

SCHERING-PLOUGH AND IN RE TAMOXIFEN: **LAWFUL REVERSE PAYMENTS IN THE** **HATCH-WAXMAN CONTEXT**

By Jeff Thomas

In 2005, the United States spent \$2.0 trillion on health care, accounting for 16% of the country's gross domestic product.¹ Expenditures for prescription drugs alone reached \$201 billion.² The U.S. government has struggled to contain health care spending.³ Congress passed the Hatch-Waxman Amendments in 1984 to address high drug costs.⁴ The Amendments provide regulatory and financial incentives that ease access to generic versions of branded pharmaceutical drugs. The Hatch-Waxman provisions have been highly successful in this regard.⁵ When Congress passed the Amendments, generic drugs accounted for about 19% of drug prescriptions, but today they account for more than half.⁶ Generic drugs, which typically cost 30-80% less than their branded pharmaceutical equivalent, save consumers billions of dollars each year.⁷

In order to expedite the market availability of generic drugs, the Hatch-Waxman provisions encourage generic manufacturers to challenge drug patents by providing a limited period of market exclusivity to the initial generic challenger. Under these provisions, the assertion of patent in-

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1. These data are maintained by the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health & Human Services (HHS), <http://cms.hhs.gov/statistics/nhe/default.asp>.

2. *See id.*

3. *See generally* FTC & DOJ Report, *Improving Health Care: A Dose of Competition Executive Summary*, 31 J. HEALTH POL. POL'Y & L. 437 (2006).

4. Formally known as the Drug Price Competition and Patent Term Restoration Act, the legislation amends the Federal Food, Drug and Cosmetic Act. The amendments were sponsored by Representative Henry Waxman and Senator Orrin Hatch. Provisions of the Hatch-Waxman Amendments are found within titles 21, 35 and 42 of the U.S.C.

5. *See generally* FDA, Generic Competition and Drug Prices, http://www.fda.gov/cder/ogd/generic_competition.htm (last visited February 20, 2007); CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (1998) [hereinafter CBO STUDY], <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>.

6. *See* FTC, FTC GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at i (2002) [hereinafter FTC GENERIC DRUG STUDY], <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

7. *See, e.g.*, CBO STUDY, *supra* note 5, at xi (noting that consumers saved \$ 8-\$ 10 billion from generic drugs in 1994).

validity or non-infringement in a filing with the Food & Drug Administration (FDA) for approval of a generic drug forces the branded drug manufacturer to respond with an infringement suit to protect its exclusive rights to the drug. The filing is an “artificial” act of patent infringement because the generic manufacturer has yet to make any sales and does not risk damages for the patentee’s lost profits. But the branded drug manufacturer risks losing patent rights worth hundreds of millions to billions of dollars. Given the high stakes and the uncertainty of trial, branded drug manufacturers have settled litigation with their generic challengers, sometimes making payments to the generic manufacturer. Because patent litigation settlements typically entail some form of payment from the defendant to the plaintiff, payments in which money flows instead from the patentee to the alleged infringer are called “reverse payments.”

This Note discusses recent responses by government agencies and the courts to reverse payment settlements in the Hatch-Waxman context. Part I provides background on the interplay of the patent and antitrust laws, describes the statutory scheme of the Hatch-Waxman generic drug approval process, and examines two 2003 circuit court opinions that disagreed over the legal standard for judging antitrust liability for reverse payment settlements arising from Hatch-Waxman patent litigation. Part II summarizes two recent circuit court cases, *Schering-Plough Corp. v. FTC*⁸ from the Eleventh Circuit and *In re Tamoxifen Citrate Antitrust Litigation*⁹ from the Second Circuit, which held that reverse payments are not inherently unlawful but that courts should determine whether reverse payment settlements extend the patentee’s exclusionary power beyond the bounds of the patent. Part III describes how Hatch-Waxman creates incentives for reverse payments, sets forth the legal standard announced by the *Schering-Plough* and *In re Tamoxifen* courts, and analyzes the courts’ reasoning. This Part also analyzes the recent petition for certiorari by the *In re Tamoxifen* plaintiffs. Part IV concludes that the approach taken by the Second and Eleventh Circuits is appropriate for determining the legality of reverse payment settlements in the Hatch-Waxman context.

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

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

I. BACKGROUND

A. Intersection of the Patent and Antitrust Laws

1. *Patent and Antitrust Laws*

Patent law is intended to encourage innovation by granting inventors the exclusive right to their inventions for a limited term.¹⁰ Infringing acts include making, using, selling, or offering to sell the patented invention without the patentee's authorization.¹¹ In reality, a patent confers only the right to sue to exclude an alleged infringer because patent validity or infringement are uncertain until the end of litigation.¹² If the court rules in the patentee's favor, the court may enjoin the infringing acts¹³ or order the infringer to pay damages.¹⁴ A court can also award treble damages in the case of willful infringement.¹⁵ Given these powerful remedies and the uncertainty of litigation, the vast majority of patent litigation is settled without trial.¹⁶

The antitrust laws prohibit behavior which is anticompetitive or constitutes an unfair business practice, such as price-fixing, bid-rigging, geographic market allocation between competitors, and monopolistic behavior.¹⁷ The Federal Trade Commission (FTC) is empowered by the Federal Trade Commission Act and Clayton Act to investigate anticompetitive behavior including collusion, monopolization or unlawful trade restraints.¹⁸ The Antitrust Division of the Department of Justice (DOJ) cooperates with the FTC to enforce the antitrust laws.¹⁹ The FTC may request

10. U.S. CONST. art. I, § 8 ("Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").

11. 35 U.S.C. § 271(a) (2004).

12. See Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 75 (2005).

13. 35 U.S.C. § 283.

14. 35 U.S.C. § 284.

15. *Id.*

16. Lemley & Shapiro, *supra* note 12, at 75. For example, a settlement agreement might require the alleged infringer to obtain a license from the patentee.

17. See generally HERBERT HOVENKAMP, *ANTITRUST LAW* (1999 & 2004 Supp.).

18. 15 U.S.C. § 45 (2000).

19. See Federal Trade Commission Bureau of Competition, <http://www.ftc.gov/ftc/antitrust.htm>.

that parties cease anticompetitive practices, or it may sue in federal court or in an administrative proceeding.²⁰ Private parties can also bring actions against allegedly anticompetitive behavior under the Sherman Antitrust Act.²¹

Courts employ two standards to analyze potential antitrust violations: the rule of reason and *per se* illegality. Courts scrutinize all but the most egregious anticompetitive behavior under the rule of reason.²² Under this approach, courts consider a number of factors when determining whether the “questioned practice imposes an unreasonable restraint on competition.”²³ These factors include “the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.”²⁴ Under the rule of reason, the antitrust plaintiff bears the initial burden to demonstrate market power and anticompetitive effect.²⁵ If the antitrust defendant rebuts this assertion by showing a pro-competitive objective,²⁶ the burden switches back to the plaintiff to demonstrate that the restraint is unnecessary to meet this objective.²⁷

Alternately, anticompetitive behavior may be ruled unreasonable *per se* “[o]nce experience with a particular kind of [behavior] enables the Court to predict with confidence that the rule of reason will condemn it.”²⁸ Unlike the rule of reason analysis, the *per se* approach imposes a “conclusive presumption” of illegality—one that cannot be rebutted by showing lack of market power or pro-competitive effect.²⁹ If a court finds that unlawful behavior has occurred under either a rule of reason or *per se* analysis, the plaintiff must still demonstrate an “antitrust injury,” meaning an injury of the type the antitrust laws are meant to prevent, in order to state a valid claim.³⁰

20. *See id.*

21. *See* 15 U.S.C. §§ 1-2.

22. *See* State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

23. *Id.*

24. *Id.*

25. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065 (11th Cir. 2005) (citing FTC v. Ind. Fed’n of Dentists, 476 U.S. 447, 460-61 (1986)), *cert. denied*, 126 S. Ct. 2929 (2006).

26. *Id.* (citing Nat’l Soc’y of Prof’l Eng’rs v. United States, 435 U.S. 679 (1978)).

27. *Id.* (citing Bhan v. NME Hosps., Inc., 929 F.2d 1404, 1413 (9th Cir. 1991)).

28. Arizona v. Maricopa County Med. Soc., 457 U.S. 332, 344 (1982).

29. *See id.*

30. Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977).

2. *The Patent Right to Exclude and Antitrust Liability*

Because patents confer a legal right to exclusionary behavior, courts apply a different legal standard to determine antitrust liability when a patent is involved.³¹ In such cases, the patentee risks antitrust liability for behavior that extends the patentee's realm of exclusivity beyond that granted by the patent laws.³² For example, courts have imposed antitrust liability for patent misuse and "bad faith" patent enforcement. At least three forms of patent misuse potentially violate the antitrust laws: (1) "tying" the license or sale of patented articles to the purchase or licensing of unpatented articles, (2) prohibiting licensees from producing competing goods, or (3) requiring licensees to agree to licenses that extend beyond the life of the patent.³³ To determine when patent misuse has violated the antitrust laws, courts inquire whether the patentee is solely exercising his statutory patent rights.³⁴ If the answer is yes, the patentee should not face antitrust liability regardless of whether the conduct would constitute an antitrust violation in the absence of the patent.³⁵ Bad faith patent enforcement arises when a patentee attempts to enforce a patent that is almost certainly invalid.³⁶

31. Historically, the patent and antitrust laws were considered at odds because patents were perceived as limited-term lawful monopolies whereas antitrust strives to prohibit monopolistic behavior. *See, e.g.*, *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1203 (2d Cir. 1981) ("[T]he patent and antitrust laws necessarily clash."); 6 DONALD S. CHISUM, *CHISUM ON PATENTS* § 19.01 ("The third major defense [that can preclude patent enforcement] is misuse or violation of the antitrust laws."). More recently, courts and commentators have recognized that the two systems are actually focused on similar goals, which consist of "encouraging innovation, industry and competition." *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990). The law now recognizes that patents do not inherently provide monopolistic market power, but only give the holder the right to exclude others from the specific area covered by the patent. *See Lemley & Shapiro, supra* note 12; *see also* *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 126 S. Ct. 1281 (2006) (holding that a patent does not necessarily confer market power); Puneet V. Kakkar, Note, *Still Tied Up: Illinois Tool Works v. Independent Ink*, 22 *BERKELEY TECH. L.J.* 47 (2007).

32. *See U.S. v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[T]he possession of a valid patent . . . does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."). *See generally* David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 *FOOD & DRUG L.J.* 321 (2000); Herbert Hovenkamp, Mark Janus & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 *MINN. L. REV.* 1719 (2003).

33. *See* CHISUM, *supra* note 31, § 19.04.

34. *Id.*

35. *Id.*

36. *See id.* § 19.06; *see, e.g.*, *Conceptual Eng'g Assocs. Inc. v. Aelectronic Bonding Inc.*, 714 F. Supp. 1262, 1270 (D.R.I. 1989) ("[T]he plaintiff brought the patent suit in

B. The Hatch-Waxman Amendments

The goals of the Hatch-Waxman Amendments are two-fold: (1) strengthen the patent award for branded drug developers, and (2) make it easier to bring generic drugs to market, thereby benefiting consumers with cheaper drugs.³⁷ The first goal was met by extending patent duration for branded drugs to compensate for the inability to market the drug during the lengthy FDA approval process.³⁸ The second goal was accomplished by introducing an abbreviated FDA approval process for generic drugs.³⁹

Prior to passage of the Amendments, generic manufacturers were required to wait for the branded drug patent to expire before beginning development work on the patented product. Afterwards, the generic manufacturer was required to undertake full clinical trials to prove safety and efficacy. The reward for undertaking this lengthy and expensive approval process was an unpatented product facing entrenched competition from the branded drug. These barriers effectively extended the branded manufacturers' monopolies for years, sustaining high drug costs. When the Hatch-Waxman provisions were passed in 1984, 150 branded drugs whose patent protection had expired lacked a generic equivalent.⁴⁰

The Hatch-Waxman Amendments introduced the Abbreviated New Drug Application (ANDA). Under an ANDA, the generic manufacturer can rely on the safety and efficacy data used for FDA approval of the branded drug, and need only show that the generic and brand drugs are bioequivalent.⁴¹ The Hatch-Waxman provisions further created an exemp-

bad faith, knowing that the patent was invalid because he had concealed the fact that there was a co-inventor; that the plaintiff intended to monopolize the relevant market, and pursued a campaign to do just that, . . . ; and that the attempt to monopolize the market had a dangerous probability of success.”).

37. See H.R. REP. NO. 98-857, pt. 2, at 5-6 (1984).

38. See 35 U.S.C. § 156.

39. See 21 U.S.C. § 355(j) (2004).

40. Kristen E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247, 249 (2002).

41. See 21 U.S.C. § 355(j); 21 C.F.R. § 320.1(e) (2006) (defining bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study”). Note that the Hatch-Waxman Amendments address pharmaceutical but not biological therapeutics. Representative Waxman, joined by Senators Charles E. Schumer and Hillary Rodham Clinton and others, recently introduced a bill to establish an ANDA process for biologics. Access to Life-Saving Medicine Act, H.R. 6257, 109th Cong. (2d Sess. 2006); S. 4016, 109th Cong. (2d Sess. 2006). At the end of the 109th U.S. Congress, the bill was assigned to committee in both the House and the Senate.

tion so that development of drugs for FDA approval does not infringe.⁴² Thus, a generic manufacturer may begin drug development before the drug patent expires.

When filing an ANDA, a generic manufacturer must certify to the FDA that the generic drug will not infringe any patent rights on the branded drug. This certification must attest to one of the following: no patent rights exist (Paragraph I); patent rights have expired (Paragraph II); the generic will not be marketed until patent rights expire (Paragraph III); or that the generic does not infringe or that any applicable patents are invalid or unenforceable (Paragraph IV).⁴³ A party filing a Paragraph IV Certification must notify any affected patent holders of the filing.⁴⁴ The patent holders then have forty-five days to sue for infringement.⁴⁵ If no timely infringement suits are filed, the FDA may immediately approve the ANDA.⁴⁶ If a patent holder does sue for infringement, FDA approval of the generic drug is stayed for thirty months or until a district court declares the patent invalid or not infringed.⁴⁷ As an incentive for generic drug manufacturers to file a Paragraph IV Certification, the first manufacturer to file an ANDA is granted 180 days of exclusivity after the “first commercial marketing” of the generic product.⁴⁸

Congress recently amended the ANDA process to end certain abuses that were inadvertently allowed under the 1984 Hatch-Waxman Amendments. These enactments had the unintended consequences of allowing drug manufacturer to game the 30 month stay and 180-day exclusivity periods to delay the marketing of generic drugs. For example, a branded manufacturer could pay the first generic challenger to stay off the market while avoiding trigger of its 180-day exclusivity period, thereby barring other generic manufacturers from entering the market. Alternately, the

42. See 35 U.S.C. § 271(e).

43. 21 U.S.C. § 355(j)(2)(A)(vii). The regulations state [T]he applicant shall provide the patent number and certify, in its opinion and to the best of its knowledge, . . . that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the abbreviated application is submitted. The applicant shall entitle such a certification ‘Paragraph IV Certification’.

21 C.F.R. § 314.94(a)(12)(i)(A)(4)

44. 21 U.S.C. § 355(j)(2)(B)(ii).

45. *Id.* § 355(j)(5)(B)(iii).

46. *Id.*

47. *Id.* If the 30 month stay expires before the district court makes a ruling, the FDA may approve the ANDA. However, the generic manufacturer faces potential infringement penalties if the patent is ultimately upheld.

48. 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II).

branded manufacturer could pay generic challengers to settle near the end of the 30 month stay, and each future challenge would trigger another 30 month stay. Congress addressed these issues in 2003 with the Greater Access to Affordable Pharmaceuticals Act (GAAP).⁴⁹ GAAP only allows one 30 month stay and requires forfeiture of the 180-day exclusivity period under certain conditions, such as delayed market entry or decertifying a Paragraph IV challenge.⁵⁰ The 2003 amendments also charged the FTC and DOJ with reviewing settlement agreements between parties engaged in Paragraph IV litigation.⁵¹

C. Reverse Payment Settlements of ANDA Infringement Suits

Parties often settle patent litigation through an agreement for the accused infringer to make payments to the patent holder and/or license the patent in suit.⁵² However, several settlement agreements have arisen in the context of a Paragraph IV Certification that reverse the norm and feature the branded drug manufacturer making payments to the generic competitor. Such payments are called reverse payments because money is flowing from the patentee to the alleged infringer.⁵³ Reverse payment settlements in the Hatch-Waxman context appeared in the years following passage of the Amendments, several of which resulted in lawsuits alleging antitrust violations.⁵⁴ Two 2003 appellate cases grapple with these alleged violations. In *In re Cardizem CD Antitrust Litigation*, the Sixth Circuit held that a reverse payment agreement was unlawful *per se* because it was a horizontal restraint of trade.⁵⁵ On similar facts in *Valley Drug Co. v. Geneva Pharmaceuticals*, the Eleventh Circuit explicitly declined to follow the *per se* analysis of *In re Cardizem*, instead focusing on whether the set-

49. GAAP was enacted under Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and modified portions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355.

50. For further discussion of these issues, see generally Larissa Burford, *In re Cardizem & Valley Drug Co.: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform*, 19 BERKELEY TECH. L.J. 365 (2004) and Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165 (2005).

51. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-1118 (2003).

52. See generally Hovenkamp et al., *supra* note 32.

53. Reverse payments are alternately referred to as exclusionary payments, exit payments, or branded payments.

54. For discussion of a number of such cases, see M. Elaine Johnston and Matthew J. Galvin, *Antitrust Aspects of Settling Intellectual Property Litigation*, 867 PLI/PAT 159 (2006).

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

tlement agreement extended the patentee's realm of exclusivity beyond the scope of the patent.⁵⁶

1. *In re Cardizem CD Antitrust Litigation*

In re Cardizem involved a settlement agreement between Hoechst Marion Roussel, Inc. ("HMR") and Andrx Pharmaceuticals, Inc. ("Andrx") over HMR's Cardizem, a prescription drug used to treat angina and hypertension.⁵⁷ Andrx was the first manufacturer to seek approval for a generic version of the drug.⁵⁸ At the time, HMR's original patent on Cardizem had expired but the company had a patent on a time-release drug formulation.⁵⁹ Andrx filed an ANDA with Paragraph IV Certification, asserting that its generic drug would not infringe HMR's formulation patent.⁶⁰ In response, HMR sued for infringement.⁶¹ HMR and Andrx reached an agreement nine days after the FDA tentatively approved Andrx's ANDA, dependent on the outcome of the pending litigation.⁶² The settlement agreement specified that HMR pay Andrx \$40 million each year that Andrx stayed off the market.⁶³ And because Andrx retained control of Hatch-Waxman's 180-day exclusivity period, its failure to market generic Cardizem also prevented other generic manufacturers from competing with Cardizem.⁶⁴

Purchasers of Cardizem filed a class action lawsuit, alleging that HMR and Andrx's agreement violated state and federal antitrust laws.⁶⁵ The district court granted the plaintiffs' motion for summary judgment, holding that the agreement constituted a horizontal restraint of trade and a *per se* antitrust violation.⁶⁶ The court noted that the settlement agreement precluded Andrx from marketing any version of Cardizem, even those not at issue in the patent litigation, and required Andrx to block other generics by maintaining the 180-day exclusivity period.⁶⁷ The Sixth Circuit af-

56. *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1310 (11th Cir. 2003).

57. *In re Cardizem*, 332 F.3d at 901.

58. *Id.* at 902.

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.* Note that Andrx would have been forced to relinquish the exclusivity period for failure to market its product under the GAAP Amendments of 2003. *See supra* Section I.B.

65. *Id.* at 900.

66. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 685 (E.D. Mich. 2000).

67. *Id.* at 699.

firmed,⁶⁸ finding that the agreement was not a mere attempt at enforcing patent rights or settling litigation, but that the agreement “was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.”⁶⁹

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

Abbott Laboratories (“Abbott”) held a number of patents for tabular and capsular terazosin hydrochloride, a prescription drug used to treat hypertension and enlarged prostate.⁷⁰ During the mid-1990s, two generic manufacturers, Geneva Pharmaceuticals (“Geneva”) and Zenith Goldline Pharmaceuticals (“Zenith”), filed ANDAs with Paragraph IV certification to produce generic versions of the drug and Abbott sued for infringement.⁷¹ Geneva conceded that its tabular formulation infringed but asserted patent invalidity.⁷² Abbott overlooked to file a suit against Geneva for the capsular version, but began efforts to amend its complaint against Geneva when the FDA approved Geneva’s ANDA for the capsular form in 1998.⁷³ Zenith sought a declaratory judgment that its proposed generics did not infringe two Abbott patents that issued after Zenith’s ANDA filing.⁷⁴ Abbott counterclaimed for infringement.⁷⁵

In 1998, while litigation was underway, Abbott reached agreements with both generic competitors.⁷⁶ In exchange for dropping its ANDA challenge, Abbott paid Zenith \$3 million up front, \$3 million after three months, and \$6 million every three months thereafter.⁷⁷ Unlike Zenith, Geneva did not disclaim its ANDA challenge, but agreed not to market any version of the drug and not to transfer any rights under its ANDA filings, including the 180-day exclusivity periods.⁷⁸ In return, Abbott paid

68. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 896, 915 (6th Cir. 2003).

69. *Id.* at 908.

70. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1298 (11th Cir. 2003).

71. *Id.* at 1298-99.

72. *Id.* at 1299.

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.* at 1300.

77. *Id.* The payments were to continue for two years.

78. *Id.* Under the terms of the settlement agreement, Geneva agreed not to market any form of the drug—recall that the FDA approved its capsular terazosin hydrochloride—until the underlying patent litigation was resolved with a final judgment from which no appeal could be taken, including petition for certiorari to the Supreme Court.

Geneva \$4.5 million each month pending resolution of the ongoing patent litigation.⁷⁹

Valley Drug Co. and others sued Abbott, Geneva and Zenith alleging that the settlements were unlawful restraints on trade.⁸⁰ The district court granted plaintiff's motion for summary judgment, holding that the agreements were *per se* antitrust violations of the Sherman Act.⁸¹ The Eleventh Circuit reversed and remanded. It disagreed with the Sixth Circuit's reasoning in *In re Cardizem* to the extent that the Sixth Circuit appeared to find a *per se* antitrust violation "merely" because of delayed market entry by the accused infringer during ongoing patent litigation in exchange for payments.⁸² Rather, the Eleventh Circuit held that reverse payments are not unlawful *per se* but that a proper analysis must consider whether the exclusionary effect of the settlement extends beyond the scope of the patent.⁸³

On remand, the district court examined the patent's likelihood of validity under a process similar to that used in deciding a motion for a preliminary injunction.⁸⁴ The court again found a *per se* antitrust violation on the grounds that Abbott's patent was likely invalid at the time of settlement.⁸⁵ The court noted that, prior to the settlement agreement, Abbott had admitted in ongoing patent litigation that it sold the claimed product more than one year before it applied for the patent, in violation of the on-sale bar.⁸⁶

II. RECENT CASES

Two recent cases at the circuit court level further addressed the legality of reverse payment settlement agreements in the context of Hatch-Waxman. In both cases, the courts followed the approach of *Valley Drug*.

79. *Id.*

80. *See id.* at 1295-96.

81. *Id.* at 1301.

82. *Id.* at 1311 n.26. The Eleventh Circuit recognized that the Sixth Circuit had other grounds for utilizing a *per se* analysis in *In re Cardizem*, including Andrx's agreements to game the 180-day exclusivity period and refrain from selling non-infringing products.

83. *Id.*

84. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1306-07 (S.D. Fla. 2005).

85. *Id.* Abbott's patent was indeed invalidated after the settlement agreements were reached under the on-sale bar, 35 U.S.C. § 102(b). *Abbott Labs. v. Geneva Pharms.*, 182 F.3d 1315 (Fed. Cir. 1999).

86. *Terazosin*, 352 F. Supp. 2d at 1289-90.

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

Potassium chloride is a supplement taken with prescription drugs that treat high blood pressure or congestive heart disease.⁸⁷ Schering-Plough Corp. (“Schering”) manufactures and markets K-Dur 20, a time-release microencapsulated form of potassium chloride.⁸⁸ Although potassium chloride is a common substance and is not patentable, Schering held a patent for the time-released coating used to encapsulate K-Dur 20.⁸⁹

Upsher-Smith Laboratories (“Upsher”) filed an ANDA with Paragraph IV Certification for its time-released version of potassium chloride in 1995.⁹⁰ Schering timely sued, alleging that Upsher’s product infringed the patent covering K-Dur 20.⁹¹ While awaiting trial, Schering and Upsher entered settlement talks.⁹² Refusing to pay Upsher to simply withhold marketing its product, Schering proposed a compromise wherein Upsher could enter the market five years before Schering’s patent expired.⁹³ Schering also agreed to license several products from Upsher, including a time-released form of niacin, a product which Schering had previously sought to license from another competitor and valued at about \$250 million.⁹⁴ The final settlement called for Schering to pay to Upsher an upfront licensing fee of \$60 million, \$10 million in milestone payments, and royalty payments for the licensed products.⁹⁵ Ultimately, the market for time-release niacin proved disappointing and Schering never sold any of the licensed products.⁹⁶

ESI Lederle, Inc. (“ESI”) filed an ANDA with Paragraph IV Certification for generic time-release potassium chloride in 1995.⁹⁷ Schering sued ESI for infringement and the trial judge directed the parties to enter mediation.⁹⁸ Schering agreed to allow ESI to enter the market almost three years before the patent on K-Dur 20 expired, but ESI also demanded payment to

87. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

88. *Id.*

89. *Id.* at 1058. The patent, U.S. Patent No. 4,863,743 (February 19, 1986), expired on September 5, 2006.

90. *Schering-Plough*, 402 F.3d at 1058.

91. *Id.* at 1059.

92. *Id.*

93. *Id.*

94. *Id.* at 1059-60. Niacin is used to lower cholesterol but has unwanted side effects including elevation and flushing of liver enzymes.

95. *Id.* at 1060.

96. *Id.*

97. *Id.*

98. *Id.*

settle the case.⁹⁹ At the suggestion of the magistrate judge presiding over the mediation, Schering agreed to pay ESI \$5 million for attorney's fees and another \$10 million if ESI's ANDA was approved by a specified date.¹⁰⁰ Schering further agreed to license two products from ESI for \$15 million.¹⁰¹

The FTC filed an administrative complaint against Schering, Upsher and ESI alleging that the settlement agreements were unlawful restraints of trade and that Schering conspired to monopolize the market for potassium chloride supplements.¹⁰² An Administrative Law Judge (ALJ) dismissed the complaint.¹⁰³ The ALJ rejected a *per se* analysis of Schering's payments to Upsher or ESI, instead performing a rule of reason analysis that considered the scope of Schering's patent.¹⁰⁴ The FTC had shown neither that the patent was likely invalid at the time of the settlement agreements nor that Upsher or ESI would not infringe, and therefore the FTC failed to establish that generics would have been marketed sooner absent the reverse payments.¹⁰⁵ The ALJ distinguished the settlement under consideration from those in *In re Cardizem* or *Valley Drug*, on the grounds that those settlements did not settle the ongoing patent litigation or allow the generics to enter the market before patent expiration.¹⁰⁶

On appeal, the full Commission of the FTC reversed.¹⁰⁷ The Commission also applied a rule of reason standard, but, unlike the ALJ, it did not consider the possibility that the patent might be held valid.¹⁰⁸ Rather, the Commission concluded that the licenses were insufficient consideration for the payments from Schering to Upsher or ESI,¹⁰⁹ and that the payments therefore bought delayed marketing of the generics to the ultimate detriment of consumers.¹¹⁰ The Commission further prohibited exchange of any item of value from the patentee to the alleged infringer, with the ex-

99. *Id.*

100. *Id.* at 1060-61 & n.8.

101. *Id.* at 1061 n.8.

102. *Id.* at 1061.

103. *Id.*

104. *Id.*

105. *Id.*

106. Schering-Plough Corp., 2002 WL 1488085 (F.T.C. No. 9297) (June 27, 2002) (not reported).

107. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1062 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

108. *See id.* at 1064-65.

109. *Id.* at 1062.

110. *Id.*

ception of legal fees not to exceed \$2 million.¹¹¹ Schering and Upsher appealed the Commission's findings to the Eleventh Circuit.¹¹²

The Eleventh Circuit framed the issue on appeal as whether the Commission's findings were legally sufficient to establish that the agreements between Schering and Upsher/ESI amounted to an "unreasonable" restraint of trade.¹¹³ The Commission allowed the FTC to show a detrimental market effect and then required the settling parties to rebut by demonstrating procompetitive benefit.¹¹⁴ The Commission declined to address the exclusionary power of the patent, but focused only on whether Upsher or ESI would have entered the market earlier in the absence of payments from Schering.¹¹⁵ The Eleventh Circuit was clearly unimpressed with the "contradictory nature of the Commission's opinion,"¹¹⁶ stating that "the Commission grounds its decision in the untenable supposition that without a payment there would have been different settlements"¹¹⁷ and that "[i]t would seem as though the Commission clearly made its decision before it considered any contrary conclusion."¹¹⁸

Unlike the ALJ or the Commission, the Eleventh Circuit stated that it would adopt neither a *per se* nor rule of reason analysis, but reiterated the reasoning set forth in *Valley Drug*.¹¹⁹ The court stated that agreements to allocate markets are "clearly anticompetitive" unless one of the parties holds a patent, in which case the proper inquiry focuses on: "(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."¹²⁰

The court first analyzed the exclusionary power of Schering's patent on the K-Dur 20 formulation.¹²¹ The court stated that a patent is presumed valid and its holder is lawfully permitted to exclude others from practicing

111. *Id.*

112. *Id.* A plaintiff can appeal a cease and desist order from the Commission in any federal circuit court where the questioned behavior is practiced or the plaintiff resides or does business. 15 U.S.C. § 45(c) (2000).

113. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1063 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

114. *Id.*

115. *Id.* at 1066 n.15.

116. *Id.* at 1062 n.10.

117. *Id.*

118. *Id.* at 1065.

119. *Id.* at 1063-64.

120. *Id.* at 1066.

121. *Id.* at 1066-67.

the patented subject matter.¹²² No one had shown that Schering's patent was invalid, and Schering was thus within its rights to exclude infringers.¹²³ Indeed, the FTC could not prove that Upsher or ESI could have entered the market prior to the patent's expiration.¹²⁴ The Eleventh Circuit next considered the scope of the settlement agreements.¹²⁵ The court strongly disagreed with the Commission's assertion that Schering's \$60 million payment to Upsher was not made as consideration for the licensed products but rather as payment for Upsher to delay marketing generic K-Dur 20.¹²⁶ In support, the court noted that Schering estimated the net present value of just one of the licensed products at \$254 million at the time of agreement.¹²⁷ The court was no more persuaded by the Commission's deliberations over Schering's settlement with ESI,¹²⁸ noting that the FTC failed to rebut Schering's evidence that it would have won in litigation, and that the potential \$10 million payment was suggested by the federal magistrate during mediation and ended what promised to be bitter patent litigation.¹²⁹ The Eleventh Circuit concluded that "the agreements fell well within the protections of [Schering's] patent, and were therefore not illegal."¹³⁰

The FTC petitioned for certiorari. The FTC asked the Court to decide "[w]hether an agreement between a pharmaceutical patent holder and a would-be generic competitor, in which the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger's entry into the market, is an unreasonable restraint of trade."¹³¹ As characterized by the FTC, the Eleventh Circuit in *Schering-Plough* "essentially imposes a rule that a patentee is presumptively entitled to buy protection from all competition for the full patent term, even if such payments effectively augment the patent's actual exclusionary power."¹³² The Solicitor

122. *Id.* at 1066 (citing 35 U.S.C. § 282).

123. *Id.* at 1067.

124. *Id.* at 1068.

125. *Id.*

126. *Id.* at 1071 ("[W]e think [the Commission's] conclusion that [time-release niacin] was not worth \$ 60 million, and that settlement payment was to keep Upsher off the market is 'not supported by law or logic.'").

127. *Id.* at 1070.

128. *Id.* at 1071-72 ("We do not pretend to understand the Commission's profound concern with this settlement . . .").

129. *Id.* at 1072.

130. *Id.* at 1076.

131. Petition for a Writ of Certiorari at i, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2005 WL 2105243.

132. *Id.* at 12.

General and DOJ recommended that certiorari be denied.¹³³ Noting the FTC's disdain for reverse payments,¹³⁴ these parties stated that "competing considerations suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful."¹³⁵ The Supreme Court denied certiorari.¹³⁶

B. *In re Tamoxifen Citrate Antitrust Litigation*

Tamoxifen is the most widely prescribed drug to treat breast cancer.¹³⁷ In 1985, Imperial Chemical Industries, PLC ("ICI") received a patent on tamoxifen¹³⁸ and Barr Laboratories, Inc. ("Barr") filed an ANDA including a Paragraph IV Certification to produce a generic version of the drug.¹³⁹ ICI filed a timely suit for infringement.¹⁴⁰ At trial, the district court found that the patent was unenforceable for inequitable conduct.¹⁴¹ While the trial was ongoing, AstraZeneca Pharmaceuticals LP and Zeneca, Inc. ("Zeneca") acquired the tamoxifen patent.¹⁴²

In 1993, while the case was on appeal before the Federal Circuit, Zeneca and Barr entered into a settlement agreement.¹⁴³ Zeneca paid Barr \$21 million to withdraw its claims against the tamoxifen patent and agree not to market generic tamoxifen until the patent expired or was invalidated by another challenger.¹⁴⁴ The settlement also licensed Barr to sell Zeneca-manufactured tamoxifen in the U.S.¹⁴⁵ In response to the settlement agreement, the Federal Circuit agreed to vacate the district court's ruling.¹⁴⁶ As a result, Zeneca's tamoxifen patent remained valid, and Barr began selling Zeneca-manufactured tamoxifen for about five percent be-

133. Brief for the United States as Amicus Curiae at 1, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2006 WL 1358441.

134. *Id.* at 12.

135. *Id.* at 11.

136. *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006).

137. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193 (2006).

138. *Id.*

139. *Id.*

140. *Id.*

141. *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992).

142. *In re Tamoxifen*, 466 F.3d at 193.

143. *Id.*

144. *Id.*

145. *Id.*

146. *Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 1993 WL 118931, 991 F.2d 811, **1 (Fed. Cir. 1993) (unpublished).

low the price of the Zeneca-branded drug.¹⁴⁷ Zeneca later successfully defended the tamoxifen patent against three other generic competitors.¹⁴⁸

Thirty lawsuits were brought in response to the settlement agreement between Zeneca and Barr.¹⁴⁹ The consolidated class action lawsuit alleged that the settlement allowed Zeneca and Barr to: (1) revive the tamoxifen patent from the finding of unenforceability, (2) confine all manufacture of tamoxifen to a single party (Zeneca), (3) share monopoly profits, (4) avoid competition, and (5) exclude other generic manufacturers.¹⁵⁰ Plaintiffs further alleged that the Federal Circuit would have affirmed the original finding of inequitable conduct in *ICI v. Barr Labs*, which would have allowed generic tamoxifen to enter the market years earlier.

The district court granted defendants' motion to dismiss pursuant to Rule 12(b)(6).¹⁵¹ First considering whether the settlement of the patent litigation could violate antitrust law, the court noted that patents provide a legal monopoly, and only bad faith settlements that extend the monopoly beyond the bounds of the patent run afoul of the Sherman Act.¹⁵² The court held that plaintiffs had not presented facts showing that the settlement was in bad faith.¹⁵³ In contrast, Zeneca acted to protect the validity of its patent, and Barr received a license to market tamoxifen in return.¹⁵⁴ By settling their litigation, Zeneca and Barr "cleared the field" for other generic drug manufacturers to file ANDAs and challenge the patent.¹⁵⁵ The court distinguished the settlement agreement from those in *In re Car-dizem* or *Valley Drug* because those settlements prolonged litigation and thus extended the patentee's monopoly period.¹⁵⁶ In addition, Barr was required to relinquish the 180-day exclusivity period under the FDA regulations in place at the time.¹⁵⁷

147. *In re Tamoxifen*, 466 F.3d at 195 n.9.

148. *See Zeneca Ltd. v. Novopharm, Ltd.*, 1997 WL 168318, 111 F.3d 144, **1 (Fed. Cir. 1997) (unpublished); *Zeneca Ltd. v. Pharmachemie B.V.*, No. 96-12413, 2000 WL 34335805, at *15 (D. Mass. 2000) (unreported). A third generic challenger, Mylan Pharmaceuticals, agreed to be bound by the *Pharmachemie* decision. *See Tamoxifen*, 466 F.3d at 196 n.11.

149. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 127 (E.D.N.Y. 2003).

150. *Id.* at 128.

151. *Id.* at 140.

152. *Id.* at 129-130.

153. *Id.* at 136.

154. *Id.* at 133.

155. *Id.*

156. *Id.*

157. Plaintiff's alleged that Barr agreed to petition the FDA for the 180-day exclusivity period as the first to file a Paragraph IV ANDA if another challenger attempted to

The plaintiffs further argued that the agreement effectively revived an unenforceable patent to consumer detriment because generic drug manufacturers could have relied on the initial ruling to collaterally estop Zeneca from asserting its patent rights.¹⁵⁸ The court dismissed this argument on the grounds that at the time of settlement not even Barr could rely on the invalidity ruling because of the ongoing appeal.¹⁵⁹ The court also noted that the Federal Circuit may not have affirmed the finding of inequitable conduct.¹⁶⁰ Indeed, the Federal Circuit later upheld the tamoxifen patent, agreeing with a finding of no inequitable conduct.¹⁶¹

The Second Circuit affirmed the dismissal.¹⁶² The first ground for appeal was that the tamoxifen patent should have been presumed invalid when considering the complaint, based on the invalidity finding in Barr's initial lawsuit.¹⁶³ The court responded by noting that patent cases are often settled and that the court system encourages settlement.¹⁶⁴ The court worried that presuming the patent invalid would disregard the agreement between Zeneca and Barr, and thus reduce the incentive for litigating parties to settle.¹⁶⁵ The plaintiffs tried to bolster their argument by maintaining that the Federal Circuit would have upheld the initial district court's finding of inequitable conduct.¹⁶⁶ The Second Circuit was not persuaded but rather declined to guess the outcome of an untried appeal, and held that

market generic tamoxifen. *See id.* at 125. However, at the time of the Zeneca-Barr settlement in 1993, the FDA granted the 180-day exclusivity period to the first generic challenger to successfully defend a Paragraph IV certification in court. Thus, Barr lost its right to the exclusivity period by settling with Zeneca. *See id.* at 134. In 1997, the FDA's "successful defense" requirement was invalidated as conflicting with the plain language of the Hatch-Waxman Amendments. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1070-73 (D.C. Cir. 1998). In contrast, the settlements in *In re Cardizem* and *Valley Drug* were reached after 1997 and stipulated that the generics hold their 180-day exclusivity periods to block other challengers. *See supra* Section I.C. The GAAP Amendments of 2003 addressed these abuses. *See supra* Section I.B.

158. *In re Tamoxifen*, 277 F. Supp. 2d at 138.

159. *Id.* ("A complainant has not any vested right in the decree of the district court while it is subject to review.") (citing *Asselta v. 149 Madison Ave. Corp.*, 79 F. Supp. 413, 415 (S.D.N.Y. 1948)).

160. *Id.*

161. *Zeneca Ltd. v. Novopharm, Ltd.*, 1997 WL 168318, 111 F.3d 144, **1 (Fed. Cir. 1997) (unpublished).

162. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006).

163. *Id.* at 202.

164. *Id.* at 202-03.

165. *Id.* at 203.

166. *Id.* at 204.

that the plaintiffs must allege more than just settlement of an ongoing patent litigation to state a valid claim of an antitrust violation.¹⁶⁷

The plaintiffs further alleged that the reverse payment from Zeneca to Barr was “excessive,” thus demonstrating the anticompetitive nature of the settlement agreement.¹⁶⁸ Citing *Schering-Plough*, the court noted that the environment created by the Hatch-Waxman Amendments “encourages” reverse payments because the branded manufacturer faces the potential loss of its patent, whereas the generic has yet to sell any product and thus is free from paying damages.¹⁶⁹ Given this setting, the court stated that reverse payments themselves are not necessarily anticompetitive.¹⁷⁰ Rather, the court reasoned that the payments, regardless of size, are not unlawful unless they extend monopoly power beyond the scope of the patent.¹⁷¹ For example, sham payments that keep an almost certainly invalid patent alive might illegally extend the scope of the patent.¹⁷² In the present case, Zeneca was willing to litigate the patent and successfully defended it in later infringement proceedings, suggesting that the company’s belief in the validity of the tamoxifen patent was not misplaced.¹⁷³

Like the district court, the Second Circuit distinguished the Zeneca-Barr settlement agreement from those in *In re Cardizem* or *Valley Drug*. First, the settlement did not preclude the marketing of unrelated or non-infringing products.¹⁷⁴ Second, other generic drug manufacturers were free to challenge the tamoxifen patent after Barr agreed to vacate the trial court decision.¹⁷⁵ Finally, Zeneca’s licensing of tamoxifen to Barr did in fact reduce the price of tamoxifen by a few percent.¹⁷⁶

Despite a vigorous dissent from the panel opinion,¹⁷⁷ the Second Circuit denied rehearing and rehearing *en banc*.¹⁷⁸ On December 13, 2006, the class action plaintiffs filed a brief to the Supreme Court requesting cer-

167. *Id.* at 203.

168. *Id.* at 208.

169. *Id.* at 206-07.

170. *Id.* at 207.

171. *Id.* at 212-13.

172. *Id.* at 208-09.

173. *Id.* at 210-11.

174. *Id.* at 213-14.

175. *Id.* at 214-15.

176. *Id.* at 215-16.

177. Judge Pooler disagreed with the legal standard announced by the majority and believed that the case should not have been dismissed without discovery. *Id.* at 232 (Pooler, J., dissenting).

178. *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641-cv (2d Cir. Sept. 14, 2006) (unreported).

tiorari.¹⁷⁹ The question presented to the Court asked “[u]nder what circumstances is an agreement by a brand pharmaceutical manufacturer (and patent holder) to share a portion of its future profits with a generic market entrant (and alleged patent infringer), in exchange for the generic’s agreement not to market its product, a violation of the antitrust laws?”¹⁸⁰ Although the Second Circuit derived its legal standard in large part from *Valley Drug* and *Schering-Plough*,¹⁸¹ the petitioners characterized the Second Circuit’s rule as “markedly different” from those announced by both the Sixth Circuit in *In re Cardizem* and the Eleventh Circuit in *Valley Drug*, and urged the Court to resolve the alleged circuit split.¹⁸² Petitioners’ arguments are analyzed below in Section III.D.

III. ANALYSIS

A. The Hatch-Waxman Provisions Induce Reverse Payment Settlements

1. *The Hatch-Waxman Balance: Cheaper Drugs Versus Incentives for Pharmaceutical Innovation*

In the *Schering-Plough* certiorari petition, the FTC’s attack on reverse payments relied heavily on the consumer benefits of reduced drug pricing.¹⁸³ The FTC noted that eleven of the twenty top-selling prescription drugs, with annual sales close to \$25 billion, faced challenges from vari-

179. Petition for a Writ of Certiorari, *In re Tamoxifen Citrate Antitrust Litig.*, No. 06-830 (Dec. 13, 2006).

180. *Id.* at i.

181. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (“[W]e think that the question is whether the ‘exclusionary effects of the agreement’ exceed the ‘scope of the patent’s protection.’” (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006))).

182. Petition for a Writ of Certiorari at 8, *In re Tamoxifen Citrate Antitrust Litig.*, No. 06-830 (Dec. 13, 2006).

183. See Petition for a Writ of Certiorari at 1 n.1, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2005 WL 2105243. The FTC argued:

The Commission has exercised its authority to represent itself before this Court only twice previously, in the 30 years that it has had that authority. . . . The Commission takes this step now not only to seek correction of a ruling that conflicts with fundamental antitrust and administrative law principles, but because of the great urgency of the matter, in light of the billions of dollars of consumer savings on prescription drugs that the ruling below jeopardizes.

Id.; *id.* at 1 (“In light of the large number of leading drugs that are the subject of patent challenges, the economic stakes for the American consumer in this issue are staggering.”).

ous generic competitors.¹⁸⁴ Likewise, the *In re Tamoxifen* petitioners urged that “delays in generic entry, result[] in billions of dollars in overpayments for pharmaceuticals or, sadly, some consumers’ inability to afford needed medication.”¹⁸⁵ Given the importance of pharmaceutical products to consumer welfare combined with the high cost of health care, there is a strong policy argument that consumers should not be burdened by monopoly rents for drugs that are covered by invalid patents.¹⁸⁶ As an incentive for generic drug manufacturers to challenge drug patents and thereby reduce consumer drug pricing, the Hatch-Waxman Amendments have been highly successful.¹⁸⁷

However, reduced drug prices are not the only relevant policy considerations: profits realized by the branded pharmaceutical industry are used to fund the development of new drugs.¹⁸⁸ Drug development is enormously risky and expensive. Some estimate that only one in 10,000 screened compounds will receive FDA approval, and the cost of bringing a new compound to market may exceed \$1 billion.¹⁸⁹ According to Representative Waxman, “[i]t would be fine to say the consumer could get the same drug at a lower price if there were generics of the new drug. But there would not be a new drug to copy if the first company did not put in the money to develop it.”¹⁹⁰ The Hatch-Waxman Amendments attempt to maintain incentives for pharmaceutical innovation by extending the term of drug patents up to five years to compensate patent holders for the lengthy drug development and approval process.¹⁹¹

2. *The Hatch-Waxman Process Invites Reverse Payments*

In a typical patent infringement suit, the alleged infringer faces substantial risk in the form of damages.¹⁹² A court can further treble damages

184. *Id.* at 3.

185. Petition for a Writ of Certiorari at 6, *In re Tamoxifen Citrate Antitrust Litig.*, No. 06-830 (Dec. 13, 2006).

186. *Cf. Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64 (1969) (“It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.”) (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

187. FTC GENERIC DRUG STUDY, *supra* note 6, at i.

188. *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).

189. *Id.* at 623.

190. 130 CONG. REC. H9124 (daily ed. Sept 6, 1984).

191. 35 U.S.C. § 156.

192. 35 U.S.C. § 284. Lost profit damages could be enormous in the case of a drug with annual sales in the hundreds of millions or billions of dollars.

for willful infringement.¹⁹³ This risk provides a barrier to entry that deters many would-be infringers. Facing possible infringement, the patent holder must also decide whether to bring an action for litigation and risk losing its patent rights. Given the uncertainties of patent litigation,¹⁹⁴ both parties have strong incentive to settle. Settlements agreements commonly stipulate the terms of a licensing arrangement.¹⁹⁵

The Hatch-Waxman context alters this scenario because the Amendments create an artificial act of infringement when a generic manufacturer files an ANDA with Paragraph IV Certification.¹⁹⁶ At the time of filing, the generic has not sold or offered to sell any product and is not liable for lost profits. Thus, the generic challenger risks losing the costs of litigation, but might gain a 180-day exclusivity period and concomitant first mover advantage in the generic market.¹⁹⁷ On the other hand, the branded manufacturer faces litigation costs and the loss of enormously valuable patent rights, without the upside possibility of obtaining damages for lost profits. Because this scenario “redistributes the relative risk assessments” of the parties involved in this litigation, courts have noted that “reverse payments are a natural by-product of the Hatch-Waxman process.”¹⁹⁸

B. Legal Standard for Judging Reverse Payment Settlements

Although recognizing that there is something “suspicious” about reverse payments,¹⁹⁹ the Second and Eleventh Circuits declined to apply a

193. *Id.*

194. See generally John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1998).

195. See Hovenkamp et al., *supra* note 32, at 1721.

196. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2).

197. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 207 n.19 (2d Cir. 2006) (noting a strong first mover advantage in the generic drug market).

198. *In re Ciprofloxacin Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003); accord *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005) (quoting *In re Ciprofloxacin*), *cert. denied*, 126 S. Ct. 2929 (2006); *In re Tamoxifen*, 466 F.3d at 206 (quoting same). The pressure on branded drug manufacturers to keep generics off the market is further heightened by market constraints that are unique to the heavily regulated drug industry. See generally Bernard & Tom, *supra* note 188. For example, pharmacists are allowed to substitute generic drugs when filling prescriptions unless the doctor specifies otherwise. See *id.* at 624. In some settings, substitution of generic drugs is mandated by law. See *id.* It should come as no surprise that the pharmaceutical industry relies on patent protection more than any other industry. See *id.* at 623 (citing 1 FED. TRADE COMM’N, STAFF REPORT, ANTICIPATING THE 21ST CENTURY: COMPETITION IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE CH 6, 6-8 (1996), http://www.ftc.gov/opp/global/report/gc_v1.pdf).

199. *In re Tamoxifen*, 466 F.3d at 208.

per se rule or rule of reason analysis.²⁰⁰ Rather, the courts asked whether the exclusionary effects of the settlements, taken as a whole, exceed the exclusionary power of the patent.²⁰¹ This legal standard accords with the traditional approach taken when a patentee is alleged to have violated the antitrust laws. As noted in Section I.A.2, *supra*, a similar query is made to determine whether a party found guilty of patent misuse or bad faith patent enforcement has thereby violated the antitrust laws.

The legal standard announced by the Eleventh Circuit first asks whether one of the parties owns a patent, and, if so, considers “(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.”²⁰² The Second Circuit added that if the settlement was not found to exclude beyond the scope of the patent, the court should inquire “whether the underlying infringement lawsuit was ‘objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.’”²⁰³ This query accounts for “sham” litigation, in which the patent holder almost certainly knows that its patent would not survive judicial scrutiny and thus pays off potential infringers to avoid litigation.²⁰⁴ If a reverse payment settlement agreement is found to extend the patentee’s exclusivity beyond the patent’s scope, presumably the agreement constitutes a *per se* antitrust violation.²⁰⁵

200. *Schering-Plough*, 402 F.3d at 1063-64; *In re Tamoxifen*, 466 F.3d at 206, 212 n.26.

201. *Schering-Plough*, 402 F.3d at 1073-75; *In re Tamoxifen*, 466 F.3d at 212-13.

202. *Schering-Plough*, 402 F.3d at 1066.

203. *In re Tamoxifen*, 466 F.3d at 213 (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993)). In practice, this does not appear to add a new element to the standard announced in *Schering-Plough*, because that opinion explicitly noted that enforcing an almost certainly invalid patent would violate the antitrust laws, albeit by extension of exclusivity beyond the scope of the patent.

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

Schering-Plough, 402 F.3d at 1067 (quoting *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (Posner, J., sitting by designation)).

204. *In re Tamoxifen*, 466 F.3d at 208.

205. Note that precise implementation of the legal standards announced the Eleventh and Second Circuits remains uncertain because the only district court to apply the standard as of this writing is the remand in *Valley Drug*. See *infra* Section III.C.6.

C. Reverse Payments Are Not Inherently Unlawful

Drawing on the reasoning of the Second and Eleventh Circuits, several grounds exist for determining the lawfulness of a reverse payment settlement by considering whether the agreement extends the patentee's exclusivity beyond the scope of the patent.

1. A Patent is Presumed Valid

Alden F. Abbott and Suzanne T. Michel, two FTC employees writing on their own behalf, argue that the patent holder is relying on payment, not the patent, to exclude competition when reverse payments are made before the patentee has proven infringement.²⁰⁶ The authors argue that the terms of a settlement agreement reflect each party's estimated probability of the patent will be upheld, thereby demonstrating the true exclusionary power of the patent at the time of settlement.²⁰⁷ Reverse payments then shift the settlement terms in favor of the patentee—for example, by delaying the generic's market entry beyond that which the parties would agree to without reverse payments—and thus extend exclusionary power beyond the scope of the patent in violation of the antitrust laws.²⁰⁸

The Commission in *Schering-Plough* similarly reasoned that because the validity of a patent is uncertain before judicial determination, the exclusionary power of the patent is likewise unknown when considering the antitrust issues surrounding reverse payment settlements.²⁰⁹ Instead, the Commission opined that if the generic manufacturers would enter the market at an earlier date but for the reverse payments, the payments are presumptively anticompetitive.²¹⁰

In contrast, the Eleventh Circuit relied on the statutory rule that patents are presumed valid and a patentee therefore enjoys a presumptive right to exclude.²¹¹ The Second Circuit adopted similar reasoning in *In re Tamox-*

206. Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 867 PLI/PAT 387, 397-98 (2006) ("Exclusion achieved through payment rather than through the strength of the asserted patent is not within the scope of the patent.").

207. *Id.* at 402-04.

208. *Id.* at 404.

209. Petition for a Writ of Certiorari at 9, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2005 WL 2105243.

210. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1062 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The Commission allowed a single exception for reverse payments: \$2 million to cover legal fees. *Id.*

211. *Id.* at 1066.

ifen.²¹² Accordingly, the patentee may presumptively exclude during the term of the patent unless it is found invalid or unenforceable during litigation.

Courts applying this presumption should be careful to distinguish cases in which a Paragraph IV challenger certifies that the patent is invalid from cases from those in which the generic challenger certifies that it does not infringe.²¹³ When a generic manufacturer declares that its product does not infringe, the patent's validity may be irrelevant because the patent laws do not give one the right to exclude that which does not infringe. Indeed, the burden is on the patent holder to prove infringement. A settlement that excludes competitors from practicing non-infringing subject matter, regardless of the presence of reverse payments, is likely to constitute a *per se* violation of the antitrust laws by extending the patentee's exclusivity beyond the scope of the patent.²¹⁴ Thus, when the generic challenger certified that its product does not infringe, courts should perform an initial assessment of the grounds for infringement when determining whether the settlement agreement violates the antitrust laws.

2. *Reverse Payments Do Not Necessarily Connote Fears of Patent Invalidity*

The artificial Hatch-Waxman litigation environment undercuts the implication that a patentee willing to make a reverse payment fears its patent is invalid,²¹⁵ as illustrated by *In re Tamoxifen* and *In re Ciprofloxacin*. In

212. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208-09 (2d Cir. 2006) (“[T]he patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”).

213. The generic manufacturer might assert that its product does not infringe a formulation patent. For example, the generic's active compound could be identical to the branded drug, while the coating or inactive filler differ in ways that do not read on the patent claims. The *In re Tamoxifen* court noted that the patents covering a drug's active compound necessarily exclude all generic versions of the drug, whereas a formulation patent does not necessarily exclude all generic substitutes. *In re Tamoxifen*, 466 F.3d at 214; accord *In re Ciprofloxacin Antitrust Litig.*, 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003).

214. The Eleventh Circuit in *In re Tamoxifen* noted that because the tamoxifen patent covered the active drug compound, Zeneca could presumptively exclude all forms of generic tamoxifen. The court thus distinguished Zeneca's patent from the formulation patents in *In re Cardizem* and *Valley Drug*—two cases which found a *per se* antitrust violation. *In re Tamoxifen*, 466 F.3d at 214; accord *In re Ciprofloxacin*, 261 F. Supp. 2d at 249.

215. See, e.g., *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1310 (11th Cir. 2003) (“Given 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 set-

In re Tamoxifen, Zeneca entered into a reverse payment settlement with Barr after the district court held the patent unenforceable.²¹⁶ However, Zeneca subsequently litigated its patent against three other generic challengers.²¹⁷ The Second Circuit noted that if Zeneca settled with Barr for lack of faith in its patent rights, it seems unlikely Zeneca would have been willing to litigate the patent further.²¹⁸ Likewise, the branded drug manufacturer in *In re Ciprofloxacin* entered a reverse payment settlement with the first generic challenger and put \$398 million into an escrow account payable to the generic competitor should the patent in question be subsequently invalidated.²¹⁹ But the patent was later upheld on voluntary reexamination before the United States Patent & Trademark Office (USPTO), and the patentee was subsequently successful at litigation against four other generic challengers.²²⁰ Again, the patentee's willingness to enter a reverse payment settlement did not necessarily correlate with strong doubts about the patent's validity.

Moreover, the Second Circuit in *In re Tamoxifen* noted that even if reverse payments betray doubts as to a patent's strength, "we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it."²²¹ Judge Posner of the Seventh Circuit, sitting by designation in *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, pointed out that, "the 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."²²² He further noted that to hold a patentee liable for antitrust issues because of doubts about prevailing at litigation could chill almost any patent holder's willingness to bring suit to enforce the patent, because "[n]o one can be *certain* that he will prevail in a patent suit."²²³

tlement."); *In re Tamoxifen*, 466 F.3d at 210 ("Whatever the degree of the patent holder's certainty, there is always some risk of loss that the patent holder might wish to insure against by settling.").

216. *In re Tamoxifen*, 466 F.3d at 193.

217. *Id.* at 194-95.

218. *Id.* at 210-11.

219. *In re Ciprofloxacin*, 261 F. Supp. 2d at 196.

220. *Id.* at 197.

221. *In re Tamoxifen*, 466 F.3d at 210.

222. *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003) (Posner, J., sitting by designation); accord *In re Tamoxifen*, 466 F.3d at 210 (quoting *Asahi Glass*).

223. *Asahi Glass*, 289 F. Supp. 2d at 993; accord *In re Tamoxifen*, 466 F.3d at 210 (quoting *Asahi Glass*).

3. *Patent Settlements Implicitly Involve Consideration Flowing to the Alleged Infringer*

Some courts have emphasized that reverse payments constitute consideration flowing from the patentee to the infringer, but that such “reverse” consideration is actually commonplace.²²⁴ A patentee’s willingness to extend a naked license is a type of reverse payment if the patentee would not have extended the license without the risk of invalidity. Indeed, reverse consideration flows anytime the patentee settles for less than the likely damages gained from successful litigation.

A rule that condemns reverse payments solely because the defendant realizes a gain would call into question any patent litigation settlement agreement, and thus “discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation.”²²⁵ Judge Posner stated:

[A]ny settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden ‘reverse payment,’ we shall have no more patent settlements.²²⁶

Because reverse payments are a form of reverse consideration, it may not always be clear when a reverse payment has been made. For example, in *Schering-Plough*, Schering was unwilling to make direct payments to Upsher to settle the litigation but Upsher demanded a cash infusion.²²⁷ The parties compromised by Schering licensing several products from Upsher.²²⁸ Although Schering provided evidence that the \$60 million payment to Upsher was valid consideration for the licensed products, the FTC Commission discounted Schering’s business judgment and held that the license fee arrangement was a sham attempt to keep generics off the market.²²⁹ The Eleventh Circuit disagreed, stating “[t]o borrow from the

224. See *In re Ciprofloxacin*, 261 F. Supp. 2d at 252 (“[E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer.”); accord *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005) (quoting *In re Ciprofloxacin*), cert. denied, 126 S. Ct. 2929 (2006); *In re Tamoxifen*, 466 F.3d at 207 n.20 (quoting same).

225. *Schering-Plough*, 402 F.3d at 1074 (quoting *In re Ciprofloxacin*, 261 F. Supp. 2d at 252).

226. *Asahi Glass*, 289 F. Supp. 2d at 994; accord *Schering-Plough*, 402 F.3d at 1074 (quoting *Asahi Glass*); *In re Tamoxifen*, 466 F.3d at 207 n.20 (quoting same).

227. *Schering-Plough*, 402 F.3d at 1059.

228. *Id.*

229. *Id.* at 1070.

Commission's own words, we think its conclusion that [one of the licensed products] was not worth \$60 million, and that settlement payment was to keep Upsher off the market is 'not supported by law or logic.'"²³⁰

4. *Reverse Payments Can Facilitate the Settlement of Patent Litigation*

The courts in *Schering-Plough* and *In re Tamoxifen* also recognized a strong public policy towards settling litigation and noted that reverse payments can facilitate settlement.²³¹ Patent litigation is costly, time-consuming and expends both public and private resources.²³² Restricting the type of settlements that patent litigants could enter could potentially increase the number of lawsuits, thereby increasing uncertainty in the patent system and undermining the patent system's incentives to innovate.²³³ Although the Second Circuit recognized that any settlement may strengthen an otherwise "weak" patent whose validity is dubious, the court recognized that this "troubling dynamic" is always present and that settlement of patent litigation is nevertheless allowed and encouraged by the legal system.²³⁴

5. *Reverse Payments Are Neither Necessarily Exclusionary nor Anticompetitive*

Abbott and Michel refer to reverse payments as "exclusionary payments" because the patentee is paying to exclude competition. They further assert that such payments are outside the patentee's exclusionary rights and are therefore necessarily anticompetitive.²³⁵ However, Judge Posner noted that banning reverse payments could also have anticompetitive effects by reducing the options for settling patent litigation, and that a reverse payment settlement could not be more anticompetitive from a consumer viewpoint than if the patentee excludes the infringer after winning

230. *Id.*

231. See *In re Tamoxifen*, 466 F.3d at 203 (quoting *Asahi Glass*, 289 F. Supp. 2d at 991 (Posner, J., sitting by designation) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.")); accord *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). On the other hand, the Hatch-Waxman Amendments favor validity challenges. See *supra* Section I.B.

232. See Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 757-59 (2002).

233. *In re Tamoxifen*, 466 F.3d at 203 (citing *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1308 (11th Cir. 2003)); Crane, *supra* note 232, at 749.

234. *In re Tamoxifen*, 466 F.3d at 211.

235. Abbott & Michel, *supra* note 206, at 391.

at patent litigation.²³⁶ Such pro-competitive and non-exclusionary effects of reverse payment settlements are not only theoretical. In *Schering-Plough*, the settlements involved the exchange of licenses from the generic manufacturers back to the patent holder, which could increase competition in the market for the licensed products.²³⁷ Moreover, the settlements allowed both generic competitors to enter the market years before the patent expired. If the generic competitors had lost at litigation and been excluded from the market, consumers would have lost several years savings from the decreased price of time-release potassium chloride. And in *In re Tamoxifen*, the court noted that the settlement resolved the litigation, requiring Barr to relinquish the 180-day exclusivity period, and thus “cleared the field for other generic manufacturers to challenge [Zeneca’s] patent.”²³⁸

Moreover, the Second Circuit noted that reverse payment settlements are self-limiting propositions.²³⁹ Each reverse payment reduces the patent holder’s profits derived from its patent.²⁴⁰ Therefore, the number of reverse payment settlements is limited to the point at which there are no more monopoly rents.²⁴¹ Eventually, it will make more economic sense for the patent holder to litigate the patent and take its chances in court. For example, Schering recently filed suit for patent infringement against 13 companies that filed Paragraph IV Certifications to produce generic versions of the allergy medication Clarinex.²⁴² Under these circumstances such as these, it is questionable how long a branded manufacturer will continue to profit by “paying off” each successive generic challenger.

236. *Asahi Glass*, 289 F. Supp. 2d at 994 (“[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, and so might well be thought anticompetitive.”); accord *Schering-Plough*, 402 F.3d at 1075 (11th Cir. 2005) (quoting *Asahi Glass*); *In re Tamoxifen*, 466 F.3d at 206 (quoting same).

237. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).

238. *In re Tamoxifen*, 466 F.3d at 197 (quoting *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 133 (E.D.N.Y. 2003)).

239. *Id.* at 211-12.

240. *Id.* at 212.

241. *Id.*

242. See *Schering Corp. v. Zydus Pharms., USA, Inc.*, No. 3:06-CV-04715 (D.N.J. filed September 29, 2006) (listing parties sued by Schering for patent infringement in response to Paragraph IV certification filings). For a compilation of Paragraph IV certifications, see FDA, Paragraph IV Patent Certifications, <http://www.fda.gov/cder/ogd/ppiv.htm>.

6. *The Standard Announced by the Eleventh and Second Circuits Does Not Give Patent Holders Free Reign to Pay Off Generic Competitors*

In its petition to the Supreme Court in *Schering Plough*, the FTC argued that the rule announced by the Eleventh Circuit would “vitiating” the Hatch-Waxman Amendments by allowing patent holders free reign to pay off generic manufacturers.²⁴³ However, there is strong evidence that such fears are unfounded. On remand in *Valley Drug*, the district court inquired whether the plaintiff was likely to succeed at proving the patent invalid on the merits to decide whether the settlement extended beyond the scope of the patent.²⁴⁴ Using this approach, the district court judge found that the agreements were *per se* unlawful on the grounds that the patent was almost certainly invalid.²⁴⁵ The Eleventh Circuit indicated its approval of this finding in *Schering-Plough* by distinguishing the settlement at issue in that case from the settlement in *Valley Drug*, noting that the agreement in *Valley Drug* “tended to prolong that dispute to Abbott’s advantage, delaying generic entry for a longer period of time than the patent or any reasonable interpretation of the patent’s protections would have provided.”²⁴⁶

D. *In re Tamoxifen* and the Petition for Certiorari

In December 2006, the *In re Tamoxifen* plaintiffs petitioned the Supreme Court for certiorari. The petitioners urge that “review by this Court is necessary to reconcile radically conflicting standards adopted by the Courts of Appeals relative to a matter of vital importance to all Americans, i.e., the escalating cost of prescription drugs.”²⁴⁷ According to the petitioners, the Second Circuit adopted a rule limiting antitrust review of reverse payments settlements to (1) whether the infringement claim is a sham or fraud, or (2) whether the settlement is limited to the facial scope

243. See Petition for a Writ of Certiorari at 21, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2005 WL 2105243 (“The court of appeals’ approach to antitrust analysis of patent settlements in the Hatch-Waxman context will vitiate these congressional enactments.”); *id.* at 14 (“The standard the court set down gives patentees free rein to ‘buy off’ potential competitors.”); *id.* at 15 (“[I]t appears that the court below would recognize only limited exceptions to its rule that settlements within the outer, nominal bounds of patent claims are presumed lawful.”).

244. See *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1306-07 (S.D. Fla. 2005).

245. *Id.* at 1286.

246. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 n.14 (11th Cir. 2005) (quoting *In re Terazosin*, 352 F. Supp. 2d at 1309), *cert. denied*, 126 S. Ct. 2929 (2006).

247. Petition for a Writ of Certiorari at 6, *In re Tamoxifen Citrate Antitrust Litig.*, No. 06-830 (Dec. 13, 2006).

of the patent.²⁴⁸ The petitioners characterize this rule as “outside the mainstream of judicial and academic analysis” of such settlements, and “markedly different” from the rules adopted by the Sixth and Eleventh Circuits.²⁴⁹ They describe the Eleventh Circuit as having “its own test” that questions the validity of the patent at the time of the settlement before questioning the validity of the settlement itself.²⁵⁰ Finally, petitioners state that the Sixth Circuit considers reverse payment settlements *per se* illegal.²⁵¹

The petitioners fail to recognize that the Second Circuit essentially adopted the standard of the Eleventh Circuit. The Second Circuit purported to add that even if the agreement does not extend the realm of exclusivity beyond the scope of the patent, the court should inquire whether the litigation was baseless on the merits.²⁵² But this addition is largely a matter of semantics.²⁵³ The Eleventh Circuit also recognized that sham litigation violates the antitrust laws, but, in its view, such behavior extends beyond the scope of the patent.²⁵⁴ Nor is it clear whether the Sixth Circuit would consider all reverse payment settlements *per se* antitrust violations. In *In re Cardizem*, the agreement stipulated that the generic manufacturer refrain from marketing *any* generic version of Cardizem, whether alleged to infringe or not.²⁵⁵ Thus, the Sixth Circuit applied the *per se* rule in a traditional price-fixing setting wherein one party paid another to stay off the market regardless of patent rights.²⁵⁶

The practical extent of the alleged circuit split is uncertain because few cases have arisen under these standards. In *In re Cardizem* and *Valley Drug*, the settlements at issue stipulated that the generic challengers refrain from marketing any generic version of the drugs at issue, regardless of whether they were alleged to infringe.²⁵⁷ Because foreclosing the sale of

248. *Id.* at 8.

249. *Id.*

250. *Id.* The petitioners appear to overlook that the Eleventh Circuit adopted what is essentially a traditional rule used to determine whether a patentee has violated the antitrust laws. *See supra* Section III.B.

251. Petition for a Writ of Certiorari at 8, *In re Tamoxifen Citrate Antitrust Litig.*, No. 06-830 (Dec. 13, 2006).

252. *See supra* note 203.

253. *See id.*

254. *Id.*

255. *See supra* note 67 and accompanying text.

256. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908-09 & n.4 (6th Cir. 2003).

257. The *In re Tamoxifen* court further distinguished the *In re Cardizem* and *Valley Drug* settlements on other grounds. *See supra* notes 174-176 and accompanying text. In

non-infringing products blatantly extends beyond the scope of patent rights, it is likely that such agreements would be held *per se* unlawful under any circuit's legal standard. There are fewer grounds for speculating how the Sixth Circuit would have ruled in *Schering-Plough* or *In re Tamoxifen*. In *In re Cardizem*, the Sixth Circuit stated "the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation."²⁵⁸ Because the *Schering-Plough* and *In re Tamoxifen* agreements *could be*—and were—characterized as attempts to enforce valid patent rights,²⁵⁹ it is plausible the Sixth Circuit might have ruled differently given the facts of these cases.

Although it is debatable whether the Second, Sixth and Eleventh Circuits adopted "radically conflicting standards" for examining reverse payment settlements, the issue would nonetheless benefit from the Supreme Court's guidance. Since the GAAP Amendments of 2003, the FTC is charged with reviewing agreements to settle Hatch-Waxman litigation, but antitrust defendants can forum shop the circuit courts in effort to obtain a favorable ruling on appeal. Thus, the FTC cannot be certain what legal standard to apply when assessing the legality of reverse payment settlements. A legal standard promulgated by the Court would guide the FTC in directing its resources toward settlements between branded manufacturers and their generic counterparts that are likely to violate the antitrust laws. In this regard, *In re Tamoxifen* may present an appealing case for certiorari because the petitioners simply asked the Court to promulgate the proper legal standard for determining the antitrust liability of reverse payment settlements in the Hatch-Waxman context.²⁶⁰ Furthermore, this issue

addition, the patentee in *Valley Drug* had admitted to violating the on-sale bar, 35 U.S.C. § 102(b), at the time of the settlement agreement. See Section III.C.6, *supra*.

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

259. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005) ("FTC complaint counsel acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006."), *cert. denied*, 126 S. Ct. 2929 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 215 (2d Cir. 2006) ("[T]he stated terms of the Settlement Agreement include nothing that would place it beyond the legitimate exclusionary scope of Zeneca's patent . . ."). *But see id.* at 224 (Pooler, J., dissenting) ("[T]he majority has, in my view, wrongly (1) accorded dispositive deference to Zeneca's patent rights when its patent had been declared invalid at the time of the settlement; (2) focused on subsequent litigation concerning patent validity rather than the litigation posture at the time of settlement . . .").

260. See *supra* note 180 and accompanying text. In contrast, the FTC presented a loaded question to the Court in *Schering-Plough*. See *supra* note 131 and accompanying text.

is likely to continue appearing before the Court because reverse payment settlements are on the rise after a several year hiatus that commenced when the FTC started reviewing Hatch-Waxman settlement agreements.²⁶¹

Alternately, Congress may address this issue through legislation. On February 15, 2007, the Senate Judiciary Committee approved the “Preserve Access to Affordable Generics Act” for consideration by the full Senate.²⁶² This bill aims to “enhance competition in the pharmaceutical market by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market.”²⁶³ The bill would prohibit ANDA filers from “receiving anything of value” to delay marketing of generic product, with an exception allowing settlements if the consideration received by the generic manufacturer is market entry before the patent’s expiration date.²⁶⁴ Whether this bill provides optimal consumer benefit remains to be explored.²⁶⁵

IV. CONCLUSION

Due to unforeseen consequences of the originally enacted Hatch-Waxman Amendments, pharmaceutical patent holders had incentive to collude with generic challengers by paying the challengers to (1) stay off the market and (2) bar other generic competition by avoiding trigger of the 180-day exclusivity period. The 2003 GAAP amendments addressed the latter scheme—by forcing generic challengers to relinquish the exclusivity period if they fail to market their drug—but questions over reverse payments remain. Ire over reverse payment settlements is understandable giv-

261. See Prepared Statement of the Federal Trade Commission Before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: the Benefits of a Legislative Solution, at 16 (January 17, 2007), http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf (noting that reverse payments had disappeared from Hatch-Waxman settlements in the five years before the *Schering-Plough* and *In re Tamoxifen* decisions, but that at least 17 such settlements have been entered into since those opinions were announced).

262. See S. 316, 110th Cong. (1st Sess. 2007).

263. See *id.*

264. See *id.*

265. Part of the consideration given to the generic manufacturer in *In re Tamoxifen* was a license to sell the patented drug at a discount. See *supra* note 145 and accompanying text. Although the “Preserve Access to Affordable Generics Act” would apparently disallow such consideration, in some circumstances this option could be more beneficial to consumers than the exception allowed by the Act. By restraining settlement options, the bill might also upset incentives to innovate within the pharmaceutical industry. See *supra* note 233 and accompanying text.

en unethical actions of branded and generic drug manufacturers in gaming the Hatch-Waxman system. Nevertheless, several courts have noted that reverse payments are neither inherently anticompetitive nor exclusionary and are simply an extension of commonplace reverse consideration that facilitates settlement. Rather than broadly condemning reverse payments, the Eleventh and Second Circuits adopted a fairly traditional legal standard that questions whether the overall settlement agreement extends the patentee's exclusionary rights beyond the scope of the patent. In one application of this rule, the remand in *Valley Drug*, the district court answered this question in the affirmative. Thus, rather than suggesting that the Eleventh and Second Circuit vitiated Hatch-Waxman by providing patent holders free reign to pay off all competition, the courts' holdings suggest that future antitrust plaintiffs should attack the patent, not the payment.