, and Zenith agreed not to market a generic version until another generic entered the market or one specific patent held by Abbott for the drug expired in two years.¹⁸³ In exchange, Zenith received, in essence, a \$2 million per month payment until the agreement terminated.¹⁸⁴

Although the court found Abbott's patent invalid just months after the Geneva and Zenith settlements were reached, both generic manufacturers continued to honor the deals by refraining to market their generic versions in exchange for the payments.¹⁸⁵ Still, because the parties signed the agreements prior to the finding of patent invalidity, the Eleventh Circuit "reject[ed] the district court's characterization of the instant Agreements as illegal *per se*."¹⁸⁶ The Eleventh Circuit focused on Geneva and Zenith's admission that if the patent were valid, they would have infringed.¹⁸⁷ The court stated that "exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives" favoring settlement over the costs and risks of litigation.¹⁸⁸ The court acknowledged that its position rejecting *per se* illegality was in conflict with the Sixth Circuit's ruling in *Cardizem*, but found that "[w]hen the exclusionary power of a patent is implicated, . . . the antitrust analysis cannot ignore the scope of the patent exclusion."¹⁸⁹ The court then reversed the partial summary judgment for the

179. *Valley Drug*, 344 F.3d at 1299.

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.* at 1300.

184. *Id.*

185. *Id.* at 1301.

186. *Id.* at 1304.

187. *Id.* at 1305-06.

188. *Id.* at 1308.

189. *Id.* at 1310.

plaintiffs and remanded the case back to the district court for a full antitrust analysis of the settlements.¹⁹⁰

On remand, the district court scrupulously followed the directives of the circuit court and evaluated the exclusionary scope of the patent to determine if the settlements were in violation of the Sherman Antitrust Act.¹⁹¹ The district court's three-part test, which took "into account both the Eleventh Circuit's opinion and Professor Hovenkamp's analytical approach," examined the exclusionary scope of the patent, evaluated the potential outcomes of patent litigation, and evaluated "whether the settlement represented a reasonable implementation of the protections afforded by the '207 patent, in light of the applicable law, the then-pending litigation, and the general policy justifications supporting settlements of intellectual property disputes."¹⁹² The court ultimately held that the settlement agreement exceeded the scope of the patent and was not a reasonable implementation of patent protection.¹⁹³ As such, the district court again found that the agreement was a per se antitrust violation and summarily found for the plaintiffs.¹⁹⁴

3. *Schering-Plough Corp. v. FTC*

The Eleventh Circuit's rejection of the initial per se finding in *Valley Drug* facilitated its hearing the appeal of the FTC's holding that Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products/ESI Lederle violated section 5 of the Federal Trade Commission Act.¹⁹⁵ Because the FTC Act permits corporations to appeal an FTC decision in any circuit where they do business,¹⁹⁶ the Eleventh Circuit's refusal to apply per se illegality and its deference to patent validity in *Valley Drug* made that circuit a natural choice to appeal the FTC's reversal of the Administrative Law Judge's decision. The Eleventh Circuit did not disappoint the manufacturers. In stating that "[i]t would seem as though the Commission clearly made its decision before it considered any contrary conclusion," the court blasted the FTC's rule of reason analysis and finding of antitrust violations.¹⁹⁷

190. *Id.* at 1313.

191. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1294-1310 (S.D. Fla. 2005).

192. *Id.* at 1295-96.

193. *Id.* at 1319.

194. *Id.*

195. *Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (Fed. Trade Comm'n Dec. 8, 2003) (final order), *vacated*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

196. 15 U.S.C. § 45(c) (2000).

197. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

The Eleventh Circuit then reemphasized its *Valley Drug* holding, further stating that “neither the rule of reason nor the *per se* analysis is appropriate in this context.”¹⁹⁸ The court then delineated its three-part test for analyzing antitrust liability when a patent is involved, stating “we think the proper analysis . . . requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”¹⁹⁹ The court then applied its own test to the settlements between Schering-Plough and Upsher-Smith and Schering-Plough and ESI Lederle.²⁰⁰

The Schering-Upsher settlement agreement called for a \$60 million payment for “initial royalty fees” and an additional \$10 million in “milestone royalty payments” to Upsher-Smith in exchange for a delay in the marketing of Upsher’s generic, as well as Upsher granting Schering-Plough licenses for five of Upsher’s products.²⁰¹ The initial Schering-ESI settlement agreement called for an initial \$5 million payment to ESI Lederle, which would increase to \$10 million if ESI’s generic received FDA approval. In exchange, ESI’s generic could not enter the market for seven years, but its entry would still occur almost three years prior to patent expiration.²⁰² The final settlement agreement called for a \$5 million payment for “legal fees,” a \$10 million payment contingent on FDA approval of ESI’s generic, and an additional \$15 million payment for licenses for two of ESI’s products.²⁰³

In applying its own test, the Eleventh Circuit found these settlements did not exceed the scope of Schering-Plough’s patent and, thus, were not illegal.²⁰⁴ The court stated,

that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the “asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.”²⁰⁵

In its analysis of the settlement agreements, the court gave great weight to the presumption that all patents are considered valid and that a large payment from

198. *Id.*

199. *Id.* at 1066.

200. *Id.* at 1066-76.

201. *Id.* at 1058-60.

202. *Id.* at 1060-61.

203. *Id.* at 1061 n.6.

204. *Id.* at 1076.

205. *Id.* at 1075 (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003)).

a patent holder to a potential infringer involving delayed market entry is not an indication of patent weakness.²⁰⁶ The court also accepted statements by the parties and their experts that the license fees and royalty payments were legitimate business transactions unrelated to the delayed entry of the generic products, finding no evidence to the contrary.²⁰⁷ A somewhat stunning reversal, given that, based on the same evidence, the FTC found that “the Upsher licenses were worth nothing to Schering” and the \$60 million reverse payment was simply for the delayed generic entry.²⁰⁸ The court further noted the exchange of value in settling patent infringement suits was endorsed by the Supreme Court and reverse payment settlements flow naturally from the Hatch-Waxman Act.²⁰⁹ According to the court, a ban on reverse payment settlements would actually reduce the incentives for paragraph IV abbreviated new drug applications challenging patents because it would limit the options available for settling any infringement suit that could follow.²¹⁰

The Eleventh Circuit ruling in *Schering-Plough* thus provided a blueprint for the development of reverse payment settlements in the pharmaceutical industry able to withstand an antitrust challenge within that jurisdiction.²¹¹ The settlement may involve large payments as long as the patent can presumptively be found valid, the generic is allowed entry to the market at some point prior to the patent expiring, and the payments are ostensibly provided for licenses and royalties for generic products. A settlement in which the patent holder knew of its patent invalidity or the license payments were clearly sham payments would still presumably be antitrust violations in the Eleventh Circuit.

4. *In re Tamoxifen Citrate Antitrust Litigation*

In *In re Tamoxifen Citrate Antitrust Litigation*,²¹² the Second Circuit held that reverse payment settlements that do not exceed the exclusionary scope of the patent are presumptively lawful, mirroring the Eleventh Circuit’s holding in *Schering-Plough*. The *Tamoxifen* litigation was brought by consumers, third-

206. *Id.* at 1066-76.

207. *Id.* at 1071.

208. *Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (Fed. Trade Comm’n Dec. 8, 2003) (final order), *vacated*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

209. *Schering-Plough*, 402 F.3d at 1074.

210. *Id.* at 1075.

211. Interestingly, the United States District Court for the District of New Jersey, ruling in a civil suit that paralleled the FTC action, found the same settlements between *Schering-Plough*, *Upsher-Smith*, and *ESI Lederle* to be illegal under its own rule of reason analysis. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004).

212. 466 F.3d 187, 205-13 (2d Cir. 2006), *cert. denied sub nom.*, *Joblove v. Barr Labs, Inc.*, 127 S. Ct. 3001 (2007).

party medical beneficiary providers, and consumer advocacy groups challenging a 1993 settlement between patent-holders Zeneca, Inc., AstraZeneca Pharmaceuticals, and AstraZeneca PLC (collectively Zeneca) and generic manufacturer Barr Laboratories, Inc.²¹³ Zeneca held the patent for Tamoxifen, the most widely prescribed treatment for breast cancer, which was obtained by Zeneca's predecessor in August 1985.²¹⁴ Barr filed an abbreviated new drug application four months after the patent issued and later amended its ANDA to a paragraph IV certification.²¹⁵ Zeneca filed a timely infringement suit against Barr and its raw material provider, but lost when the patent was declared invalid in April 1992.²¹⁶

Zeneca appealed, but while the appeal was pending, Zeneca and Barr entered into a confidential settlement agreement settling the infringement action and restoring Zeneca's patent. Barr received \$21 million and a license to market Zeneca's Tamoxifen under the Barr label.²¹⁷ In exchange, Barr changed its ANDA certification from paragraph IV to paragraph III, thus preventing Barr from marketing its own generic until the patent expired in 2002.²¹⁸ Barr reserved the right to alter its certification back to paragraph IV if any subsequent final and unappealable infringement litigation declared the patent unenforceable or invalid.²¹⁹ Zeneca also paid Barr's supplier \$9.5 million at the time of the settlement "and an additional \$35.9 million over the following ten years."²²⁰

The individual consumer, third-party beneficiary provider, and consumer advocacy group actions challenging the 1993 settlement agreement were consolidated into a class action suit in the Eastern District of New York.²²¹ The district court granted the defendants' motion to dismiss in a ruling emphasizing the patent exceptions to antitrust principles.²²² In an opinion that borrowed heavily from the Eleventh Circuit's decisions in *Valley Drug* and *Schering-Plough*, the majority decision of the Second Circuit affirmed the district court's dismissal of the charges.²²³ The court stated that settlements are favored in patent litigation and reverse payments are to be expected in Hatch-Waxman litigation due to the incentives built into the Hatch-Waxman Act; as such, a per

213. *Id.* at 190.

214. *Id.* at 193.

215. *Id.*

216. *Id.*

217. *Id.*

218. *Id.* at 193-94.

219. *Id.* at 194.

220. *Id.*

221. *Id.* at 196.

222. *Id.* at 198.

223. *Id.* at 201-21.

se bar to reverse payments would be inappropriate.²²⁴ The majority's holding exceeds that of the Eleventh Circuit, in stating that no antitrust violation is possible in a patent reverse payment settlement unless the patent has been obtained by fraud or the patent enforcement action is "objectively baseless."²²⁵ The majority additionally found that while payments exceeding the generic's expected profits may be suspicious, they are not illegal.²²⁶ In short, as long as a settlement does not exceed the presumptively valid patent's scope, it will not violate antitrust laws.²²⁷

The Second Circuit adopted and expanded the Eleventh Circuit's logic from *Valley Drug* and *Schering-Plough* and focused the antitrust analysis of reverse payment settlements on the exclusionary ability of patents and the anticompetitive effects of expanded patent power. A settlement that allows generic entry prior to patent expiration is presumptively valid, regardless of patent strength, absent knowledge of patent invalidity or clearly sham settlement payments. According to the Second and Eleventh Circuits, neither the direction nor the magnitude of the payment should generally factor into the analysis, as long as the settlement does not exceed the exclusionary scope of the patent. The presumption of patent validity, even in the face of tens or hundreds of millions of dollars given in payment to protect the patent through a reverse payment settlement, is highly respected in both the Second and Eleventh Circuits.

One important factor differentiates the settlements in *Schering-Plough* and *In re Tamoxifen* from the Sixth Circuit's per se holding in *In re Cardizem*: the generic manufacturer in *In re Cardizem* retained and did not invoke the 180-day market exclusivity period and, thus, blocked other generics from obtaining FDA approval, something that could not be done under the current regulatory scheme.²²⁸ In *Schering-Plough* and *In re Tamoxifen*, none of the generic

224. *Id.* at 205-13.

225. *Id.* at 213 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (2005)).

226. *Id.* at 209-13.

227. *Id.* at 202-21. Interestingly, in his amicus brief recommending the Supreme Court deny certiorari of *In re Tamoxifen*, the Solicitor General acknowledges that the standard applied by the majority in *Tamoxifen* "is erroneous" and that the dissent's analysis is correct, Brief for the United States as Amicus Curiae at 12-13, *Joblove v. Barr Labs., Inc.*, 127 S. Ct. 3001 (2007) (No. 06-830), 2007 WL 1511527, but still recommends the denial of certiorari because "[t]he federal antitrust claims in this case appear to be moot, the factual setting is atypical and unlikely to recur, and subsequent regulatory changes may undercut one of the theories of competitive harm advanced by petitioners." *Id.* at 17. The brief concludes: "To the extent the Court is inclined to address the validity of [this] type of settlement in particular, it may be preferable to do so in a case that arises under the current regulatory regime." *Id.* at 20.

228. *See supra* Part II.C.

manufacturers were held to such terms. Other generics were free to challenge Schering-Plough and Zeneca's patents and possibly receive FDA approval prior to patent expiration. Ultimately, the differences between the Sixth Circuit and the Eleventh and Second Circuits might not be as great as they first appear.

The Third and Ninth Circuits may potentially weigh in on the issue of reverse payment settlements in the pharmaceutical industry as well. Both plaintiffs and defendants appealed the jury's verdict for the defendants in *Kaiser Foundation v. Abbott Laboratories* to the Ninth Circuit, involving the settlement the Eleventh Circuit ruled on in *Valley Drug*.²²⁹ Likewise, the Third Circuit may have a chance to rule on the same settlement the Eleventh Circuit ruled on in *Schering-Plough*.²³⁰ Given the amount of litigation working its way through the court system,²³¹ the public policy implications of reverse payment settlements, and the variation in judicial response to antitrust actions against reverse payment settlements, guidance from the Supreme Court is required.

IV. Academic Commentary on Reverse Payment Settlements

When the Supreme Court does take up a reverse payment settlement case, it will find several distinct academic approaches to the antitrust and patent issues raised by reverse payment settlement agreements. One common argument is that reverse payment settlements should be presumptively illegal, or otherwise deemed illegal per se if the payment exceeds potential litigation costs. In direct opposition to this are the arguments in favor any patent settlement, including those involving large reverse payments, almost to the point of a presumption of legality. A middle ground is forged by various rule of reason analyses that may or may not treat such settlements as presumptively illegal, but still argue that, under certain conditions, payments vastly in excess of litigation costs could ultimately be legal.

A. Reverse Payment Settlements as Presumptively Illegal

The argument that large reverse payment settlements should be considered presumptively illegal is usually based on two distinct points: "(1) the size of the

229. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1573 n.85 (2006).

230. *Id.*

231. See, e.g., *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003); *Biovail Corp. v. Mylan Labs., Inc.*, 217 F.R.D. 380 (N.D. W. Va. 2003); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002); Amended Complaint and Demand for Jury Trial, *Kroger Co. v. Sanofi-Aventis*, No. 1:06-CV-163-HJW (S.D. Ohio July 31, 2006), 2006 WL 2503664.

[reverse] payment and (2) the impact of the [reverse] payment on third party entry prospects.”²³² It is argued that as the magnitude of the payment increases, the more likely it is that the patent holder is protecting a weak or noninfringed patent, and the settlement violates antitrust principles.²³³ Noted antitrust scholar Herbert Hovenkamp contends that when payments greatly exceed potential litigation costs,

the infringement plaintiff must have significant doubts about the validity of its patent or the defendant’s status as an infringer. Thus, a larger payment suggests a more socially costly outcome — namely, preserving the exclusion power of the patent, at least vis-a-vis this particular defendant, even though the patent is likely to be invalid. The result is to deny the public the benefits of competition that it could otherwise obtain.²³⁴

The social costs, also referred to as consumer harm, is the difference between what consumers would gain if the patent litigation were seen through to completion and what consumers actually receive as a result of the patent settlement. These social costs factor heavily in arguments favoring presumptive liability or per se illegality for reverse payment settlements.²³⁵

For example, social costs rise significantly when third party generics not involved in the settlement agreement are kept from entering the market.²³⁶ Settlements entered into prior to the amendments to the Hatch-Waxman Act in 2003 raise particular concerns about third party entry prospects since the paragraph IV first filer is able to retain, but not invoke the 180-day market exclusivity period. This ability to prevent further generic approval was a

232. Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25 (2004); *see also* Brodley & O’Rourke, *supra* note 105, at 55; Hemphill, *supra* note 229, at 1596; Hovenkamp, Janis & Lemley, *supra* note 69, at 1759; Maureen A. O’Rourke & Joseph F. Brodley, *Commentary, An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1767, 1782 (2003); Carl Shapiro, *Antitrust Analysis of Patent Settlement Between Rivals*, ANTITRUST, Summer 2003, at 70, 76.

233. Hemphill, *supra* note 229, at 1596; Hovenkamp, *supra* note 232, at 25; Hovenkamp, Janis & Lemley, *supra* note 69, at 1759; O’Rourke & Brodley, *supra* note 232, at 1782; Shapiro, *supra* note 232, at 76.

234. Hovenkamp, *supra* note 232, at 25.

235. Joel Schrag, *The Value of a Second Bite at the Apple: The Effect of Patent Dispute Settlements on Entry and Consumer Welfare* (Fed. Trade Comm’n, Working Paper No. 281, 2006), available at <http://www.ftc.gov/bef/workpapers/wp281.pdf>; *see also* Hemphill, *supra* note 229, at 1580-96; O’Rourke & Brodley, *supra* note 232, at 1786.

236. Hemphill, *supra* note 229, at 1583-91; Hovenkamp, *supra* note 232, at 24-26.

significant factor in the Sixth Circuit's finding of per se illegality in *In re Cardizem*.²³⁷

Nevertheless, C. Scott Hemphill makes a persuasive argument that this is not the only manner in which generics may be kept out of the market. Because only the paragraph IV first filer is eligible for the 180-day market exclusivity period,

[g]eneric firms other than the first filer will lag behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue a challenge. The subsequent filers' return on a challenge, aside from being smaller, depends upon the outcome of the first filer's suit (and possible settlement) It is therefore inaccurate to assert, as some cases have, that "[i]n a reverse-payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market." The settlement does secure an important change in the competitive situation; it removes from consideration the most motivated challenger, and the one closest to introducing competition.²³⁸

While the 2003 amendments to the Hatch-Waxman Act can cause the paragraph IV first filer to forfeit the 180-day market exclusivity period, they do not then make the market exclusivity period available to subsequent paragraph IV filers.²³⁹ Therefore, no subsequent paragraph IV filer will have the same competitive motivation to undertake a patent challenge.

Because presumptive liability proponents see large reverse payments as a sign of patent vulnerability and delayed generic entry as socially costly, a common proposal is to shift "the burden of proof to the infringement plaintiff."²⁴⁰ A quick look antitrust approach would be appropriate for such a proceeding.²⁴¹ The infringement plaintiff/antitrust defendant would show that, at the time of the settlement, they would likely prevail had the lawsuit progressed and that the payment is not excessive.²⁴² Generally, liability proponents see payments greater than expected litigation and collateral

237. See *supra* Part III.B.1.

238. Hemphill, *supra* note 229, at 1586 (quoting *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003)) (bracketed alteration in original) (footnote omitted).

239. See *supra* Part II.C.

240. Hovenkamp, Janis & Lemley, *supra* note 69, at 1759.

241. See Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 532-38 (2002).

242. *Id.*; see also Brodley & O'Rourke, *supra* note 105, at 55.

expenses as excessive, resulting in a per se antitrust violation.²⁴³ This enhances the benefit of the presumptive liability position in further saving judicial resources, though not as much as outright per se liability would. The drawback of the presumptive liability position is that it might deter parties from entering into valid settlements involving reverse payments and therefore result in unnecessary patent litigation.

B. The Legislative Per Se Solution

This drawback is magnified by the legislative response to the Supreme Court's refusal to hear *Schering-Plough*.²⁴⁴ Disregarding any potential benefits of reverse payment settlements, legislators introduced the Preserve Access to Affordable Generics Act to the Senate the day after the Court denied certiorari.²⁴⁵ The Preserve Access to Affordable Generics Act, and the more recent Protecting Consumer Access to Generic Drugs Act of 2007, would make any settlement a per se violation of section 5 of the Federal Trade Commission Act if the settlement provided "anything of value" to an ANDA filer and the ANDA filer agrees to delay marketing its generic.²⁴⁶ This is a clear return to the standard the FTC imposed when it first began investigating pharmaceutical reverse payment settlements, and only reluctantly moderated in its *Schering-Plough* arguments.²⁴⁷ Significant difficulties could arise under these acts, however. Most notably, what constitutes receiving "anything of value" and what would be considered delayed marketing.

As several commentators point out, settlements that involve splitting the remaining patent term into a period of branded exclusivity followed by entry of the ANDA filer potentially transfers significant value to the generic in the form of earlier entry to the market.²⁴⁸ While the entry of the generic occurs prior to patent expiration, it is "delayed" with respect to the potential entry date at the lapse of the thirty-month stay period or the completion of litigation. It is

243. Hemphill, *supra* note 229, at 1561-62, 1595-96; Hovenkamp, *supra* note 232, at 25; Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, Correspondence, *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payment*, 88 MINN. L. REV. 712, 719 (2004); Hovenkamp, Janis & Lemley, *supra* note 69, at 1758-60; O'Rourke & Brodley, *supra* note 232, at 1786.

244. 152 CONG. REC. S6577 (daily ed. June 27, 2006) (statement by Sen. Kohl).

245. S. 3582, 109th Cong. (2006). The same act was reintroduced to the 110th Congress in both the Senate and House. S. 316, 110th Cong. (2007), H.R. 1432, 110th Cong. (2007). An even more expansive version of this Act has been introduced in the House as the Protecting Consumer Access to Generic Drugs Act of 2007. H.R. 1902, 110th Cong. (2007).

246. S. 316, 110th Cong. § 2 (2007), H.R. 1432, 110th Cong. § 2 (2007), H.R. 1902, 110th Cong. § 2 (2007).

247. See *supra* Part III.A.

248. See, e.g., Hemphill, *supra* note 229, at 1588-91; Schildkraut, *supra* note 96, at 1046-48.

possible that the acts, if enacted as currently proposed, could essentially bar all settlements of patent litigation between branded and generic manufacturers.²⁴⁹ While such a stringent per se standard decreases administrative costs and increases efficiency if the parties settle, ultimately it results in an increase in complex patent litigation. And by severely restricting the settlement option, the Acts could lead to fewer generic challenges of pharmaceutical patents.²⁵⁰ Further, it would unduly restrict the parties' ability to act in accordance with their own unique perceptions of several significant factors within the patent litigation, including: the risks involved and the willingness to accept those risks, the probabilities of litigation success or failure, knowledge of potential future competitor drugs in the market, and the individual financial status of each participant.²⁵¹

C. *The Argument in Favor of Settlements; Presumptive Legality*

Strong proponents of patent settlements, including settlements that include reverse payments, emphasize these individualized concerns in arguing in favor of presumptive legality for patent settlements.²⁵² Presumptive legality also increases efficiency and reduces administrative costs by placing a great emphasis on the presumption of patent validity, much as the Eleventh and Second Circuits did in *Schering-Plough* and *In re Tamoxifen*.²⁵³ One proposed standard borrows directly from Judge Posner's opinion in *Asahi Glass v. Pentech Pharmaceuticals, Inc.*²⁵⁴ that both circuit court opinions cited. The standard finds "a settlement . . . legitimate 'unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.'"²⁵⁵ In essence, a "reverse" quick look analysis.

249. Cf. Schildkraut, *supra* note 96, at 1067 (stating that even traditional patent settlements transfer value to the infringer through reduced damage awards and thus should be considered reverse payment settlements, and also stating that "[i]f reverse payments are to be condemned without more, we may have no patent settlements at all").

250. Cf. *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) ("A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement . . .").

251. Cf. *id.* at 992 ("[T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case.").

252. *Id.*

253. See, e.g., Schildkraut, *supra* note 96, at 1067-68.

254. 289 F. Supp. 2d 986.

255. Bernard & Tom, *supra* note 96, at 632. It should be noted, however, that Kent S. Bernard, one of the authors of the article, is the Vice President and Assistant General Counsel at Pfizer Inc. who heads the group responsible for Pfizer's antitrust matters. *Id.* at 617 n.1.

Another common denominator of both courts and commentators who favor patent settlements is a strong, traditional rule of reason application and recognition of the Intellectual Property Guidelines of the Department of Justice and the FTC.²⁵⁶ Prominent antitrust and trade regulation litigator and former Assistant Director for the Bureau of Competition at the FTC, Marc G. Schildkraut,²⁵⁷ enhances this analysis by proposing a two-tiered analysis to circumvent anticonsumer results that can flow from the application of the traditional burdens of proof to both the patent and antitrust aspects of the settlement.²⁵⁸ The traditional burdens of proof are used to determine the merits of the patent.²⁵⁹ If the antitrust plaintiff

shows that the alleged [patent] infringer would have prevailed and also establishes the other things necessary to make an antitrust violation . . . , it establishes a prima facie case against the settling parties. The burden then shifts to the [antitrust] defendant to show that the efficiency effects of the settlement outweigh the anticompetitive effects.²⁶⁰

In order to show that the infringer would prevail in the patent suit, the antitrust plaintiff must overcome the presumption of patent validity. If this were accomplished, a separate standard, such as his “uncertain competition methodology” is used to evaluate the antitrust aspects of the settlement to determine if there is a net social benefit or loss.²⁶¹ Unfortunately, as Schildkraut acknowledges, his proposed two-tiered analysis is “quite complex and suffers from several deficiencies.”²⁶² Therefore, he notes it may be preferable to simply adopt the “rule of virtual per se legality” of the Eleventh Circuit and Judge Posner’s decision in *Asahi Glass*.²⁶³

Schildkraut also makes the argument that many patent settlements, not just those taking place under the Hatch-Waxman Act, include reverse payments.²⁶⁴ The Hatch-Waxman settlements tend to receive much more attention simply because they involve large monetary payments. Schildkraut believes that conventional patent settlements may involve “implicit [reverse] payments that

256. Bernard & Tom, *supra* note 96, at 633-34; Schildkraut, *supra* note 96, at 1050-52.

257. It should also be noted that Schildkraut was part of the litigation team that represented Schering-Plough in its appeal of the FTC decision. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1057 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

258. Schildkraut, *supra* note 96, at 1055-57.

259. *Id.* at 1055-56.

260. *Id.* at 1056.

261. *Id.*

262. *Id.*

263. *Id.* at 1057.

264. *Id.* at 1067.

reduce the expected damages award” had the litigation continued.²⁶⁵ Therefore, “[i]f reverse payments are to be condemned without more, we may have no patent settlements at all.”²⁶⁶ In SchilDKraut’s opinion, given the difficulty of analyzing the antitrust aspects of patent settlements, “there is something to be said for simply declaring settlements arguably within the scope of the patent to be per se legal.”²⁶⁷ This, of course, is exactly the position of the Second and Eleventh Circuits, which the Supreme Court refused to review when it rejected certiorari of *Schering-Plough* and *In re Tamoxifen*. This approach has the benefit of only requiring a quick look at the settlement to determine if the patent rights have been expanded or not. Unfortunately, a significant drawback is that antitrust principles are accorded a corresponding diminished role in the presumptive legality approach.

D. The Middle Ground Between Presumptive/Per se Illegality and Presumptive Legality

A rule of reason antitrust analysis, or some variation on a rule of reason analysis between the quick look approach and the traditional rule of reason analysis combined with the presumption of patent validity, occupies the middle ground between this presumptive legality standard of the Second and Eleventh Circuits and the presumptive or per se illegality standard. In an attempt to minimize the over and under inclusive effects of these two extremes, many commentators attempt to devise strategies to maximize antitrust principles without unduly infringing on patent principles. This position is best voiced by Thomas F. Cotter, who writes: “[f]or antitrust law to undermine the value of valid and infringed patents, which a rule discouraging reverse payments would in some instances do, is troubling.”²⁶⁸ Primarily, this middle ground differs from the presumptive liability position in that reverse payments in excess of litigation and collateral expenses are not treated as per se illegal.²⁶⁹ Middle ground proponents distinguish themselves from presumptive legality proponents in that middle ground proponents argue that as the size of the reverse payment increases, the likelihood that the settlement is anticompetitive increases.²⁷⁰

265. *Id.*

266. *Id.*

267. *Id.* at 1068.

268. Cotter, *Refining*, *supra* note 90, at 1810.

269. *Id.* at 1802; Daniel A. Crane, Correspondence, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 703-05 (2004) [hereinafter Crane, *Ease Over Accuracy*].

270. Cotter, *Refining*, *supra* note 90, at 1814; Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 788 (2002) [hereinafter Crane, *Exit Payments*]; Kristopher L. Reed, *A Return to Reason: Antitrust Treatment of Pharmaceutical Settlements Under the Hatch-Waxman Act*, 40 GONZ. L. REV. 457, 478 (2005).

Differences appear within the middle ground as to where the burden of proof would lie however. Cotter holds to the presumptive illegality principle that shifts the burden of proof to the patent plaintiff/antitrust defendant.²⁷¹ However, he is more concerned than Hovenkamp and other presumptive liability proponents that limiting reverse payment settlements to litigation costs could “materially affect patent owners’ *ex ante* incentives by reducing the expected payoff from invention.”²⁷²

Daniel A. Crane places even greater emphasis on the patent owners’ rights and opposes the presumptive illegality of reverse payment settlements.²⁷³ As Crane writes,

[s]ound public policy must begin with a recognition of the substantial social costs on both sides of the equation — both to permitting and to prohibiting exit payments. . . .

. . . [T]he chief indicator of these competing costs is the merit of the patentee’s infringement claim. Exit payments should therefore be permitted when the patentee’s claims appear *ex ante* to have substantial merit and disallowed when they are likely to fail.²⁷⁴

Crane also agrees with presumptive legality proponents and argues that the burdens of proof should remain with the patent defendant/antitrust plaintiff.²⁷⁵

The middle ground position attempts to limit the over and under inclusiveness that is inherent in both the presumptive illegality and presumptive legality positions by requiring a more stringent analysis of the settlement and the patent and antitrust principles involved. To achieve this, however, they would incur greater administrative costs and decreased efficiency due to the requirement for a more thorough investigation of the settlement agreement and the underlying patent infringement claim.²⁷⁶

V. A Call for Supreme Court Guidance

A *per se* illegal standard avoids these administrative costs, but does not respect patent rights enough, provides too much strength to antitrust principles, and disallows pharmaceutical patent settlements that are potentially beneficial to consumers. In contrast, the presumptive legality standard set by the Second

271. Cotter, *Refining*, *supra* note 90, at 1815.

272. Cotter, *Antitrust Implications*, *supra* note 81, at 1092.

273. Crane, *Ease Over Accuracy*, *supra* note 269, at 705-06, 709; Crane, *Exit Payments*, *supra* note 270, at 757-65; *see also* Reed, *supra* note 270, at 478-79.

274. Crane, *Exit Payments*, *supra* note 270, at 797.

275. *Id.* at 709; *see also* Reed, *supra* note 270, at 478.

276. Cotter, *Antitrust Implications*, *supra* note 81, at 1093; Crane, *Exit Payments*, *supra* note 270, at 785-87; Reed, *supra* note 270, at 478.

and Eleventh Circuits, while also minimizing administrative costs and increasing efficiency, provides too much deference to the presumption of patent validity, gives too little respect to antitrust principles, and allows for pharmaceutical patent settlements that are potentially very harmful to consumers. While these shortcuts in the patent-antitrust analysis have the benefit of increasing efficiency and reducing costs, all shortcuts result in over or under inclusiveness and potential harm to consumers. It is time for the Supreme Court to take up a pharmaceutical reverse payment settlement case and provide clear guidance to the lower courts and the industry as to where the line should be drawn. While balancing the policy choices involved in maximizing efficiency and minimizing costs, the Court will need to develop an analysis geared to unique patent, antitrust, and regulatory strictures of the pharmaceutical industry.

The per se illegal standard is ill-adapted for application to reverse payment settlements in the pharmaceutical industry because it “give[s] almost no weight to the patent holder’s right to exclude”²⁷⁷ Given the enormous costs of developing new drugs, patent rights play a vital role in pharmaceutical innovation.²⁷⁸ A particularly risk adverse pharmaceutical patent holder who predicts a probability of prevailing in litigation at eighty percent may be willing to enter into a reverse payment settlement for expected litigation expenses to protect the patent rights. If the settlement also splits the remaining patent term and allows generic entry to the market a year or two prior to patent expiration, the generic manufacturer may also see this as a very favorable outcome. Even if the generic manufacturer predicts its own probability of success in litigation at forty percent, twice the expectation of the patent holder, it may favor the settlement given its own risk aversion tendencies. Even by the generic manufacturer’s more optimistic litigation expectation, it would still face a sixty percent chance of losing the infringement action and be barred from entry until patent expiration. In addition, a cash-starved generic manufacturer may be willing to accept the reverse payment settlement alone, without the patent-splitting term. Applying a per se antitrust standard to all reverse payment settlements negates the ability of the both branded and generic manufacturers to protect their rights and interests as they best see fit.

In addition, the Supreme Court is increasingly unwilling to expand the number of per se antitrust applications.²⁷⁹ In *Leegin Creative Leather Products, Inc. v. PSKS, Inc.* the Court states: “*Per se* rules may decrease administrative costs, but that is only part of the equation. Those rules can be counterproductive.

277. Schildkraut, *supra* note 96, at 1039.

278. Hemphill, *supra* note 229, at 1562-63 (noting that unlike in other industries, patents in the pharmaceutical industry are seen as necessary to recoup initial investment).

279. See ERNEST GELLHORN, WILLIAM E. KOVACIC & STEPHEN CALKINS, ANTITRUST LAW AND ECONOMICS IN A NUTSHELL 259-62 (5th ed. 2004).

They can increase the total cost of the antitrust system by prohibiting procompetitive conduct the antitrust laws should encourage.”²⁸⁰ And in *Texaco Inc. v. Dagher* the Court stated that “[p]er se liability is reserved for only those agreements that are ‘so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality.’”²⁸¹ Given that the Hatch-Waxman Act creates a unique regulatory scheme for the pharmaceutical industry, virtually all analyses of branded-generic patent settlements requires an elaborate study of the industry specific issues involved. In addition, the *Dagher* Court goes on to state that when the economic impact of the actions of the parties is not immediately obvious, the Court is reluctant to adopt a per se standard.²⁸² This is an extension of the Court’s principle that “a new per se rule is not justified until the judiciary obtains considerable rule-of-reason experience with the particular type of restraint challenged.”²⁸³ Because of the small number and disparate nature of circuit decisions in reverse payment settlement cases, it is doubtful that the Court would find enough judicial experience in the area to adopt a per se standard.

The presumptive legality standard, in essence a per se legality, should be rejected by the Court for the same reasons. The Eleventh Circuit’s decision in *Schering-Plough* highlights the consequences of courts taking short-cuts in patent-antitrust analysis when they do not have a strong judicial history to rely on. In *Schering-Plough*, the court stated that “we find that the agreements fell well within the protections of the ‘743 patent, and were therefore not illegal.”²⁸⁴ The court based this decision on the fact that the generics were granted market entry prior to patent term expiration.²⁸⁵ But the settlement agreement covered more than just the generics for which the manufacturers submitted abbreviated new drug applications. Upsher-Smith agreed not only to delay the entry of the generic in question, but also agreed not to enter the market with any other similar new generic versions as well, even if the additional generic versions would not infringe Schering-Plough’s patent.²⁸⁶ It is beyond the exclusionary scope of Schering-Plough’s patent to block future noninfringing generics,²⁸⁷ yet

280. 127 S. Ct. 2705, 2718 (2007).

281. 547 U.S. 1, 5 (2006) (quoting *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692 (1978)).

282. *Id.*

283. *Arizona v. Maricopa County Med. Soc’y*, 457 U.S. 332, 349 n.19 (1982).

284. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

285. *Id.* at 1067-68.

286. *Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (Fed. Trade Comm’n Dec. 8, 2003) (final order), *vacated*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

287. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 532-33 (D.N.J. 2004).

they gained that power through the settlement. By taking a quick look at the dates of generic entry and ignoring other factors of the settlement, the Eleventh Circuit deemed the agreement within the patent's power.

The Eleventh Circuit's approach paid too little heed to the application of antitrust principles to reverse payment settlements within the industry. As a result, this approach permits undue consumer harm by allowing patent holders to expand the scope of their patents and prevent lawful generic entry. An artificial monopoly results through decreased generic competition; exactly what concerned the FTC when they began investigating reverse payment settlements in the 1990s.

The FTC investigation ended the practice of delayed generic entry and reverse payments until the Eleventh Circuit's *Schering-Plough* decision in 2005.²⁸⁸ However, in fiscal year 2006 (which ran from October 1, 2005 to September 30, 2006), forty-five settlement agreements were filed with the FTC under the Medicare Reform Act's reporting requirements, more than double the number filed in each of the previous two years.²⁸⁹ Thirty-six of these settlements were between branded and generic manufacturers.²⁹⁰ Of the thirty-six branded-generic settlements, twenty-eight were final settlements of active patent litigation, and of those, twenty involved a restriction on generic entry to the market.²⁹¹ Fourteen of twenty settlements that restricted generic entry also included some form of reverse payment to the generic manufacturer.²⁹² *Schering-Plough* reopened the reverse payment settlement floodgates by giving the settling parties a script to follow that emphasizes the exclusionary power of the patent, whether such power truly exists or not. Unfortunately, the Eleventh Circuit's *Schering-Plough* analysis focuses on general patent and antitrust issues and does not pay adequate attention to the unique regulatory scheme that exists under the Hatch-Waxman Act and how that scheme alters the patent-antitrust landscape in the pharmaceutical industry.

While considerable commentary exists about the general patent and antitrust conditions created by the Hatch-Waxman Act in the pharmaceutical industry,²⁹³ little has been written about how this regulatory scheme alters the patent and antitrust playing field.²⁹⁴ Generic discussions of patent and antitrust principles have much less probative value when focusing specifically within the pharmaceutical industry. Several aspects of the Hatch-Waxman Act require

288. *See supra* Part II.C.

289. FTC AGREEMENTS REPORT 2006, *supra* note 2, at 1.

290. *Id.* at 2.

291. *Id.* at 2-3.

292. *Id.* at 3-4.

293. *See supra* Part IV.

294. Hemphill, *supra* note 229, offers by far the strongest commentary on this issue.

particular attention in any discussion of the patent and antitrust aspects of reverse payment settlements in the industry: the artificial nature of the patent infringement action in Hatch-Waxman litigation, the 180-day market exclusivity period gained by the paragraph IV first filer, and the legislative incentives to litigated challenges of patents within the industry.²⁹⁵

Hatch-Waxman Act patent infringement suits differ markedly from typical patent infringement suits. The Hatch-Waxman Act is designed to insure that the potentially infringing generic manufacturer has full knowledge of any patents that may be relevant and the manufacturer deliberately opts to undertake the patent challenge.²⁹⁶ By submitting the paragraph IV abbreviated new drug application, the generic manufacturer must provide notice to the patent holder and include a legal opinion as to why they will not infringe the patent or why the patent is invalid.²⁹⁷ Additionally, in a traditional patent infringement action, if the infringer were to prevail in litigation and the patent were declared invalid, all potential competitors would have immediate access to the market. Such a scenario enhances the likelihood of settlement in traditional infringement suits due to the potential for increased competition the defendant would face if they should prevail.²⁹⁸ The Hatch-Waxman mitigates this settlement incentive by providing the 180-day market exclusivity period for the ANDA paragraph IV first filer.

However, since only the paragraph IV first filer is awarded the 180-day market exclusivity period under the Hatch-Waxman Act, only the first filer has maximum incentive to challenge the branded manufacturer's patent.²⁹⁹ A settlement between the branded manufacturer and the paragraph IV first filer effectively removes the most viable patent challenger.³⁰⁰ Such a settlement would tend to negate the purpose of the Hatch-Waxman's market exclusivity provision. The market exclusivity period provides enormous benefits to the first filer, not only in the form of profits gained during the market exclusivity period, but also from the ability to establish a market presence and capture a significant market share. A settlement between a branded manufacturer and a paragraph IV first filer that allows the first filer to retain and utilize the market exclusivity period actually provides the generic manufacture with considerable additional value,³⁰¹ without the corresponding consumer benefit. As Hemphill notes, "[t]he [branded manufacturer] will accept a settlement only if the entry date is set late

295. *Id.* at 1583-92, 1612-16.

296. *Id.* at 1615.

297. *See supra* Part II.A.

298. Hemphill, *supra* note 229, at 1603.

299. *Id.* at 1583.

300. *Id.* at 1586.

301. *Id.* at 1590.

enough to compensate the innovator for the value thereby transferred to the generic firm. On average, that date leaves consumers with less benefit than they would receive through litigation.”³⁰² Such patent-splitting settlements could have similar adverse effects for consumers as settlements involving large cash reverse payments,³⁰³ although this potential seems markedly reduced with a pure patent-splitting settlement.

However, if the settlement also includes a reverse payment to the generic for further delay in generic entry, consumers suffer even greater harm. Further, by providing significant incentives to the paragraph IV first filers, one of the goals of the Hatch-Waxman Act is to increase consumer access to low cost generics through drug patent litigation, not through patent settlements.³⁰⁴ “[T]he promotion and delay of litigation are central preoccupations of the regulatory regime” of the Hatch-Waxman Act.³⁰⁵ The ease of settling pharmaceutical patent infringement claims through reverse payments seems contradictory to the purpose behind the Hatch-Waxman Act’s market exclusivity period. Just because “[r]everse payments are a natural by-product of the Hatch-Waxman process,”³⁰⁶ that does not mean they should gain presumptive legality status.³⁰⁷ As Hemphill notes, “[n]o doubt many government actions . . . make price-fixing easier. But such an action provides no necessary protective coloration to oligopolists who subsequently choose to collude.”³⁰⁸

Nevertheless, because settlements do play a significant role in patent litigation, a strict per se antitrust liability standard would have too chilling an effect on the ability of the settling parties to act in their own self interest without causing undue harm to consumers. As Cotter, Crane, Hemphill, and Schildkraut all point out, conditions exist in which a branded-generic reverse payment settlement could be beneficial to consumers.³⁰⁹ Each company’s risk aversion, calculations of the probabilities of litigation outcome, knowledge of other potential drugs that could be introduced to the market to compete, and financial standing all could come into play as settlement talks progress. However, due to the potential for anticompetitive behavior between branded and generic manufacturers, the presumptive legality standard espoused by the Eleventh and

302. *Id.*

303. *Id.*

304. *Id.* at 1614.

305. *Id.*

306. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005) (bracketed alteration in original), *cert. denied*, 126 S. Ct. 2929 (2006).

307. Hemphill, *supra* note 229, at 1577.

308. *Id.* at 1577-78.

309. Cotter, *Antitrust Implications*, *supra* note 81; Cotter, *Refining*, *supra* note 90; Crane, *Ease Over Accuracy*, *supra* note 269; Crane, *Exit Payments*, *supra* note 270; Hemphill, *supra* note 229; Schildkraut, *supra* note 96.

Second Circuits should also be rejected. The ability of branded manufacturers to settle infringement actions through massive reverse payments to protect a noninfringed or invalid patent requires a more thorough analysis of patent strength. The unique regulatory nature of the Hatch-Waxman Act creates conditions that do not lend themselves to such a simplified analysis.

Rather, the Supreme Court should adopt a standard that places the burden of proof on the pharmaceutical patent settling parties to show that the settlement agreement is within the scope of the exclusionary power of the patent and that the settlement does not unduly harm consumers. A settlement shown to place consumers in a position similar to what would have resulted from the patent litigation should withstand an antitrust challenge. This requires an inquiry into patent strengths and weaknesses and the validity of the generic manufacturer's challenge, and any statement by the settling parties as to the patent's validity should not be accorded undue deference, given the potential for the parties to be protecting an anticompetitive settlement. Attention should also be given to the effects of the settlement on the entry of competing generics to adequately assess consumer harm.

In addition, ancillary patent licensing agreements from the generic manufacturer to the branded manufacturer as part of a reverse payment settlement, as in *Schering-Plough*, should be subject to careful examination by the court. Payments that vastly exceed the value of the license should indicate anticompetitive behaviors. Further, the Court should hold that reverse payment settlements exceeding a de minimus standard, possibly twice that of potential litigation costs to account for collateral expenses, should be subject to a full patent examination in order to withstand antitrust liability and show that the settlement is not protecting an invalid or noninfringed patent.

These recommendations are true to an original intent of the Hatch-Waxman Act; facilitating generic entry through challenges to invalid or noninfringed patents. Further, they still allow patent-splitting settlement agreements with small to moderate reverse payments in which value is also conferred to the generic through early entry and the benefits of the 180-day market exclusivity period that do not result in undue consumer harm. Branded-generic settlements involving reverse payments close to expected litigation expenses should remain a viable settlement alternative in pharmaceutical patent litigation. To foreclose such settlement opportunities could result in fewer paragraph IV challenges to patents which ultimately could result in greater consumer harm. In addition, the lack of this settlement option might force the parties agreeable to settlement into the unpredictable world that is patent litigation. Also, since such settlements would be banned by the Preserve Access to Affordable Generics Act and Protecting Consumer Access to Generic Drugs Act of 2007, these acts should not be enacted. The benefits of ease of administration and theoretical reduction

of the administrative costs come at too high a price to the participants in high-stakes pharmaceutical patent litigation cases.

It is true that these recommendations waste some of the benefits of settling the patent litigation and run contrary to the general patent principles favoring settlement, but general patent principles are much less persuasive in the pharmaceutical industry given the unique regulatory scheme created by the Hatch-Waxman Act. It is likely that if the Supreme Court were to adopt such a standard, the number of large reverse payment settlements would decline dramatically as parties opt to proceed with the patent litigation or settle the matter by splitting the patent term and allowing generic entry at an earlier date. However, due to differences in the risk aversion tendencies and expectations of probable success in litigation by each party, a few moderately large reverse payment settlements could still emerge from the industry.

VI. Conclusion

The Hatch-Waxman Act provides for a unique regulatory scheme in which generic pharmaceutical manufacturers are provided significant incentives to challenge the patents of branded manufacturers. Because of these unique conditions, the potential for anticompetitive behavior between branded and generic manufacturers is greater than that found in more traditional industries. The enormous costs and profits absorbed by the pharmaceutical industry further this potential for anticompetitive behavior. Because of this risk of anticompetitive behavior, the Supreme Court needs to grant certiorari to a pharmaceutical reverse payment settlement case and provide guidance to lower courts and the industry on what would be acceptable settlement behaviors. The Supreme Court should place the burden on the settling parties to show that the settlement and any ancillary licensing agreements were within the exclusionary scope of the patent and did not violate antitrust principles. Further, the Court should require that a settlement involving a large reverse payment be subject to thorough patent examination to ensure that the settlement is not protecting an invalid or noninfringed patent. The proposed legislative solutions, the Preserve Access to Affordable Generics Act and the Protecting Consumer Access to Generic Drugs Act of 2007, should be rejected by Congress as too heavy-handed an approach to the concerns that have arisen within the pharmaceutical industry.

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