2007

Do Reverse Payment Settlements Violate the Antitrust Laws?

Christopher M. Holman

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DO REVERSE PAYMENT SETTLEMENTS VIOLATE THE ANTITRUST LAWS?

Christopher M. Holman†

Abstract

The term "reverse payment" has been used as shorthand to characterize a variety of diverse agreements between patent owners and alleged infringers that involve a transfer of consideration from the patent owner to the alleged infringer. Reverse payment settlements are particularly associated with drug patent challenges mounted by generic drug companies under the Hatch-Waxman Act. Many, including the Federal Trade Commission, would characterize these agreements as antitrust violations. However, courts have generally declined to find these agreements in violation of the antitrust laws based solely on the presence of a reverse payment.

This article begins in Section II with an overview of the diverse array of patent settlement agreements that have been classified within the general taxonomy of "reverse payment settlements." Section III discusses a variety of specific factors that have led to a natural proliferation of reverse payments patent settlements between branded and generic drug companies. Section IV traces the development of the FTC's position, which would find most reverse payment settlements presumptively illegal, focusing in particular on its recent ill-fated enforcement action against Schering-Plough. Section V reviews the courts' response to antitrust challenges against reverse payment settlements, and identifies an emerging consensus position that will find a violation of the antitrust laws only in cases where the challenged agreement contains restrictions on competition that exceed the exclusionary potential of the patent. The article concludes in Sections VI and VII with a discussion of the future prospects for the antitrust treatment of reverse payments settlements, including a suggestion that in evaluating the anticompetitive implications of these agreements more explicit consideration be paid to barriers to market entry facing potential third party generic competitors.

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I. INTRODUCTION

On June 26, 2006, U.S. consumers suffered a severe setback when the Supreme Court denied a petition for writ of certiorari in the case of FTC v. Schering-Plough Corp. At least that is the position taken by the Federal Trade Commission ("FTC"), which asserts that the Eleventh Circuit's holding in Schering-Plough opens the door to collusive and anticompetitive agreements between branded drug companies and their potential generic competitors that keep generic drugs off the market. In particular, the FTC sees these agreements as circumventing provisions of the Hatch-Waxman Act specifically intended to promote challenges to patents that delay generic market entry. By derailing patent challenges and blocking generic competition, the FTC argues these agreements seriously undermine the ability of generic competition to bring down consumer drug prices.

The FTC is not alone in its concern – a number of high-powered amici joined the Commission in urging the Supreme Court to grant certiorari in Schering-Plough, including attorneys general representing 34 states and the District of Columbia, the National Association of Chain Drug Stores, the American Association of Retired People ("AARP"), and Congressman Henry Waxman, one of the two sponsors of the Hatch-Waxman amendments. The amendments are largely to be credited for the current vitality of the generic drug industry. A number of commentators have also weighed

2. See, e.g., Jon Leibowitz, Comm'r, FTC, Prepared Statement of the FTC Before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry 14-19 (July 20, 2006), http://www.ftc.gov/os/2006/07/P052103BarriertosGenericEntryTestimonySenate07202006.pdf [hereinafter FTC Statement Before Aging Committee].
3. See infra Section IV.
4. See, e.g., FTC Statement Before Aging Committee, supra note 2, at 17-19.
7. Brief for American Association of Retired People as Amicus Curiae Supporting Petitioner, Schering-Plough, 126 S. Ct. 2929 (No. 05-273), 2005 WL 2454841.
8. Brief for Representative Henry A. Waxman as Amicus Curiae Supporting Petitioner, Schering-Plough, 126 S. Ct. 2929 (No. 05-273), 2005 WL 2462026.
9. See infra Section III.B.2.
in on the side of the FTC, including leading scholars in the fields of economics, intellectual property, and antitrust law.\textsuperscript{10}

\textit{Schering-Plough} involved an appeal of an FTC enforcement action\textsuperscript{11} taken against two so-called “reverse payment” settlement agreements between Schering-Plough ("Schering"), a branded drug company and patent owner, and two potential generic competitors who attempted to enter the market prior to patent expiration by challenging the patent.\textsuperscript{12} The FTC found the agreements to be unreasonable and illegal restraints of trade, and characterized them as horizontal market allocation agreements, which are generally per se violations of the antitrust laws.\textsuperscript{13} The Commission announced a standard of antitrust review that would effectively find any agreement in which the generic drug company agreed to defer market entry in exchange for monetary compensation presumptively anticompetitive and illegal under the antitrust laws, at least when the amount of the payment exceeded the expected costs of litigating the case.\textsuperscript{14} However, on appeal, the Eleventh Circuit rejected this standard and the FTC’s legal arguments purporting to support it.\textsuperscript{15} The court held that the FTC erred in giving too little deference to the fact that the generic products excluded by the agreement were apparently covered by a presumptively valid patent.\textsuperscript{16} In the view of the court, the FTC failed to provide sufficient evidence to support a conclusion that the agreement was anything more than a settlement of a legitimate patent dispute, which courts have actively encouraged.\textsuperscript{17} In particular, the court rejected the FTC’s argument that the existence and size of the reverse payments in and of themselves rendered the agreements presumptively illegal.\textsuperscript{18}

\begin{itemize}
\item \textsuperscript{11} For a description of FTC’s ability to bring enforcement actions, see FTC, A Brief Overview of the FTC’s Investigative and Law Enforcement Authority (2002), http://www.ftc.gov/ogc/briefoverview.htm (last visited Feb. 27, 2007).
\item \textsuperscript{12} \textit{Schering-Plough Corp. v. FTC}, 402 F.3d 1056, 1061-62 (11th Cir. 2005), \textit{cert. denied}, 126 S. Ct. 2929 (2006).
\item \textsuperscript{13} \textit{In re Schering-Plough Corp.}, No. 9297, slip op. at 86-87 (F.T.C. Dec. 18, 2003), http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf, \textit{vacated}, 402 F.3d 1056 (11th Cir. 2005).
\item \textsuperscript{14} \textit{Id. at} 12, 40.
\item \textsuperscript{15} \textit{Schering-Plough Corp. v. FTC}, 402 F.3d 1056 (11th Cir. 2005), \textit{cert. denied}, 126 S. Ct. 2929 (2006).
\item \textsuperscript{16} \textit{Id. at} 1068.
\item \textsuperscript{17} \textit{Id. at} 1075.
\item \textsuperscript{18} \textit{Id.}
The Eleventh Circuit is not alone in rejecting the FTC's theory of presumptive illegality for reverse payment settlements. In fact, numerous district and appellate courts have considered the issue, and the emerging consensus is that a reverse payment does not violate the antitrust laws nor raise any presumption of illegality. Furthermore, in a rare split between the two federal agencies tasked with enforcing the nation's antitrust law, the Department of Justice ("DOJ") declined to endorse the FTC's position with regard to the legality of these agreements. To the contrary, the Solicitor General filed an amicus brief on the behalf of the U.S. government recommending that the Supreme Court deny the FTC's petition for writ of certiorari in Schering-Plough, suggesting that "the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful.

Section II of this article provides an overview of the diverse array of patent settlement agreements that have been characterized within the general taxonomy of "reverse payment settlements." Section III discusses a variety of specific factors that have led to a natural proliferation of reverse payments patent settlements between branded and generic drug companies. Section IV traces the development of the FTC's position, which would find most reverse payment settlements presumptively illegal, focusing in particular on its ill-fated enforcement action against Schering. Section V reviews the courts' response to antitrust challenges against reverse payment settlements, and identifies an emerging consensus position that will find a violation of the antitrust laws only in cases where the challenged agreement contains restrictions on competition that exceed the exclusionary potential of the patent. The article concludes in Sections VI and VII with a discussion of the future prospects for the antitrust treatment of reverse payments settlements, including a suggestion that in evaluating the anticompetitive implications of these agreements more explicit consideration be paid to barriers to market entry facing potential third party generic competitors.

19. See infra Section V.A.
21. Id. at 11.
II. REVERSE PAYMENT SETTLEMENT DEFINED

The term "reverse payment" has been used as shorthand to characterize a variety of diverse patent settlement agreements that involve a transfer of consideration from the patent owner to the alleged infringer. In this article, the term is used in a broad sense to reference any agreement between patent litigants, or potential litigants, wherein the patent owner agrees to provide some compensation to the alleged infringer, and the alleged infringer agrees to delay developing or marketing a product. The "reverse" designation refers to the direction of the payment from the patentee to alleged infringer; in most patent litigation settlements, any payment will typically flow from the alleged infringer to the patentee.

Although reverse payment settlements can and probably do occur in other contexts, it appears that all of the reverse payment settlements that have been challenged as antitrust violations have occurred in the context of challenges by generic drug companies of branded drug patents, referred to herein as "Paragraph IV litigations." Because of the huge drop in drug price that occurs when such patent challenges succeed and the atypical direction of payment flow, these settlements have garnered much interest from the FTC and others.

The quintessential and most extreme example of a reverse payment settlement would be an agreement terminating litigation, pursuant to which the potential generic competitor would agree to stay off the market for the full duration of the patent term in exchange for cash payments. This tends to be the popular perception of reverse payments settlements by a public demanding lower drug prices and

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23. Reverse payments are also sometimes referred to as "exclusion payments" or "brand payments." These terms are generally used interchangeably herein.
24. At least when the payment is in the form of cash and the like. As explained by Judge Posner, generally any patent settlement will include compensation to the alleged infringer in some form, else there would be no reason to settle, but usually this compensation is not in the form of a cash payment and hence will tend to be harder to identify and quantify. See discussion infra Section V.D.
25. The term "Paragraph IV litigation" references 21 U.S.C. § 355(j)(2)(A)(vii)(IV), the statutory provision that provides the basis for generic drug companies to challenge the patents of branded (i.e., innovator) drug companies. See infra Section III.B.2.
26. See infra Section IV.
deeply suspicious of the pharmaceutical industry. In fact, however, a closer look at the facts of individual cases reveals that few, if any, reverse payment settlements are as simple as that or as blatantly anti-competitive.

For example, most agreements that terminate a patent dispute involve a negotiated market entry date for the generic product that substantially precedes the date of patent expiration. This negotiated market entry date typically occurs later than would have likely occurred if the generic company had prevailed in the patent dispute, i.e., the parties split the remaining patent term. In Schering-Plough, for example, Schering’s patent was set to expire September 5, 2006. Schering’s 1997 agreements with two generic patent challengers, Upsher and ESI, allowed for generic entry by Upsher on September 1, 2001, (roughly splitting the remaining patent term in half) and by ESI on January 1, 2004. Settlements such as this, involving a negotiated generic entry date prior to patent expiration, can promote competition by providing a guaranteed reduction in the effective patent term that would not have occurred absent the patent challenge. Of course, depending upon the merits of the case, a litigation carried through final judgment might better serve consumer interests by facilitating accelerated generic competition. A final judgment favoring the generic challenger would not only result in an earlier date of generic entry, but defeating the patent might also open up the market to third party generic competition. Still, a negotiated early entry date clearly attenuates some of the competition concerns raised by the more extreme scenario whereby the patent challenger agrees to stay off the market for the entire remaining term of the patent.

In another common twist on the simple model of reverse payment settlement, the litigants do not settle the underlying dispute, but the generic company agrees to stay off the market for some period of time while the patent litigation remains pending. These types of agreements are often referred to as “interim settlements,” or “partial settlement agreements,” and can take on the attributes of a privately

29. Id. at 1059-60.
30. “Third party generic competition” refers to generic competition from generic companies not party to the settlement agreement.
negotiated preliminary injunction. Various attributes of partial settlement agreements can render them potentially more or less pro-competitive than final settlement agreements.

On the positive side, partial settlement agreements can allow the parties to diligently pursue the underlying litigation to final judgment without exposing both parties to the huge potential losses facing each party if the generic enters the market but is subsequently found to have infringed a valid patent. Of course, many would argue that the same could be accomplished by means of a preliminary injunction. However, for various reasons the parties might prefer a privately negotiated agreement to defer market entry. For example, instead of being required by the court to post a large bond, the patent owner might prefer to make negotiated payments. There is always a chance that a court might decline to enter a preliminary injunction, even if there is substantial merit to the case. Alternatively, even without a preliminary injunction, the generic competitor could simply stay off the market to avoid the risk of adverse judgment, but this could be extremely expensive, particularly for a small, cash-strapped generic company. The deferral of anticipated cash flow, and the huge potential profits that they will have forfeited if they had ultimately prevailed in the litigation, might make it infeasible for the generic to delay market entry without some form of compensation. Negotiated payments allow the parties to share the costs of avoiding the risk of premature market entry, under terms determined by their assessment of the merits of the case and other pertinent factors.

On the other hand, interim settlements can tend to prolong litigation. Because the generic company is benefiting from a steady, and typically substantial, incoming flow of cash payments, and the branded company is continuing to reap supracompetitive profits as the

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31. Three out of four FTC challenges mentioned in FTC Generic Drug Study involved interim settlements. Only one out of twenty final settlements was challenged, the one at issue in Schering-Plough. See FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, 24, 25 & nn.2-3 (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf [hereinafter FTC GENERIC DRUG STUDY].

32. See, e.g., Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1359 (Fed. Cir. 2001) (“In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.”).

sole purveyor of the patented drug, there is little incentive for either party to push for a speedy resolution of the matter. Compounding the problem is the fact that in many cases these agreements effectively restrict market entry by third party generic manufacturers. The anticompetitive potential of interim settlement agreements is substantial, and both the FTC and the courts have treated interim settlement agreements as generally more problematic than final settlements. For example, in its 2003 Generic Drug Study, the FTC identified twenty final settlements that settled litigation between brand-name company and a first generic applicant, but apparently chose to challenge only one with an enforcement action (5%). On the other hand, the FTC identified only four interim settlements, and challenged three out of the four (75%). All of the challenged settlements involved reverse payments.

Turning to the courts, four appellate level decisions have considered the legality of reverse payments settlements. The two cases involving partial settlements ultimately resulted in a determination of illegality, while in the other two cases involving final settlements, the legality of the agreements was upheld.

Other deviations from the simple model occur when the payment is not a simple transfer of cash. For example, in some interim settlements, the payment is contingent upon the defendant prevailing on appeal, i.e., a functional equivalent of the escrow account that would be required in a court-ordered preliminary injunction. In other cases, payment is contingent upon the generic company achieving marketing approval from FDA.

34. See infra Sections IV.A, V.A.
35. See FTC GENERIC DRUG STUDY, supra note 31, at 34-35.
36. Id. at 25 & n.2.
37. Id. at 25 & n.3.
38. See infra Section IV.A-B.
40. Valley Drug, 344 F.3d 1294 (agreement held illegal on remand in In re Terazosin Hydrochloride Antitrust Litig. (Terazosin II), 352 F. Supp. 2d 1279, 1319 (S.D. Fla. 2005)); Cardizem, 332 F.3d at 915.
41. Tamoxifen, 466 F.3d 187; Schering-Plough, 402 F.3d 1056.
42. FTC GENERIC DRUG STUDY, supra note 31, at 35.
43. Schering-Plough, 402 F.3d at 1061 n.8.
In many cases the "payment" comes in the form of a side deal, i.e., an agreement ancillary to the patent settlement. For example, in some cases there is an ancillary agreement pursuant to which the defendant licenses one or more of its products to the patentee.\textsuperscript{44} If the licensing payments exceed the fair market value of the in-licensed technology, one may infer that the excess amount represents a camouflaged payment for delayed generic market entry. One agreement at issue in \textit{Schering-Plough}, for example, involved a payment of $60 million\textsuperscript{45} that Schering agreed to make in exchange for the right to market several of the generic company's proprietary drug products.\textsuperscript{46} The FTC went to great lengths in an attempt to establish that the size of Schering's payment exceeded its actual valuation of the in-licensed drug products.\textsuperscript{47} On appeal, however, the court rejected the FTC's conclusion that the terms of the ancillary agreements were anything but the product of legitimate arm's-length business negotiations.\textsuperscript{48}

There are potential pro-competitive aspects to ancillary agreements such as those entered into by the parties in \textit{Schering-Plough}, which might explain the hostility with which the court responded to the FTC's ex post attack on the legitimacy of the terms of the agreements.\textsuperscript{49} For example, the licensing of the products to the branded drug company could facilitate their commercialization, fostering competition in the ancillary drug market. To the extent the ancillary agreements were legitimate business deals, the \textit{Schering-Plough} agreements were effectively cross-licensing agreements, a form of patent licensing that the FTC and courts have found to be generally pro-competitive.\textsuperscript{50}

In some cases, reverse "payment" takes the form of an ancillary agreement pursuant to which the patent owner grants the defendant a license to sell a drug other than the one that is the subject of the patent

\textsuperscript{44} See FTC GENERIC DRUG STUDY, \textit{supra} note 31, at 31-32.
\textsuperscript{45} \textit{Schering-Plough}, 402 F.3d at 1060.
\textsuperscript{46} \textit{Id.} at 1059-60.
\textsuperscript{47} \textit{Id.} at 1070.
\textsuperscript{48} The Eleventh Circuit ultimately held the FTC failed to prove that the amount of the payments exceeded Schering's actual valuation of the in-licensed drug products. The court was highly critical of the FTC's attempt to second-guess the merits of the parties' business decisions, noting the policy concerns raised. \textit{See infra} Section V.F.
\textsuperscript{49} \textit{See infra} Section V.F.
As with the case where the generic company licenses a product to the patent owner, these agreements can promote competition in the ancillary market. Of course, to the extent the payment is less than a legitimate valuation of the product, the license to sell the other product can function as a disguised payment for delay in the marketing of the product allegedly covered by the disputed patent.

Furthermore, in other cases, the reverse "payment" is an ancillary agreement pursuant to which the patent owner grants the defendant a license to sell the patented drug, manufactured by the patent owner, under a generic label. This type of agreement has pro-competitive potential, because this generic labeled product will typically come at a price lower than the branded drug product. However, the price discount is limited by the terms under which the branded company supplies the drug to the generic company, and the drop in price is generally much less than would be expected in the case of true generic competition. Nevertheless, there will generally be some consumer benefit, at least compared to an alternative where the patent challenge never occurred, or where the patent owner ultimately prevails in the litigation.

In some cases, the parties characterize reverse payments as "saved litigation expenses." The FTC and some commentators have proposed that reverse payments should not raise a presumption of illegality where the payment is limited to the litigation costs that the patentee would expect to save by discontinuing the litigation. The rationale is that even a patent owner convinced of the merits of its patent case might still legitimately settle a nuisance suit by paying the patent challenger an amount representing the amount of money that
would otherwise be spent on litigation costs. The FTC would also limit the settlement to no more than $2 million in any event, a limitation that the Eleventh Circuit found to be arbitrary in Schering-Plough. One problem with this limitation to saved litigation expenses is that it neglects the substantial non-litigation expenses associated with a nuisance patent suit, such as: the drain on company executive time, the burden of complying with discovery requests, the impact on company valuation, the general cost of the cloud of uncertainty created by ongoing litigation, and the potential for the inadvertent disclosure of proprietary and confidential information that accompanies any litigation-associated discovery.

In other cases, an alleged reverse payment takes the form of an ancillary agreement, pursuant to which the generic company receives payments to co-promote the branded drug company’s product. Sometimes the co-promoted product is the product at issue in the litigation; at other times, it is another product.

In further cases, the reverse payment comes in the form of an ancillary agreement under which the generic receives compensation for agreeing to supply the branded drug company with either raw materials for the manufacture of the brand product or with finished drug product. In some cases, the compensation to the generic company consists of an agreement by the brand company not to launch an authorized generic during the first-filer generic company’s 180-day exclusivity period for the product at issue in the litigation. Further, in other cases, the payment is actually an agreement on the part of the brand company to pay the generic up-front payments, milestones, sales percentages, or development fees for unrelated products to be developed using the generic company’s technology.

58. Schering-Plough, 402 F.3d at 1075.
59. Eli Lilly’s recent experience with Zyprexa illustrates the limited ability of court protective orders to protect confidential information from public disclosure. Lilly’s travails are described, e.g., at Electronic Frontier Foundation, Eli Lilly Zyprexa Litigation, http://www.eff.org/legal/cases/zyprexa/ (last visited Feb. 27, 2007).
60. SUMMARY OF AGREEMENTS, supra note 51, at 4.
61. Id.
62. Id. at 4-5.
63. Id. at 5.
64. Id.
The FTC and commentators have asserted that reverse payment settlements are rare outside the context of Paragraph IV litigation.\(^\text{65}\) The FTC has declined to take a position as to whether reverse payment settlements would be illegal in other contexts.\(^\text{66}\) As discussed below, there are clearly unique incentives at play in Paragraph IV litigations that encourage reverse payments.\(^\text{67}\) Nevertheless, it should be borne in mind that the fact that few reverse payment settlements have been identified in other contexts does not necessarily prove that they are unique to Paragraph IV litigations.

As with most litigation settlements, the terms of patent settlement agreements are normally confidential, so it is hard to know how often they might occur outside the pharmaceutical arena.\(^\text{68}\) According to the FTC’s Generic Drug Study, reverse payment settlements of Paragraph IV litigations occurred at least as early as 1993, but the FTC did not begin to officially take notice until 1999.\(^\text{69}\) Further, until they subpoenaed these confidential agreements from companies in 2001, the FTC had no idea how prevalent such agreements were.\(^\text{70}\) Since the FTC’s scrutiny of reverse payments settlements has apparently focused solely on agreements between drug companies, our lack of knowledge of such agreements in other contexts does not necessarily prove that they do not occur. Of course, the FTC could use its subpoena powers to access patent litigation settlement agreements in a non-technologically discriminatory manner. However, to date, the FTC has not expressed an interest in such a global survey.

One notable recent example of a non-pharmaceutical reverse payment settlement occurred in 2004 in the resolution of a trademark dispute between Microsoft and Lindows.\(^\text{71}\) Microsoft sued Lindows for trademark infringement, charging that the mark LINDOWS was confusingly similar to Microsoft’s well-known WINDOWS trademark.\(^\text{72}\) Microsoft stopped pursuing the case aggressively after a pretrial ruling that would have instructed the jury to consider whether

\(\text{\textsuperscript{65}}\) See Hovenkamp et al., supra note 10, at 1751.
\(\text{\textsuperscript{67}}\) See infra Section III.B.
\(\text{\textsuperscript{69}}\) FTC GENERIC DRUG STUDY, supra note 31, at 3, 31.
\(\text{\textsuperscript{70}}\) Id. at 1-3.
\(\text{\textsuperscript{72}}\) Id.
"windows" was a generic term before Microsoft introduced software with that name in 1985. Faced with a real prospect of losing its mark, Microsoft settled the litigation by making a reverse payment of a reported $20 million to Lindows in exchange for Lindows agreeing to exit the market with respect to Microsoft's allegedly infringed intellectual property.

The Microsoft-Lindows agreement demonstrates that reverse payments are rational and do occur outside the pharmaceutical context. Still, the Microsoft-Lindows settlement did not generate the kind of antitrust scrutiny reverse payments typically receive when they occur in the settlement of a Paragraph IV litigation. Of course, the argument can be made that the injury to consumer welfare is attenuated in the trademark context; instead of keeping a competing product off the market, it merely restricts a competitor's ability to use a trademark derived from an allegedly generic term. However, any distinction between patent and trademark is best viewed as one of degree. Consumers clearly have an interest in returning a generic mark to the public domain. This public interest is at the heart of the prohibition against granting trademark rights to generic terms, and misuse of trademark can violate antitrust laws.

III. SPECIFIC FACTORS PROVIDING INCENTIVES FOR REVERSE PAYMENT SETTLEMENTS IN THE DRUG INDUSTRY

Whether or not the phenomenon of reverse payment settlements is truly restricted to Paragraph IV patent challenges, it seems clear that they are particularly prevalent in this context. The FTC's Generic Drug Study identified a high percentage of reverse payment settlements in the period before it began to take a strong enforcement position against such agreements. After the FTC began challenging reverse payment settlements, there was a period where they were rare

75. See, e.g., 15 U.S.C. § 1115(b)(7) (2000) (use of a mark to violate antitrust laws is a defense against an assertion that a trademark is uncontestable).
76. The report found that nine out of twenty final settlements and three out of four interim settlements involved reverse payments. FTC GENERIC DRUG STUDY, supra note 31, at 31, 34.
or nonexistent. However, the FTC reports that recently reverse payment settlements have experienced a resurgence, which they attribute to the refusal of the courts to support the FTC’s position that such payments render patent settlements presumptively illegal. This section discusses some of the specific factors driving the proliferation of reverse payment settlements in the context of Paragraph IV litigations.

A. Innovative Drugs Have Intrinsically High Social Utility

A fundamental reality driving large reverse payments is the amount of profits that can be made in the sale of prescription drugs, particularly “blockbuster” drugs that offer unique and substantial therapeutic benefit relative to other products on the market. Consumers and health plans spend over a hundred billion dollars per year on prescription drugs, and high profit margins create a potential for huge profits for the purveyors of these drugs. However, a branded drug company’s profit margins are to a large extent dependant upon the market exclusivity provided by patents. When patent protection ends, generic competition quickly erodes margins and market share, resulting in precipitous declines in profitability. The high profitability of branded drugs motivates drug patent owners to take

77. For fiscal year 2004, the FTC reported that none of the fourteen agreements filed pursuant to the MMA of 2003 contained a reverse payment accompanied by deferred generic entry. Jon Leibowitz, Comm’r, FTC, Exclusion Payments to Settle Pharmaceutical Patent Cases: They’re B-a-a-a-ck!, Remarks at the Second Annual In-House Counsel’s Forum on Pharmaceutical Antitrust 3-4 (Apr. 24, 2006), http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf [hereinafter Leibowitz Speech].

78. FTC Commissioner Leibowitz reported that in the six-month period subsequent to the Second Circuit’s rejection of presumptive illegality for reverse payment settlements in In re Tamoxifen Citrate Antitrust Litigation, “more than two-thirds of approximately ten agreements between brands and generics included a payment from the brand and an agreement to defer generic entry.” Id. at 5.

79. A number of other commentators have also previously advanced positions challenging on various grounds the presumption that reverse payment settlements are antitrust violations. See, e.g., Burling, supra note 66 at 42-43; Daniel A. Crane, Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications, 54 FLA. L. REV. 747, 748-49 (2002); Langenfeld & Li, supra note 33 at 778.


81. See infra notes 88-93 and accompanying text.

82. See infra notes 88-93 and accompanying text.
extreme measures to maintain and enforce their patent rights. The large profits also attract the scrutiny of the FTC and Congress, who would welcome an opportunity to take a bite out of this profitability for the benefit of patients as well as insurers, employers and the government, who ultimately bear the majority of the cost of prescription drugs.

High profits reflect the relative inelasticity of consumer demand for patented prescription medications, particularly in the case of a true blockbuster drug with no reasonably acceptable substitute. In lobbying for greater drug accessibility and affordability, consumer and patient advocates commonly point out the plight of seniors living on a fixed income and forced to decide between buying food or prescription drugs. Such stories tug at our heartstrings, and rightly so, but also highlight the extreme value society places on innovative drugs. Few other cutting-edge, innovative technologies possess comparable social value; while we appreciate the tremendous innovations that have occurred in the information and communication technology sectors, most of us would feel far less sympathy for the senior forced to choose between food and the latest cell phone technology or access to high-speed Internet. It is important to remain cognizant of this high social utility in drug innovation. The patent system is the primary engine driving the highly risky and expensive machine that is modern drug development. Any attempts to restrict the rights of pharmaceutical patent owners should only be undertaken while bearing in mind the potential harm to incentives for innovation, and ultimately the impact this might have on the next generation of innovative drugs.

The introduction of generic competition dramatically reduces the profitability of a prescription drug. According to FDA, analysis of

83. See infra Section V.
84. See infra Sections IV, VI.B.
85. See Merril Hirsh, Partner, Ross, Dixon, and Bell LLP, Paying Off Generics to Prevent Competition with Brand Name Drugs, Testimony Before the United States Senate Committee on the Judiciary (Jan. 17, 2007), http://judiciary.senate.gov/print_testimony.cfm?id=2472&wit_id=5983.
86. About.com: Senior Health, Prescription Drug Costs, http://seniorhealth.about.com/cs/prescriptiondrugs/a/drug_cost.htm (last visited Feb. 28, 2007) ("For some it has become a choice between buying drugs or buying food.").
retail data shows that the price of a generic drug averages 94% percent of the brand price when there is one generic competitor on the market, and that the entry of a second generic competitor reduces prices to 52% of brand price. 89 For products that attract a large number of generic competitors, the average branded price can drop to 20% of the branded price or lower. 90 A study by the Congressional Budget Office ("CBO") that looked at twenty-one drugs that first encountered generic competition between 1991 and 1993 came to a similar conclusion. 91 After one year, these drugs had lost an average of 44% of sales revenue, and 42.8% of prescriptions, from drugs dispensed through pharmacies to their generic counterparts. 92 The CBO study also found that the retail price of the generic drugs was 25% less than that of the brand-name drugs, on average. 93 It follows that the existence of reverse payments, and their sizeable magnitude, can in large part be attributed to the branded and generic companies' exposure to enormous potential financial losses and gains, respectively, should the patent challenge succeed.

B. Barriers to Generic Market Entry

Substantial barriers to market entry confront potential generic drug competitors, and these barriers tend to incentivize reverse payments settlements. This section discusses specific regulatory provisions that interact with the drug development process to create barriers to entry that are unique to the drug industry. It also discusses the relationship between entry barriers and the anticompetitive

89. Id.
90. Id.
92. Id. See also Caves et al., supra note 87, at 36 (finding the price of the first generic producer is about 40% below the pre-patent expiration branded price of the drug); Richard G. Frank & David S. Salkever, Generic Entry and the Pricing of Pharmaceuticals, 6 J. ECON. & MGMT. STRATEGY 75, 89 (1997) ("The substantial shift in market share from brand-name to generic producers (40%-50%) along with the significantly reduced price of generic substitutes (25%-30% lower) means that the average price of a prescription for a compound subject to generic competition has fallen."); Henry G. Grabowski & John M. Vernon, Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act, 35 J.L. & ECON. 331, 335 (1992) ("The general pattern is that generic products enter at a significant discount to the pioneering product [and] . . . the prices of the pioneering brands remain higher than their generic competitors and actually increase in nominal terms . . . [T]he average market price [weighted by sales of the brand and generic] declined by a little more than 10 percent per year in the first two years after generic entry.").
93. CBO REPORT, supra note 91, at 28.
potential of reverse payments settlements. It is shown that a consideration of barriers to market entry, and the source of these barriers, is critical in any assessment of the anticompetitive potential of a specific agreement, as well as reverse payment settlements in general.

1. The Relevance of Entry Barriers to Anticompetitive Potential

Fundamentally, reverse payments are motivated by a desire on the part of the patent owner to preclude generic competition by means of a privately negotiated agreement, rather than relying on enforcement of the patent in courts. In general, a branded drug company attempting to maintain market exclusivity by paying a potential generic competitor to stay off the market will be successful only to the extent it can also keep third party generic competitors off the market. This is where barriers to third party generic entry become so critical. In the absence of such barriers, and in the wake of a reverse payment settlement, the branded company would be expected to experience a parade of subsequent third party generic companies challenging the patent and threatening to enter the market. Eventually, the cost of paying off all the potential competitors would outstrip the profits of even the most lucrative blockbuster drug. On the other hand, if there are high barriers preventing, or at least significantly delaying third party market entry, then an agreement to pay a single potential competitor to stay off the market can effectively exclude any generic competition, rendering the strategy highly attractive to the branded drug company and correspondingly raising anticompetitive concerns.

Many of the proposed rationales that would support treating reverse payment settlements as presumptively illegal are based on an apparent assumption that barriers to third party generic entry are high, or at times even insurmountable in the context of a Paragraph IV

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94. The term "third party generic competitors" and "third party market entry" refers to generic competitors other than the party to the reverse payment settlement.

95. The fact that antitrust law treats such horizontal market allocation agreements as per se illegal, in the absence of a patent, can be justified by the logical inference that the existence of the payment infers sufficient barriers to third party entry to make the payment rational.
litigation. For example, the FTC argued in a brief seeking a denial of certiorari in *In re Cardizem CD Antitrust Litigation* that:

A variety of factors unique to the pharmaceutical industry, including the effects of state laws and various policies of health care institutions that accelerate and magnify the economic impact of generic entry and the contours of the Hatch-Waxman regulatory scheme, have created incentives for the use of reverse payment provisions in pharmaceutical patent litigation. For example, reverse payment settlements may be attractive to the patentee in this context because they may forestall entry not only by the alleged infringer, but by other generic firms as well.

Arguments made by others advocating a rule of presumptive illegality for reverse payment settlements also tend to assume unusually high, or even insurmountable, barriers to third party generic entry. For example, Hovenkamp et al. state that the appearance of reverse payments settlements in Paragraph IV disputes is “[u]ndoubtedly [due to] . . . the fact—unique to pharmaceutical patents—that a properly defined settlement-plus-exit-payment keeps not only the immediate infringement defendant out of the market for a time, but also keeps other generic firms from entering as well.” These scholars go on to assert that by making reverse payments pharmaceutical patentees are able to achieve “a guaranteed insulation from competition, without the risk that the patent [will be] held invalid.” Of course, these conclusions rest on an implicit assumption of unusual barriers to third party generic entry in the context of Hatch-Waxman patent challenges.

Underscoring this assumption, in the same article, Hovenkamp et al. discuss patent settlement agreements pursuant to which the patent owner grants the alleged infringer a license to practice the patented invention. While acknowledging that such an agreement has the potential to create cartel conditions, they conclude nonetheless that the agreement poses “reasonably small” antitrust risks because “[i]f the patent is invalid, then the agreement *does not necessarily exclude*
anyone, for others will be able to challenge the patent as well.”

Bear in mind that the creation of a price-restricting cartel would clearly be anticompetitive, and, in the absence of a patent, normally treated as per se illegal. These scholars’ divergent assessment of the inherent antitrust risks of the two types of agreements appears to be based primarily on an assumed difference in barriers to third party generic entry. It might be worth considering whether the focus on reverse payments is to some extent misplaced; perhaps it is barriers to third party generic entry unique to the settlement of Paragraph IV litigations that should be the real concern.

A number of courts have explicitly considered the role of third party barriers to entry in assessing antitrust challenges to reverse payment settlements. In contrast to the FTC and many scholars, the courts who have explicitly considered the issue have tended to assume relatively low, or at least not unusually high, barriers to third party generic entry. These courts tend to conclude that reverse payments do not necessarily raise substantial anticompetitive concerns because they do not prevent third party generic competition. In fact, some courts have gone so far as to find that reverse payment settlements can be pro-competitive, in that they have the potential to reduce barriers to third party entry and clear the field for third party generic competitors.

To a large extent, barriers to third party generic entry in the wake of a Paragraph IV settlement arise out of the regulatory framework governing generic drug development and marketing. Pharmaceutical regulations tend to not only bolster the exclusionary power of patents, but also to impose substantial barriers to third party market entry. This includes the potential for Paragraph IV litigants to arrive at settlement terms that effectively preclude market entry by any generic competitor. Before delving into the specifics, it will be useful to review some pertinent aspects of the regulatory regime governing the development and marketing of drugs, focusing particularly on generics.

102. Id. (emphasis added).
103. See infra Section VII.
104. See infra Section V.H.
105. See infra Section V.H.
106. See infra Section V.H.
107. See infra Section V.H.
108. See infra Section III.B.2-3.
109. See infra Section III.B.2-3.
110. See infra Section III.B.2-3.
2. The Regulatory Framework Governing Generic Market Entry

In the United States, the development and marketing of human drugs is primarily governed by the Food, Drug and Cosmetics Act ("FDCA"). Since 1962, the FDCA has required the sponsor of a new drug to provide "substantial evidence" of both safety and efficacy as a prerequisite to marketing the drug. The mechanism for gaining approval entails filing a new drug application ("NDA") with FDA, containing, inter alia, extensive data demonstrating safety and efficacy; only after FDA approves the NDA is it legal to market the drug. The cost of filing and obtaining approval of an NDA is enormous; it is generally estimated that it costs on average $800 million to bring each new drug to market, and much of this can be attributed to compliance with pre-marketing approval processes. Much of the expense arises from the need to conduct extensive clinical trials with human subjects, a process that is inherently expensive, but necessary to establish the required "substantial evidence" of safety and efficacy.

The primary objective of the safety and efficacy requirement is consumer protection. However, because of the high costs and the substantial time and risk of failure associated with securing NDA approval, compliance with the safety and efficacy requirement represents a substantial barrier to market entry. This barrier particularly impacts would-be generic competitors, who, prior to 1984, were required to comply with the same NDA requirements as the innovator drug company that first developed and brought the drug


to market. At that time, FDA estimated that there were approximately 150 brand-name drugs whose patents had expired but for which there was no generic equivalent, and this deficiency was attributed in large part to the high cost of securing NDA approval for the generic.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, better known as the “Hatch-Waxman Act,” for the express purpose of facilitating generic competition in the prescription drug industry. Hatch-Waxman amended the FDCA in multiple ways intended primarily to lower the entry barriers to generic competition, based on the rationale that increased competition and market forces would drive down drug price. Overall, the legislation was highly successful, as demonstrated by the large number of generic drugs that became available subsequent to the legislation and the well-documented correlation between generic entry and price reductions.

One way in which Hatch-Waxman effectively lowered the barrier to generic entry was by providing the Abbreviated New Drug Application, or ANDA, as an alternative to the traditional NDA. The ANDA route to pre-marketing approval essentially allows a generic company to free ride on much of the costs incurred by the branded drug company in obtaining approval of the original NDA. Under the ANDA process, a generic manufacturer can obtain approval by demonstrating that the proposed generic product (1) contains the same active ingredient as, and (2) is “bioequivalent” to, the branded drug. Significantly, the ANDA filer can rely on the

118. FTC GENERIC DRUG STUDY, supra note 31, at 3-4.
122. FTC GENERIC DRUG STUDY, supra note 31, at i (“Beyond any doubt, Hatch-Waxman has increased generic drug entry.”).
124. 21 U.S.C. § 355(j)(2)(A)(iv) (2000). There are other requirements – as with an NDA application, the ANDA must also include:
   (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as
data submitted by the innovator in the original NDA to establish the requisite reasonable evidence of drug safety and efficacy, thereby avoiding, for example, the expense of conducting redundant human clinical trials.\textsuperscript{125} In practice, this allows the generic company to obtain marketing approval at a fraction of the cost incurred by the innovator company. Commentators acknowledged that the substantial reduction of this entry barrier has led to a pronounced expansion of the generic drug market.\textsuperscript{126} According to the CBO, in 1994 alone, Hatch-Waxman resulted in consumer savings of $8-10 billion on retail prescription drug purchases.\textsuperscript{127}

The role of patents also figures prominently in Hatch-Waxman reforms, and understandably so, since they can represent the most formidable barrier to the entry of generic competition.\textsuperscript{128} Some period of marketing exclusivity for innovator drug companies is clearly desirable, as a mechanism for recouping the sizable investment required to bring a new drug to market, and to acknowledge the inherent risk involved in drug development.\textsuperscript{129} Hatch-Waxman reflects this concern, by providing a number of statutory provisions that specifically bolster the patent rights of innovator drug components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug.


\textsuperscript{125} FTC GENERIC DRUG STUDY, \textit{supra} note 31, at 5.

\textsuperscript{126} For example, a CBO study reported that for thirteen major drugs with patents expiring between 1990 and 1993, eleven had generic entry within two months of patent expiration. DAVID REIFFEN & MICHAEL R. WARD, GENERIC DRUG INDUSTRY DYNAMICS 6 (2002), http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf. In contrast, a study of pre-Hatch-Waxman entry (between 1976 and 1982) found that only two of the top thirteen drugs had generic entry within one year of patent expiration. \textit{Id.}

\textsuperscript{127} CBO REPORT, \textit{supra} note 91, 13.


\textsuperscript{129} There are many risks associated with drug development. Only a fraction of promising drug leads prove to have the requisite safety and efficacy in clinical trials; the rest are abandoned along with the investment made prior to clinical trials. Even safe and effective drugs are not always commercially successful for a variety of reasons. Furthermore, successful drugs are sometimes found to have substantial adverse side effects, in many times years after market entry, resulting in potentially huge product liability, as recently seen with the COX-2 inhibitor Vioxx. See, \textit{e.g.}, Press Release, Merck, Vioxx Trial Update: Statement on Vioxx Product Liability Trial Scheduled in Starr County, Texas (Jan. 10, 2006), http://www.merck.com/newsroom/press_releases/corporate/2006_0110.html.
companies.\textsuperscript{130} One example is a patent term extension provision, which allows pharmaceutical patent owners to obtain substantial extensions of their patent term to compensate for time spent obtaining FDA approval for the drug.\textsuperscript{131}

At the same time, patents delay generic competition and facilitate supra-competitive pricing, so it is important to ensure that drug innovators do not improperly extend their term of patent exclusivity, for example by means of invalid patents or patents whose scope does not encompass any or all potential generic variants of a branded drug.\textsuperscript{132} Hatch-Waxman addresses this concern by provisions that limit the rights of pharmaceutical patent owners and promote challenges of patent validity and scope of coverage.\textsuperscript{133} For example, while on the one hand Hatch-Waxman extends patent terms for innovator drug companies to compensate for delays in FDA approval process, it also creates a statutory research exemption allowing generic drug manufacturers to complete studies necessary to achieve FDA approval prior to patent expiration without incurring liability for patent infringement.\textsuperscript{134}

When considering the issue of reverse payments settlements, the most relevant patent-related provisions of Hatch-Waxman relate to the listing of patents in an FDA publication commonly referred to as the Orange Book.\textsuperscript{135} Hatch-Waxman requires an NDA filer to list certain patents relating to the drug in the Orange Book: particularly all patents covering the drug's active ingredient, patents on specific formulations or compositions of the drug, and patents covering the methods of using the drug.\textsuperscript{136} A number of important consequences
flow from the listing of a patent in the Orange Book; some tending to bolster the rights of the patent owner, and others facilitating challenges to the listed patent. In the aggregate, they reflect Congress’ intent to balance the interests of branded and generic drug companies in a manner that benefits consumers. In explaining the competing policy objectives embodied in Hatch-Waxman, one federal appellate judge noted that the legislation “emerged from Congress’ efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”\(^{137}\)

Every ANDA must include a certification for each patent listed in the Orange Book with respect to the NDA of the drug targeted for generic competition.\(^{138}\) The certification for each listed patent must be one of four types,\(^{139}\) commonly referred to as the Paragraph I-IV certifications. In an ANDA containing only Paragraph I, II, and/or III certifications, the applicant effectively acknowledges the existence of the listed patents, and agrees not to enter the market until all of the patents have expired.\(^{140}\) In this case, FDA will only grant final approval to the ANDA after all the listed patents have expired.\(^{141}\)

Alternatively, a generic drug company can challenge a listed patent by making a Paragraph IV certification, whereby the ANDA applicant asserts that the patent is invalid or will not be infringed by the generic drug for which the ANDA applicant seeks approval.\(^ {142}\) An ANDA filer that makes a Paragraph IV certification must provide a notice to the branded drug company with a detailed statement of the factual and legal basis for the ANDA filer’s assertion that the patent is invalid or not infringed.\(^ {143}\)

Upon receiving notice of a Paragraph IV certification, the innovator patent owner has two options. One option is to bring an

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listed in the Orange Book, and there are restrictions on the listing of polymorph patents and patents on methods of use. 21 C.F.R. § 314.53(b)(1) (2006).


141. Id. § 355(j)(5)(B)(ii).


143. 21 U.S.C. § 355(j)(2)(B) (Supp. III 2005). Technically, the ANDA filer must provide notice to both the patent owner and the sponsor of the original NDA; in practice these are usually the same party, which is the manufacturer of the branded drug.
immediate, pre-marketing infringement suit against the ANDA applicant. Under Hatch-Waxman, the mere filing of an ANDA with a Paragraph IV certification is an act of constructive infringement, permitting the patent owner to bring suit as soon as the certification is filed.\textsuperscript{144} If the lawsuit is filed within forty-five days of the patent holder receiving notice of the Paragraph IV certification, that filing will invoke an automatic stay of FDA approval of the ANDA, commonly referred to as the “thirty-month stay.”\textsuperscript{145} The thirty-month stay lasts until the earliest of one of the following occurrences: (1) the expiration of thirty months from the receipt of notice of the Paragraph IV certification; (2) a final determination of patent invalidity or non-infringement by a district court; or (3) expiration of the patent.\textsuperscript{146}

Alternatively, if the patent owner that fails to sue within forty-five days, the benefit of the thirty-month stay provision is forfeited, and the generic challenger is free to market the drug upon FDA approval of the ANDA.\textsuperscript{147} Upon generic market entry, the patent owner remains free to sue the generic company in a standard patent infringement action.\textsuperscript{148}

Note that the thirty-month stay provision provides for essentially the equivalent of an automatic preliminary injunction, without requiring the patent owner to demonstrate any degree of likelihood of success on the merits or any of the other criteria normally required of a patent owner moving for preliminary injunction.\textsuperscript{149} Furthermore, there is no requirement that the patentee post any sort of bond to cover the defendant’s losses for the time enjoined, payable in the event the defendant ultimately prevails.\textsuperscript{150} The thirty-month stay

\textsuperscript{144} Id. § 355(j)(5)(B)(iii). Some courts have referred to this as an “artificial” form of patent infringement. See, e.g., Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).


\textsuperscript{147} Id.


\textsuperscript{149} In order for a patent owner to succeed in a motion for preliminary injunction, it normally must establish: “(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction’s favorable impact on the public interest.” See, e.g., Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001).

\textsuperscript{150} This is generally a requirement when an actual preliminary injunction is granted, and in the case of a blockbuster drug the size of the bond could be substantial. For example, a district court recently required a $400 million bond of a branded drug company as a condition for entering a preliminary injunction to stop the sale of generic Plavix while the case was being litigated. Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1374 (Fed. Cir. 2006).
provision confers a substantial benefit on the patent owner, for it provides an absolute, although time-limited, right to exclude a competitor from the market, regardless of the likelihood that the marketing of the generic product would actually infringe a valid patent.

Orange Book listing effectively bolsters the exclusionary power of a patent. In any other context, a patent represents nothing more than a right to try to exclude competitors. Actual exclusion will only occur if a patent owner can convince a court to issue an injunction or temporary restraining order, which very often does not occur, or, alternatively, after the patent litigation has concluded in favor of the patent owner.\textsuperscript{151} In contrast, FDA will not grant final marketing approval for a generic drug under the ANDA process until all listed patents have expired, unless the generic company makes an affirmative substantiated certification that the listed patent is invalid or not infringed.\textsuperscript{152} Even then, the generic company is subject to the automatic thirty-month stay and suit for patent infringement prior to market entry.\textsuperscript{153}

At the same time, other provisions of Hatch-Waxman substantially attenuate the patent rights of branded drug companies, by essentially placing a bounty on each patent listed in the Orange Book in order to incentivize patent challenges.\textsuperscript{154} In particular, the first generic applicant to file an ANDA containing a Paragraph IV certification is eligible for 180 days of marketing exclusivity, during which FDA may not approve any subsequent ANDA corresponding to the same branded product.\textsuperscript{155} Note that this 180 days of generic exclusivity ("GE") is granted for the mere act of filing a Paragraph IV certification.\textsuperscript{156} In other words, the patent owner is not required to respond with a lawsuit, nor is the Paragraph IV filer required to succeed in the challenge. In fact, the first Paragraph IV filer can retain its GE even if it never succeeds in entering the market prior to patent expiration, and even if a subsequent Paragraph IV filer does successfully challenge the patent.\textsuperscript{157} The 180-day GE provisions play

\textsuperscript{151} See Hovenkamp et al., \textit{supra} note 10, at 1761.
\textsuperscript{154} Engelberg, \textit{supra} note 121, at 391.
\textsuperscript{155} \textit{Id}.
\textsuperscript{156} \textit{Id}.
\textsuperscript{157} Senator Hatch has noted the potential unfairness of awarding GE to the first-filer as opposed to the first to successfully challenge a patent in court in his comments regarding the
a prominent role in most reverse payments settlements, and are discussed in more detail below.\textsuperscript{158}

The incentives for listing a patent in the Orange Book are somewhat perverse, in that the benefits to the patent owner are inversely correlated with the strength of the patent. If the patent is weak, either because it is likely invalid or would not be infringed by a generic product, listing is highly advantageous because it provides for an automatic thirty-month stay, without requiring the patent owner to convince a court to grant a preliminary injunction based on the merits of the case. On the other hand, if the patent is strong, the thirty-month stay is less valuable, because the patent owner could probably establish the reasonable likelihood of success necessary to secure a preliminary injunction, to a large extent rendering the thirty-month stay superfluous.\textsuperscript{159} The prospect of GE will incentivize generic companies to challenge even an apparently strong patent, in view of the huge potential profits if the Paragraph IV filer succeeds and the unpredictability of patent litigation. Courts frequently make mistakes, and every patent challenge represents some potential that a court will mistakenly invalidate even an objectively strong patent.

3. 180-day Generic Exclusivity Can Delay Third-Party Market Entry

In the context of Hatch-Waxman, there is one barrier to third party generic entry that has the potential to dominate over all the others, and that is the ability of a first Paragraph IV filer, or a "first-filer," to indefinitely "park" its 180-day exclusivity period.\textsuperscript{160} Not only is this barrier unique to Paragraph IV patent challenges, it is also potentially insurmountable, because a parked GE can create a bottleneck in FDA regulatory process preventing the approval of any third party generic competitor, at least until the expiration of the challenged patent.

The potential to park GE arises out of the criteria used to trigger the awarding of GE and the initiation of the GE period. Recall that

\textsuperscript{158}See infra Section III.B.3.

\textsuperscript{159}Of course, no matter how strong the patent, the thirty-month stay can be preferable over a preliminary injunction. For example, the automatic stay avoids the vagaries of litigation and the requirement that the patent holder post a bond, which in the case of a prescription drug would typically amount to a substantial sum. See, e.g., Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1374 (Fed. Cir. 2006).

\textsuperscript{160}FTC GENERIC DRUG STUDY, supra note 31, at vii-xi.
GE is awarded to the first-filer and generally does not commence until after the first-filer begins marketing a generic version of the drug, or a decision is reached in a lawsuit filed in response to the Paragraph IV litigation.161 If the parties to a Paragraph IV litigation reach an agreement pursuant to which the first-filer agrees to delay or forgo market entry, the 180-day GE period will not begin until after the patent litigation is decided in the first-filer’s favor.162 If the agreement is a final settlement, resulting in dismissal of the infringement action, the 180-day GE period is never triggered; if it never begins, it can never end.163 As a consequence, the parties can agree to “park” the GE indefinitely, creating a bottleneck that will prevent any third party generic from entering the market, even if that third party is never sued for patent infringement, or succeeds in establishing in court that the patent is invalid or not infringed.164

The legal right of a first-filer to park GE is even more clear-cut in the case of a partial settlement, where a subsequent generic challenger cannot even argue that the first-filer has forfeited GE by agreeing to terminate the litigation.165 In this case, GE will not be triggered until after a final court judgment, and, in light of the often protracted timeline of patent litigation, this can result in a bottleneck lasting for years. Importantly, with the partial settlement agreement in

161. 21 U.S.C. § 355(j)(5)(B)(iv) (Supp. III 2005). This characterization of the triggering events is an oversimplification of extremely complex statutory language. However, it is sufficient to understand the statutory basis for the potential to park GE. Originally, 21 U.S.C. § 355(j)(5)(B)(iv) provided that commencement of the 180-day GE period would be triggered by either the first commercial marketing of the generic drug by the first-filer, or by a court decision holding the patent invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Pursuant to substantial amendments in the Medicare Modernization Act of 2003, GE is now only triggered by first commercial marketing, but success in court can result in forfeiture of the 180-day exclusivity. 21 U.S.C. § 355(j)(5)(D) (Supp. III 2005). All of the antitrust challenges to reverse payment settlements brought so far involve agreements governed by the original version of the statute. Although the forfeiture provisions introduced by the 2003 amendments were intended to prevent blocking of GE, they were probably not entirely successful, and the potential to park GE continues to exist to some extent. This continuing problem of GE parking is addressed by the FTC in a recent prepared statement before the Senate Judiciary Committee. See Jon Leibowitz, Comm’r, FTC, Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution, Prepared Statement of the FTC Before the Committee on the Judiciary of the United States Senate 23-25 (Jan. 17, 2007), http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf [hereinafter FTC January 2007 Senate Testimony].

162. FTC GENERIC DRUG STUDY, supra note 31, at 58-60.

163. As least this is how the original version of the provisions was interpreted. Even after the 2003 amendments, according to my analysis of the statutory language and relevant case law the same potential exists, although a full explanation would exceed the scope of this paper.

164. FTC GENERIC DRUG STUDY, supra note 31, at 57.

165. See supra Section II.
place, there can be less incentive for either party to proceed diligently in court. This creates an environment ripe for collusive behavior that protracts the litigation to the benefit of both parties, but at the expense of third party generic entry and consumers.

The ability to park GE creates a huge incentive for collusive settlement agreements between branded drug companies and first-filer generic companies. By effectively creating an insurmountable barrier to third party generic entry, it allows the settling parties to share in supracompetitive profits made possible by market exclusivity. In fact, were it not for fear of antitrust liability, it would probably always be in the best interest of a branded drug company and the GE owner to reach such an agreement. The profit margins available under monopoly conditions generally exceed those available in a market with two or more competitors, and with only a single potential generic competitor both parties would be better off sharing those profits than competing.

While agreements to park GE clearly raise anticompetitive concerns, it is important to bear in mind that there are arguably legitimate reasons a GE owner would agree to park its GE. For example, most critics of reverse payment settlements, including the FTC, would condone a settlement agreement wherein the only consideration flowing to the GE owner is a negotiated early entry date. The patent challenge has worked as intended, providing consumers with generic competition prior to patent expiration, but the GE owner will be denied its reward of 180-day exclusivity if it is not allowed to park its GE until the date of market entry.

As another example, a first generic filer diligently pursuing a Paragraph IV litigation in court might legitimately desire to retain its GE until after successfully obtaining a final judgment of invalidity or non-infringement. A subsequent generic company that has obtained final approval of its ANDA, because it was not sued by the patent owner, or because it has already prevailed in court, would destroy the value of GE if it were allowed to enter the market while the first-filers’ litigation is pending. Members of Congress specifically considered this issue and declined to adopt certain proposed reforms to the 180-day exclusivity provisions that would have limited the

166. See infra Section IV.A.

167. The incentives for collusive settlements parking GE are described in more detail by Hovenkamp et al., supra note 10, at 1755-62.

168. Id. at 1762. See also Preserve Access to Affordable Generics Act, S. 316, 110th Cong. § 2 (2007).
ability to park GE, but at the same time would have caused the first-filer to forfeit its GE under this scenario.\textsuperscript{169} Note the fundamental tension here. It will be very difficult, if not impossible, to amend the GE provisions of Hatch-Waxman to eliminate the potential for parking GE without, at the same time, creating situations where first-filers lose their GE, even in cases where there is no collusion with the patent owner, or reverse payments.

4. The ANDA Approval Process Acts as a Barrier to Generic Market Entry

While the relatively streamlined ANDA approval process has reduced the regulatory burden on generic drug companies, it still imposes its own substantial monetary and temporal barriers to entry for third party generic competition. The process typically requires a would-be generic competitor twelve months and around $1 million just to generate and compile the data necessary to file an ANDA.\textsuperscript{170} If that is the case and the ANDA includes a Paragraph IV certification that results in an automatic thirty-month stay, a time lag of at least forty-two months between commencement of approval process and ability to market the drug can be expected.

Even in cases where the patent owner does not file suit, and thus the thirty-month stay does not come into play, the time required for ANDA approval is substantial. In most cases, FDA rejects the initial ANDA, requiring the applicant to conduct additional tests or submit additional material.\textsuperscript{171} The time it takes to secure ANDA approval varies substantially on a case-by-case basis, reportedly averaging about nineteen months and in some cases taking much longer, so in total an ANDA can expect at least two to three years to elapse between the time it decides to enter a market and actual entry, even in cases where a patent is not asserted.\textsuperscript{172} Approval can in some cases take much longer; it is not uncommon for a Paragraph IV filer not to receive final approval until well after expiration of the thirty-month stay.\textsuperscript{173}

\begin{itemize}
  \item \textsuperscript{169} Natalie M. Derzko, The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation, 45 IDEA 165, 228-29 (2005).
  \item \textsuperscript{170} For example, an approved source of materials and adequate production facilities are required at the time of the application. See REIFFEN & WARD, supra note 126, at 6-7.
  \item \textsuperscript{171} Id. at 6. A typical approved applicant has gone through two or three resubmissions before it obtains approval. Id.
  \item \textsuperscript{172} Id. at 6-7.
  \item \textsuperscript{173} See, e.g., Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1372-73 (Fed. Cir. 2006) (relating how approval of an ANDA for the generic form of Plavix took over four years).
\end{itemize}
The cost barrier to entry for filing the ANDA is probably not too much of a factor, when one considers the profits available to the generic manufacturer, even without the benefit of GE. If a generic company can at least be one of the first generics on the market, they stand to earn substantial returns, particularly in view of the first mover advantages seen to accrue to the first generic filers. Even in a market with a substantial number of generic competitors, generic drug companies are believed to earn profits exceeding the average cost—the expected return in a hypothetical truly competitive market.

However, the regulatory burden can impose a substantial temporal barrier to entry. Although a reverse payment settlement can leave third party generic companies free to enter the market, it will take them at least several years to obtain marketing clearance from FDA, unless they have already started the process prior to the settlement. For a blockbuster drug with annual sales in the billions of dollars, even a few years of market exclusivity would be extremely valuable and highly incentivize substantial reverse payments to one or a few generic companies that are well along in the approval process.

On the other hand, one can imagine a scenario where multiple third party generic companies have filed ANDAs with Paragraph IV certifications shortly after the first-filer. Depending upon how these third parties are faring in the approval process, they might represent viable generic competition, reducing the potential for a reverse payment settlement between the patent owner and a single generic company to restrict all generic competition. Since the regulatory burden is primarily temporal, as opposed to fiscal, the anticompetitive potential of the agreement depends to a large extent on the number of other generic companies seeking ANDA approval at the time of the agreement and their status in the approval process. This fact is normally not explicitly addressed in analyzing the legality of reverse payment settlements, but should be a relevant consideration in assessing the potential for anticompetitive harm.

In practice, the first scenario where there are no other generic competitors seeking ANDA approval at the time of the settlement agreement seems unlikely, at least in the case of blockbuster drugs, which are the primary concern of the FTC and other critics of reverse payment settlements. Highly profitable drugs with tremendous

174. REIFFEN & WARD, supra note 126, at 7 n.7.
175. Id. at 3-4.
176. See supra notes 171-173 and accompanying text.
therapeutic utility should and do generally attract multiple generic challengers. Under this dynamic, settlement with one generic company will not necessarily prevent the other generics from obtaining regulatory approval and entering the market, at least without parking GE.

5. Drug Patents Can Be Difficult to Design Around

Another way in which drug regulation encourages reverse payment settlements of Paragraph IV litigation is by bolstering the effective exclusionary potential of drug patents. To understand this effect, it is useful to consider a hypothetical non-regulated drug market, with consumers directly selecting and paying for their drugs. In a non-regulated environment where price and output decisions are driven by market factors, drug companies would face fewer constraints in designing around a rival's patent. While designing around is generally a legitimate means for circumventing a competitor's patent, it is often difficult to accomplish in the context of prescription drugs.

Imagine that Company A markets a patented and branded drug, and Company B designs around the patent by developing a drug with essentially equivalent pharmacologic properties but containing an active ingredient with a different chemical structure. Even if the difference in structure is trivial and the resulting effect on function insignificant, if the patent is avoided, then Company B has succeeded in designing around the patent and should be able to compete directly in the market.

However, in the real world, strict regulatory controls make it significantly more difficult for a Company B to successfully design around an Orange Book-listed patent. If the design around process involves any change to the chemical structure of the active ingredient of the drug or results in a product that is not bioequivalent to the original patented product, Company B will generally not be able to take advantage of the ANDA process. Instead, it will be required to go through the full-blown NDA process, resulting in a drastic increase in the time and expense required to secure marketing approval. This, in

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177. See, e.g., In re Tamoxifen Citrate Antitrust Litigation, which attracted three subsequent generic challengers, and Schering-Plough, where there were two ANDA filers, both discussed infra Section V.A. This pattern of multiple ANDA filers is typical.

178. See infra notes 179-184 and accompanying text.

179. This is assuming that consumers are only interested in the branded drug's function and will find the two products to be close substitutes for one another.

part, explains why generic companies expend so much energy challenging patents, rather than attempting to design around them. That is not to say that drug companies are unable to design around patents. Drug companies are often quite successful in designing around formulation patents, which do not cover the active ingredient per se. 181 However, drug companies' efforts are still severely limited by the fact that any design around involving an alteration of the structure of the active ingredient or lack of bioequivalence will preclude marketing approval by means of an ANDA.

The various rules restricting the ability of pharmacies to make substitutions for prescribed drugs impose another impediment to designing around pharmaceutical patents. If consumers were free to purchase any drug they liked, and if they paid for their drugs directly, they might be induced to purchase Company B's alternate, but technically not "generic," product. This is true, particularly if it were priced less than Company B's branded drug, since the two drugs are close functional substitutes. However, in the case of prescription drugs, consumers are normally unable to do this. Pharmacies are only permitted to substitute what are referred to as "AB-rated drugs," essentially generic versions of the prescribed drug that would qualify under the ANDA process. 182 They are not allowed to substitute functional equivalents, even if requested by the patient, unless the substitute is an AB-rated generic. 183 Since the active ingredient in Company B's design-around is different from that in Company A's branded product, substitution by the pharmacy would not be allowed. Also, because patients generally do not pay for drugs out of their own pockets, there is little incentive to research the options and request their doctors to prescribe the less expensive, but functionally equivalent, product. This inertia is reinforced by the substantial marketing efforts typically associated with branded drugs. 184

181. See, e.g., In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 902-03 (6th Cir. 2003), for a case where a generic company apparently successfully designed around a formulation patent but was still able to take advantage of ANDA process.


183. See, e.g., id.

184. The FTC recently noted that a competing drug that is not bioequivalent to a branded drug is unlikely to have a significant impact on the market for the branded drug. Complaint ¶ 15, In re Hoechst Marion Roussel, Inc., No. 9293 (F.T.C. Mar. 16, 2000), http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm.

Another way in which the provisions of Hatch-Waxman promote reverse payment settlements is by effectively reallocating the potential upside pay off and downside risk between parties to a Paragraph IV litigation, relative to the situation in a more conventional patent litigation. Normally, a patent infringement suit is filed subsequent to substantial commercial and allegedly infringing activities. Often these activities continue through the course of the litigation, and settlement might not occur until years after the initial filing of the suit. As a consequence, the alleged infringer is typically exposed to a risk of potentially large damages if it loses the lawsuit, so large that they might far exceed any profits attributable to the infringement. The upside potential for the alleged infringer should it prevail in the litigation, on the other hand, is typically limited to the right to continue its pre-litigation activities that resulted in the lawsuit.

The patent owner in a conventional patent litigation often stands to reap a windfall in damages if successful in the litigation. Conversely, the downside potential, should the patent owner lose, is essentially maintenance of the status quo. The defendant is free to continue what were alleged to be infringing activities, just as it would have if the patentee had simply decided not to enforce its patent.

In contrast, the relative allocation of risk and upside potential is substantially redistributed in a Paragraph IV litigation. Paragraph IV lawsuits are generally filed long before the proposed generic product has even received marketing approval, and hence before any damages have accrued. Under Hatch-Waxman, the only remedy available to a Paragraph IV plaintiff is an injunction, provided the generic company has not commercialized the drug.

Furthermore, because of the unique economics of the prescription drug market, driven in large part by the dominance of

185. See Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1073-74 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006). See also Embrex, Inc. v. Serv. Engin’g Corp., 216 F.3d 1343, 1352-53 (Fed. Cir. 2000) (Rader, J., concurring) (noting that de minimis infringement will result in only de minimis damages, thereby reducing the incentive to bring suits for non-commercial infringement).

186. Often after a critical judicial ruling, or on the eve of trial.

187. It might also benefit from the strengthening of its patent by the court’s affirmation of the patent’s validity and scope.

188. See supra Section III.B.2 and infra Section V.

government and other third party payers and the importance of favorable formulary listings, even a brief period of marketing a generic drug can result in irreversible damage to the market for the branded product.\textsuperscript{190} Even if the patent owner ultimately prevails in the litigation, chances are high that it will not be fully compensated by court-ordered damages.\textsuperscript{191} The patent owner's losses would be expected to far exceed the generic company's profits resulting from the infringement, and might outstrip the assets of a modest-sized generic company.\textsuperscript{192} Although the patent owner's losses might be very real, proving them with sufficient rigor to justify an award of lost profits might require sophisticated economic arguments that a court might not understand, or find too speculative to serve as the basis for an award of huge money damages.\textsuperscript{193}

The patent owner in a Paragraph IV litigation faces enormous downside potential. As discussed above, the exclusionary potential of a pharmaceutical patent can substantially exceed that of a typical patent, because it allows for an automatic thirty-month stay and because of the practical difficulty in designing around such patents.\textsuperscript{194} It follows that the invalidation of a pharmaceutical patent will tend to be more devastating to the interests of the patent owner than the invalidation of a patent in another technology sector.

Compounding patent owner risk is the fact that it only takes one successful patent challenge to invalidate a patent, and that it is not uncommon for multiple generic companies to challenge a single patent.\textsuperscript{195} For example, in \textit{In re Tamoxifen Citrate Antitrust Litigation}, the first Paragraph IV filer was successful at the district court level in having the patent declared invalid and unenforceable under a variety of theories including inequitable conduct.\textsuperscript{196} The case was appealed, but the parties settled prior to the Federal Circuit deciding the
Subsequent to the settlement, three other generic companies filed Paragraph IV certifications and litigated the validity and enforceability of the patent, but all three subsequent court challenges were unsuccessful. Thus, three out of the four courts to consider the charge of inequitable conduct rejected it, but, without the settlement, a single outlier decision could have rendered an otherwise valid patent unenforceable.

Consider how the case might have played out if the patent holder was not able to settle the litigation after the first adverse district court decision. The standard of review for the district court’s ruling of inequitable conduct is quite deferential, with reversal appropriate only where the district court is found to have committed clear error. Given this deferential standard of review, it seems plausible that the Federal Circuit might have upheld the district court’s decision even if it was objectively weak on the merits. The risk of a flawed court decision destroying an objectively valid patent is present in any litigation, and is one explanation for a patent owner making substantial reverse payments to settle in cases where it feels it should prevail on the merits.

Even a patent owner confident in the legitimacy of its patent rights might nonetheless find itself in a compromised position in a particular litigation, either because of an error in litigation strategy, an unfavorable ruling, or perhaps a hostile court. The patent owner will have a strong incentive to settle that particular case, even making substantial reverse payments in order to foreclose the possibility of an anomalous adverse ruling improperly destroying its valuable patent. The same patent owner might decide to litigate another parallel litigation to completion, where the circumstances of that particular litigation appear more favorable to upholding the patent. This appears to be what occurred in Tamoxifen.

The alleged infringer in a Paragraph IV litigation, on the other hand, faces a huge upside potential, should it prevail. If it was a first-

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197. *Id.* at 193-94.
198. *Id.* at 194-95.
199. Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1351 (Fed. Cir. 2005) ("The ultimate determination of inequitable conduct is therefore a matter ‘committed to the discretion of the trial court’ and is reviewed for an abuse of discretion.") (citation omitted).
201. See *infra* Section V.A. See also FTC GENERIC DRUG STUDY, supra note 31, at 35 (noting the settlement rate with second generic applicants is much lower than with first generic applicants).
filer, it will have a minimum of 180-days of generic exclusivity, an extremely lucrative market position, particularly in light of the documented first mover advantage accruing to the first generic market entrant.202

Consider the effect of this redistribution of risk and upside potential on incentives to settle. In the case of a conventional patent infringement suit, even a defendant reasonably confident in ultimately prevailing in the litigation might decide to liquidate its risk of potentially large damages by agreeing to pay the patentee some percentage of the potential damages. Even a defendant perceiving a 20% likelihood of being found liable and estimating a potential of $100 million damages might rationally decide to settle for $20 million.203 By settling, the defendant might even be able to negotiate an acceptable royalty and continue to practice the patented invention. On the other hand, if the litigation continues and the patentee prevails, the patentee will more than likely be able to get a permanent injunction, thereby barring the defendant from the technology for the remainder of the patent term,204 or at least substantially strengthen the patent owner’s bargaining position in any licensing negotiation. The infringer, being already on the market, will likely find it more costly to exit the market than a Paragraph IV defendant that has yet to enter the market.205

Conversely, in a Paragraph IV litigation, the lack of potential damages and the potentially catastrophic consequences of an adverse ruling place the patent owner in a relatively weaker position. Even a patent owner confident in the merits of its case might reasonably decide to make substantial reverse payments to insure against an adverse ruling. The patent challenger, on the other hand, having already sunk the costs of preparing and filing its ANDA and facing no prospect of money damages, has little incentive to settle in the

202. REIFFEN & WARD, supra note 126, at 7 n.7.
203. Admittedly an overly simplistic example used to illustrate a point. In view of the apparent high rate of error by courts deciding patent cases, a rational patent owner would probably never predict more than an 80% probability of success. See, e.g., Alan C. Marco, Learning by Suing: Structural Estimates of Court Errors in Patent Litigation 17 (Oct. 21, 2006) (unpublished manuscript, on file with the First Annual Conference on Empirical Legal Studies), available at http://ssrn.com/abstract=913408 (finding that errors wherein a valid patent is erroneously found to be invalid by a court occur with an estimated probability of 20 to 25%).
205. The expense of filing and gaining approval of the ANDA is a sunk cost, but, even if the patent challenge is unsuccessful, the investment is not lost. The generic company can still use the ANDA as the basis for marketing a generic product, albeit at a later date (after the patent has expired).
absence of reverse payments. This reversal of risk, to a large extent, explains the proliferation of such payments in Paragraph IV litigation settlements. As discussed below, a number of courts have specifically noted this reallocation of risk and upside potential in Paragraph IV litigations, and the resulting unique incentive for reverse payments in the settlement of these cases.206

IV. THE FTC AND REVERSE PAYMENT SETTLEMENTS

Over the last ten years, FTC scrutiny of the pharmaceutical industry has expanded dramatically, driven by a rapid rise in the nation's expenditure on prescription drugs.207 One area of particular concern is the potential for anticompetitive settlements of Paragraph IV patent challenges.208

A. The FTC Originally Focused on Settlement Agreements That Parked Generic Exclusivity or Covered Noninfringing Products

The FTC has long been aware of reverse payment settlements, but until recently the agency did not appear to have been overly concerned with the anticompetitive implications of reverse payments per se.209 Instead, FTC scrutiny focused primarily on terms in patent settlement agreements that either had the potential to park the 180-day GE, or that extended to activities and/or products not covered by the patent.210

In 1999, the FTC ordered twenty-eight brand name drug companies and fifty generic companies to submit for review any agreements the companies had entered into subsequent to December 31, 1994, that related to an ANDA filing, including any full or partial

206. See infra Section V.C.
208. See, e.g., FTC GENERIC DRUG STUDY, supra note 31.
209. Reverse payment settlement agreement to Paragraph IV litigations is not a new phenomenon. For example, the FTC GENERIC DRUG STUDY, supra note 31, at 31, identifies one that was executed in March 1993. Note that there were probably reverse payment settlement agreements prior to this one. The FTC study gathered agreements that were executed after December 31, 1994, or that were still in force as of the date that information was requested in 2001. Id. at 3, A-22 & n.7.
210. See infra notes 221-229 and accompanying text.
settlements to patent litigation. The results of this survey were analyzed and became the basis for a report entitled Generic Drug Entry Prior to Patent Expiration: An FTC Study (“FTC Generic Drug Study”), published in July 2002. The study provides, inter alia, a detailed analysis of the agreements and their effect on competition, along with a variety of specific and general recommendations for legislative changes to Hatch-Waxman to address competition concerns identified in the study. Most of the proposed legislative fixes were intended to curtail anticompetitive gaming of the ANDA processes, which, in the view of the FTC, at times subverted the legislation’s purpose of promoting generic competition.

The study begins with an “Executive Summary and Legislative Recommendation” section, which prescribes two primary recommendations, one having to do with reform to the thirty-month stay provisions and the other relating to the parking of 180-day GE. No recommendations were made with respect to reverse payments settlements, which were referred to in the study as “brand payments.” To the contrary, the section concludes by noting that Paragraph IV litigation settlements are generally not problematic, so long as there is no potential for parking GE.

Although the FTC study specifically identifies a number of agreements with reverse payments, including some of the earliest Paragraph IV settlements identified in the study, it never suggests that reverse payments in and of themselves raise anticompetitive concerns, or should render an otherwise legitimate agreement presumptively illegal. To the contrary, the study makes clear that it “does not reach any conclusions about the competitive effects of [settlements involving brand payments].”

The study does identify four interim settlement agreements as being particularly suspect, including the agreements which ultimately

211. The special orders were sent out pursuant to section 6(b) of the Federal Trade Commission Act. 15 U.S.C. § 46(b) (2000); FTC GENERIC DRUG STUDY, supra note 31, at 3.
212. FTC GENERIC DRUG STUDY, supra note 31.
213. Id. at i-xi.
214. The study recommended legislation to prevent branded drug companies from obtaining multiple thirty-month stays, and also to limit the ability of companies to park GE. Id. at ii-vi.
215. Id. at i-xi, 17.
216. Id. at viii.
217. At least one of the agreements dates back to 1993. Id. at 31.
218. See id. at 31 (nine out of twenty agreements included reverse payments).
219. Id. at 25.
reached the Eleventh Circuit in Schering-Plough, and notes that enforcement actions had been taken against three out of the four agreements. Incidentally, all of the interim settlement agreements subject to enforcement action involved reverse payments, but the study never particularly points to this fact. Instead, the study identifies as the primary basis for antitrust concern the potential of the challenged agreements to park GE.

The FTC’s initial focus on parking GE and other barriers to third party generic entry, not reverse payments, is also evident in a number of public statements by FTC commissioners. For example, in a 2000 speech, FTC Commissioner Anthony identified reverse payments as problematic, but primarily because they facilitate agreements that park GE, or that otherwise extend beyond the reasonable exclusionary potential of the patent, for example, by requiring the generic company to refrain from marketing any form of the generic drug, even forms not covered by the patent.

The FTC’s initial concern with GE parking and restrictions exceeding the exclusionary potential of the patent, as opposed to a concern with reverse payments per se, is also reflected in its selection of enforcement targets. The first two reported FTC enforcement actions to challenge Paragraph IV settlements were brought against Abbott and Hoechst Marion Roussel on March 16, 2000. Both FTC complaints alleged that the challenged agreements resulted in the parking of GE. They also alleged that the challenged agreements included products that were not covered by the patent; for example, the agreement included restrictions exceeding the exclusionary

220. Id. at 25 & n.3. For comparison, note that the study indicates the FTC had only taken an enforcement action against one out of the twenty final Paragraph IV settlement agreements. Id. at 25 n.2.
221. Id. at 57-58.
potential of the patent. The cases resulted in consent orders in 2000 and 2001, respectively, requiring Abbott and Hoechst Marion Roussel to refrain from entering any agreement with terms that would require the generic company to park its GE, or that would require the generic company to research or market a drug product that is not the subject of the litigation. The companies were also required to refrain from entering partial settlement agreements involving reverse payment. Interestingly, there is no requirement that the parties refrain from reverse payments in a final settlement agreement that would terminate the litigation. The terms of the consent order suggest that, while the FTC was opposed to agreements requiring the generic company to park GE, agreements that extend to products not covered by the patent, and partial settlement agreements involving reverse payments, the FTC did not view reverse payments as per se problematic, at least in the context of a final settlement agreement.

The FTC has, on a number of occasions, testified before Congress regarding the anticompetitive concerns with Paragraph IV settlement that improperly "game" Hatch-Waxman. However, until recently, this testimony had focused on the potential for the parties to


229. It is hard to imagine a reverse payment settlement that does not include reverse payments. Why should a generic company agree to stay off the market without requiring some consideration? Of course, the generic company could choose to stay off the market during the course of the litigation, but why enter into a contract promising to stay off the market without receiving some consideration?

park GE and thereby block entry of potential third party generic competition, rather than on the existence of reverse payments per se, or on theories based on the probabilistic nature of patents or a right of consumers to the benefit of a litigation maintained to final judgment.231

In a prepared statement before the Senate Judiciary Committee on June 17, 2003, Commissioner Muris stressed that all of the early enforcement actions against reverse payment settlements “alleged that the brand-name company used the generic company’s rights to the 180-day exclusivity under Hatch-Waxman to impede entry by other generic competitors.”232 Commissioner Muris made a number of recommendations for congressional action with respect to Hatch-Waxman, including revisions to the 180-day GE provisions.233 Many of these recommendations were adopted in the 2003 Medicare Modernization Act.234 For example, the FTC recommended that brand-name companies and first generic applicants be required to provide copies of settlement agreements to the FTC and the DOJ.235 The sole reason identified by Commissioner Muris for requiring this submission was to allow review of the agreements to “ensure that the 180-day provision is not manipulated in a way to delay entry of additional generic applicants.”236 There was no suggestion that the review provision was intended to police against reverse payments per se. Commissioner Muris also urged implementation of the recommendations for legislative action made in the FTC study, such as forfeiture provisions to prevent parking of GE – no recommendations were made regarding reverse payments.237

B. The FTC’s Attention Has Shifted to Reverse Payments

More recently, the FTC has shifted its position on reverse payment settlements. It has come to equate them with horizontal market allocation agreements, which are normally per se antitrust

231. See Pitofsky, supra note 230.
232. Muris, supra note 230, pt. III.A.
233. Id. pt. IV.F.
236. Muris, supra note 230, pt. IV.F.
237. Id.
violations when no patent is involved.\textsuperscript{238} The FTC advocates a rule that would essentially find such agreements presumptively illegal, independent of the existence of GE parking or restrictions extending beyond the exclusionary potential of the patent.\textsuperscript{239}

This is in contrast to the position taken by most courts, which have generally held that an agreement settling a legitimate patent dispute does not violate the antitrust laws.\textsuperscript{240} Although an agreement to stay off the market would be illegal per se in the absence of a patent, most courts would recognize that a patent provides a legitimate and independent basis for excluding an alleged infringer, and that a settlement agreement is legal so long as it does not restrict competition to an extent exceeding the reasonable exclusionary potential of the patent.\textsuperscript{241} Courts tend to point to the fact that patents are, in a sense, anticompetitive by their very nature, but this is part and parcel of their ability to incentivize innovation.\textsuperscript{242} They also point to the presumption of validity conferred by statute upon issued patents.\textsuperscript{243}

In contrast, the FTC evinces considerable skepticism regarding the presumption of patent validity, and points out that any exemption from the application of normal antitrust rules to patents settlements does not apply if the patent is invalid, or does not cover the restricted activities.\textsuperscript{244} The agency points to statistics showing that courts routinely find asserted patents to be invalid or not infringed,\textsuperscript{245} particularly in the case of Paragraph IV patent challenges, and would

\textsuperscript{238} See, e.g., Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49 (1990) (quoting United States v. Topco Assocs., Inc., 405 U.S. 596, 608 (1972) (observing that an agreement between competitors to allocate territories is a "classic example" of a per se violation of the Sherman Act, with no purpose other than to reduce competition)).

\textsuperscript{239} As noted by the Eleventh Circuit in Schering-Plough, the FTC's rule "would make almost any settlement involving a payment illegal." Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) (further noting the FTC's rule was directly contrary to the Eleventh Circuit's holding in Valley Drug), cert. denied, 126 S. Ct. 2929 (2006).

\textsuperscript{240} See infra Section V.

\textsuperscript{241} Schering-Plough, 402 F.3d at 1066-67.

\textsuperscript{242} Id. at 1067.

\textsuperscript{243} Id. at 1066.


\textsuperscript{245} FTC Petition for Certiorari in Schering-Plough, supra note 244, at 5, 17 (citing FTC GENERIC DRUG STUDY, supra note 31, at 19-20; John R. Allison & Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents, 26 AIPLA Q.J. 185, 205-06 (1998)).
infer from a patent owner's willingness to make sizeable reverse payments that it considers its patent case to be weak. For example, the FTC in its petition for writ of certiorari in *Schering-Plough* cites to a leading treatise of antitrust law for the "fact" that a firm "certain that a patent was valid . . . would have no incentive whatsoever to pay another firm to stay out of the market." 

The FTC's position relies heavily on a body of scholarly literature that stresses the uncertainty of patent litigation and the "probabilistic" nature of patent rights. These theories characterize the patent right as inherently "probabilistic" because of the general uncertainty with respect to validity and scope of a patent prior to court decision. As expressed by Hovenkamp et al., a patent is best viewed not as a right to exclude competition, but more correctly as "a right to *try* to exclude competition."

The FTC has essentially taken the position that in every Paragraph IV litigation, consumers have an expectation interest in the finite probability that the patent challenge will succeed. In effect, the FTC would treat this consumer expectation as a probabilistic property right. The FTC argues that any settlement between the parties that deprives consumers of the value of this expectation interest is a presumptive violation of the antitrust laws.

The FTC would allow parties to settle by compromising on an entry date prior to the patent's expiration, without cash payments, because "the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent." The FTC views these agreements as neutral, or even pro-competitive, since they resolve the uncertainty of the litigation early and provide some guaranteed benefit to consumers in proportion to the probability that the patent challenge would succeed. The FTC would generally find

246. FTC Petition for Certiorari in Schering-Plough, *supra* note 244, at 17. A patent might be weak if likely to be invalid or unenforceable, or if the claims would likely be construed so as to not cover the proposed generic product.

247. See *Id.* at 18 (quoting 12 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046, at 339 (Supp. 2004)).

248. *Id.* at 16 (citing Hovenkamp et al., *supra* note 10, at 1761; Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPECTIVES 75 (2005); Shapiro, *supra* note 10, at 395).

249. *Id.* at 16-17.

250. Hovenkamp et al., *supra* note 10, at 1761.


252. See *Id.* at 19.

253. *Id.* at 18.

254. *Id.*
any reverse payment settlement anticompetitive, because it fails to provide as much consumer benefit as what it considers to be the "benchmark" agreement with a negotiated early entry date and no payments to the patent challenger.\(^{255}\) The FTC would infer that any payment is a quid pro quo for delayed generic entry, and that were it not for the payment the parties would have either settled on an earlier entry date, or not settled and litigated the case to completion—either scenario benefiting consumers relative to the reverse payment settlement.\(^{256}\) Note that under the FTC's approach, essentially any reverse payment settlement will be found illegal, regardless of the strength or weakness of the patent case. This is consistent with the FTC's position that an inquiry into the merits of the underlying patent case is inappropriate, except in cases of an objectively baseless or sham patent suit.\(^{257}\)

While the FTC considers an inquiry into the merits of the underlying patent dispute generally unwise and unwarranted in assessing antitrust liability, it clearly has no such reticence when it comes to speculating on the merits of a negotiated business agreement. For example, in *Schering-Plough*, most of the allegedly illegal payments were in the form of licensing fees provided for in an ancillary licensing agreement.\(^{258}\) The FTC conducted an extensive analysis of the business justifications for the agreement, delving deep into the negotiations leading up to the licensing agreement, the market for the products, the expected value of the in-licensed products, and the ultimate failure of Schering to commercialize the products.\(^{259}\) Ultimately, the FTC concluded that Schering paid more for the in-licensed technology than they would have in an arm's-length business negotiation, supporting an inference that licensing fees were in reality merely camouflaged payments in exchange for delayed generic entry.\(^{260}\) However, as discussed below, on appeal the Eleventh

\(^{255}\) *Id.*

\(^{256}\) *Id.* at 9.


\(^{258}\) The settlement agreement that the FTC found most problematic, between Schering and Upsher, did not include any direct payment to the patent challenger. However, as part of the settlement, Schering agreed to license the right to market five Upsher products in exchange for $60 million in initial royalty fees, $10 million in milestone royalty payments, and 10% or 15% royalty on sales. *Schering-Plough* Corp. v. FTC, 402 F.3d 1056, 1059-60 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

\(^{259}\) *Id.* at 1069-70.

\(^{260}\) *Id.* at 1070.
Circuit rejected the FTC’s conclusion that the licensing payments were actually payments for delayed market entry and criticized the methodology used to arrive at that conclusion.\footnote{261}

Courts favor and encourage settlement, particularly in patent cases.\footnote{262} Most district courts find it difficult to deal with the intricacies of law and technology that so often pervade patent litigations, and patent cases also generally consume more judicial resources than other types of litigation.\footnote{263} For this reason, courts sometimes compel patent litigants to participate in court-supervised mediation, wherein the court actively proposes settlement terms, pressures the parties to reach agreement, and affirmatively approves the resulting settlement.\footnote{264} One might think that the pervasive, perhaps even coercive, role played by a federal court, and the court’s affirmative sanctioning of the resulting agreement, would justify some inference that the agreement is not illegal under the antitrust laws. However, based on the Commission’s decision in \textit{Schering-Plough}, it appears that the FTC does not hold this view.

In that case, Schering-Plough engaged in 15 months of court-supervised mediation with ESI, a generic company that had filed a Paragraph IV challenge to a Schering patent. The mediation resulted in nothing more than an impasse.\footnote{265} At this point the parties agreed, in principle, to a settlement splitting the remaining patent, pursuant to which ESI would enter almost three years prior to patent expiration.\footnote{266} However, ESI demanded that the settlement include some form of payment.\footnote{267} The federal judge overseeing the mediation actively intervened, working with Schering to develop a proposal whereby Schering would make payments to ESI,\footnote{268} which the FTC later characterized as reverse payments in exchange for delayed market entry. ESI accepted the proposal including payment, and the settlement was signed in the judge’s presence.\footnote{269}

\footnote{261}{See infra Section V.F.}\footnote{262}{See infra Section V.B.}\footnote{263}{Robert M. Isackson & Bridgette Y. Ahn, \textit{Legislation Proposes Pilot Program Toward Development of Specialized District Court Judges}, N.Y. L.J., Dec. 4, 2006, available in reprinted form at http://www.orrick.com/news_events/news/orrick_nylj_dec2006.pdf.}\footnote{264}{\textit{Schering-Plough}, 402 F.3d at 1060.}\footnote{265}{Id.}\footnote{266}{Id. at 1060-61.}\footnote{267}{Id. at 1061.}\footnote{268}{Id. at 1060-61.}\footnote{269}{Id. at 1061.}
In its hearing before the Commission, Schering defended the legality of the payments by pointing to the active involvement and approval of a federal judge.\textsuperscript{270} The Commission did not refute Schering's allegation, explicitly acknowledging that Schering was subject to "intense, and perhaps unseemly, judicial pressure" from a "settlement-minded judge," and that in view of this pressure the company may well have been concerned about its future litigation prospects; for example, the court's pressure to settle could have adversely affected Schering's perceived bargaining position.\textsuperscript{271} However, the Commission faulted Schering essentially for not standing up to the judicial pressure, stating that Schering should have attempted to find creative solutions that would have allowed it to reach a settlement without resorting to payments.\textsuperscript{272}

On appeal, the Eleventh Circuit seemed troubled by the FTC's failure to place any weight on the courts pervasive, perhaps even coercive, role in crafting and sanctioning the settlement terms.\textsuperscript{273} The court noted that "[v]eritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence."\textsuperscript{274}

FTC commissioners and other representatives have also become increasingly outspoken in their concerns regarding reverse payments in a variety of forums outside the context of litigation. In an April 24, 2006 presentation at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, FTC Commissioner Jon Leibowitz characterized two appellate court decisions rejecting antitrust challenges to reverse payments settlements as "misguided" and as posing a substantial threat to the "delicate balance of Hatch-Waxman."\textsuperscript{275} According to Commissioner Leibowitz, unless these decisions are reversed, drug companies "will have carte blanche to avoid competition and share resulting profits, and we will see minimal competition before patent expiration."\textsuperscript{276}

\textsuperscript{270} In re Schering-Plough Corp., No. 9297, slip op. at 82 (F.T.C. Dec. 18, 2003), http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf, vacated, 402 F.3d 1056 (11th Cir. 2005).

\textsuperscript{271} Id.

\textsuperscript{272} See id.

\textsuperscript{273} See Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1071-72 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).

\textsuperscript{274} Id. at 1072.

\textsuperscript{275} Leibowitz Speech, supra note 77, at 1.

\textsuperscript{276} Id. at 8.
On July 20, 2006, in a prepared statement before the Senate's Special Committee on Aging, the FTC reiterated its position that reverse payment agreements are anticompetitive and ought to be presumptively illegal, and warned that the Second and Eleventh Circuits' rejection of this position in *In re Tamoxifen Citrate Antitrust Litigation* and *Schering-Plough* had "staggering" negative economic implications and would result in "tremendous" cost to consumers, insurers, employers and the government.\(^{277}\)

The FTC's position on reverse payment on settlements has been characterized as presumptive illegality, \(^{278}\) and from a practical standpoint, that is probably an apt characterization.\(^{279}\) A number of academic commentators have taken even stronger positions against settlements including reverse payments.\(^{280}\) For example, Hovenkamp et al. have suggested the following rule:

In an antitrust challenge, a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful, shifting the burden of proof to the infringement plaintiff. The infringement plaintiff can defend by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.\(^{281}\)

Taken literally, this standard would apparently render any patent settlement involving a reverse payment exceeding litigation costs per se illegal. Some members of Congress would go even further; a bill was recently introduced in the Senate that would essentially find reverse payments settlements per se illegal, with no exception even for payments less than or equal to expected savings on litigation costs.\(^{282}\)

In contrast, the FTC would apparently recognize pro-competitive justifications for even sizeable reverse payments in certain circumstances. In *Schering-Plough*, the Commission accepted, in

\(^{277}\) FTC Statement Before Aging Committee, *supra* note 2, at 17, 19.


\(^{279}\) *See* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).

\(^{280}\) *See*, e.g., Hovenkamp et al., *supra* note 10.

\(^{281}\) *Id.* at 1759.

\(^{282}\) *See infra* Section VI.B.
principle, the argument that, in some circumstances, a reverse payment to a "cash-starved" generic company might enable the generic company to enter the market earlier and more effectively, and such a payment could be pro-competitive.\textsuperscript{283} The Commission also recognized that in cases where the generic company is relatively small and considers itself "judgment-proof," it might "hold out for 'unreasonable' settlement terms because its downside risk[] of damage exposure [is] small."\textsuperscript{284} It further accepted the argument that in some cases, where the generic challenger perceives a higher likelihood of success in the patent litigation than the patent owner, the only way to bridge the difference in expectations might be by means of cash payments.\textsuperscript{285}

C. Schering-Plough Exemplifies This Shift in FTC Focus

The FTC's shift in emphasis from agreements with the potential to park GE, and other restrictions extending beyond the exclusionary potential of the patent, to a focus on reverse payments as anticompetitive in and of themselves can be traced in its enforcement action against Schering, which ultimately became the basis for its petition for certiorari in \textit{Schering-Plough}. The enforcement action targeted two agreements between Schering and Paragraph IV filers Upsher and ESI.\textsuperscript{286} When the enforcement action was initially filed, it included an allegation that an agreement between Schering and Upsher, the first-filer, required Upsher to park its GE and thereby kept "all other potential generic competitors out of the market."\textsuperscript{287} With respect to the other agreement, the complaint alleged that ESI had agreed to refrain from marketing the allegedly infringing product or "any other generic version of [the product], regardless of whether such product would infringe Schering's patents."\textsuperscript{288} Thus, as was the case with the earlier enforcement actions filed against Abbott and Hoechst Marion Roussel, the FTC focused on barriers to third party generic entry or restrictions on products not covered by the patent.\textsuperscript{289}

\begin{footnotesize}
\begin{itemize}
  \item 284. \textit{Id.} at 38.
  \item 285. \textit{Id.}
  \item 287. \textit{Id.} at 1-2 (emphasis added).
  \item 288. \textit{Id.} at 7-8 (emphasis added).
  \item 289. \textit{See supra} Section IV.A.
\end{itemize}
\end{footnotesize}
To the extent these restrictions could be characterized as exceeding the exclusionary potential of the patent, as has been held by a number of courts, they would be illegal under the application of standard antitrust law.

However, an administrative law judge ("ALJ") sided with Schering and rejected the FTC's theory of antitrust liability, explicitly finding that the FTC had failed to establish that the agreement with Upsher imposed any barrier on third party generic entry, or that the GE period was manipulated or even discussed by Schering and Upsher. The ALJ's opinion does not address the allegation that the ESI agreement extended to non-infringing products. However, the FTC complaint counsel made the same allegation with respect to the Upsher agreement. It was alleged, for example, that the class of products Upsher covenanted not to market was broader than the scope of the patent claims. The ALJ rejected this argument, finding that the scope of products covered by the agreement did not extend beyond a reasonable interpretation of the patent claims, and no more than "reasonably necessary" to accomplish the goals of the agreement. In short, the FTC's original case against the agreements based on terms extending beyond the scope of the patent or parking GE apparently did not survive serious scrutiny.

Nevertheless, the FTC did not drop the action, but instead shifted its focus to the presence of reverse payments. On appeal, the Commission did not dispute the ALJ's determination that the Upsher agreement did not park GE, nor did they address the issue of

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291. Id.

292. Id.

293. Id. at 114-15.

294. Professor Calkins has observed that the FTC, unlike the DOJ, is generally more interested in winning its cases than in educating courts about economics. Stephen Calkins, Developments in Merger Litigation: The Government Doesn't Always Win, 56 ANTITRUST L.J. 855, 883 (1987).

295. See In re Schering-Plough Corp., No. 9297, slip op. at 87 (F.T.C. Dec. 18, 2003), http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf, vacated, 402 F.3d 1056 (11th Cir. 2005). The Eleventh Circuit stated that:

The order is modeled on Complaint Counsel's proposed remedy, with one significant exception. We delete in their entirety proposed provisions relating to a first-filing generic's 180-day exclusivity. We have not analyzed the effects of any such agreements in this opinion and believe it is inappropriate to address them in the order.

Id.
whether the agreements extended beyond the exclusionary potential of the patent. Instead, the Commission's analysis focused on the existence and substantial size of reverse payments, and an assumption that, in the absence of payments, any settlement agreement would have included an earlier generic entry date. Based solely on a factual determination that the payments were in exchange for delayed generic entry, the Commission found the agreement to be illegal.

V. REVERSE PAYMENT SETTLEMENTS IN THE COURTS

Much to the chagrin of the FTC and others, courts have repeatedly refused to find a basis for antitrust liability in reverse payments. Some percentage of antitrust challenges to reverse payments settlements have succeeded, but in those cases the determination of illegality was based on other factors, not on the basis of a reverse payment per se. Generally, courts will only find an antitrust violation if terms of the agreement restricts competition to an extent exceeding the exclusionary potential of the patent. This most typically occurs when the agreement is found to result in a parking of GE, creating a bottleneck blocking all third party generic market entry, or when the agreement requires the generic company to refrain from marketing or developing products that would not infringe the patent. This standard is consistent with a line of earlier court decisions that have generally found that agreements involving patents do not violate the antitrust laws, so long as the terms of the agreement do not extend beyond the exclusionary potential of the patent. It is
also consistent with the FTC’s early enforcement actions, which only targeted agreements with restrictions alleged to exceed the exclusionary potential of the patent.\textsuperscript{303}

\textit{A. The Consensus Test of the Eleventh and Second Circuits}

The emerging consensus test for analyzing the legality of reverse payment settlements under the antitrust laws, which focuses on the extent to which the terms of the agreement exceed the exclusionary potential of the patent, is exemplified by the Eleventh Circuit’s holdings in \textit{Valley Drug Co. v. Geneva Pharmaceuticals, Inc.}\textsuperscript{304} and \textit{Schering-Plough.}\textsuperscript{305} In \textit{Valley Drug}, the court rejected a lower court’s ruling on partial summary judgment that two reverse payment agreements were per se violations of section 1 of the Sherman Act.\textsuperscript{306} The appellate court acknowledged that the decision below would have been correct were it not for the patent, reiterating the general rule that an agreement to pay a potential competitor to stay off the market is a per se antitrust violation.\textsuperscript{307} However, in view of the existence of a presumptively valid patent, the district court’s per se treatment to the agreement was in error.\textsuperscript{308} Instead, the Eleventh Circuit held that any antitrust analysis of such an agreement must include a “consideration of the scope of the exclusionary potential of the patent, the extent to which the provisions of the Agreements exceed that scope, and the anticompetitive effects thereof.”\textsuperscript{309}

In \textit{Schering-Plough}, the Eleventh Circuit essentially reiterated the \textit{Valley Drug} standard, holding that “the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”\textsuperscript{310} The court cited as an example of an agreement exceeding the exclusionary potential of the patent an agreement intended merely

\begin{itemize}
\item \textsuperscript{303} See \textit{supra} Section IV.A.
\item \textsuperscript{304} \textit{Valley Drug Co. v. Geneva Pharms., Inc.}, 344 F.3d 1294 (11th Cir. 2003).
\item \textsuperscript{305} \textit{Schering-Plough Corp. v. FTC}, 402 F.3d 1056 (11th Cir. 2005), \textit{cert. denied}, 126 S. Ct. 2929 (2006).
\item \textsuperscript{306} \textit{Valley Drug}, 344 F.3d at 1304 (characterizing them as geographic market allocation agreements between horizontal competitors).
\item \textsuperscript{307} \textit{Id.}
\item \textsuperscript{308} \textit{Id.} at 1305.
\item \textsuperscript{309} \textit{Id.} at 1312.
\item \textsuperscript{310} \textit{Schering-Plough}, 402 F.3d at 1066 (citing \textit{Valley Drug}, 344 F.3d at 1312).
\end{itemize}
to circumvent antitrust laws, or where the settlement resolves a patent litigation involving a patent which the patent owner knows is almost certainly invalid.\textsuperscript{311} The court noted that when a patent is involved the mere existence of anticompetitive effects cannot be the basis for antitrust liability, since patents are by their very nature anticompetitive.\textsuperscript{312} Antitrust liability only attaches when anticompetitive effects exceed the exclusionary potential of the patent.\textsuperscript{313} In view of the fact that the FTC had never even alleged that the Schering patent was invalid or would not have been infringed by the proposed generic product, it could not establish anticompetitive effects exceeding those inherent in the patent grant.\textsuperscript{314}

Recently, the Second Circuit essentially adopted the Eleventh Circuit’s standard, holding that “absent an extension of the monopoly beyond the patent’s scope, . . . and absent fraud, . . . the question is whether the underlying infringement lawsuit was ‘objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.’”\textsuperscript{315} Consistent with the Eleventh Circuit, the Second Circuit held that “the central criterion as to the legality of a patent settlement agreement is whether it exceeds the scope of the patent’s protection.”\textsuperscript{316} The Second Circuit concluded that a patent settlement, regardless of whether it includes a reverse payment, is generally not in violation of the antitrust laws so long as the patent holder is not acting in bad faith “beyond the limits of the patent monopoly” to restrain or monopolize trade.\textsuperscript{317} The court stressed that reverse payments settlements could be unlawful under certain circumstances, such as if the settlement is merely a device for circumventing the antitrust laws, for example, a “sham” or otherwise baseless litigation involving a patent that would almost certainly not survive a judicial challenge.\textsuperscript{318} But the court stated that if “there is nothing suspicious about the circumstances of a patent settlement,

\textsuperscript{311} Id. at 1067 (citing Asahi Glass Co., Ltd. v. Pentech Pharmas., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003)).
\textsuperscript{312} Id. at 1065-66.
\textsuperscript{313} Id. at 1066.
\textsuperscript{314} See id. at 1066 n.15.
\textsuperscript{316} Id. at 213 n.27 (internal quotes omitted).
\textsuperscript{317} Id. at 197, 213 (quoting United States v. Line Material Co., 333 U.S. 287, 308 (1948)) (internal quotes omitted).
\textsuperscript{318} Id. at 208 (citing Asahi Glass Co., Ltd. v. Pentech Pharmas., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003)).
then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation."\(^{319}\)

In *In re Cardizem CD Antitrust Litigation*,\(^{320}\) the first appellate decision to assess the antitrust liability of a reverse payment settlement, the Sixth Circuit held a reverse payment settlement agreement to be per se illegal.\(^{321}\) Nevertheless, the decision was entirely consistent with the Eleventh and Second Circuits’ consensus “exceeding the reasonable exclusionary potential of the patent” standard. The case involved Cardizem CD, a timed-release version of a drug widely prescribed for use in the treatment of angina and hypertension and for the prevention of heart attack and strokes.\(^{322}\) The core patent covering the drug’s active ingredient diltiazem hydrochloride expired in 1992.\(^{323}\) However, the drug’s manufacturer Hoechst Marion Roussel (“HMR”) in-licensed rights to a patent that they represented covered the timed-release formulation embodied in Cardizem CD.\(^{324}\) They listed the patent in the Orange Book,\(^{325}\) resulting in a de facto extension of patent exclusivity. While generic companies were free to market some generic version of the drug’s active ingredient,\(^{326}\) they could not obtain FDA approval to compete in the presumably much more lucrative market for the time-released formulation without challenging the formulation patent.\(^{327}\) However, not surprisingly, in view of the commercial success of Cardizem CD, a generic company did file an ANDA with a Paragraph IV certification challenging the formulation patent, and HMR timely

\(^{319}\) *Id.* (quoting *Asahi Glass*, 289 F. Supp. 2d at 992) (internal quotes omitted).

\(^{320}\) *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 896 (6th Cir. 2003). This appears to be the first appellate decision to specifically assess the legality of a reverse payment settlement.

\(^{321}\) *Id.*

\(^{322}\) *Id.* at 901.

\(^{323}\) *Id.*

\(^{324}\) *Id.* at 902.

\(^{325}\) Center for Drug Evaluation and Research, FDA, Electronic Orange Book Home Page, http://www.fda.gov/cder/ob/ (follow “Search by Patent” hyperlink; then follow “Search by Patent Number” hyperlink; then enter “5470584” in text box and click “Submit” button).

\(^{326}\) Generally, in similar circumstances, the branded company focuses its marketing efforts on switching customers to the patented time-release formulation, based on the supposed superior efficacy of the follow-up product (in this case, the benefits of a time-released formulation).

\(^{327}\) Technically, a generic company could seek approval through the full-blown NDA process, but because of the substantially higher costs compared to an ANDA, this route to approval was probably not practically feasible.
responded by filing a lawsuit within forty-five days to trigger the automatic thirty-month stay.\textsuperscript{328}

Andrx, the generic challenger, obtained tentative approval of its ANDA on September 15, 1997,\textsuperscript{329} and represented to the court hearing the patent case that it intended to enter the market immediately upon expiration of the thirty-month stay in July 1998, regardless of whether the litigation had been decided at that point.\textsuperscript{330} However, on September 24, 1997, well prior to the possibility of market entry by the generic, the parties reached an interim settlement whereby Andrx essentially agreed to refrain from marketing a generic version of the branded drug until the patent litigation had been finally decided, up through and including any appeal to the Supreme Court, in exchange for quarterly payments of $10 million beginning the date Andrx received final FDA approval.\textsuperscript{331} Significantly, the agreement required Andrx to park its 180-day GE, thereby creating a bottleneck preventing the approval of any other generic version of the drug.\textsuperscript{332} Furthermore, the agreement was not limited to timed-release formulations covered by the patent at issue, but extended to any generic version of Cardizem CD, including generic versions that would not infringe the patent.\textsuperscript{333}

The Sixth Circuit held that the agreement was an illegal restraint of trade and a per se violation of section 1 of the Sherman Act.\textsuperscript{334} The decision is somewhat opaque as to the specific basis for the per se designation; however, it is worth stressing that the Sixth Circuit never indicated that the existence of reverse payments in and of themselves rendered the agreement illegal. The court’s criticism of the agreement focuses primarily on the parking of Andrx’s 180-day GE and the effect of the agreement to exclude third party generic entry.\textsuperscript{335} The

\textsuperscript{328} Cardizem, 332 F.3d at 902.
\textsuperscript{329} Id. Tentative approval of the ANDA indicates that FDA is satisfied with the bioequivalency and other technical requirements for ANDA approval, and that final approval is contingent merely upon expiration or termination of the thirty-month stay. Id.
\textsuperscript{330} Id. Entering the market prior to resolution of the patent dispute is referred to as entry “at risk,” owing to the generic company’s exposure to huge potential damages if the generic product is ultimately found to infringe a valid patent.
\textsuperscript{331} Id.
\textsuperscript{332} Id.
\textsuperscript{333} See id. In view of the fact that the core patent covering the drug’s active ingredient had long expired, in principle, such a design was quite possible. In fact, Andrx certified to HMR that it had successfully developed a timed-release formulation of the drug that it did not infringe the formulation patent. Id. at 903.
\textsuperscript{334} Id. at 907-08.
\textsuperscript{335} Id.
court states that "[b]y delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer."336 The court went on to find that the agreement illegally "bolster[ed] the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."337

In essence, the Sixth Circuit found that the agreement restricted competition in a manner that exceeded the reasonable exclusionary potential of the patent. Normally the exclusionary potential of the patent is limited by the requirement that a patentee convince a court to enjoin allegedly infringing activity. Even in the context of a Paragraph IV filing, where the exclusionary potential is enhanced by the thirty-month stay provisions available for patents listed in the Orange Book, a generic challenger is able to gain marketing approval after the thirty-month stay has run its course.338 However, a parked GE has the potential to block all generic competition indefinitely, without the showing of a reasonable likelihood of success on the merits that would be required for a preliminary injunction.339

The agreement also exceeded the exclusionary potential of the patent by barring Andrx from marketing any generic version of Cardizem CD, which would include potential variations falling outside the nominal scope of the patent claims.340 The patent at issue literally claimed only timed release formulations whose dissolution profile resulted in the release of from 0-45% of the total active ingredient within 18 hours.341 Andrx's ANDA specified that the dissolution profile for its generic product was not less than 55% of the total active ingredient released within 18 hours;342 if true, Andrx's product clearly avoided the literal scope of the patent. Nevertheless, according to the terms of the agreement Andrx was barred from marketing even a clearly non-infringing generic variant.343 The district court decision emphasized the significance of this extension of

336. Id. at 907.
337. Id. at 908.
338. See supra Section III.B.3.
339. See supra Section III.B.3.
340. Cardizem, 332 F.3d at 902.
341. Id.
342. Id.
343. Id.
the patent's exclusionary power in its determination that the agreement was per se illegal.\textsuperscript{344}

Lower courts have also generally been unreceptive to allegations of antitrust liability based solely on the presence of reverse payments.\textsuperscript{345} In fact, the only notable district court decision finding a patent settlement illegal based on the existence of a reverse payment was \textit{Terazosin I},\textsuperscript{346} the decision subsequently reversed by the Eleventh Circuit in \textit{Valley Drug}.\textsuperscript{347} On remand in \textit{Terazosin II}, the district court again found the agreement to be per se illegal, but this time not based on the presence of reverse payments.\textsuperscript{348} Instead, paying heed to the admonition from the Eleventh Circuit, the court focused on the extent to which the agreement exceeded the exclusionary potential of the patent.\textsuperscript{349} The court assessed the merits of the patent case, and found that, in view of the questionable validity of the patent, the district court would have been unlikely to grant a preliminary injunction.\textsuperscript{350} The district court posited that, prior to a final judgment on the merits, the exclusionary potential of a patent is restricted to the ability to obtain a preliminary injunction, and an agreement having the effect of a preliminary injunction exceeds the exclusionary potential of the patent, if such an injunction is unlikely to be granted.\textsuperscript{351}

Perhaps more importantly, the district court characterized as "undisputed and dispositive" the fact that the agreement parked the generic's GE and prevented any other generic company from entering the market.\textsuperscript{352} The court was also influenced by the fact that the agreement "barred Geneva from marketing any terazosin

\begin{footnotes}
\item 347. \textit{Id.}
\item 349. \textit{Id. at} 1286.
\item 350. \textit{Id. at} 1306.
\item 351. \textit{Id. at} 1294-96. It is far from clear that the district court's analysis was true to the spirit of the direction provided by the Eleventh Circuit in \textit{Valley Drug}.
\item 352. \textit{Id. at} 1314-15.
\end{footnotes}
hydrochloride product, including those that were not at issue in the patent case," even though the core patent covering the drug had expired. Since the court found that the agreement exceeded the exclusionary potential of the patent, by creating a bottleneck to third party generic entry and by extending to clearly non-infringing products, and because the patentee probably would have not been able to obtain a preliminary injunction, the court had no need to rely solely on the presence of reverse payments to presume antitrust liability.

In In re Ciprofloxacin Hydrochloride Litigation, a district court residing in the Second Circuit rejected any presumption of illegality based on reverse payment, thus anticipating that circuit’s subsequent adoption of the consensus test in Tamoxifen. The Ciprofloxacin court held that although it went “without saying that patents have adverse effects on competition,” the ultimate question was “whether any adverse effects on competition stemming from the [a]greements were outside the exclusionary zone of the . . . [p]atent.” Because the agreements did not exceed this exclusionary potential, the court found that plaintiffs had not established illegality.

In contrast, courts are generally receptive to the argument that a reverse payment agreement is illegal because its terms exceed the exclusionary potential of the patent, particularly in cases where the agreement has the effect of parking GE. As discussed above, this was the case in Cardizem. Likewise, in Andrx Pharmaceuticals, Inc. v. Biovail Corp. International, the first appellate decision to comment upon the legality of reverse payment settlements in general, the D.C. Circuit held that an agreement to park GE, and thereby exclude third party generic entry, is a restraint of trade cognizable under antitrust laws. Recently, in Andrx Pharmaceuticals, Inc. v. Elan Corp., PLC, the Eleventh Circuit held that the allegation that an agreement parked GE and blocked third party generic entry stated

353. Id. at 1317.
355. Id.
356. Id. at 523.
357. Id. at 540-41. Likewise, in Asahi Glass Co. v. Pentech Pharmaceuticals, Inc., 289 F. Supp. 2d 986, 994 (N.D.Ill. 2003), Judge Posner (sitting by designation) provides his own reasoned explanation as to why it would be inappropriate to presume illegality based solely on the presence of reverse payments. Id.
358. See, e.g., In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).
359. See supra notes 335-337 and accompanying text.
antitrust restraint of trade claims under sections 1 and 2 of the Sherman Act. 361 Further, in Asahi Glass Co. v. Pentech Pharmaceuticals, Inc., Judge Posner also endorsed the view that reverse payment settlements would violate the antitrust laws if the terms clearly exceeded the reasonable exclusionary potential of the patent. 362

The Second Circuit also specifically noted the relevance of GE parking in the antitrust inquiry. 363 In distinguishing the agreements at issue in Tamoxifen from those that were found illegal in Cardizem and Terazosin II, the court noted that the agreements found to be illegal in those cases effectively blocked any third party generic competition. 364 In contrast, the court noted that the Tamoxifen agreement actually had the opposite effect, by "clear[ing] the way for other generic manufacturers to seek to enter the market." 365 It was also apparent that the Tamoxifen agreement did not extend to non-infringing products; because the patent at issue covered the drug's active ingredient and thus, by definition, any generic version of the drug, an agreement not to sell any generic version of the drug would not exceed the scope of the claims. 366 In contrast, recall that the agreements in Cardizem and Terazosin II extended to all generic products, while the patents were limited to specific formulations and therefore might not have encompassed a design-around generic. 367

361. Andrx Pharms., Inc. v. Elan Corp., PLC, 421 F.3d 1227, 1235-36 (11th Cir. 2005). This would seem to refute claims made by some that after Schering-Plough reverse payment settlement agreements are per se legal in the Eleventh Circuit. See, e.g., FTC Petition for Certiorari in Schering-Plough, supra note 244, at 12. Clearly that is not the case, at least where GE is parked.


364. Id. at 215.

365. Id. This "clearing" effect was a consequence of the way in which FDA interpreted Hatch-Waxman's 180-day exclusivity provisions at the time of the agreement. Under that interpretation, FDA would only grant 180-day exclusivity to the first Paragraph IV filer to "successfully defend" its patent challenge. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998). By entering a final settlement (as opposed to the interim settlement in Cardizem and the Terazosin cases) that terminated litigation, Barr Labs, the first Paragraph IV filer, forfeited its right to 180-day exclusivity, thereby removing one impediment to third party generic entry. FDA's successful defense requirement was later eliminated by a court decision finding it contrary to the plain meaning of the statute, Mova, 140 F.3d at 1076, but that does not change the fact that at the time of the agreement the parties would have thought the agreement cleared the field for other competitors.

366. Tamoxifen, 466 F.3d at 214.

367. Id.
B. Courts Generally Favor Settlement

Courts cite to a variety of rationales supporting the consensus rejection of presumptive illegality based on reverse payment. For example, courts typically point to a general policy in favor of the settlement of litigation, particularly with respect to complex and judicial resource intensive patent disputes.\textsuperscript{368} In \textit{Valley Drug}, the Eleventh Circuit cited to this policy favoring settlement and concluded that to find an "ostensibly reasonable settlement of patent litigation gives rise to \textit{per se} antitrust liability... would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally."\textsuperscript{369} In \textit{Schering-Plough}, the same court noted that there "is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation."\textsuperscript{370}

In \textit{Tamoxifen}, the Second Circuit concurred with the Eleventh Circuit's assessment, noting further that rules restricting the ability of parties to settle might actually delay generic entry and be contrary to the goals of the patent system.\textsuperscript{371} In that decision, the court stressed the public's interest in encouraging settlement, particularly in the context of patent litigation, citing to a "longstanding adherence to the principle that 'courts are bound to encourage' the settlement of litigation."\textsuperscript{372} The Second Circuit cited to a strong public interest in settlement, particularly where a case is complex and expensive, and the court's duty to protect the interest of the public and parties by encouraging fair and efficient resolution.\textsuperscript{373} The court further noted that "[i]t is well settled that '[w]here there are legitimately conflicting [patent] claims ..., a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act,' although such a settlement may ultimately have an adverse effect on competition."\textsuperscript{374} The weakening of the patent right that would result from limitations on a patentee's ability to settle a legitimate patent infringement suit, and


\textsuperscript{369} \textit{Valley Drug Co. v. Geneva Pharms., Inc.}, 344 F.3d 1294, 1309 (11th Cir. 2003).

\textsuperscript{370} \textit{Schering-Plough}, 402 F.3d at 1075.

\textsuperscript{371} \textit{Tamoxifen}, 466 F.3d at 203 (citing \textit{Valley Drug}, 344 F.3d at 1308).

\textsuperscript{372} \textit{Id.} at 202 (quoting Gambale v. Deutsche Bank AG, 377 F.3d 133, 143 (2d Cir. 2004)).

\textsuperscript{373} \textit{Id.} (citing United States v. Glens Falls Newspapers, Inc., 160 F.3d 853, 856-57 (2d Cir. 1998)).

\textsuperscript{374} \textit{Id.} (quoting Standard Oil Co. v. United States, 283 U.S. 163, 171 (1931)).
the resulting attenuation of the incentive effect of patents on innovation, was also cited as justification for a deferential posture with respect to an apparently reasonable patent settlement.\textsuperscript{375}

As noted above, the FTC and some courts have tended to treat interim settlements with more skepticism than agreements that finally settle the underlying patent litigation.\textsuperscript{376} However, other courts have posited that even interim settlements that block GE and involve reverse payments might nonetheless be legitimate and even procompetitive.\textsuperscript{377} For example, in \textit{Valley Drug}, the lower court concluded that an interim settlement agreement was detrimental to the public interest because it tied the payments to the duration of the litigation, thereby incentivizing the parties to delay the litigation.\textsuperscript{378} The Eleventh Circuit rejected this conclusion.\textsuperscript{379} While acknowledging the existence and perversity of the cited incentive, the court found it to be unavoidable if the parties wished to further the perfectly reasonable objective of compensating the generic company for potential lost profits resulting from delayed market entry during the course of litigation, much like a bond posted as part of a preliminary injunction.\textsuperscript{380}

\textbf{C. Reallocation of Litigation Risk and Upside Potential}

A number of courts have also expressly endorsed the theory described above that the Hatch-Waxman scheme has substantially reallocated that relative risks and potential rewards of patent litigation, effectively reversing the incentives for payments in exchange for settlement.\textsuperscript{381} Based on this redistribution of risks, rewards and incentives to settle, courts have held that even a patent owner substantially confident in the merits of its patent will still find it rational to make sizeable reverse payments.\textsuperscript{382} Essentially, the presence of reverse payments is seen as a natural by-product of the statute, not indicative of a weak patent case or bad intent on the part

\begin{itemize}
\item \textsuperscript{375} \textit{Id.} at 203 (citing \textit{Valley Drug}, 344 F.3d at 1308); Joseph F. Brodley & Maureen A. O'Rourke, \textit{Preliminary Views: Patent Settlement Agreements}, \textit{Antitrust}, Summer 2002, at 53; Crane, supra note 79, at 749).
\item \textsuperscript{376} See supra Sections II, IV.A, V.A.
\item \textsuperscript{377} See, e.g., \textit{Valley Drug}, 344 F.3d 1294.
\item \textsuperscript{378} Id. at 1310.
\item \textsuperscript{379} Id.
\item \textsuperscript{380} Id.
\item \textsuperscript{381} See, e.g., Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).
\item \textsuperscript{382} See \textit{id.} at 1075 (citing \textit{Valley Drug}, 344 F.3d at 1310).
\end{itemize}
of the settling parties, and thus not a legitimate basis for imposing antitrust liability.

The Eleventh Circuit endorsed this view in Schering-Plough, noting that "Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude." 383 The court cited with approval a more detailed exposition of the theory provided in Ciprofloxacin, 384 wherein that court noted that Hatch-Waxman "has the unintended consequence of altering the litigation risks of patent lawsuits" and concluded that "reverse payments are a natural by-product of the Hatch-Waxman process." 385

Cardizem represents a prime example of a case where the normal risks and upside potential of patent litigation have been substantially reapportioned between the parties. The generic company Andrx filed its ANDA on September 22, 1995, prior to the issuance of the formulation patent which eventually became the subject of the patent dispute. 386 Not only that, at the time the ANDA was filed, the patent application was owned by another company, Carderm Capital, which had yet to license it to the branded company HMR. 387 At that time, pending patent applications were generally not publicly accessible, 388 so it is unclear whether Andrx was even aware of the existence of the patent application. Only after the patent issued in November of 1995 did Carderm license the patent to HMR, thereby compelling Andrx to file a Paragraph IV certification on December 30, 1995. 389

In short, at the time Andrx made the decision to invest in the filing of an ANDA, it was probably unaware that its approval would require a successful challenge of a yet-to-be-issued patent. By the time the parties reached partial settlement, Andrx had already secured tentative approval of its ANDA. 390 Most of its non-litigation costs were already sunk, resulting in little exposure to risk if they did not succeed in the patent challenge, but a huge upside potential if they did

383. Id. at 1074 (citing In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003), summary judgment granted by, complaint dismissed at 363 F. Supp. 2d 514 (E.D.N.Y. 2005)).
384. Id. (citing Ciprofloxacin, 261 F. Supp. 2d at 251).
387. Id.
389. Cardizem, 332 F.3d at 902.
390. Id.
succeed, enhanced by the 180-days of generic exclusivity. Simple economics would dictate that Andrx would have little incentive to settle without some substantial consideration from HMR, regardless of their objective assessment of the merits of their case.

D. Courts Find Little Meaningful Distinction Between Reverse Payment Settlements and Other Patent Settlements

A number of courts express skepticism as to the existence of any principled distinction between reverse payment settlements and "ordinary" patent settlements. These courts note that most, if not all, settlement agreements include some form of compensation from the patent owner to the alleged infringer. Even where a settlement involves a defendant making a "forward" payment to the patentee, presumably this is in exchange for the patentee agreeing to forgo pursuing the money damages that would be assessed in the event the patent was found to be valid and infringed. The patentee's forbearance is the consideration flowing to the accused infringer, and it has a monetary value in the same way as a reverse payment, albeit the nature of the payment renders it less apparent and more difficult to value. While the reverse payment in a Paragraph IV settlement is easier to detect and quantify than the consideration flowing to the defendant in most patent settlements, courts have expressed a reluctance to find antitrust liability based solely on this, particularly when the reverse payment is seen as a natural by-product of the Hatch-Waxman scheme.

In Tamoxifen, the Second Circuit noted that "even the typical settlement of the ordinary patent infringement suit appears to involve what may be characterized as a reverse payment." Similarly, in Ciprofloxacin, the court concluded that "even in the traditional context, implicit consideration flows from the patent holder to the
alleged infringer. 396 Sitting by designation in *Asahi Glass*, Judge Posner, renowned for his application of economic theory to legal decision-making, observed that “*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. If any settlement agreement is thus to be classified as involving a forbidden ‘reverse payment,’ we shall have no more patent settlements. 397

Commentators also question the distinction between reverse payment settlements and other patent settlements. For example, Daniel Crane asserts that “[i]t makes no sense to single out exclusion payments for disfavor when the same potential for collusion arises in any settlement involving the defendant’s exit.”398 Thus, these courts and commentators essentially conclude that the distinction between reverse payment settlements and other patent settlements is to a large extent illusory, reflecting the ease with which compensation in the form of cash payments is observable and quantifiable rather than any meaningful difference. Finding little principled basis to single out reverse payments settlements, they reject the notion of antitrust liability based purely on reverse payments.

**E. Courts Will Not Infer a Weak Patent Case from Reverse Payments**

Courts have also been reluctant to infer from the presence of reverse payments that the patent owner must have viewed the patent case as weak, even in cases involving very large payments. 399 Courts tend to defer to the statutory presumption of patent validity, in contrast with the FTC, which downplays the significance of the presumption and characterizes the patent grant as nothing more than “probabilistic rights,” or a right to “try” to exclude competition. 400 The Second Circuit has held that “so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of

the patented product." The Eleventh Circuit also expressed deference to the presumption of validity, stating that "[b]y virtue of its [patent], Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the [patent] was invalid or that their products . . . did not infringe."

In Valley Drug, the Eleventh Circuit cautioned against inferring from the size of reverse payments that the parties lacked faith in the validity of the patent. The court pointed specifically to the uncertainty inherent in any attempt to accurately assess: (1) a branded drug company's lost profits, (2) potential profits for the generic companies, (3) the risk of the defendant's inability to satisfy a judgment, (4) the true cost of litigation, or (5) how much of the payment might have been in exchange for provisions of the agreements other than an acknowledgement of patent validity.

Valley Drug cites to Ciprofloxacin as an example of a case where substantial reverse payments were made, even though subsequent objective indicators suggested that the patent owners actually had a strong patent case. A patent settlement agreement described in Ciprofloxacin required the patentee to pay an alleged infringer $49.1 million to acknowledge the validity of the patent, and at least $398 million for the alleged infringer to remain off the market. The validity of the disputed patent was subsequently upheld by the United States Patent and Trademark Office ("Patent Office") on reexamination and in three court challenges, which the Valley Drug court took as objective evidence of the patent's inherent strength.

Valley Drug court refused to infer from the presence of reverse payments that the parties believed that the merits of the

401. Tamoxifen, 429 F.3d at 392.
402. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066-67 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006). The FTC and others have criticized this statement of the law as incorrect to the extent it suggests a presumption of infringement. See, e.g., FTC Petition for Certiorari in Schering-Plough, supra note 244, at 12. Clearly, there generally is no presumption of infringement. However, this was likely just a case of the court speaking too loosely. The question of whether the patent was valid or infringed was never an issue in the antitrust litigation. To the contrary, the FTC steadfastly refused to speculate on the merits of the patent case, characterizing any such inquiry as "not supported by law or logic." Schering-Plough, 402 F.3d at 1068 n.18 (internal quotes omitted).
404. Id. at 1310.
405. Id. (citing In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 196, 234 (E.D.N.Y. 2003), summary judgment granted by, complaint dismissed at 363 F. Supp. 2d 514 (E.D.N.Y. 2005)).
406. Id. (citing Ciprofloxacin, 261 F. Supp. 2d at 196, 234).
407. Id. (citing Ciprofloxacin, 261 F. Supp. 2d at 196, 234).
patent case were weak. To the contrary, the court provided an expansive analysis showing that the decision of a patent owner to make even very large reverse payments could be rational and compatible with a relatively high expectation of success on the merits.

The Second Circuit in Tamoxifen specifically considered and rejected the argument that "excessive" reverse payments could lead to a presumption of antitrust liability. The plaintiffs argued that the size of reverse payments "greatly exceeded the value [of the generic company's 'best case scenario' in winning the appeal] and entering the market with its own competitive generic product," and that it was the excessive nature of the payment, as opposed to the mere presence of a reverse payment, that constituted an antitrust violation.

The Tamoxifen court began by observing that under certain circumstances a reverse payment settlement could be illegal, particularly if the settlement is merely a device for circumventing the antitrust laws. The court cited, as an example, a scenario where the underlying patent litigation is a "sham," or otherwise objectively baseless, involving a patent that would almost certainly not survive a judicial challenge. However, in cases where there "is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." The court then posited that even if one were to assume that the large reverse payments belied the fact that the patent owner lacked confidence in prevailing in the patent litigation, such a lack of confidence does not amount to an antitrust violation. The court endorsed Judge Posner's assessment in Asahi Glass that:

408. See Ciprofloxacin, 261 F. Supp. 2d at 251-52.
409. Id.
411. Id. at 208. Note that the plaintiff's theory is more permissive towards reverse payments than approaches advocated by the FTC and others that would essentially find any reverse payment settlement unlawful, at least in cases where the payment amount exceeds some de minimis reflecting saved litigation costs. See supra Sections II, IV.B-C.
412. Tamoxifen, 466 F.3d at 208 (citing Asahi Glass Co., Ltd. v. Pentech Pharmas., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003)).
413. Id. (citing Asahi Glass, 289 F. Supp. 2d at 991).
414. Id. (quoting Asahi Glass, 289 F. Supp. 2d at 992).
415. Id. at 210.
[T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud ... ), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment. It is not "bad faith" to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be certain that he will prevail in a patent suit.416

The Tamoxifen court concluded that even “excessive” payments to settle a lawsuit are not necessarily unlawful.417 Essentially, the court found that the antitrust laws do not prevent a patent owner from paying to protect even a weak patent claim. Under this approach, the size of the payment becomes irrelevant, because, even if one were to take it as evidence of a subjective lack of confidence in the merits of the patent case, a mere lack of confidence does not lead to antitrust liability for settling the case.

F. Courts Have Rejected the FTC’s Theories of Antitrust Liability

Courts have not been receptive towards the FTC’s theory of antitrust liability based on the probabilistic nature of the patent right, nor the related theory of a consumer expectation interest in the possibility that the patent challenge might have succeeded were it not for the settlement. In Schering-Plough, the Eleventh Circuit was particularly critical of the FTC’s contention that Paragraph IV litigants are required to settle their disputes by means of a negotiated early entry date, or some other terms that benefit consumers to an extent comparable to continuing with the lawsuit.418 The court found no basis in law for requiring patent litigants to choose between a settlement that benefits consumers or being compelled to continue

416. Id. (quoting Asahi Glass, 289 F. Supp. 2d at 992-93 (citation omitted)).
417. Id. at 213.
with the litigation to final judgment.\textsuperscript{419} It also rejected the FTC’s arguments based on the probabilistic nature of patents.\textsuperscript{420}

In \textit{Ciprofloxacin}, the plaintiffs essentially advanced the FTC’s theory that patents are mere probabilistic property rights, and that parties to a Paragraph IV patent settlement are required by the antitrust laws to settle their dispute in a manner that benefits consumers.\textsuperscript{421} The court rejected these arguments, referring heavily to the rationale articulated in \textit{Schering-Plough}.\textsuperscript{422}

The Second Circuit took a similar view in \textit{Tamoxifen}, holding that it is well settled that """where there are legitimately conflicting [patent] claims . . . , a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," although such a settlement may ultimately have an adverse effect on competition."\textsuperscript{423}

As discussed above, in \textit{Schering-Plough}, the FTC concluded that licensing fees provided for in an ancillary licensing agreement relating to a product not covered by the patent were in fact disguised reverse payments — a quid pro quo for the generic’s agreement to delay market entry.\textsuperscript{424} On appeal, the Eleventh Circuit rejected the FTC’s conclusion that the licensing payments under the ancillary agreements were actually payments for delayed market entry.\textsuperscript{425} The court essentially criticized the FTC approach as paying too little deference to the outcome of what, on their face, appeared to be legitimate arm’s-length negotiations.\textsuperscript{426} With the benefit of hindsight, it was clear that the deal had not paid off for Schering, but the court noted that it is typical for pharmaceutical companies to invest large sums of money on compounds that ultimately never make it to the market.\textsuperscript{427} The fact that, in retrospect, Schering paid too much for the

\begin{itemize}
\item \textsuperscript{419} \textit{Id.}
\item \textsuperscript{420} \textit{Id.}
\item \textsuperscript{421} \textit{In re} Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 531 (E.D.N.Y. 2005).
\item \textsuperscript{422} \textit{Id.} at 531-33. According to the U.S. Solicitor General, as of May, 2006, \textit{Ciprofloxacin} was the only decision where a court specifically considered (and rejected) the FTC’s expected value approach. U.S. Brief Recommending Denial of Certiorari in \textit{Schering-Plough}, supra note 20, at 16.
\item \textsuperscript{424} \textit{See supra Section IV.C.}
\item \textsuperscript{425} \textit{Schering-Plough}, 402 F.3d at 1070 (criticizing the conclusion as “not supported by law or logic”) (internal quotes omitted).
\item \textsuperscript{426} \textit{See id.} at 1070-71.
\item \textsuperscript{427} \textit{Id.} at 1071.
\end{itemize}
in-licensed products is not evidence that the terms of the agreement
did not appear reasonable to Schering at the time the agreement was
entered into. The court also identified a number of objective
indications of a legitimate business negotiation, such as the fact that
the company personnel involved in negotiating the terms of the
ancillary agreement were different from those involved in negotiating
a resolution of the patent dispute, and Schering's "long-documented
and ongoing interest" in licensing one of the products.

G. The FTC and Courts Agree That the Antitrust Analysis
Should Generally Not Involve an Assessment of the
Merits of the Underlying Patent Case

One issue on which the courts and the FTC are in substantial
agreement is that the analysis of the legality of a reverse payment
settlement under the antitrust laws should generally not entail any
evaluation of the merits of the underlying patent case, at least in cases
where the patent case does not appear to be a sham or objectively
baseless, or the patent does not appear to have been obtained by
fraud.

The FTC made it clear on a number of occasions that, as a
general policy, it does not consider it appropriate for the antitrust
inquiry to delve into the merits of the underlying patent dispute. For
example, in the Commission's decision in Schering-Plough, the FTC
"question[ed] the utility of a rule that would give decisive weight to
an after-the-fact inquiry into the merits of the patent issues in a settled
case." The FTC went on to note that:

An after-the-fact inquiry by the Commission into the merits of the
underlying litigation is not only unlikely to be particularly helpful,
but also likely to be unreliable. As a general matter, tribunals
decide patent issues in the context of a true adversary proceeding,
and their opinions are informed by the arguments of opposing
counsel. Once a case settles, however, the interests of the formerly
contending parties are aligned. A generic competitor that has
agreed to delay its entry no longer has an incentive to attack

428. Id.
429. Id. at 1069.
(E.D.N.Y. 2005) (collecting and analyzing cases to reach this conclusion).
431. See, e.g., In re Schering-Plough Corp., No. 9297 (F.T.C. Dec. 18, 2003),
http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf, vacated, 402 F.3d 1056
(11th Cir. 2005).
432. Id. at 33.
vigorously the validity of the patent in issue or a claim of infringement.\textsuperscript{433}

The FTC concluded that determining antitrust liability based on the merits of the underlying patent case would not be "supported by law or logic."\textsuperscript{434}

An alternative rationale supporting the FTC’s position is that the FTC probably lacks the technical proficiency to analyze the merits of a patents case, outside of extreme cases where the patent litigation is clearly objectively baseless or fraudulent. FDA has taken that position with respect to its own technical competence, adamantly refusing to assess either the validity or scope of patents listed in the Orange Book.\textsuperscript{435} This has led to problems in cases where branded drug companies appear to be listing patents of questionable validity, or that appear likely not to claim the branded drug.\textsuperscript{436} Nevertheless, FDA has stuck to its guns, pointing out that an analysis of patent validity or scope is a highly specialized skill with which the agency has no institutional competence.\textsuperscript{437}

The FTC’s rejection of any assessment of the merits of a patent case, of course, has required it to find some other basis for characterizing reverse payment settlements illegal, which has likely led to their focus on reverse payments, “probabilistic” patent rights, and theories of consumer expectation interest in the outcome of Paragraph IV litigations. However, as discussed throughout this paper, the courts have not been receptive to these alternate theories. In \textit{Schering-Plough}, the Eleventh Circuit chastised the FTC for finding the agreement illegal without any allegation that the patent was invalid or would not have been infringed by the generic product.\textsuperscript{438}

\begin{itemize}
\item \textsuperscript{433} Id. at 34.
\item \textsuperscript{434} Id. at 9.
\item \textsuperscript{437} See Ranbaxy Labs., Ltd. v. Leavitt, 459 F. Supp. 2d 1, 4 (D.D.C. 2006). \textit{See also} 21 C.F.R. 314.53(f) (2006); Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. at 36,683. The high rate at which the Federal Circuit reverses district court claim constructions is one example of the difficulty of accurately construing the scope of patent terms. If federal courts have so much difficulty, even after the benefit of a full Markman hearing, does it make sense to think FDA will be able to accurately construe claim scope based on a mere filing in the Orange Book?
\item \textsuperscript{438} Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1067-68 (11th Cir. 2005), \textit{cert. denied}, 126 S. Ct. 2929 (2006).
\end{itemize}
The Eleventh Circuit’s position is based on the logic that, if the restrictions imposed by the settlement agreement do not exceed those that could be obtained by assertion of the presumptively valid patent rights, then there cannot be an antitrust violation. Some have interpreted Schering-Plough as mandating a fairly probing inquiry into the merits of the underlying patent dispute in any antitrust analysis of a reverse payment settlement. However, as discussed in more detail below, in my view it would be a mistake to assume that the Eleventh Circuit is mandating any inquiry beyond that required to rebut a charge that the patent suit was fraudulent or objectively baseless, or that the agreement extends to subject matter clearly exceeding the scope of the patent claims.

As previously discussed, both Tamoxifen and Asahi Glass express the view that even the patent owner’s subjective belief would not be relevant in assessing the legality of a settlement under the antitrust laws. As a corollary, Judge Posner in Asahi Glass concluded that it would be improper to independently assess the merits of the patent case, except in cases where the patent was almost certainly invalid or obtained by fraud. Similarly, in Tamoxifen, the Second Circuit held that a reverse payment settlement is only illegal if the patent litigation was a sham or objectively baseless, suggesting that an inquiry into the merits of the case is inappropriate, except in these extreme circumstances. Likewise, in Cardizem, the Sixth Circuit found the agreement to be illegal without engaging in any analysis of the merits of the patent case.

Some have interpreted the test in the Eleventh Circuit as requiring an inquiry into the merits of the underlying patent dispute. In fact, some have argued that this asserted requirement constitutes a substantial split between the Second and Eleventh Circuits that would warrant a grant of certiorari by the Supreme Court. For example, in its petition for certiorari, the Tamoxifen

439. Id. at 1068.
440. See infra Section VI.A.
441. See infra Section VI.A.
442. See supra Section V.E.
446. See infra note 448 and accompanying text.
447. See infra Section VI.A.
plaintiffs argue that the Eleventh Circuit's test "inquires into the underlying validity of the patent at the time of the exclusion payment before judging the validity of the reverse payment agreement." In contrast, they characterize the Second Circuit's Tamoxifen test as conferring presumptive legality on reverse payment settlements in the absence of a sham lawsuit.

Clearly the Eleventh Circuit test, as articulated in both Valley Drug and Schering-Plough, implicitly requires some level of inquiry into the merits of underlying patent case. Any test involving an assessment of the exclusionary potential of a patent necessarily requires some determination of the scope of the patent and its likely validity. As examples of agreements exceeding the exclusionary potential of the patent, the court pointed to agreements extending to products outside the scope of the patent, or where the patent dispute is a sham. A determination on the first question clearly implicates some construction of the claims, and the second some level of inquiry into both the scope and likely validity of the patent.

But the same can be said of the Second Circuit's test, which essentially adopts the Eleventh Circuit approach of looking to the exclusionary potential of the patent, thus also implying some level of inquiry into the merits of the patent case. In fact, neither the Eleventh nor Second Circuits appears to be advocating any probing inquiry into the merits of the case, or determination on points of validity or claim construction with respect to which reasonable minds would disagree. Instead, the level of inquiry in both circuits would seem to be, at most, a perfunctory assessment at to whether there is at least some

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449. Petition for Certiorari in Tamoxifen, supra note 448, at 8, 12.

objective non-fraudulent basis for the suit, and whether the excluded products fall within the nominal outer boundaries of the claims. Assuming these criteria are met, neither circuit shows any inclination for a more probing inquiry into the merits of the case; to the contrary, both courts stress the negative policy implications of any such probing inquiry.

The Tamoxifen plaintiffs characterized Valley Drug as establishing a general test requiring an inquiry into the merits of the underlying patent case.\footnote{See supra note 448 and accompanying text.} However, in Valley Drug, the Eleventh Circuit makes it clear that its holding was intended to be narrow, owing to the early stage of the litigation.\footnote{Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1306 (11th Cir. 2003).} The court stressed the importance of the presumption of validity of issued patents, and concluded that settling parties should not be exposed to “antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid,” because to do so would “undermine the patent incentives.”\footnote{Id. at 1308 (emphasis added).} In the words of the court, “[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.”\footnote{Id. at 1307 (citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965); United States v. Line Material Co., 333 U.S. 287, 309 (1948)).} The court advocates a very high threshold for finding antitrust liability based on the merits of the patent case, citing to a long string of cases that found antitrust immunity based on the existence of a patent.\footnote{Id. (citing Walker Process, 382 U.S. at 177).} The court also notes that the only Supreme Court decision to address the circumstances under which this immunity could be pierced was Walker Process Equipment, Inc. v. Food Machine & Chemical Corp., wherein the Court held that the antitrust claimant must prove that the patentee knew that the patent had been obtained from the Patent Office by fraud.\footnote{Id. at 1311.}

As to the appropriate level of inquiry into the scope of the patent claims, Valley Drug refers to the exclusionary “potential” of the patent, implying a liberal interpretation of the scope of exclusion.\footnote{Id. at 1308 (emphasis added).}

This test does not seem to advocate that the court conduct any
rigorous construction of the claims along the lines of a Markman hearing, but rather an assessment of the nominal boundaries of the claim, such as would be required under the Second Circuit test.\textsuperscript{458} Valley Drug does acknowledge that it might be sufficiently apparent that antitrust liability would be justified for certain unreasonable settlements, such as those involving patents obtained by fraud, or cases where the patentee knew the patent was invalid or not infringed.\textsuperscript{459}

Valley Drug reversed and remanded the lower court's finding of per se illegality based on reverse payment.\textsuperscript{460} On remand, the district court in Terazosin II proceeded to assess the merits of the patent case.\textsuperscript{461} After determining that the patentee would likely not have been able to obtain a preliminary injunction, the district court concluded that the agreement exceeded the exclusionary potential of the patent and proceeded to find the agreement per se illegal.\textsuperscript{462} To the extent that the district court appears to have conducted a fairly rigorous inquiry into the merits of the underlying patent dispute, it arguably deviated from the test articulated by the Eleventh Circuit.\textsuperscript{463} In Schering-Plough, decided after Terazosin II, the Eleventh Circuit took pains in attempting to reconcile the district court's decision with the test announced in Valley Drug and Schering-Plough.\textsuperscript{464} In particular, the appellate court pointed out that the decision on remand emphasized that the illegal agreement delayed generic entry for a longer period of time than "any reasonable interpretation of the patent's protections would have provided."\textsuperscript{465} Thus, as characterized by the Eleventh Circuit, Terazosin II is not inconsistent with a test requiring a very limited inquiry into the merits of the patent case – an agreement extending beyond "any reasonable interpretation" of the

\begin{itemize}
\item \textsuperscript{458} A Markman hearing is a pre-trial hearing limited to the issue of claim interpretation. MERGES & DUFFY, supra note 388, at 896.
\item \textsuperscript{459} Valley Drug, 344 F.3d at 1308-09.
\item \textsuperscript{460} Id. at 1313.
\item \textsuperscript{461} See supra Section V.A.
\item \textsuperscript{462} See supra Section V.A.
\item \textsuperscript{463} It is not at all clear that the district court decision is consistent with the test set forth by Eleventh Circuit. The district court purported to find the agreement per se illegal after the Eleventh Circuit specifically held that per se treatment was not available in the case of a patent settlement. See supra Section V.A.
\item \textsuperscript{464} Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).
\item \textsuperscript{465} Id. at 1065 n.14 (quoting In re Terazosin Hydrochloride Antitrust Litig. (Terazosin II), 352 F. Supp. 2d 1279 (S.D. Fla. 2005)).
\end{itemize}
patent would seem to satisfy the Second Circuit’s test of “objectively baseless” and/or “exceeding the exclusionary potential of the patent.”

Terazosin II appears to be the only case where a court inquired into the merits of the patent case in determining the legality of a reverse settlement agreement. This same court had initially found the agreement per se illegal based on the presence of reverse payments; having already determined the agreement to be illegal, the court might have succumbed to the temptation to apply a strained interpretation of Valley Drug to arrive at the same conclusion on remand.

Consistent with Valley Drug, in Schering-Plough, the Eleventh Circuit does not necessarily advocate a probing inquiry into the merits of the patent case substantially exceeding the Second Circuit’s test. Recall that Schering-Plough involved a case where the FTC had found the agreements to be illegal based solely on the size of reverse payments, and its conclusion that the parties could have settled under terms that would have been more beneficial to consumers; the FTC explicitly refrained from any inquiry into the merits of the patent case.466 The Eleventh Circuit rejected the FTC’s approach, noting that the agreement could not be found illegal without some assessment of the underlying patent case.467 However, Schering-Plough says nothing about the level of inquiry that this assessment would entail – the example it cites to of an agreement exceeding the exclusionary potential of the patent is one involving a patent that is “‘almost certainly invalid.’”468 It does not suggest the necessity of any probing inquiry into the merits of the case.

The FTC and others have also interpreted the Eleventh and Second Circuit tests as substantially consistent with one another as to the level of inquiry into the merits of the patent case. For example, in characterizing Schering-Plough, the FTC has stated that “the only circumstance in which [the Eleventh Circuit in Schering-Plough] indicated the parties would exceed the exclusionary potential of the patent was that of ‘sham’ infringement claims.”469 The FTC also acknowledged that other courts interpret Schering-Plough as establishing a test requiring an inquiry only into the nominal reach of the patent, and not an assessment of the likelihood that the patent

466. Id. at 1066 n.15.
467. Id. at 1066.
468. Id. at 1067 (quoting Asahi Glass Co., Ltd. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003)).
469. FTC Petition for Certiorari in Schering-Plough, supra note 244, at 14.
owner would prevail in the litigation.\textsuperscript{470} For example, \textit{Ciprofloxacin} rejects an argument that \textit{Schering-Plough} and \textit{Valley Drug} mandate an inquiry into the potential invalidity of the patent, and finds that \textit{Schering-Plough} should instead be "more fairly read as requiring an evaluation of the scope of the patent's claims, and not a \textit{post hoc} analysis of the patent's validity, an approach which . . . has not been endorsed by any court other than the \textit{Valley Drug} district court on remand."\textsuperscript{471}

The district court in \textit{Ciprofloxacin} also refused to conduct an independent assessment of the underlying validity of the patent, finding that such an inquiry might chill patent settlements altogether.\textsuperscript{472} The district court also noted that the Sixth and Eleventh Circuits, the FTC, and various district courts all held that such an inquiry would be inappropriate in this context.\textsuperscript{473}

Courts are also generally unreceptive to attempts to prove a reverse payment settlement agreement was illegal based on the fact that the patent is ultimately determined to be invalid. This was the case in \textit{Valley Drug}, where the plaintiffs argued that the subsequent invalidation of the patent rendered the settlement agreement per se illegal.\textsuperscript{474} The Eleventh Circuit rejected this argument, finding that, in order to protect the value of patents and thus their utility as incentives for innovation, it is important to shield facially legitimate patent settlements from exposure to potential antitrust liability, based merely on a subsequent finding that the patent is invalid.\textsuperscript{475}

Courts have also declined to find an agreement illegal based on the fact that, at the time the agreement was entered into, the patent was held invalid in a non-final decision. This was the case in \textit{Tamoxifen}, where, at the time the parties entered the reverse payment settlement, the patent case was pending on an appeal to the Federal Circuit of a lower court's determination that the patent was invalid and unenforceable.\textsuperscript{476} On appeal, plaintiffs emphasized the fact that

\begin{itemize}
\item \textsuperscript{470} FTC Statement Before Aging Committee, \textit{supra} note 2, at 16.
\item \textsuperscript{471} \textit{In re Ciprofloxacin Hydrochloride Antitrust Litig.}, 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005).
\item \textsuperscript{472} \textit{Id.} at 530.
\item \textsuperscript{473} \textit{Id.} at 524-30.
\item \textsuperscript{474} \textit{Valley Drug Co. v. Geneva Pharms., Inc.}, 344 F.3d 1294, 1306 (11th Cir. 2003).
\item \textsuperscript{475} \textit{Id.} at 1308.
\item \textsuperscript{476} \textit{In re Tamoxifen Citrate Antitrust Litig.}, 466 F.3d 187, 193 (2d Cir. 2006), \textit{petition for cert. filed}, 75 U.S.L.W. 3333 (U.S. Dec. 16, 2006) (No. 06-830). This was based on the court's conclusion that the patentee "had deliberately withheld `crucial information' from the [Patent Office] regarding tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug." \textit{Id}. 
\end{itemize}
the patent was ultimately found invalid by a court, but the Second Circuit determined this fact had little probative effect. The court pointed to the inherent uncertainty with respect to predicting outcomes of patent litigation, and the fact that no one could accurately predict what the outcome of the appeal would have been, if the parties had failed to settle. For example, the court pointed to the fact that, subsequent to the district court’s patent decision, three other generic companies had filed Paragraph IV certifications challenging the patent, and all three subsequent challenges had failed. In other words, other courts rejected the conclusion of the first district court, suggesting at least the possibility that the Federal Circuit would have done so as well, and highlighting the uncertainty of patent litigation.

It bears to note that the Tamoxifen plaintiffs apparently never specifically alleged that the patent was invalid or not infringed, but instead sought to rely solely on the first district court decision invalidating the patent to establish antitrust liability. However, the patent owner’s successful defense of the patent’s validity in three subsequent litigations tends to refute any inference that the first patent litigation was either a sham or objectively baseless.

The DOJ has endorsed the view that some limited inquiry into the merits of the patent case is appropriate in determining the legality of a reverse payment settlement. In its amicus brief recommending against a grant of certiorari in Schering-Plough, the Solicitor General posits that an “appropriate legal standard [in assessing the legality of a reverse payment settlement] should take into account the relative likelihood of success of the parties’ claims.” However, he clarifies that

[a] court would not need to conduct a full trial on the merits of the patent claims in order to make a determination regarding the likelihood of a patent owner’s litigation success. Rather, a court could conduct a limited examination into the relative merits of the

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477. See id. at 204.
478. Id.
479. Id.
480. See id. at 194-95, 204.
481. Id. at 202.
482. Id. at 211.
483. U.S. Brief Recommending Denial of Certiorari in Schering-Plough, supra note 20, at 11.
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patent claims and other relevant factors surrounding the parties' negotiations.\textsuperscript{484}

\textbf{H. Barriers to Third Party Generic Entry Are Relevant in Assessing Potential Anticompetitive Effect}

A consideration of barriers to third party generic entry is relevant in any assessment of the potential anticompetitive effect of a settlement agreement. As previously discussed, in the absence of significant barriers to third party generic entry, a reverse payment settlement with one generic company might have little effect on competition overall, whereas, in the presence of substantial barriers to third party generic entry, an agreement with a single generic company might effectively foreclose any generic competition.\textsuperscript{485} Agreements with the potential to park GE are of the most concern, but there are also other substantial barriers to third party generic entry, primarily arising from the lengthy FDA pre-marketing approval process.

The FTC and some other critics of reverse payment settlements implicitly assume very high barriers to third party generic entry, which facilitates a reverse payment settlement between two parties with the potential to effectively block all generic competition.\textsuperscript{486} However, aside from parking GE, they normally do not explicitly point out and assess other specific barriers to third party generic entry.

Courts, on the other hand, often implicitly assume that barriers to third party generic entry are not overly high, with the exception of cases of GE parking. For example, a number of courts noted that, in general, a reverse payment settlement should not be effective in foreclosing competition, particularly where the merits of the patent case are weak, because of the ability of third parties to challenge the patent.\textsuperscript{487} This, of course, ignores the issue of the regulatory barrier to third party generic entry discussed above. Only in cases where there are a sufficient number of other Paragraph IV filers waiting in the wings will it be correct that an agreement with the first-filer does not impede market entry by any generic competition.

Courts clearly recognize that GE parking has a high potential to be anticompetitive, and have on a number of occasions classified GE parking as a restriction exceeding the exclusionary potential of the

\textsuperscript{484.} \textit{Id.} at 11 n.1.
\textsuperscript{485.} \textit{See supra} Section III.B.
\textsuperscript{486.} \textit{See supra} Section IV.
\textsuperscript{487.} \textit{See, e.g., Tamoxifen,} 466 F.3d at 211 (citing \textit{In re Ciprofloxacin Hydrochloride Antitrust Litig.}, 363 F. Supp. 2d 514, 534 (E.D.N.Y. 2005)).
patent, thereby bringing settlement agreements containing such provisions outside the antitrust immunity generally conferred upon patent settlements. 488

In Tamoxifen, the Second Circuit noted that a challenged reverse payment settlement was not in violation of the antitrust laws, because it did not entirely foreclose competition in the market for the patented compound. 489 The court posited that a strategy of simply paying potential generic competitors to stay off the market would ultimately fail, because, at some point, the cost of paying off subsequent generic challengers would exceed the ability of the patentee's supracompetitive prices to support them. 490 Essentially, the court challenged the plaintiff's implicit assumption that an agreement with one generic firm could block all generic competition. 491 In that case, it is true that at least three subsequent generic companies challenged the patent after Zeneca settled with the first challenger Barr, and Zeneca did not settle with any of them. 492 Instead, Zeneca fully litigated the cases and successfully defended its patent rights, thereby keeping these generic competitors off of the market. 493

To the extent the Second Circuit's analysis is interpreted as applying to reverse payment settlements in general, however, it seems unrealistic in assuming minimal barriers to subsequent third party generic entry. The analysis also seems inconsistent with general antitrust doctrine. In general, it is true that horizontal market allocation agreements would not negatively impact competition were it not for some barrier to third party market entry, but courts have classified such agreements as per se illegal regardless of the size of entry barriers. 494

Ciprofloxacin also endorses the position taken in Tamoxifen and elsewhere that "it is unlikely that the holder of a weak patent could

488. See Andrx Pharms., Inc. v. Elan Corp., PLC, 421 F.3d 1227, 1236 (11th Cir. 2005). See also Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 815 (D.C. Cir. 2001); Ciprofloxacin, 261 F. Supp. 2d at 211-12, 242-43.
490. See id. at 211-212.
491. In other words, the court assumed high barriers to generic entry.
492. Tamoxifen, 466 F.3d at 194-96.
493. Id.
stave off all possible challengers with exclusion payments because the economics simply would not justify it."\textsuperscript{495}

In \textit{Tamoxifen}, the Second Circuit posited that:

\begin{quote}
While the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid. There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt, however, that this scenario is realistic. Every settlement payment to a generic manufacturer reduces the profitability of the patent monopoly. The point will come when there are simply no monopoly profits with which to pay the new generic challengers. "[I]t is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it."\textsuperscript{496}
\end{quote}

The reasoning in \textit{Tamoxifen} is surely correct, if we are to assume that barriers to third party generic entry are not prohibitive. However, to the extent barriers to entry impede subsequent generic challengers, the Second Circuit's rationale would appear to falter. In fact, as previously discussed, the barriers to entry for subsequent generic competitors can be substantial.\textsuperscript{497} With effective barriers to third party generic entry in place, a reverse payment strategy could be economically feasible and highly effective even in situations where the merits of the patent case are weak, raising substantial competition concerns.

On the other hand, barriers to third party generic entry are generally not insurmountable, as evidenced by the number of cases where reverse payment settlements have not prevented subsequent third parties from entering the market.\textsuperscript{498} The barriers to generic entry

\begin{footnotes}
\item 496. \textit{Tamoxifen}, 466 F.3d at 211-12 (quoting \textit{Ciprofloxacin}, 363 F. Supp. 2d at 534-35) (citation omitted).
\item 497. \textit{See supra} Section III.B.
\item 498. \textit{Tamoxifen}, 466 F.3d at 215 (the settlement agreement "clear[ed] the way for other generic manufacturers to seek to enter the market."); Schering-Plough Corp. v. FTC, 402 F.3d
\end{footnotes}
will vary dramatically on a case-by-case basis. Significantly, Hatch-Waxman has created an environment where the terms of the settlement agreement itself can create substantial, or even, for a time, insurmountable barriers to third party generic entry. These barriers to third party generic entry should figure prominently in any analysis of the antitrust implications of reverse payment settlements.

An FTC commissioner recently acknowledged that reverse payment settlements do not necessarily preclude third party generic competition, but nevertheless expressed concern that a branded drug company could successfully preclude all competition by entering into reverse payment settlements with each and every potential generic competitor, thereby foreclosing all competition. One taking the view of the Second Circuit might question the long-term economic feasibility of such an approach, in view of the large number of potential generic competitors, but it could be effective if barriers to entry do in fact restrict the number of potential generic competitors to a manageable pool. Until recently, it appears to have been rare for a branded drug company to enter into reverse payment settlements with multiple generic drug companies. Branded drug companies typically only enter reverse settlement agreement with the first Paragraph IV filer, not with subsequent ANDA filers.

It bears noting that the FTC has a long history of, at times, overzealous enforcement of the antitrust laws that have only been reined in by the courts. Often, with the benefit of hindsight, even the FTC comes to realize that an overly aggressive posture in enforcing the antitrust laws, while motivated by a desire to protect U.S. consumers, can actually have the opposite effect, by focusing unduly on competition and ignoring the importance of efficiencies and incentives to innovation in promoting the public interest.

1056, 1072-76 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006) (reverse payment agreements with two generic companies did not exclude other potential generic competition).

499. See supra Section III.B.


501. See, e.g., FTC GENERIC DRUG STUDY, supra note 31.

502. *Tamoxifen* is just one example where the branded company enters a reverse payment settlement with a first Paragraph IV filer but fully litigated the case against three subsequent patent challengers. The FTC Generic Drug Study found that only one out of forty-three studied Paragraph IV lawsuits involving second generic patent challengers were settled by means of an agreement including a reverse payment. FTC GENERIC DRUG STUDY, supra note 31, at 35-36.

There are many examples of enforcement excesses by the FTC and DOJ, particularly in the area of patents and patent-related agreements. For example, during the 1970's, these agencies promulgated the now infamous “Nine No-No's,” nine types of licensing terms that were essentially treated as per se illegal. Today, the FTC acknowledges that this approach was misguided, “lack[ing] both a sound economic foundation and a sufficient appreciation of the incentives for innovation that intellectual property and intellectual property licensing can provide.” In a 2003 report by the FTC that discusses and makes recommendations for the patent system to maintain a proper balance with competition law and policy, the agency acknowledged that it erred in the past by treating “grant-back clauses” in patent licensing agreements as per se illegal. The FTC now notes that “antitrust enforcers recognize that '[g]rantbacks can have procompetitive effects,' for example, by encouraging a patentee to license its patent in the first place, thereby enabling the licensee's improvement.” The report openly acknowledges that the FTC’s “overzealous antitrust enforcement can undermine the innovation that patents promote.” In this regard, it is interesting to note that the other federal agency tasked with enforcing the antitrust laws, the DOJ, refused to back the FTC in its attempt to premise antitrust liability on the existence of reverse payments.

VI. THE FUTURE OF REVERSE PAYMENT SETTLEMENTS

As of now, arguments for presumptive illegality for reverse payment settlement agreements have met with little success in the courts, where the current consensus would not condemn such settlements based merely on the existence or “excessiveness” of reverse payments. However, the FTC and other critics of reverse payments
payments continue to push their position on a number of fronts, both in the courts and with Congress.\footnote{511} In the courts, repeated attempts have been made to overturn decisions rejecting presumptive illegality for reverse payment settlements, particularly \textit{Valley Drug}, \footnote{512} \textit{Schering-Plough} \footnote{513} and \textit{Tamoxifen}.\footnote{514} So far these attempts have met with no success, and, at this point, the prospect for reversing the consensus approach as set forth by the Second and Eleventh Circuits seems slim. Petitions for rehearing en banc were denied with respect to \textit{Valley Drug}, \footnote{515} \textit{Cardizem} \footnote{516} and \textit{Schering-Plough}, \footnote{517} and the Supreme Court has already denied petitions for certiorari in \textit{Valley Drug}, \footnote{518} \textit{Cardizem} \footnote{519} and \textit{Schering-Plough}.\footnote{520} A petition for certiorari is pending with respect to \textit{Tamoxifen}, but the Supreme Court is unlikely to grant the petition, primarily because of the absence of any significant split between the circuits on the issue.\footnote{521}

\textbf{A. Supreme Court Intervention Is Unlikely to Occur Soon}

Of course, those familiar with the debate over the antitrust implications of reverse payment settlements will recognize the oft-
made assertion that there exists a significant circuit split regarding the legality of reverse payment settlements. This assertion is based primarily on an interpretation of Cardizem as setting forth a rule of per se illegality for reverse payment settlements in the Sixth Circuit. The Eleventh and Second Circuit holdings in Valley Drug, Schering-Plough and Tamoxifen have, in contrast, been variously characterized as establishing either a rule of reason approach or presumptive legality, but, in any event, a standard at odds with the alleged rule of per se illegality in the Sixth Circuit.

However, as explained above, a close reading of Cardizem reveals that it actually never characterizes reverse payments as per se illegal. The analysis instead focuses on the agreement's effect of parking GE, thereby blocking third party generic market entry, and to a lesser extent upon the extension of the agreement to non-infringing products. While the court clearly viewed reverse payments as a troubling element of the agreements, it was read in the context of the agreement as a whole, and because the payments were seen as the quid pro quo in exchange for which the patent challenger agreed to restrictions exceeding the exclusionary potential of the patent. Parking GE and the inclusion of non-infringing products are classic examples of what courts characterize as the terms exceeding the exclusionary potential of the patent, and an agreement having these terms can clearly be found illegal under the Second and Eleventh Circuit consensus tests.

The U.S. Solicitor General, the FTC, and some commentators previously noted the lack of significant divergence between Cardizem

522. See supra Section V.A.

523. Various commentators have also asserted that a split exists between the circuits. See, e.g., John Fazzio, 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. & POL.Y 1, 28 (2006) ("The Eleventh Circuit Court of Appeals recently disagreed with the Sixth Circuit Court of Appeals’ application of a per se illegality standard for analyzing patent settlements"); Lisa M. Natter, Infringement Lawsuits: The Continuing Battle Between Patent Law and Antitrust Law in the Pharmaceutical Industry, 18 LOY. CONSUMER L. REV. 363, 364-65 (2006) ("The Supreme Court has repeatedly refused to grant certiorari in order to decide whether it is unlawful per se under the Sherman Act for a pharmaceutical patentee to pay a competitor to keep the competitor’s generic drug off the market during pending litigation between the patentee and the competitor. The Sixth Circuit held that such an agreement is inherently a horizontal agreement to eliminate competition for the drug in question, and is therefore unlawful per se under the Sherman Act. In direct contrast, the Eleventh Circuit held that such agreements were not unlawful per se, in part because the exclusion of infringing competition 'is the essence of the patent grant.'" (citations omitted).

524. The extension to non-infringing products received more attention in the district court decision.

525. See In re Cardizem CD Antitrust Litig., 332 F.3d 896, 907-08 (6th Cir. 2003).
and the consensus approach that focuses on restrictions exceeding the exclusionary potential of the patent. In recommending the Supreme Court deny certiorari in Schering-Plough, the U.S. Solicitor General pointed out that the Cardizem decision involved payment to exclude drugs that did not fall within the scope of the patent alleged to be infringed, and thus it is far from clear that the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case. In view of the fact that the agreements at issue in Tamoxifen and Schering-Plough did not extend to drugs outside the patent claim, the Solicitor General concluded that there was not necessarily any tension between the approaches taken by the Sixth Circuit versus the Second and Eleventh Circuits. The end, the Solicitor General concluded that there was no circuit split that would justify Supreme Court review.

The FTC also initially expressed the view that there is no tension between Cardizem and the consensus approach of the Second and Eleventh Circuits. In its brief opposing certiorari in Cardizem, the FTC argued that although the outcomes of Cardizem and Valley Drug diverged there is no necessary tension between the two decisions. The FTC pointed out that the agreement at issue in Cardizem had been construed to exclude non-infringing and potentially non-infringing products — restrictions extending beyond the exclusionary potential of the patent — and thus could have been found illegal under the Valley Drug test. However, the FTC’s later interpretation of Cardizem appeared to shift. In its petition seeking certiorari in Schering-Plough, the FTC suggests that Cardizem established a per se rule against reverse payments settlements in the Sixth Circuit, and cites to this as a basis for an alleged circuit split. Things have apparently come full circle, however, for in a prepared statement

526. See, e.g., Burling, supra note 66 ("Notwithstanding an earlier Sixth Circuit decision holding a Hatch-Waxman settlement per se illegal, there is no real split among the circuits. Indeed, there is an emerging consensus in favor of the principles articulated by the Eleventh Circuit." (citations omitted).
527. U.S. Brief Recommending Denial of Certiorari in Schering-Plough, supra note 20, at 17.
528. Id.
529. Id. at 17-20.
530. See FTC Brief Opposing Grant of Certiorari in Cardizem, supra note 96, at 15 ("[T]he Eleventh Circuit was properly hesitant to recognize a square conflict between the two decisions . . . .").
531. Id. at 13.
532. See FTC Petition for Certiorari in Schering-Plough, supra note 244.
533. Id. at 22.
before Congress on January 18, 2007, the FTC does not suggest that the rule in the Sixth Circuit is per se illegality for reverse payment settlements.\textsuperscript{534}

In their brief in support of its petition for certiorari, the plaintiffs in \textit{Tamoxifen}, not surprisingly, attempt to characterize the Second Circuit’s decision as creating a split with both the Eleventh and Sixth Circuits,\textsuperscript{535} but the attempt is not overly convincing. With respect to the Sixth Circuit, they simply repeat the tired assertion that \textit{Cardizem} announced a rule of per se illegality for reverse payment settlements.\textsuperscript{536} The \textit{Tamoxifen} plaintiffs also attempt to identify a split between the Eleventh and Second Circuits, alleging that the Eleventh Circuit’s test “inquires into the underlying validity of the patent at the time of the exclusion payment before judging the validity of the reverse payment agreement,” citing to \textit{Valley Drug} for this alleged test, while the Second Circuit test would find reverse payment settlements per se legal absent fraud.\textsuperscript{537} However, as explained above, the Eleventh and Second Circuit tests can both be reasonably interpreted as requiring only a minimal inquiry necessary to establish whether the agreement exceeds the exclusionary potential of the patent, and it is not clear that there is any substantial split between the circuits on this point either.\textsuperscript{538} The \textit{Tamoxifen} plaintiffs provide no analysis of the case law to support their conclusory assertion that the Eleventh and Second Circuit tests conflict with the other with respect to the level of inquiry into the merits of the underlying patent dispute, nor do they even cite to specific pages in \textit{Valley Drug} or \textit{Schering-Plough} as a source for the asserted rule.\textsuperscript{539} However, they do expand upon other alleged inconsistencies between the tests of the two circuits, but, once again, the attempt to establish a split is unconvincing.\textsuperscript{540}

First, they note correctly that \textit{Valley Drug} states that per se illegality is inappropriate when, at the time of agreement, the patent had not been held invalid or unenforceable.\textsuperscript{541} However, in what appears to be a flawed application of logic, they assert that it

\textsuperscript{534} See infra note 549.
\textsuperscript{535} See Petition for Certiorari in Tamoxifen, supra note 448.
\textsuperscript{536} \textit{Id.} at 8.
\textsuperscript{537} \textit{Id.} (citing Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003)). See supra note 448 and accompanying text.
\textsuperscript{538} See supra Section V.G.
\textsuperscript{539} See generally Petition for Certiorari in Tamoxifen, supra note 448.
\textsuperscript{540} \textit{Id.} at 13-14.
\textsuperscript{541} \textit{Id.} at 13 (citing \textit{Valley Drug}, 344 F.3d at 1306 & n.18).
necessarily follows that, under the Eleventh Circuit’s test, a patent that has been found invalid by a district court at the time of the agreement, but with an appeal pending, would be per se illegal.\textsuperscript{542} One does not follow from the other: a statement that under certain conditions an agreement cannot be per se illegal does not require any inference that, under different conditions, an agreement would be per se illegal. To the contrary, \textit{Valley Drug} and \textit{Schering-Plough} both clearly state that per se illegality is inappropriate for antitrust analysis of any agreement involving a patent.\textsuperscript{543} The fact that the \textit{Tamoxifen} plaintiffs would even make this argument might be viewed as indicative of the weak foundation for the allegation of a circuit split.

The other argument the \textit{Tamoxifen} plaintiffs make in support of an alleged circuit split is somewhat hard to follow, but appears to rest on an assertion that the Eleventh Circuit would allow the court to infer from an “excessive” reverse payment that the patentee knew that the patent was invalid or procured by fraud, or that there was no objective basis to believe that patent was valid.\textsuperscript{544} If true, this would constitute a divergence from \textit{Tamoxifen}, wherein the Second Circuit emphatically rejected plaintiff’s argument that excessive size of the payments was sufficient to prove that the agreements were illegal.\textsuperscript{545} However, this characterization of the Eleventh Circuit test is based on an apparent misreading of the cases. In \textit{Schering-Plough}, the court explicitly states that “[w]e have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy.”\textsuperscript{546} This is also consistent with the FTC’s interpretation of the Eleventh Circuit test with respect to the relevance of the size of payment. In its petition for certiorari in \textit{Schering-Plough}, the FTC states that the Eleventh Circuit in \textit{Schering-Plough} “concluded that the existence or size of such a payment cannot be used to show that the patent holder has obtained a greater degree of market exclusion than its patent justified.”\textsuperscript{547} Once again, bearing in mind the different facts at issue in the specific cases, there is no apparent substantial divergence between the Eleventh and Second Circuit tests with respect to the legality of even “excessive” reverse payment settlements.

\textsuperscript{542} \textit{Id.}
\textsuperscript{543} Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065 (11th Cir. 2005) (citing \textit{Valley Drug}, 344 F.3d at 1311 n.27), cert. denied, 126 S. Ct. 2929 (2006).
\textsuperscript{544} Petition for Certiorari in Tamoxifen, supra note 448, at 13-14.
\textsuperscript{545} See supra Section V.E.
\textsuperscript{546} \textit{Schering-Plough}, 402 F.3d at 1075 (emphasis added).
\textsuperscript{547} FTC Petition for Certiorari in Schering-Plough, supra note 244, at 11.
Even the FTC espouses the view that a split does not exist between the Eleventh and Second Circuits. In a prepared statement before the Senate's Special Committee on Aging, the FTC states that Tamoxifen "followed the Eleventh Circuit's holding [in Schering-Plough] and expressly embraced the 'sham' standard."\(^{548}\) In its most recent testimony before Congress, the FTC also backed off from earlier characterizations of Cardizem as establishing a rule of per se illegality for reverse payment settlements in the Sixth Circuit, instead merely describing Cardizem as "holding a challenged exclusion payment arrangement unlawful."\(^{549}\) In that statement, the FTC also reiterated its interpretation of Tamoxifen as following the holding of Schering-Plough, with the test in both circuits requiring "only an inquiry into the nominal reach of the patent."\(^{550}\)

With both the DOJ and FTC taking the position that there is no split, and in view of the Tamoxifen plaintiff's weak attempt to identify a circuit split in their petition for certiorari, it appears likely that, with Tamoxifen, the Supreme Court will continue its practice of declining to intervene and overturn the consensus "exclusionary potential" test.

Not only is there no substantial split with respect to the consensus standard for reviewing reverse payments settlements, the consensus standard is consistent with longstanding judicial practice. In a variety of contexts, agreements that would be treated as per se antitrust violations, were it not for the presence of a patent dispute, have been found legal, so long as any anticompetitive effects of the agreement were limited to the exclusionary potential of the patent.\(^{551}\) These courts noted that, by their very nature, patents are anticompetitive, but that courts accept this as the nature of a patent, and that the incentive value of patents outweighs these anticompetitive consequences.\(^{552}\)

Some have implied that, without Supreme Court intervention, the Second Circuit's test will essentially be locked in as the law of the land, because defendants will appeal all FTC decisions to the Second

\(^{548}\) FTC Statement Before Aging Committee, supra note 2, at 16 & n.52.

\(^{549}\) FTC January 2007 Senate Testimony, supra note 161, at 14.

\(^{550}\) Id. at 15-16.

\(^{551}\) See Monsanto Co. v. McFarling, 302 F.3d 1291, 1298 (Fed. Cir. 2002) (citing General Talking Pictures Corp. v. Western Elec. Co., 305 U.S. 124, 127 (1938)) (in order to constitute an antitrust violation, a contractual restriction must be beyond the patent grant). See cases cited supra note 302.

\(^{552}\) See Monsanto, 302 F.3d at 1298; United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1128 (D.C. Cir. 1981); SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1204-06 (2d Cir. 1981).
However, it should be recognized that plaintiffs and state attorneys general can challenge reverse payment settlements under the FTC theory of presumptive illegality, and these cases can be brought in any circuit. In fact, such cases have been brought or are currently pending in a variety of other circuits. Moreover, in a recent statement, FTC Commissioner Leibowitz specifically suggested a strategy pursuant to which the FTC would challenge reverse settlement agreements in various federal district courts in an attempt to obtain a favorable ruling in a sympathetic circuit. Assuming the Commissioner is correct in this assertion, clearly even the FTC has latitude to seek a favorable decision in another circuit that would create the desired circuit split. Of course, with the prolonged nature of litigation, it is not surprising that the FTC would like a quicker solution to the adverse precedent created by the decisions in the Second and Eleventh Circuits.

B. Congress May Act to Ban Reverse Payment Settlements

On January 17, 2007, Senator Kohl (D-WI) and others introduced the Preserve Access to Affordable Generics Act (“PAAG”), a bill that would ban certain reverse payment settlements. The bill’s “Congressional Findings and Declaration Purposes” comes out in strong support for the FTC’s treatment of reverse payment settlements, and criticizes the Eleventh and Second Circuits’ Schering-Plough and Tamoxifen decisions for “revers[ing] the Federal Trade Commission’s long-standing position [by upholding the reverse payment settlements challenged in those cases].” The bill would introduce into the Clayton Act a new

553. See Lemley Brief Supporting Grant of Certiorari in Tamoxifen, supra note 448, at 9 n.9.

554. See, e.g., FTC Statement Before Aging Committee, supra note 2. There are reportedly a number of reverse payment cases currently pending in other circuits, including the Third and Ninth Circuits. Furthermore, there are motions to transfer some appeals to the Federal Circuit, each representing a potential opportunity for a court to find a reverse payment settlement illegal and create the circuit split sought by the FTC. See Bayer Brief Opposing Grant of Certiorari in Schering-Plough, supra note 278, at 6 (identifying In re K-Dur Antitrust Litigation, 338 F. Supp. 2d 517 (D.N.J. 2004), and Kaiser Foundation v. Abbott Laboratories, No. 2:02cv2443 (C.D. Cal. filed March 22, 2002); and stating that there are motions to transfer some or all of the appeals in the Second Circuit Tamoxifen and Ciprofloxacin litigations to the Federal Circuit).

555. Leibowitz Speech, supra note 77, at 8.

556. Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007). It is essentially an expanded version of Senate Bill 3582, a bill of the same name that was introduced on June 27, 2006, but never acted on. See Preserve Access to Affordable Generics Act, S. 3582, 109th Cong. (2006).

557. S. 316 § 2(a)(8).
"Unlawful Interference with Generic Marketing" section that would make it unlawful

for any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim which – (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.\textsuperscript{558}

In some ways, the bill proposes a standard that is much more restrictive than that advocated by the FTC and most mainstream critics of reverse payments settlements. For example, the bill would outlaw even de minimis payments representing saved litigation costs,\textsuperscript{559} which the FTC and many commentators would concede as legitimate.\textsuperscript{560} Even the FTC has noted that some reverse payments might be pro-competitive, particularly when the generic company is cash-strapped and the payments allow it to more rapidly and effectively enter the market.\textsuperscript{561} However, such payments would be explicitly outlawed under the bill’s heavy-handed approach.\textsuperscript{562}

The bill adopts an expansive definition of "reverse payments settlements."\textsuperscript{563} It defines the term "payment" broadly as "anything of value [other than an agreement to allow generic entry prior to patent expiration],"\textsuperscript{564} and "delay" as an agreement on the part of the generic company not to "research, develop, manufacture, market, or sell [the generic product] for any period of time."\textsuperscript{565} The term "settlement" is defined so as to encompass any situation involving an allegation of patent infringement, "whether or not included in a complaint filed with a court of law."\textsuperscript{566}

Furthermore, the bill is not limited to Paragraph IV settlements, which were the focus of most critical commentary and of the FTC’s enforcement activities.\textsuperscript{567} Its language would appear to apply to any patent infringement suit filed, or even alleged, that involves an ANDA applicant, even in cases where the patent owner is a third

\textsuperscript{558.} Id. § 3.
\textsuperscript{559.} Id.
\textsuperscript{560.} See supra Section II.
\textsuperscript{561.} See supra Section IV.B.
\textsuperscript{562.} S. 316 § 3.
\textsuperscript{563.} Id.
\textsuperscript{564.} Id.
\textsuperscript{565.} Id.
\textsuperscript{566.} See id.
\textsuperscript{567.} See supra Section II, IV.
party and not the NDA holder.\textsuperscript{568} For example, it would apparently encompass a settlement of a patent dispute between two rival generic companies – such generic versus generic lawsuits are reportedly becoming increasingly common.\textsuperscript{569}

However, in certain respects, the PAAG defines reverse payment settlements more narrowly than would the FTC and other critics of reverse payments. For example, the bill’s prohibition on reverse payment settlements only applies to agreements that resolve or settle the patent infringement claim, which would seem to exclude interim settlements.\textsuperscript{570} This is somewhat surprising, since, as discussed above, it is interim settlements, not final settlements, which have generally been viewed most negatively by the FTC and the courts.\textsuperscript{571} Cardizem and Terazosin, two cases where reverse payments settlements were found illegal, both involved interim settlements,\textsuperscript{572} and, to date, most FTC enforcement actions have targeted interim settlements.\textsuperscript{573}

Perhaps the bill’s sponsors subscribe to the view that a restriction on interim settlements substantially reduces the value of the 180-day GE, by requiring a GE-holder with an approved ANDA to choose either to enter the market “at risk” or to forgo any revenue prior to final resolution of the patent litigation. Such a restriction would render the GE exclusivity less attractive to generic companies, and thus could act as a disincentive to future patent challenges, an outcome contrary to the bill’s primary objective of promoting patent challenges.

The bill is also limited in that it only pertains to reverse payment settlements that involve the sale of a drug product and an ANDA filer.\textsuperscript{574} While reverse payments settlements are considered rare outside the context of Hatch-Waxman, they probably do exist.\textsuperscript{575} If reverse payments are so lacking in any pro-competitive justification to warrant per se illegality, which is essentially what the bill would

\textsuperscript{568} See Preserve Access to Affordable Generics Act, S. 316, 110th Cong. § 3 (2007).
\textsuperscript{569} Aaron F. Barkoff, Orange Book Blog: Generic vs. Generic (Jan. 24, 2007), http://www.orangebookblog.com/2007/01/generic_vs_gene.html (citing Teva Pharmaceuticals’ recent announcement that it has “sued several generic rivals who filed ANDAs for generic Zoloft (sertraline HCI), alleging that the companies infringe Teva’s patents on processes for making sertraline HCI”).
\textsuperscript{570} S. 316 § 3.
\textsuperscript{571} See supra Sections II, IV.A, V.A.
\textsuperscript{572} See supra Section V.A.
\textsuperscript{573} See supra Section IV.A.
\textsuperscript{574} S. 316 § 3.
\textsuperscript{575} The Microsoft-Lindows settlement is an example, albeit with a different form of IP. See supra notes 71-74.
establish, why not an across the board ban on reverse payment settlements of patent litigation, or, for that matter, intellectual property litigation in general? In fact, courts repeatedly find that reverse payment agreements arise naturally out of the Hatch-Waxman scheme, even in cases where the patent owner is quite confident in the merits of its patent case.\textsuperscript{576} Outside the Hatch-Waxman context, it seems more likely that reverse payments are indicative of bad intent such as a sham or objectively baseless litigation, or collusion on the part of the settling parties.

The bill’s scope is effectively limited to the relatively small category of patents that might be asserted in a Paragraph IV litigation, in particular, patents covering drugs or methods of using drugs. This could potentially raise the issue of TRIPS compliance.\textsuperscript{577} Under TRIPS Article 27.1, member nations are required to make “patents... available and patent rights enjoyable without discrimination as to... the field of technology.”\textsuperscript{578} Arguably, the bill in its current form is discriminatory against a particular area of technology, drugs, because a substantial limitation on the freedom to settle patent litigation substantially reduces the value of these patents.

In considering whether the proposed bill would violate the anti-discrimination provisions of Article 27.1, it is instructive to consider Canada–Patent Protection of Pharmaceutical Products (Canada–Generic Medicines), a case decided by the World Trade Organization (“WTO”) in 2000.\textsuperscript{579} The case was brought by the European Union (“EU”), which charged that various provisions of Canadian patent law violated Article 27.1 by discriminating against pharmaceutical patent owners.\textsuperscript{580} In particular, the EU challenged section 55.2(1) of the Canadian Patent Act, referred to as the “regulatory review exception,” which provided that “[i]t is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada... that regulates the manufacture, construction, use or sale of any product.”\textsuperscript{581}

\textsuperscript{576} See supra Section V.C.


\textsuperscript{578} Id. art. 27.1.


\textsuperscript{580} Id. ¶ 3.1.

\textsuperscript{581} Id. ¶ 2.1.
There was no dispute that the provision was aimed primarily at facilitating the timely approval of generic drugs, analogous to a similar provision provided by U.S. law. The EU argued that, although the language of the statute literally applied to any patented invention used in securing regulatory approval for any product, the purpose of the exemption was aimed entirely to benefit generic drug manufacturers, and that the de facto effect of the provision was limited to pharmaceutical products.

If these allegations had been proven, the WTO Panel hearing the case might have found the Canadian provision to be in violation of Article 27.1. However, the Panel concluded that the EU failed to establish discrimination. It began by finding no literal discrimination, noting that the exemption was literally not limited to pharmaceutical products, but is available to any product subject to regulatory approval. The Panel intimated that if the practical effect of the provision was limited to pharmaceuticals, it could be considered de facto discrimination in violation of TRIPS. However, the Panel concluded that the EU did not demonstrate a discriminatory effect that was limited to pharmaceutical products. The Panel agreed with the EU that the legislative history and public discourse relating to the adoption of section 55.2(1) clearly indicated that the purpose of the legislation was to target pharmaceuticals, but this in itself was not enough to prove that the statutes literal extension to non-pharmaceutical patents was a "sham, or of no actual or potential importance." In the absence of a sham, the motivation behind the passage of the statute was not enough to infer literal or de facto discriminatory effect.

GAAP, on the other hand, on its face, applies particularly to pharmaceutical patents and substantially weakens the rights of the owners of the patents relative to the rights of other patent owners. Under the test applied by the WTO Panel in Canada–Generic Medicines, it is not clear that the provision would withstand a challenge at the WTO for a violation of Article 27.1.

584. Id. ¶¶ 7.99-7.105.
585. Id. ¶ 7.99.
586. Id. ¶ 7.101.
587. Id. ¶ 7.102.
588. Id. ¶ 7.104.
589. Id.
In view of the low probability that the Supreme Court will grant certiorari on *Tamoxifen*, it should come as no surprise that the FTC is lobbying hard to convince Congress to intervene and make reverse payment settlements illegal by statute. On January 17, 2007, FTC Commissioner Leibowitz testified before the Senate Judiciary Committee to voice the FTC’s support for the intent behind the PAAG.\(^{591}\)

The FTC was careful never to specifically endorse the PAAG, at least in its current form, but rather restricted itself to an endorsement of the intent behind the legislation.\(^{592}\) The FTC implicitly recommended revision of the current version of the bill and offered a number of suggestions in that regard.\(^{593}\) First, the FTC stressed that the legislation must be sufficiently broad to “encompass the various ways that a branded firm may share its profits with the generic, including not only the ways we have seen to date, but also those that may arise in the future.”\(^{594}\) After many years of experience with Hatch-Waxman, the FTC is only too aware of the virtually unlimited creativity of pharmaceutical companies and their lawyers in devising strategies for delaying generic competition while staying within the letter of the law. The FTC also stressed how important it was for the law to encompass all arrangements that are part of the settlement, even if not part of the written agreement.\(^{595}\) This concern seems to be addressed by section 4 of the bill, which provides, inter alia, that a responsible corporate official must execute and file with the Assistant Attorney General and the FTC “written descriptions of any oral agreements, representations, commitments, or promises between the parties” to a patent settlement agreement between a generic and a branded company.\(^{596}\)

On the other hand, the FTC warned against legislative measures that might unduly deter settlement.\(^{597}\) The FTC endorses the view of Judge Posner and others that all settlements provide some compensation to the generic, even if nothing more than termination of the litigation.\(^{598}\) It advises Congress to be careful not to restrict settlement options unlikely to involve a sharing of profits preserved

\(^{591}\) FTC January 2007 Senate Testimony, *supra* note 161, at 22.

\(^{592}\) See *id.*

\(^{593}\) *Id.*

\(^{594}\) *Id.*

\(^{595}\) *Id.*


\(^{598}\) *Id.*
by avoiding competition, citing as specific examples: agreements to split the time to patent expiration, a waiver of the brand’s market exclusivity based on testing of a drug for pediatric use, or “a waiver of patent infringement damages against a generic for entry that has already occurred.” Under the bill’s current language, it is unclear whether at least the second and third scenarios would be legal.

VII. CONCLUSION

Courts are generally unreceptive to attempts to characterize patent settlements as illegal based on the mere presence or amount of reverse payments, or to theories of antitrust liability based on the probabilistic nature of patents or a consumer expectation interest in the chance a patent challenge will succeed in the absence of a settlement. On the other hand, courts will find reverse payment settlement in violation of the antitrust laws to the extent that the agreement contains restrictions on competition that exceed the exclusionary potential of the patent. This typically occurs when the agreement extends to clearly non-infringing products or activities, or when the parking of GE creates a substantial, or even insurmountable, barrier to third party generic entry.

Absent GE parking or restrictions on non-infringing products, the courts are reluctant to find reverse payment settlements fundamentally different than patent settlements in general, because the reverse payments are viewed as a natural by-product of the Hatch-Waxman scheme. At the same time, the FTC and most courts conclude that any detailed assessment of the merits of the underlying patent dispute is probably unwise in the context of an antitrust analysis, at least when the patent litigation does not appear to be objectively baseless and the agreement restrictions do not exceed the nominal boundaries of the patent. Nevertheless, in some cases, these agreements seem clearly to impede the introduction of generic drugs on the market, and with the rising cost of drugs and healthcare in general, some level of antitrust scrutiny might well be in order.

An alternative analytical framework that has not received much explicit attention, with the notable exception of GE parking, is the role of barriers to third party generic entry. Perhaps it is these barriers, rather than reverse payments per se, that provide a more meaningful

599. Id. at 22-23.
600. S. 316 § 3.
601. See supra Section V.C.
602. See supra Section V.G.
basis for distinguishing anticompetitive Paragraph IV settlements from other patent settlements. A focus on barriers to third party generic entry would help to quantify the anticompetitive potential of a particular Paragraph IV settlement, and of Paragraph IV settlements in general. If barriers to third party generic entry are unusually high, then not only are these agreements likely to be effective in impeding all generic competition, they are deserving of close antitrust scrutiny. On the other hand, if barriers to third party entry are not so high, then there is less danger to competition and less need for rigorous antitrust enforcement.

An explicit assessment of third party generic entry could be relevant in several ways. First, it might be used to convince courts that Paragraph IV settlements, particularly those including reverse payments, really are fundamentally different than other patent settlements, because barriers to third party generic entry have the effect of leveraging an agreement with a single generic competitor into a tool for effectively excluding all generic competition for a substantial amount of time.

Second, even if this could not be established in the general case of Paragraph IV or reverse payment settlements, perhaps in the case of individual agreements, a sufficient showing of barriers to third party generic entry might convince a court that a particular agreement, by effectively excluding all competition for multiple years, is sufficiently anticompetitive to violate the antitrust laws. Consider, for example, a case where there is a single generic Paragraph IV filer that has received final FDA approval to enter the market with a generic, no other ANDAs have been filed, and the patent owner and generic enter a reverse payment settlement. Regardless of whether GE is parked, regulatory barriers to third party generic entry will effectively turn the settlement into a complete bar to any generic competition for at least several years. This agreement might warrant antitrust scrutiny exceeding that of a typical patent settlement, particularly if it can be shown that the patent owner or the settling generic played some role in discouraging other generic companies from filing ANDAs.

An assessment of barriers to third party entry in evaluating the antitrust implications of an agreement occurs in other contexts. For example, in the FTC and DOJ’s “Antitrust Guidelines for Collaborations Among Competitors,” the agencies discuss the necessity of evaluating whether third party entry would be “timely, likely and sufficient to counteract any anticompetitive harms” in a
Rule of Reason analysis of an alleged collaboration agreement between competitors.\footnote{LICENSING GUIDELINES, supra note 50, at 11.}

Third, it may be worth exploring whether there are approaches other than antitrust law that could have the effect of lowering barriers to third party generic entry. To the extent these barriers could be lowered, this would obviate the need for relying on antitrust enforcement to bring about generic competition. If the barriers to third party generic entry were low enough, then assertions such as those made by the court in *Tamoxifen* would actually hold true – the strategy of precluding generic competition by reverse payment settlements would encounter limited success because of subsequent third party patent challenges. Since, in the context of a Paragraph IV litigation, the barriers to third party generic entry are, to a large extent, a product of regulatory law, we would do well to at least consider whether reforms of Hatch-Waxman, or the FDCA in general, might be able to reduce the regulatory burden facing third party generic competitors. This is, of course, exactly what Hatch-Waxman did so successfully, for example, by creation of the ANDA to reduce the regulatory burden of the ANDA process.\footnote{See supra Section III.B.2.} Alternatively, reforms in the manner in which FDA implements the drug regulatory laws might also be made with the objective of reducing barriers to third party generic entry.

A prime target for any reform of Hatch-Waxman intended to reduce barriers to third party generic entry would, of course, be the 180-day GE provisions. The ability to park GE represents the most substantial Paragraph IV litigation-specific barrier to third party generic entry. In the 2003 Medicare Amendments, Congress substantially amended the Hatch-Waxman provisions relating to the 180-day GE, most importantly defining forfeiture events with the express purpose of preventing GE parking and thereby reducing this barrier to third party generic entry.\footnote{See, e.g., FTC January 2007 Senate Testimony, supra note 161.} As noted by the FTC and others, it is doubtful that the amendments were entirely successful in this regard.\footnote{Id. at 23-25.} For example, in Commissioner Leibowitz's recent testimony before the Senate Judiciary Committee, he noted the continuing problem of parking GE and proposed additional legislative amendments to address the problem.\footnote{Id. at 23-25.} Although this is a topic for
another article, I would suggest that Congress might be better served by simply eliminating GE. This would avoid the problem of parking that Congress and the courts have had so much trouble correcting. Additionally, it is not at all clear that the incentive of 180-day GE is actually required to incentivize generic companies to mount patent challenges, particularly in the case of the most important blockbuster drugs.\footnote{See Engelberg, supra note 121 (remarking that the 180-day period was “ill-conceived” and that generic manufacturers have become skilled at developing bioequivalent products around pharmaceutical patents).}