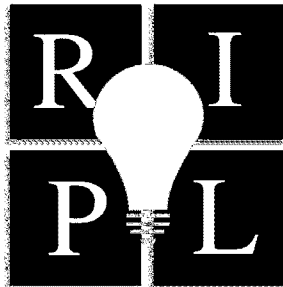


THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



THE PRESERVE ACCESS TO AFFORDABLE GENERICS ACT: WILL CONGRESS'S RESPONSE TO REVERSE PAYMENT PATENT SETTLEMENTS ENHANCE COMPETITION IN THE PHARMACEUTICAL MARKET?

REZA BAGHERIAN

ABSTRACT

In response to the Supreme Court's failure to grant writ of certiorari to *Federal Trade Commission v. Schering-Plough Corp.*, Congress proposed the Preserve Access to Affordable Generics Act to once again amend the Hatch-Waxman Act of 1984. Traditionally, the courts have used two antitrust standards, the rule of reason and the per se illegal rule, to determine whether a reverse payment patent settlement restrains trade. In *Schering-Plough*, the Eleventh Circuit articulated a third standard and held the reverse payment settlements between a pioneer drug company and two generic drug companies valid. This article proposes that traditional analysis of the rule of reason must be uniformly applied to determine the validity of reverse payment patent settlements under the antitrust laws and the proposed amendment will neither enhance competition nor benefit the public.

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THE PRESERVE ACCESS TO AFFORDABLE GENERICS ACT: WILL
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Reza Bagherian*

*The object of the patent law is to secure to inventors of what they
have actually invented or discovered, and it ought not to be defeated
by a too strict and technical adherence to the letter of the statute
or by the application of artificial rules of interpretation.*

*Justice Brown*¹

AN INTRODUCTION TO THE PROBLEM WITH REVERSE
PAYMENT PATENT SETTLEMENTS

“It takes on average 10–15 years and more than \$800 million . . . to bring a new medicine to consumers.”² Brand name or pioneer pharmaceutical companies obtain patents to protect their investment from infringing generic pharmaceutical companies.³ Article I, Section 8 of the U.S. Constitution, also known as the Copyright and Patent Clause, grants Congress the power to create laws that “promote the Progress of Science and useful Arts.”⁴ Two primary goals of the U.S. patent system are to provide incentives to invent, and to promptly disclose information to the public.⁵ In exchange for disclosure of information to the public, a

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¹ *Topliff v. Topliff*, 145 U.S. 156, 171 (1892). The *Topliff* court discussed the importance of ownership exclusivity, which patents grant to inventors of innovative technology. *Id.*

² *Paying Off Generics to Prevent Competition with Brand Name Drugs: Hearing on S. 316 Before the S. Comm. on the Judiciary*, 110th Cong. 1 (2007) [hereinafter *Tauzin Testimony*] (testimony of Billy Tauzin, CEO PhRMA); see, e.g., Joseph A. DiMasi, *New Drug Development in the United States from 1963 to 1999*, 69 CLINICAL PHARMACOLOGY & THERAPEUTICS 286, 292 (2001). Author discusses the time it takes an innovator drug company to introduce a new drug to the market. *Id.*

³ See 35 U.S.C. § 271(a) (2006). “Except as otherwise provided in this title, 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 therefore, infringes the patent.”

⁴ U.S. CONST. art. I, § 8, cl. 8. “The 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.” *Id.*

⁵ *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974) (discussing the goals of patent laws).

patent owner obtains “the right to exclude others from making, using, offering for sale, or selling the invention” for a limited period of time.⁶ Although the U.S. patent system paves the path for innovation and advancement of technology,⁷ it also raises concern over certain antitrust issues.⁸

In most cases, the patent laws are at odds with the antitrust laws.⁹ While patent laws grant limited monopolies, antitrust laws prohibit them.¹⁰ A conflict occurs between antitrust and patent laws when a pioneer drug company enters into a settlement agreement with a generic drug company to resolve a patent infringement lawsuit.¹¹ On such settlement agreement is the “reverse payment” patent settlement which involves a payment from the pioneer drug company to the generic drug company, with the promise that the generic drug company will delay its drug entry into the market.¹² The reverse payment patent settlement is a typical result of regulatory scheme that controls the pharmaceutical market.¹³

Part I of this Comment introduces the problems associated with reverse payment settlements and explains the principles of patent and antitrust laws. Part I also examines the intent behind Congress’s proposal of the Preserve Access to Affordable Generics Act (“PAAGA”). Part II analyzes federal case law, focusing on the reasoning courts use when reviewing patent infringement settlements, particularly the reverse payment settlements. Part II also analyzes the interests of the pioneer drug companies, generic drug companies, and the public. Part III proposes that the rule of reason must be established as the sole standard when addressing reverse payment settlements. Part IV concludes that the PAAGA neither enhances competition in the pharmaceutical industry nor benefits the public.

⁶ 35 U.S.C. § 154(a)(1)–(2).

⁷ *Tauzin Testimony*, *supra* note 2 (testimony of Billy Tauzin, CEO PhRMA).

⁸ *Paying Off Generics to Prevent Competition with Brand Name Drugs: Hearing on S. 316 Before the S. Comm. on the Judiciary*, 110th Cong. 1 (2007) [hereinafter *Hirsh Testimony*] (testimony of Merrill Hirsh). “The issue involves whether their settlement can take the form of a payment from the brand company to the generic in exchange for an agreement not to compete.” *Id.*

⁹ *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 386 (2d Cir. 2005). “It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal.” *Id.*

¹⁰ John Fazzino, *Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property and Antitrust Law Require a Return to the Rule of Reason*, 11 J. TECH. L. & POLY 1, 3 (2006) (noting the courts across the country realize there is a conflict between exclusionary rights of patentees and its anticompetitive effects in the pharmaceutical industry).

¹¹ *See id.*; *see also* *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1203 (2nd Cir. 1981) cert denied, 455 U.S. 1016 (1982). The court stated “the patent and antitrust laws necessarily clash.” *Id.*; *Image Technical Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1217 (9th Cir. 1997). “At the border of intellectual property monopolies and antitrust markets lies a field of dissonance yet to be harmonized by statute or the Supreme Court.” *Id.*

¹² Anne-Marie C. Yvon, *Settlements Between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments*, 75 *FORDHAM L. REV.* 1883, 1884 (2006). “[S]ettlement agreements fall into several categories, the most prevalent of which involves so-called ‘reverse payments’ from the patent holder to the alleged infringer, typically in exchange for the alleged infringer’s agreement to delay market entry of a pharmaceutical product or line of products.” *Id.*

¹³ *In re Tamoxifen*, 429 F.3d at 390–91. “[R]everse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them.” *Id.*

I. BACKGROUND: CONFLICT BETWEEN PATENT AND ANTITRUST LAWS

A. *Hatch-Waxman Act and Its Effect on the Pharmaceutical Industry*

A pharmaceutical company can market or sell a new drug in the United States only after the Food and Drug Administration (“FDA”) approves it.¹⁴ A pioneer drug company files a New Drug Application (“NDA”)¹⁵ with the FDA, submitting extensive clinical data that proves the new drug’s safety and efficacy.¹⁶ In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman Act”)¹⁷ to “make available more low cost generic drugs [and] to create a new incentive for increased expenditures for research and development of certain products, which are subject to premarket approval.”¹⁸ The Hatch-Waxman Act allows generic drug companies to use clinical studies of the pioneer drug companies without infringing the patents, thus gaining early entry into the market.¹⁹

Prior to the enactment of the Hatch-Waxman Act, the only method for a pioneer or a generic drug company to obtain FDA approval of a drug was to file the NDA.²⁰ Similar to the pioneer drug companies, the generic drug companies were required to submit safety and efficacy studies for the generic versions of the already patented drugs.²¹ In addition, if a generic drug company conducted safety and efficacy studies on a generic version of a pioneer drug before the expiration of the patent, it could be held liable under 35 U.S.C. § 271(a) for infringement.²² Therefore, Congress enacted the Hatch-Waxman Act to eliminate these barriers and make it easier for generic versions of the pioneer drugs to gain entry into the pharmaceutical market.²³

1. *The Generic Drug Approval Process*

In an Abbreviated New Drug Application (“ANDA”),²⁴ the generic drug company may use clinical data collected by the pioneer drug company to gain FDA approval.²⁵

¹⁴ 21 U.S.C. § 355(a) (2006). “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless [a new drug application or an abbreviated new drug application is approved] with respect to such drug.” *Id.*

¹⁵ 21 U.S.C. § 355(b)(1).

¹⁶ *Id.*

¹⁷ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in 21 U.S.C. § 355(j)).

¹⁸ *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (quoting H.R. REP. NO. 98-857(I), at 14 (1984), *reprinted in* 1984 U.S.C.A.N. 2647, 2647).

¹⁹ *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003) (discussing the need for enactment of the Hatch-Waxman Act in the pharmaceutical industry).

²⁰ *Id.*

²¹ *Id.*

²² 35 U.S.C. § 271 (2006); *Valley Drug Co.*, 344 F.3d at 1296.

²³ *Valley Drug Co.*, 344 F.3d at 1296.

²⁴ 21 U.S.C. § 355(j) (2006). This section of the Hatch-Waxman Act describes the method by which a generic drug company must file an abbreviated new drug application. *See id.*

²⁵ *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1059 (11th Cir. 2005). The Hatch-Waxman Act’s abbreviated new drug application process allows the generic drug companies

As part of the ANDA, the generic drug company must also certify one of four statements concerning the relevant patent(s) on the pioneer drug: (I) the information regarding the pioneer drug patent has not been filed; (II) the pioneer drug patent has expired; (III) specify the date on which the pioneer drug's patent will expire; or (IV) the pioneer drug patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.²⁶ Statement IV above is commonly known as the "Paragraph IV certification."²⁷ This Comment focuses on Paragraph IV certification because of its importance in patent infringement lawsuits filed by pioneer drug companies that lead to the controversial reverse payment settlements.²⁸

2. The ANDA Certification Process

After the FDA approval, an ANDA filer certifying under Paragraph IV certification must notify the pioneer drug company of its intent to enter the market.²⁹ If the pioneer drug company files an infringement lawsuit against the generic drug company within forty-five days after receiving the notice, then the FDA automatically institutes a thirty-month delay on the ANDA approval.³⁰ The ANDA is not approvable until: (1) a court determines that the pioneer drug company's patent is invalid; or (2) a court determines the generic drug does not infringe the pioneer patent; or (3) a thirty month time period after the date the pioneer drug company receives notice of the Paragraph IV certification.³¹

The FDA's approval of the generic drug company's ANDA creates competition for the pioneer drug company in the pharmaceutical market.³² Therefore, a reverse

to gain early entry into the pharmaceutical market. *Id.* The Hatch-Waxman Act simplifies the application process for a generic drug company and avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that its drug is bioequivalent to the already-approved pioneer drug. *Id.*

²⁶ 21 U.S.C. § 355(j)(2)(A)(vii)(I–IV).

²⁷ See *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1333 (2d Cir. 2005). "[P]ursuant to the requirements of the Hatch-Waxman Amendments, Teva filed what is termed a 'paragraph IV certification.'" *Id.*

²⁸ See *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (Dist. D.C. 2000). "A generic drug manufacturer's filing of a so-called 'Paragraph IV' certification has important legal ramifications. It automatically creates a cause of action for patent infringement." *Id.*

²⁹ 21 U.S.C. § 355(j)(2)(B); see also 21 C.F.R. § 314.52. In order to obtain approval from the FDA to engage in the commercial manufacture, use, or sale of the generic drug before the expiration of the pioneer drug company's patent, a generic drug company that files an abbreviated new drug application must send a notice stating that an application that contains data from bioavailability or bioequivalence studies has been submitted under the Act. *Id.* The application must also include a detailed statement of the factual and legal basis of the generic drug company's opinion as to why it believes that the pioneer drug company's patent is invalid or will not be infringed. *Id.*

³⁰ 21 U.S.C. § 355(j)(5)(B)(iii). Approval of the abbreviated new drug application that is filed under a Paragraph IV Certification is effective immediately, unless the patent owner of the pioneer drug brings an action for infringement of its patent within forty-five days of the receipt of the notice described in the previous endnote. *Id.* See also *Schering-Plough*, 402 F.3d at 1060.

³¹ 21 U.S.C. § 355(j)(5)(B)(iii).

³² H.R. REP. NO. 98-857(I), at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647.

payment settlement is likely to occur at the patent infringement lawsuit stage.³³ Reverse payment settlements are at odds with the antitrust laws, because of their anticompetitive qualities.³⁴

B. *Sherman Antitrust Act*

Section One of the Sherman Act states that “[e]very contract, combination . . . or conspiracy, in restraint of trade . . . , is declared to be illegal.”³⁵ Historically, only unreasonable restraints on trade have been considered anticompetitive and in violation of the Sherman Act.³⁶ In the past, the courts have used one of two methods to address reverse payment settlements: the rule of reason³⁷ and the per se illegal rule.³⁸ In *Schering-Plough Corp. v. Federal Trade Commission*,³⁹ the Eleventh Circuit Court of Appeals rejected both the rule of reason and per se illegal rule.⁴⁰

1. *Rule of Reason Approach to Antitrust Issues*

Under the rule of reason, courts consider a number of factors to determine whether an agreement concerning trade imposes an unreasonable restraint on trade. These factors may include: specific information about the relevant business; nature of the business before and after the restraint was imposed; and the restraint's history,

³³ See, e.g., *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *Schering-Plough*, 402 F.3d 1056; *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *In re Buspirone Antitrust Litig.*, 211 F.R.D. 249 (S.D.N.Y. 2002); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005).

³⁴ See *In re Tamoxifen*, 429 F.3d at 386.

³⁵ 15 U.S.C. § 1 (2006).

³⁶ See *Valley Drug*, 344 F.3d at 1303. “[I]t is understood that the ban on ‘contract[s] in restraint of trade’ means only unreasonable restraints, that is, restraints that impair competition.” *Id.* (citation omitted).

³⁷ See *Fed. Trade Comm’n v. Ind. Fed’n of Dentists*, 476 U.S. 447, 458 (1986) (noting that a restraint on trade can be held unreasonable because “it violates what has come to be known as the ‘Rule of Reason,’ under which the ‘test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition’” (quoting *Chi. Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918))).

³⁸ See *Valley Drug*, 344 F.3d at 1303. “Some types of agreements are so obviously anticompetitive, or so unlikely to be pro-competitive that such agreements can be deemed to violate the Sherman Act without much more than an examination of the agreement itself and the relationships of the parties to the agreement.” *Id.* These agreements are labeled as “per se” violations of the antitrust laws. *Id.*

³⁹ 402 F.3d 1056 (11th Cir. 2005).

⁴⁰ *Id.* at 1065. The court felt bound by its decision in *Valley Drug*, where it held that neither approaches were appropriate for an antitrust analysis of patent cases. *Id.* The court reasoned that both approaches seek to determine whether the challenged action has an anticompetitive effect on the pharmaceutical market. *Id.* This was not deemed appropriate, because it did not take into consideration the value of the pioneer drug company’s patent. See *id.*

nature, and effect.⁴¹ When applying the rule of reason, the plaintiff must first demonstrate the practice had an actual adverse effect on competition as a whole in the relevant market.⁴² The burden then shifts to the defendant to establish pro-competitive effects of the practice.⁴³ If the defendant is successful, then the burden shifts back to the plaintiff to show the same pro-competitive effect could be achieved through alternative means that are less restrictive of competition.⁴⁴ Certain courts find the anticompetitive effects of a settlement on restraint are so obvious that a lengthy rule of reason approach is not needed.⁴⁵

2. *Per Se Illegal Approach to Antitrust Issues*

A court may analyze restraints on trade as per se illegal if the type of practice involved has a “pernicious effect on competition and lacks of any redeeming virtue.”⁴⁶ The court thus presumes the illegality of certain types of practices without considering the intent behind these practices.⁴⁷

⁴¹ *Chi. Bd. of Trade*, 246 U.S. at 238. Justice Brandeis in his famous quote, which has become the most frequently cited authority on the rule of reason, stated the following:

Every agreement concerning trade, every regulation of trade, restrains. To bind, to restrain, is of their very essence. The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.

Id.

⁴² *See In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 386 (2d Cir. 2005).

⁴³ *See id.*

⁴⁴ *See id.*

⁴⁵ *See, e.g., N. Pac. R.R. Co. v. United States*, 356 U.S. 1, 5 (1958); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906 (6th Cir. 2003). There are certain restraints that are deemed per se illegal, because they have a predictable and pernicious anticompetitive effect, and a very limited potential for pro-competitive benefit on the relevant market. *Id.*

⁴⁶ *N. Pac. R.R. Co.*, 356 U.S. at 5. This court noted that certain restraints on trade are so obvious that it is not necessary to prolong the litigation and to investigate the market. *Id.*

⁴⁷ *See In re Cardizem*, 332 F.3d at 906. “The *per se* approach thus applies a ‘conclusive presumption’ of illegality to certain types of agreements, where it applies no consideration, to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint’s actual effect on competition.” *Id.* (citation omitted).

3. *The Schering-Plough Court Approach*

After rejecting both the rule of reason and the per se illegal analysis,⁴⁸ the *Schering-Plough* court stated the “ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue.”⁴⁹ The court reasoned the anticompetitive results of these settlements are simply due to ownership of the patent by one of the parties.⁵⁰ It stated that because a patent is presumed to be valid under 35 U.S.C. § 282,⁵¹ the patent grants its owner the right to exclude others from infringing upon the patented invention.⁵² Therefore, the court held that the proper analysis to determine antitrust liability is to examine: “(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.”⁵³

C. The Medicare Prescription Drug, Improvement, and Modernization Act

Congress responded to reverse payment settlements when it amended the Hatch-Waxman Act as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“The Medicare Act”),⁵⁴ which included the Access to Affordable Pharmaceuticals Act (“AAPA”).⁵⁵ The AAPA made three substantial

⁴⁸ *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1065 (11th Cir. 2005). The court decided against using either the rule of reason or the per se illegal analysis. *Id.* The Eleventh Circuit Court of Appeals in *Schering-Plough* felt bound by its decision in *Valley Drug*, where it held that neither approaches were appropriate for an antitrust analysis of patent cases. *Id.*

⁴⁹ *Id.* at 1063 (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1303–04 (11th Cir. 2003)); see also Thomas F. Cotter, *Refining the Presumptive Illegality Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1807 (2003). “[T]he plaintiff often will have an incentive to pay the defendant not to enter the market, regardless of whether the former expects to win at trial.” *Id.*

⁵⁰ *Schering-Plough*, 402 F.3d at 1065–66. The *Schering-Plough* court noted that by their very nature, patents create an environment of exclusion, and consequently, would be considered anticompetitive. *Id.* The *Schering-Plough* court held that the requirement is to analyze the extent to which the pioneer drug company’s patent prevents antitrust laws beyond the exclusionary effects of the patent. *Id.*

⁵¹ 35 U.S.C. § 282 (2006). See also *Doddridge v. Thompson*, 22 U.S. 469, 483 (1824) (holding that “[a] patent is presumed valid until the contrary is shown”); *Sure Plus Mfg. Co. v. Kobrin*, 719 F.2d 1114, 1116–17 (11th Cir. 1983). “Congress recognized the expertise of the patent office on this matter when it provided for a legal presumption in favor of patent validity for any patent issued by the patent office.” *Id.*

⁵² *Schering-Plough*, 402 F.3d at 1066. See also 35 U.S.C. § 154(a).

⁵³ *Schering-Plough*, 402 F.3d at 1066.

⁵⁴ 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 42 U.S.C. § 1395 (2006)). See also Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent*, 87 J. PAT. & TRADEMARK OFF. SOC’Y, 602, 618 (2005). “Congress recently enacted and the president signed into law on December 8, 2003, the Medicare Prescription Drug Improvement and Modernization Act, which also implements important changes clarifications to the Hatch-Waxman Act.” *Id.*

⁵⁵ 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 42 U.S.C. § 1395). See also Joel Graham, *The Legality of Hatch-Waxman Pharmaceutical Settlements: Is the Terazosin Test the Proper Prescription?*, 84 WASH. U. L. REV. 429, 437 (2006). “In response to the perceived

changes to the Hatch-Waxman Act: (1) pharmaceutical patent infringement settlements must be filed with the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”); (2) only one thirty-month stay will be approved; and (3) the 180-day exclusivity period belongs only to the first generic drug company that challenges a pioneer drug company’s patent.⁵⁶

1. Settlements Must Be Filed with FTC & DOJ

The AAPA’s first substantial amendment to the Hatch-Waxman Act requires the competing pioneer and generic drug companies that enter into settlements to file their settlement agreements with the FTC and the DOJ.⁵⁷ The FTC reviews reverse payment patent settlements in the pharmaceutical industry to ensure no antitrust problems are implicated.⁵⁸ In the event the settlement agreements violate antitrust laws, the generic drug company forfeits its 180-day exclusivity period.⁵⁹

2. The Thirty-Month Stay

The second substantial amendment modified the thirty-month delay.⁶⁰ Prior to the Medicare Act, pioneer drug companies who litigated patent infringement lawsuits could list newer patents related to the challenged patent, thereby generating successive thirty-month stays.⁶¹ The Medicare Act makes the thirty-month stay available only for patents listed prior to the ANDA submission that gave rise to the patent infringement claim.⁶² Therefore, the Medicare Act grants only one thirty-month stay.⁶³

problems with the Hatch-Waxman Act, President Bush signed into law the Access to Affordable Pharmaceuticals Act as Title XI of the Medicare Prescription Drug and Modernization Act of 2003 (Medicare Act).” *Id.*

⁵⁶ See 21 U.S.C. § 355(j)(5)(B)(iv) (2006); see also Graham, *supra* note 55, at 438–39 (discussing the changes made to the Hatch-Waxman Act, and codified at 21 U.S.C. § 355(j)).

⁵⁷ See *id.* at 439.

⁵⁸ See Barbara J. Williams, *A Presentation for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry*, 40 NEW ENG. L. REV. 1, 58 (2005). The author stated that in response to the pharmaceutical reverse payment patent settlements the FTC recommended, *inter alia*, the “FTC review . . . settlement agreements for antitrust purposes.” *Id.*

⁵⁹ 21 U.S.C. § 355(j)(5)(D)(i)(V).

⁶⁰ 21 U.S.C. § 355(j)(5)(B)(iii). See also Andrew H. Berks, *Antitrust Aspects of the “Access to Affordable Pharmaceuticals” Act: Incentives for Generics Out the Window?*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1305, 1312 (2006).

⁶¹ Berks, *supra* note 60, at 1310.

⁶² 21 U.S.C. § 355(j)(5)(B)(iii). See also Fazzio, *supra* note 10, at 14.

⁶³ 21 U.S.C. § 355(j)(5)(B)(iii). See also Berks, *supra* note 60, at 1312. The author explains that the Access to Affordable Pharmaceutical Act was enacted to modify the thirty-month stay provision to a single stay for any drug. *Id.*

3. *The 180-Day Exclusivity Period*

The third substantial amendment gives the first generic drug company a 180-day exclusivity period before the FDA can approve another ANDA.⁶⁴ This amendment encourages generic drug companies to challenge pharmaceutical patents.⁶⁵ Under the Medicare Act, the first generic drug applicant is any applicant who submits a substantially complete ANDA with Paragraph IV certification on the same day.⁶⁶ The 180-day exclusivity period begins after the date of the generic drug's first commercial marketing.⁶⁷

D. Congress Proposes the Preserve Access to Affordable Generics Act

After the Medicare Act amendments to the Hatch-Waxman Act, the FTC and other antitrust plaintiffs brought several lawsuits against pharmaceutical companies alleging antitrust violations involving reverse payment patent settlements.⁶⁸ While certain courts utilized the rule of reason,⁶⁹ other courts held the settlements to be per se illegal,⁷⁰ and the court in *Schering-Plough* applied a third analysis.⁷¹ After the *Schering-Plough* court held that the agreements between the pioneer and generic drug companies did not unreasonably restrain trade,⁷² the FTC petitioned the U.S. Supreme Court for a writ of certiorari.⁷³ The U.S. Supreme Court denied certiorari, failing to settle the uncertainty arising under the reverse payment patent settlements.⁷⁴ This uncertainty provided Congress with a reason to propose the PAAGA to further amend the Hatch-Waxman Act.⁷⁵

⁶⁴ 21 U.S.C. § 355(j)(5)(B)(iv); *see also* *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003). In *Apotex*, Circuit Judge Bryson stated “the Hatch-Waxman Act sought to strengthen the incentives for pharmaceutical development by extending the terms of certain drug patents, and by providing a 180-day period of generic market exclusivity for approved drugs during which no ANDA may be filed or approved.” *Id.* (citation omitted).

⁶⁵ *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 193 (E.D.N.Y. 2003).

⁶⁶ 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

⁶⁷ *Id.* If the abbreviated new drug application contains a Paragraph IV certification and it is for a drug for which the applicant is the first to submit the certification, then the application will be effective 180 days after the first commercial marketing of the generic drug. *Id.*

⁶⁸ *See In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 386 (2d Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1303 (2003); *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1065 (11th Cir. 2005); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906 (6th Cir. 2003); *In re Buspirone Antitrust Litig.*, 211 F.R.D. 249 (S.D.N.Y. 2002); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005).

⁶⁹ *See, e.g., In re Tamoxifen*, 429 F.3d at 405 (affirming judgment of the district court, and agreeing that a per se illegal approach was inappropriate, thereby, using the rule of reason analysis); *Valley Drug*, 344 F.3d at 1313.

⁷⁰ *See, e.g., In re Cardizem*, 332 F.3d at 915.

⁷¹ *Schering-Plough*, 402 F.3d at 1068.

⁷² *Id.* at 1076.

⁷³ *Petition for Writ of Certiorari, Fed. Trade Comm'n v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273).

⁷⁴ *Fed. Trade Comm'n*, 126 S. Ct. 2929.

⁷⁵ *See* The Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007).

On January 17, 2007, a number of Senators introduced the PAAGA to prohibit a pioneer drug company from paying a generic drug company in order to delay the generic drug's entry into the pharmaceutical market.⁷⁶ The proposed law makes it unlawful for a pioneer drug company and a generic drug company to enter into a monetary agreement prohibiting the generic drug company from entering the drug market prior to the patent life.⁷⁷ The proposed law allows settlements only where the patentee enters into an agreement with a generic drug company allowing an ANDA filer to enter the market prior to expiration of the patent term.⁷⁸ Part II of this Comment analyzes the three categories of antitrust standards courts use in addressing reverse payment patent settlements.⁷⁹

II. ANALYSIS

A. *Standard of Review for Patent Settlements*

The Second Circuit Court of Appeals used the rule of reason standard in at least two antitrust cases involving reverse payment patent settlements.⁸⁰ The Sixth Circuit Court of Appeals used the per se illegal rule to strike down a reverse payment patent settlement.⁸¹ The Eleventh Circuit Court of Appeals rejected both standards, and applied a three-prong test in three lawsuits involving reverse payment patent settlements.⁸² Many experienced judges and commentators, as well as pioneer and

⁷⁶ *Id.* § 3.

⁷⁷ *Id.* The Preserve Access to Affordable Generics Act made it illegal for anyone to be a party of a settlement agreement resolving a patent infringement lawsuit over a patented drug in the pharmaceutical industry, where "(1) an ANDA filer receives anything of value; and (2) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time." *Id.*

⁷⁸ *Id.* The Preserve Access to Affordable Generics Act does not apply to a settlement agreement of a patent infringement lawsuit, where the value paid by the pioneer drug company to the generic drug company gives the generic drug company the right to enter the pharmaceutical market earlier than the expiration of the pioneer patent. *Id.*

⁷⁹ *See* *Chi. Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918). The court recognized that a reverse payment patent settlement is a specific type of restraint that can be ruled unreasonable either because it is per se illegal, or because it violates the rule of reason analysis, under which the test of legality is "whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." *Id.*; *see also* *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1064–65 (11th Cir. 2005).

⁸⁰ *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 520 (E.D.N.Y. 2005).

⁸¹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). The Court of Appeals for the Sixth Circuit held the agreement between pioneer drug company (HMR) and generic drug companies (Andrx) was a per se illegal restraint of trade in violation of the Sherman Act, because the anticompetitive effect in the pharmaceutical market is obvious and transparent. *Id.*

⁸² *Schering-Plough*, 402 F.3d at 1065. To prevail on a claim that a patent infringement settlement agreement violates the antitrust laws, a plaintiff must prove "(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" in the relevant market. *Id.* at 1066; *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (2003); *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227, 1235 (11th Cir. 2005).

generic drug companies have hailed the rule of reason as the prevailing standard in analyzing reverse payment settlements of patent infringement disputes.⁸³

1. *The Rule of Reason Approach*

In December 1985, Barr Laboratories, Inc. (“Barr”) filed a Paragraph IV certification with the FDA to market its generic version of Tamoxifen, a breast-cancer drug.⁸⁴ Imperial Chemical Industries, PLC (“ICI”), the Tamoxifen patent holder, sued Barr within forty-five days of receiving the notice for patent infringement.⁸⁵ The lawsuit triggered the thirty-month stay, which meant that Barr could not market its drug until expiration of the stay or until a court judgment held that Barr’s generic drug did not infringe ICI’s patent, or that ICI’s patent was invalid.⁸⁶ On April 20, 1992, ICI’s patent was held invalid because it wrongfully withheld relevant material from the U.S. Patent and Trademark Office.⁸⁷ ICI appealed the determination to the Court of Appeals for the Federal Circuit.⁸⁸ In 1993, Zeneca, Inc. acquired the Tamoxifen patent from its predecessor, ICI.⁸⁹ The patent would not expire until August 20, 2002.⁹⁰ While the appeal was pending, Zeneca and Barr entered into a settlement agreement that included a reverse payment of \$21 million and a license from Zeneca to Barr to sell a generic version of Tamoxifen.⁹¹

Consumers, providers of medical benefits, and consumer advocacy groups (collectively “Plaintiffs”) brought over thirty actions in multiple districts against the patent owners of Tamoxifen and the maker of the generic version of the drug (collectively “Defendants”), challenging the validity of the settlement agreement.⁹² The suits were consolidated, and collectively the Plaintiffs claimed, *inter alia*, the agreement enabled Zeneca and Barr to reuse a patent that the district court had already held invalid, and allowed Zeneca to continue its monopolization of the market for Tamoxifen.⁹³

The district court in *In re Tamoxifen* held the Plaintiffs failed to state a claim upon which relief can be granted as required under § 12(b)(6) of the Federal Rules of Civil Procedure,⁹⁴ and the Plaintiffs appealed.⁹⁵ The Second Circuit took the case on

⁸³ *E.g.*, *In re Tamoxifen*, 429 F.3d at 370 (J. Sack); *Chi. Bd. of Trade*, 246 U.S. at 238 (J. Brandeis); *In re Ciprofloxacin*, 363 F. Supp. 2d 514, 520 (E.D.N.Y. 2005) (J. Trager); *Schering-Plough*, 402 F.3d at 1065 (J. Fay); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (J. Posner).

⁸⁴ *See In re Tamoxifen*, 429 F.3d at 377.

⁸⁵ *Id.* *See also* *Imperial Chem. Indus., v. Barr Labs., Inc.*, 126 F.R.D. 467, 469 (S.D.N.Y. 1989), *vacated*, 991 F.2d 811 (Fed. Cir. 1993).

⁸⁶ *In re Tamoxifen*, 429 F.3d at 377.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.* (Zeneca, Inc., AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca PLC (collectively “Zeneca”).

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.* at 380.

⁹³ *Id.*

⁹⁴ *Id.* at 374.

appeal, and affirmed the district court.⁹⁶ The Second Circuit held the test should be whether the exclusionary effects of the agreement exceeded the scope of the patent's protection.⁹⁷ Similar to the district court's holding in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,⁹⁸ the Second Circuit refused to consider the likelihood of the patentee's success at trial to defend its patent.⁹⁹ Unlike the Sixth Circuit Court of Appeal's use of the per se illegal standard, the court here declined to consider the amount of money involved in the reverse payment as the only determining factor.¹⁰⁰

2. The Per Se Illegal Approach

The Sixth Circuit Court of Appeals used the per se illegal standard in the *In re Cardizem CD Antitrust Litigation*¹⁰¹ case to determine the legality of reverse payment patent settlements.¹⁰² The plaintiffs, who were direct and indirect purchasers of a heart medication called Cardizem CD, filed complaints against the patent owner of the drug and the potential generic maker of the drug.¹⁰³ The plaintiffs challenged the agreement between the pioneer drug company, Hoechst Marion Roussel, Inc. ("HMR") and the generic drug company, Andrx Pharmaceuticals, Inc. ("Andrx") as a violation of federal and state antitrust laws.¹⁰⁴

In 1992, HMR began marketing Cardizem CD, with an active ingredient diltiazem hydrochloride, which is used to treat chronic chest pains, lower high blood pressure, and prevent heart attacks and strokes.¹⁰⁵ On December 30, 1995, Andrx filed a Paragraph IV certification for a generic version of Cardizem CD using diltiazem hydrochloride as its active ingredient.¹⁰⁶ Andrx was the first generic drug

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.* at 398. The court distinguished this case from the *In re Ciprofloxacin* and the *In re Cardizem* cases, where the patents at issue were formulating patents in the patents only covered specific formulations or delivery methods of compounds. *Id.* Zeneca's patent is a "patent on a compound that, by its nature, excludes all generic versions of the drug." *Id.*

⁹⁸ 363 F. Supp. 2d 548. The Eastern District of New York applied the rule of reason analysis to determine whether the settlement agreement between the pioneer drug company and the generic drug company was an unreasonable restraint on trade. *Id.* The court stated that the first element of antitrust law that the plaintiffs must prove is that "the challenged agreements had an actual adverse effect on competition in the relevant market." *Id.* The court held that plaintiffs did not provide sufficient evidence to show that the anticompetitive effects of the settlement agreement in the pharmaceutical market for ciprofloxacin were beyond the scope of the patent. *Id.* The district court noted that a "patent allows a zone of exclusion within the bounds of its claims, and that zone is undiminished by any potential invalidity of the claims." *Id.*

⁹⁹ *In re Tamoxifen*, 429 F.3d at 387.

¹⁰⁰ *Id.* at 388.

¹⁰¹ 332 F.3d 896 (6th Cir. 2003).

¹⁰² *Id.* at 915.

¹⁰³ *Id.* at 899. Purchasers and users of a heart medication called diltiazem hydrochloride brought action against the manufacturer of the patented drug and manufacturer of the generic version of the same drug under the Sherman Act and state antitrust and consumer protection statutes. *Id.*

¹⁰⁴ *Id.* at 900.

¹⁰⁵ *Id.* at 901.

¹⁰⁶ *Id.* at 902.

company to file an ANDA, which entitled it to the 180-day exclusivity period.¹⁰⁷ In January 1996, HMR filed an infringement lawsuit against Andrx triggering the thirty-month stay.¹⁰⁸

On September 15, 1997, the FDA approved Andrx's ANDA, which allowed it to enter the pharmaceutical market.¹⁰⁹ On September 24, 1997, HMR and Andrx entered into a settlement agreement, where Andrx agreed not to market its generic drug until either: Andrx obtaining a favorable, final and unappealable determination in the infringement case; HMR and Andrx entering into a license agreement; or HMR entering into a license agreement with a third party.¹¹⁰ In addition, Andrx agreed not to exercise its 180-day exclusivity period.¹¹¹ In exchange, HMR agreed to pay Andrx quarterly payments of \$40 million per year.¹¹²

The Sixth Circuit Court of Appeals held the reverse payment patent settlement between HMR and Andrx per se illegal and in violation of the Sherman Antitrust Act.¹¹³ The court considered the rule of reason standard, but decided that per se treatment of the settlement agreement was the appropriate test.¹¹⁴ The court held a per se treatment of a restraint on trade is appropriate where experience with a certain practice of restraint enables the court to predict that the rule of reason will condemn it.¹¹⁵ Therefore, in effect, the Sixth Circuit implied that the result of applying the per se illegal rule to this reverse payment patent settlement would have been the same as applying the rule of reason analysis.¹¹⁶

3. *The Schering-Plough Court Approach*

Schering-Plough is the pioneer drug company that markets K-Dur 20, an extended-release micro-encapsulated potassium chloride product.¹¹⁷ K-Dur 20 is a supplement generally taken in conjunction with prescription medicines for the treatment of high blood pressure or congestive heart disease.¹¹⁸ It is important to note that potassium chloride, which is the active ingredient in K-Dur 20, is commonly used and not patentable.¹¹⁹ Schering-Plough owns a patent on the extended-release coating, which surrounds the potassium chloride in K-Dur 20.¹²⁰ The expiration date of the patent was September 5, 2006.¹²¹

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.* at 900.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 906.

¹¹⁷ *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1058 (11th Cir. 2005).

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

In 1995, Upsher-Smith Laboratories (“Upsher”) sought FDA approval to market a generic version of K-Dur 20.¹²² Schering-Plough sued Upsher for patent infringement.¹²³ In 1997, prior to trial, Schering-Plough and Upsher entered into settlement, where Schering-Plough agreed to pay a substantial amount of money in royalty fees.¹²⁴ Schering-Plough also agreed to license Upsher’s cholesterol-lowering drug.¹²⁵

In 1995, ESI Lederle, Inc. (“ESI”), another generic drug company, sought FDA approval to market its generic version of K-Dur 20 called Micro-K 20.¹²⁶ Schering-Plough sued ESI for infringing its K-Dur 20 patent.¹²⁷ In December 1997, Schering-Plough offered to divide the remaining patent life with ESI, and allow ESI to enter the market on January 1, 2004.¹²⁸ ESI accepted this offer, but demanded on receiving monetary payment to settle the case.¹²⁹ At Judge Rueter’s suggestion, Schering-Plough agreed to pay ESI up to \$10 million if ESI received FDA approval for its Micro-K 20.¹³⁰ The FTC challenged both settlement agreements, and brought lawsuits against Schering-Plough, Upsher, and ESI for violating the antitrust laws.¹³¹

In *Schering-Plough*, the Eleventh Circuit Court of Appeals rejected both the rule of reason and the per se illegal analysis.¹³² The court stated the “ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue.”¹³³ The court reasoned the anticompetitive results of these settlements are simply due to ownership of the patent by one of the parties.¹³⁴ The Eleventh Circuit reasoned because a patent is presumed valid under 35 U.S.C. § 282,¹³⁵ a “patent grants its owner the right to exclude others” from infringing upon the patented invention.¹³⁶ The Schering-Plough patent gave its owner the right to exclude others from entering the drug market until September 5, 2006.¹³⁷

¹²² *Id.*

¹²³ *Id.* at 1059.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.* at 1060.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.* at 1061.

¹³² *Id.* at 1065.

¹³³ *Id.* at 1063 (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1303–04 (11th Cir. 2003)).

¹³⁴ *Id.* at 1065–66. The *Schering-Plough* court noted that by their very nature, patents create an environment of exclusion, and consequently would be considered anticompetitive. *Id.* The requirement is to analyze the extent to which the pioneer drug company’s patent prevents antitrust laws beyond the exclusionary effects of the patent. *Id.*

¹³⁵ *Id.*; see also *Doddridge v. Thompson*, 22 U.S. 469, 483 (1824). The Court held “a patent is presumed valid until the contrary is shown.” *Id.*; see also *Sure Plus Mfg. Co. v. Kobrin*, 719 F.2d 1114, 1117 (11th Cir. 1983). “Congress recognized the expertise of the patent office on this matter when it provided for a legal presumption in favor of patent validity for any patent issued by the patent office.” *Id.*

¹³⁶ *Schering-Plough*, 402 F.3d at 1066 (quoting *Valley Drug Co.*, 344 F.3d at 1303–04).

¹³⁷ *Id.* at 1067. In 1986, Schering-Plough received approval from the FDA to sell its K-Dur 20 tablets. *Id.*

In the first settlement agreement between the companies, Schering-Plough licensed Usher to sell its patented product more than five years before expiration of its patent.¹³⁸ In the second settlement agreement, Schering-Plough granted ESI a license to enter the drug market more than two years before its patent expiration.¹³⁹ The FTC was unable to prove the generic drug companies, Upsher and ESI, could have entered the market prior to the expiration of the Schering-Plough patent.¹⁴⁰ The court found this to be persuasive of the validity and strength of the Schering-Plough patent.¹⁴¹

Although the FTC argued and complained that these settlements were Schering-Plough's attempts to preserve its monopoly in the pharmaceutical market, the FTC made no allegation that the Schering-Plough patent was invalid.¹⁴² The Eleventh Circuit held that the FTC had to show these settlements restricted competition beyond the exclusionary effect of the Schering-Plough patent.¹⁴³ Here, the settlement agreements did not go beyond the exclusionary effect of the patent and both generic drug challengers received opportunity to enter the market before expiration of the Schering-Plough patent.¹⁴⁴ Therefore, the settlement agreements did not exceed the scope of the patent's exclusionary potential.¹⁴⁵ The Eleventh Circuit held that the settlements were not in violation of antitrust laws.¹⁴⁶

4. *The Interests Involved in Reverse Payment Patent Settlements*

Pharmaceutical patent settlements, which result from Hatch-Waxman amendments, touch on the interests of the public as well as the generic and pioneer drug companies.¹⁴⁷ The public has an interest in the availability of generic drugs.¹⁴⁸

¹³⁸ *Id.* at 1067–68.

¹³⁹ *Id.* at 1068.

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.* The court determined that without any evidence provided by the Commission to the contrary, there is a presumption that Schering-Plough's patent is valid. *Id.* The patent gives Schering-Plough the ability to exclude anyone that tries to infringe upon its patented product. *Id.* Therefore, the court held that the proper analysis that should be applied must consider whether there is substantial evidence provided by the Commission to support its conclusion that the challenged settlement agreements between the pioneer drug company and the two generic drug companies restrict competition beyond the exclusionary effects of the valid patent. *Id.* Although the Commission could not provide sufficient evidence to show either that the Schering-Plough patent is invalid or that the patent will not be infringed by the two generic drug companies' products, it dismissed the Eleventh Circuit's prior holding in *Valley Drug*, which stated that in such a situation "a determination on the merits of the underlying patent disputes was not supported by law or logic." *Id.*

¹⁴⁴ *Id.* at 1072.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ See *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 386 (2d Cir. 2005). "The trial court must protect the public interest, as well as the interests of the parties, by encouraging the most fair and efficient resolution." *Id.*

¹⁴⁸ See Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247, 250 (2002). Author balances the public's interest

Medications must not only be available to the public, but also affordable to the average consumers.¹⁴⁹ The public also has an interest in enforcement of valid patents.¹⁵⁰ In addition, the public has an interest in settlements of expensive and lengthy patent infringement litigations.¹⁵¹ Generally, the public benefits from a generic drug company's entry into the pharmaceutical market.¹⁵² If successful in gaining entry, generic drug companies create competition for the pioneer drug companies in the pharmaceutical market.¹⁵³ Generic drug companies challenging a pharmaceutical patent would gain great financial benefits if the pioneer drug company's drug patent were to be held invalid.¹⁵⁴ Considering this fact, it is of no surprise that so many generic drug companies embark upon challenging pharmaceutical patents.

Generic drug companies distribute and sell drugs at much lower costs to the public than the pioneer drug companies.¹⁵⁵ Although entering the pharmaceutical market is a very compelling factor in litigating a case, a generic drug company's dire need for financial assistance may motivate it to accept a monetary award and settle a costly patent infringement battle.¹⁵⁶ On the other hand, a pioneer drug company has great incentive to protect its patent through settlement agreements once it sees its interest is being jeopardized.¹⁵⁷

Each of these interests adequately justifies use of the rule of reason standard in judging reverse payment settlement agreements.¹⁵⁸ A per se illegal treatment of reverse payment patent settlements does not give due consideration to the patent exclusivity, public interest, and the interests of the parties involved.¹⁵⁹

in having inexpensive generic drugs available to public against the need to encourage development of new drugs. *Id.*

¹⁴⁹ See Mary Atkinson, *Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada*, 11 PAC. RIM L. & POL'Y J. 181, 183 (2002). "While the United States government has an interest in maintaining a healthy pharmaceutical industry, the government is also concerned with providing the public with affordable drugs." *Id.*

¹⁵⁰ See *Hybritech Inc. v. Abbott Lab.*, 235 F. Supp. 2d 390, 396 (Fed. Cir. 2002).

¹⁵¹ See *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003). Judge Posner stated, "[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." *Id.*

¹⁵² See H.R. REP. NO. 98-857(I), at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647.

¹⁵³ Jennifer Berman, *Using the Doctrine of Informed Consent to Improve HIV Vaccine Access in the Post-Trials Era*, 22 WIS. INT'L L. J. 273, 286-87 (2004) (stating that promotion of generic alternatives of patented drugs creates competition in the pharmaceutical industry).

¹⁵⁴ See Alison Ladd, *Integra v. Merck: Effects on the Cost and Innovation of New Drug Products*, 13 J.L. & POL'Y 311, 312 (2005).

¹⁵⁵ See *id.* "Generic drugs can be sold at much cheaper prices than their brand name counterparts, in part because their manufacturers can make use of existing research in developing drug formulas rather than originating this knowledge base." *Id.*

¹⁵⁶ *E.g.*, *Schering-Plough v. Fed. Trade Comm'n*, 402 F.3d 1056, 1059 (11th Cir. 2005). During the settlement agreement, Upsher insisted upon its need for cash prior to the agreed entry date. *Id.*

¹⁵⁷ See *id.*

¹⁵⁸ See *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 386 (2d Cir. 2005). The court noted that in a majority of cases, reverse payment patent settlements would be evaluated under a rule of reason analysis. *Id.* Under the Rule of reason analysis, the fact-finder must decide whether the challenged practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including "specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.*

¹⁵⁹ *Tauzin Testimony*, supra note 2.

III. PROPOSAL

This Comment proposes that Congress's proposed PAAGA is not necessary in light of the current antitrust analysis available to the courts, the public policy concerning settlements, and the interests of the parties involved.

A. Public Policy Encourages Settlements of Patent Disputes

Courts recognize that public policy encourages settlements.¹⁶⁰ The Eleventh Circuit, in *Schering-Plough* stated, “[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation.”¹⁶¹ Patent litigations are complex, lengthy, and expensive for all parties involved.¹⁶² The overall patent litigation cost in the United States is about one billion dollars per year.¹⁶³ The average patent infringement case lasts thirty-seven months until the court of appeals makes a decision.¹⁶⁴

Settlements create a sense of certainty and closure to ongoing litigation.¹⁶⁵ Some pioneer drug companies would prefer the certainty of settlements to even a miniscule possibility that a court may hold their patents invalid.¹⁶⁶ Moreover, reverse payments do not undermine the purpose of the Hatch-Waxman Act. In fact, parties using monetary compensations are better able to settle their differences.¹⁶⁷ Certain reverse payment settlements result in the pioneer drug company's purchase

¹⁶⁰ See, e.g., *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003); see also *Schering-Plough*, 402 F.3d at 1072; *In re Tamoxifen*, 429 F.3d at 386; *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 477 (Fed. Cir. 1991); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1296 (S.D. Fla. 2005).

¹⁶¹ *Schering-Plough*, 402 F.3d at 1075.

¹⁶² See *Tauzin Testimony*, *supra* note 2.

¹⁶³ *Schering-Plough*, 402 F.3d at 1095. Patent litigation incurs both direct and indirect costs on the litigants. *Id.* These costs range from attorney and expert witness fees to the expenses associated with discovery compliance. *Id.* Other costs associated with patent litigations are for a variety of reasons, whether they are the “result of uncompromising legal positions, differing strategic objectives, heightened emotions, lawyer incompetence, or sheer moxie.” *Id.* See also Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. REG. 359, 380 (1999) (declaring that U.S. patent litigation costs one billion dollars annually).

¹⁶⁴ *Tauzin Testimony*, *supra* note 2.

¹⁶⁵ See *Schering-Plough*, 402 F.3d at 1075. The *Schering-Plough* court stated, “[t]he intensified guesswork involved with lengthy litigation cuts against the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim.” *Id.*

¹⁶⁶ See *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 394 (2d Cir. 2005). In regard to reverse payment patent settlement, the court stated, “[w]hatever 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.” *Id.*

¹⁶⁷ See *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003). “But any settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement.” *Id.* Judge Richard Posner noted that if any settlement agreement, which involved a payment from the pioneer drug company to the generic drug company to settle a patent infringement dispute, is classified as involving a “forbidden reverse payment,” then there will not be anymore patent settlements. *Id.*

of a license for the generic drug company's other products.¹⁶⁸ Such an agreement benefits the public through introduction of a new rival into the market, which will create competition.¹⁶⁹

B. Prohibiting Reverse Payments Will Discourage Patent Settlements

Congress's proposed PAAGA makes all reverse payment settlements in the pharmaceutical industry per se illegal.¹⁷⁰ Congress's per se illegal approach to reverse payment patent settlements gives no deference to the patentee's right to exclude others from infringing upon its patent.¹⁷¹ Congress's newly proposed law is in direct conflict with the 35 U.S.C § 282, which states that a "patent shall be presumed valid."¹⁷²

Congress assumes, because the patentee enters into a reverse payment agreement with the alleged infringer, that its patent must be weak or invalid.¹⁷³ Courts have stated that a per se illegal treatment of monetary payments from pioneer drug companies to generic drug companies would chill patent settlements.¹⁷⁴ In fact, the *Schering-Plough* court rejected a per se ruling that "would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic drug's entry date, and, in an ancillary transaction, pays for other products licensed by the generic."¹⁷⁵ The court provided several reasons for rejecting per se standard: "the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements."¹⁷⁶ In addition, monetary

¹⁶⁸ See, e.g., *Schering-Plough*, 402 F.3d at 1075. In the first agreement, Schering-Plough and Upsher negotiated a three-part license deal, where Schering-Plough would pay to Upsher: (1) sixty million dollars in initial royalty fees; (2) ten million dollars in milestone royalty payments; and (3) ten to fifteen percent royalties on the sales of the drug. *Id.* In the second agreement, Schering-Plough would make a payment of fifteen million dollars in return for its right to license generic enalapril and buspirone from ESL. *Id.*

¹⁶⁹ See *Asahi Glass Co.*, 289 F. Supp. 2d at 994. "[I]n contrast, the settlements led to increased competition." *Id.*

¹⁷⁰ The Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007). Congress noted that any monetary payment from the pioneer drug company to the generic drug company, which is followed by the exclusion of the generic drug from entering the pharmaceutical market prior to the expiration of the patent life is considered as per se illegal. *Id.*

¹⁷¹ *Yvon*, *supra* note 12, at 1908. The author correctly noted that while patents may be subject to legal challenges, the presumption of validity stated by the Congress means that a challenger must bear the burden of proof to provide sufficient evidence to show that the challenged patent is in fact invalid. *Id.*

¹⁷² 35 U.S.C. § 282 (2006). "Each claim of a patent whether in independent, dependent, or multiple dependent form shall be presumed valid independently of the validity of other claim; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." *Id.*

¹⁷³ See *Schering-Plough*, 402 F.3d at 1076.

¹⁷⁴ E.g., *Asahi Glass Co.*, 289 F. Supp. 2d at 994. "If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Id.*

¹⁷⁵ *Schering-Plough*, 402 F.3d at 1076.

¹⁷⁶ *Id.*

compensations are an integral part of settlements, without which settlements will be cumbersome.¹⁷⁷

C. Certain Commentators Erroneously Challenge the Validity of Reverse Payment Patent Settlements

Certain commentators observe if reverse payments are held per se illegal, then the pioneer and generic drug companies cannot negotiate sharing a monopoly in the market.¹⁷⁸ They argue such a holding will force the interested parties to negotiate a date when the generic can enter the market.¹⁷⁹ In such a scenario, the generic drug company's incentive to gain entry into the market increases.¹⁸⁰ However, these commentators fail to realize that many alleged infringers may not be able to obtain favorable rulings from the courts that will enable them to enter the market.¹⁸¹

Several factors contribute to a generic drug company's willingness to enter into settlement agreement with the pioneer drug company: (1) the lack of funds and other resources to continue the patent litigation;¹⁸² (2) the uncertainty over how the lawsuit will be resolved;¹⁸³ (3) the incentive of gaining an early entry into the market;¹⁸⁴ and (4) the monetary award to conduct research and market its drugs.¹⁸⁵ Each one of these factors alone is a strong reason for a generic drug company to enter into a settlement agreement with the pioneer drug company.

A commentator argued the Hatch-Waxman Act "actually encourages litigation."¹⁸⁶ Mr. Merrill Hirsh, in a senate judiciary hearing, asserted the goals of the Hatch-Waxman Act are not met when pioneer and generic drug companies settle.¹⁸⁷ Rather, it is better to litigate these patent cases than to allow settlements.¹⁸⁸ These statements are in direct conflict with the often-quoted public

¹⁷⁷ See *Asahi Glass*, 289 F. Supp. 2d at 994. Judge Richard Posner of the Seventh Circuit Court of Appeals noted "any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement." *Id.*

¹⁷⁸ See *Hirsh Testimony*, *supra* note 8.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* If the pioneer drug companies and the generic drug companies are prevented from entering into settlement agreements where the pioneer drug company pays a monetary award to the generic drug company to resolve a patent infringement lawsuit, then their negotiation will be different. *Id.* According to Merrill Hirsh, these parties will no longer be able to share a monopoly over the pharmaceutical market by themselves. *Id.*

¹⁸¹ *Tauzin Testimony*, *supra* note 2.

¹⁸² See *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1059 (11th Cir. 2005). The generic drug company and the pioneer drug company agreed to September 1, 2001 as the generic drug company's earliest entry date into the pharmaceutical market. *Id.* This settlement agreement allowed the generic drug company to enter the pharmaceutical market about five years prior to the expiration of the pioneer drug company's patent life for K-Dur 20. *Id.* However, the generic drug company insisted that it had a need for cash prior to the agreed entry date. *Id.*

¹⁸³ *Tauzin Testimony*, *supra* note 2.

¹⁸⁴ See *Schering-Plough Corp.*, 402 F.3d at 1059-60. Both generic drug companies entered into settlement agreements with the pioneer drug company in exchange for early entry into the market and monetary awards from the pioneer drug company to the two generic drug companies. *Id.*

¹⁸⁵ See *id.* at 1060.

¹⁸⁶ *Hirsh Testimony*, *supra* note 8.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

policy that settlements are favored over long, expensive, and complicated litigations.¹⁸⁹

D. The Preserve Access to Affordable Generics Act Neither Enhances Competition in the Pharmaceutical Market Nor Benefits the Public

Congress proposed the PAAGA amendments to the Hatch-Waxman Act to respond to concerns about the anticompetitiveness of certain reverse payment patent settlements.¹⁹⁰ Congress's concern that there is a need to address antitrust issues involving patent infringement settlements in the pharmaceutical industry is well justified. However, the PAAGA will have the effect of freezing settlements under the Hatch-Waxman Act.¹⁹¹

Proposed amendments to the Hatch-Waxman Act will substantially harm the pioneer and generic drug companies as well as the public. Generic drug companies will be forced to litigate patent infringement lawsuits to their finality, because there will be no real incentives for them to settle.¹⁹² Certain generic drug companies may drop their Paragraph IV certification because of the very costly and timely patent litigation process.¹⁹³ Other generic drug companies may not even be able to obtain a favorable ruling from the courts that will enable them to enter the pharmaceutical market. On the other hand, pioneer drug companies will have no other choice but to litigate the patent infringement lawsuits. The pioneer drug companies will have no other means to revert the danger of losing the rights awarded to them through U.S. issued patents, which will ultimately lead to the loss of their market power.¹⁹⁴ Therefore, pioneer and generic drug companies will choose to litigate and will be forced to transfer the costs of litigation to the consumers.

Given the rich and extensive experience of the courts in dealing with antitrust issues,¹⁹⁵ Congress should reject the proposed amendments and defer to the courts' judgments. The Hatch-Waxman Act and antitrust laws are adequate in addressing reverse payments within the pharmaceutical industry. In fact, the U.S. Supreme Court's refusal to grant writ of certiorari to both the *Schering-Plough* and *In re Tamoxifen* lawsuits, where both courts held the settlements valid, infer that the Supreme Court concluded the settlements were appropriately valid given the

¹⁸⁹ See *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003).

¹⁹⁰ The Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007).

¹⁹¹ *Tauzin Testimony*, supra note 2.

¹⁹² *Hirsh Testimony*, supra note 8.

¹⁹³ *Tauzin Testimony*, supra note 2; see also *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 390 (2d Cir. 2005).

¹⁹⁴ *Hirsh Testimony*, supra note 8.

¹⁹⁵ *Chi. Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003); *In re Tamoxifen*, 429 F.3d at 386 (2d Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1303 (11th Cir. 2003); *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1065 (11th Cir. 2005); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906 (6th Cir. 2003); *In re Buspirone Antitrust Litig.*, 211 F.R.D. 249 (S.D.N.Y. 2002); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005); *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001); *Foster v. Halco Mfg. Co.*, 947 F.2d 469, 477 (Fed. Cir. 1991); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976).

circumstances of those cases. However, Congress's proposed amendments make the settlements involved in both of these lawsuits per se illegal.

As stated earlier, the *In re Tamoxifen* court used the rule of reason to analyze validity of the reverse payment patent settlement involved in that lawsuit.¹⁹⁶ The U.S. Supreme Court had an opportunity to overturn the Second Circuit court's holding in *In re Tamoxifen* if it thought the court's holding conflicted with the intent of the Hatch-Waxman Act or antitrust laws. Although the *In re Tamoxifen* case was rightly decided, the U.S. Supreme Court should grant writ of certiorari to hear a similar case dealing with reverse payment patent settlement in order to establish a uniform set of antitrust standards in the pharmaceutical industry.

CONCLUSION

Congress's proposed PAAGA holds all reverse payment patent settlements, which prohibit generic drug companies from entering the drug market prior to the patent life, per se illegal.¹⁹⁷ A per se illegal rule presumes the invalidity of a settlement simply because the agreement involves a reverse payment from a pioneer drug company to the generic drug company.¹⁹⁸ The per se illegal approach does not provide the parties with an opportunity to defend their settlement agreements. This approach essentially holds either the patent holder's patent is invalid or the generic pharmaceutical company's drug does not infringe upon the pioneer pharmaceutical company's patent without ruling on the merits. The per se illegal rule disregards the very important notion of the presumption of patent-validity established by Congress and deeply rooted in the U.S. patent system.¹⁹⁹

Traditional analysis of the rule of reason must be applied to determine the validity of the reverse payment patent settlements under the antitrust laws. The rule of reason is the perfect link that resolves the conflicts between antitrust and patent laws. A U.S. Supreme Court ruling establishing the rule of reason as the sole analysis for determining validity of reverse payment patent settlements under the antitrust laws is vital for a stabilized pharmaceutical market. This ruling will suppress any doubts as to whether a fair analysis is being applied to a reverse payment patent settlement and whether a settlement violates antitrust laws.

¹⁹⁶ *In re Tamoxifen*, 429 F.3d at 370.

¹⁹⁷ The Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007).

¹⁹⁸ *In re Cardizem*, 332 F.3d at 906.

¹⁹⁹ 35 U.S.C. § 282 (2006). *See also* *Sure Plus Mfg. Co. v. Kobrin*, 719 F.2d 1114, 1116–17 (11th Cir. 1983). The court recognized that Congress provided for a legal presumption in favor of patent validity for any patent issued by the U.S. Patent and Trademark Office. *Id.*