SETTLEMENTS BETWEEN BRAND AND GENERIC PHARMACEUTICAL COMPANIES:
A REASONABLE ANTITRUST ANALYSIS OF REVERSE PAYMENTS

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INTRODUCTION

Imagine that CureCo, Inc., is the exclusive seller of a patented product that yields hundreds of millions of dollars per year in revenues. CopyCo International announces its intention to market the product and compete with CureCo. CureCo promptly sues CopyCo for patent infringement. A federal court holds that the patent is invalid, appearing to clear the way for CopyCo to enter the market; however, CureCo appeals the decision. Before the appeal is concluded, the parties enter into a settlement agreement in which CureCo, the plaintiff, pays CopyCo, the defendant, twenty-one million dollars to refrain from marketing the product until the expiration of the invalid patent, preserving CureCo’s exclusive hold on the market. Now imagine that the product is a life-saving chemotherapy drug. Over the vehement objections of consumers, public interest groups, and antitrust enforcers, the settlement is deemed legal by a federal district court, whose decision is affirmed by the court of appeals.

These are the facts of a recent case1 that took place amid growing criticism of the pharmaceutical industry.2 Rising drug costs,3 doubts about drug safety,4 aggressive advertising to consumers,5 and questionable

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1. See In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005). This opinion was amended and superseded by In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (Fed. Cir. 2006), which predominantly made changes and corrections to the citations in the original opinion, but did not modify the court’s analysis or holding.


4. See Berenson, supra note 2.

marketing practices to physicians have precipitated a lack of consumer confidence in pharmaceutical companies. In an effort to lower health care costs, consumer advocacy groups are increasingly active in challenging the tactics that brand-name pharmaceutical companies use to prevent generic competition. These efforts are complicated by the fact that the law for evaluating these tactics is unsettled.

A potential conflict between antitrust law and patent law occurs when brand and generic pharmaceutical companies—potential competitors in the same market—enter into settlement agreements to resolve patent infringement suits. These settlement agreements fall into several categories, the most prevalent of which involves so-called “reverse payments” from the patent holder to the alleged infringer, typically in exchange for the alleged infringer’s agreement to delay market entry of a pharmaceutical product or line of products. Such arrangements between brand and generic pharmaceutical companies, particularly the unusual flow of compensation from plaintiff to defendant, may seem counterintuitive, but the arrangements arise, in part, as a result of a complex regulatory scheme that governs the approval of generic drugs. It is this regulatory structure, and the motivations it fosters, that make these settlements both attractive to the parties and a red flag to antitrust enforcers.

While public policy favors settlement of complex and costly patent disputes over litigation of such disputes, courts must ensure that the settlements do not circumvent antitrust laws. Courts are divided regarding the proper antitrust analysis of these agreements in the context of patent litigation settlements. In one of the earliest cases to examine the issue, the U.S. Court of Appeals for the Sixth Circuit held that an agreement in which a generic manufacturer refrained from marketing its product in exchange for payment by the brand company constituted a horizontal

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7. See Berenson, supra note 2.
9. See Mark L. Kovner et al., Applying the Noerr Doctrine to Pharmaceutical Patent Litigation Settlements, 71 Antitrust L.J. 609, 613-14 (2003). These payments made by the brand company are also called “exclusion payments” or “exit payments.” See, e.g., Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1309 (11th Cir. 2003); In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro II), 363 F. Supp. 2d 514, 520 n.6 (E.D.N.Y. 2005).
10. See In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 390-91 (2d Cir. 2005) (noting that “reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them”).
arrangement to eliminate competition and thus was illegal per se. In contrast, a few months later in a similar case, the Eleventh Circuit rejected the per se approach, and instead formulated a novel, three-part test to evaluate the parties’ antitrust liability. The Eleventh Circuit has reiterated and applied the three-part test in subsequent cases. In a third jurisdiction, Judge David G. Trager of the Eastern District of New York, applied a traditional rule-of-reason analysis and determined that, on balance, the defendants’ agreement did not impermissibly restrain competition in the relevant market. In an unrelated case, the Second Circuit subsequently agreed with the analysis employed by Judge Trager. There are dozens of similar cases—mainly class actions—pending in at least four other federal district courts. The U.S. Supreme Court declined the opportunity to set a unifying standard for analyzing patent infringement settlements when it recently denied a petition for certiorari in FTC v. Schering-Plough Corp.

A consistent rule for evaluating patent infringement settlements in the context of antitrust law is needed. Part I of this Note reviews the basic principles of antitrust law, the basic principles of patent law, and the tension between the two systems. Part I also explains the types of agreements at issue and the unique regulatory scheme under which these agreements arise. Part II surveys the analyses that federal courts have used to determine the legality of patent infringement settlements, particularly settlements involving payments from the infringement plaintiff to the infringement defendant, referred to herein as “reverse payments.” Part III proposes an analytical framework that takes into account the goals of both antitrust law and patent law.

15. Id. at 1312.
16. Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1235 (11th Cir. 2005); Schering II, 402 F.3d at 1066.
I. THE SPECIAL CASE OF PHARMACEUTICALS: CONFLICTS AND CORRELATIONS BETWEEN ANTITRUST LAW AND PATENT LAW

A. The Tension Between the Antitrust and Patent Systems

If one considers the basic premise of antitrust law to be the protection and stimulation of competition, in part by the prohibition of monopolies, then the granting of a legal monopoly in the form of a patent would seem to thwart that goal. Courts have discussed this tension in trying to balance antitrust and intellectual property concerns when considering potential violations of the Sherman Act in view of an intellectual property owner’s right to exclude. On the one hand, it is clear that a patent does not bestow upon its owner the right to violate the antitrust laws. On the other hand, the enforcement of exclusionary rights by a patent owner is not an antitrust violation. Therefore, courts are left in the position of determining when exclusionary action by a patentee exceeds the scope of the legal monopoly granted under the patent. The tension between antitrust law and patent law is further complicated in the pharmaceutical industry by the regulatory scheme governing the approval and marketing of generic drugs.

In spite of the seemingly incongruous objectives of the two systems, Part III of this Note proposes that perhaps the goals of antitrust law and patent law are not so disparate after all. Prior to reaching that resolution, however, a discussion of the doctrine and rationale underlying each of these areas of law, along with an explanation of the operation and effects of the regulatory system governing the pharmaceutical arena, is necessary.

B. Basic Principles of Antitrust Law

1. The Sherman Act and Antitrust Analysis

Section 1 of the Sherman Act prohibits “[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce among the
several States, or with foreign nations. The Supreme Court has construed section 1 to apply only to unreasonable restraints of trade, rather than to every agreement in restraint of trade. In determining whether a contract unreasonably restrains trade in violation of section 1, courts generally engage in one of three levels of antitrust inquiry: (1) a per se rule of illegality for restraints that are obviously anticompetitive; (2) a “quick-look” approach for restraints that have pro-competitive justifications; or (3) a “rule-of-reason” analysis for restraints that require a more extensive balancing of their pro- and anticompetitive effects. The boundaries between these categories of analysis are not fixed; rather, these approaches “are best viewed as a continuum, on which the amount and range of information needed to evaluate a restraint varies depending on how highly suspicious and how unique the restraint is.” At one end of the spectrum lies the relatively lenient and fact-intensive rule of reason, while the stricter per se rules lie at the other end, and the quick-look analysis occupies an intermediate position.

The rule-of-reason analysis was classically defined by Justice Louis Brandeis in 1918:

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

Courts apply the rule of reason as a three-part analysis with shifting burdens of proof. As the first step, the plaintiff must demonstrate that “the challenged action has had an actual adverse effect on competition as a whole in the relevant market.” The defendant then has the burden of

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33. Id.
showing that the action has “pro-competitive redeeming virtues.” If such virtues are established, “the burden shifts back to the plaintiff to show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.” Furthermore, as part of the first step, the court must determine the relevant product and geographic markets and whether the defendant had power in those markets, i.e., the power to raise prices or reduce output. While an affirmative finding is not dispositive, it is indicative of the defendant’s ability to injure competition.

On the other end of the analytical continuum are agreements that are condemned as illegal per se under section 1 of the Sherman Act because they are so clearly anticompetitive. These generally include “horizontal” arrangements—those between direct competitors in the defined market. Particular horizontal agreements that are condemned per se are horizontal price-fixing, horizontal allocation of markets, and horizontal refusals to deal. In such cases, a full inquiry into market power and anticompetitive effects would be nothing more than a waste of resources because the competitive harm is so obvious and the competitive benefit, if any, is so minimal.

Per se rules in the antitrust context have the same advantages as all bright-line rules—they provide clarity, predictability, efficiency, and judicial convenience. Nonetheless, the Supreme Court has been cautious about formulating new per se rules or extending existing rules to novel areas of law. Per se rules are more frequently applied to arrangements between direct competitors (in a “horizontal” relationship) than to arrangements between parties on different levels of the supply chain, for

35. Id.
36. Id. (internal quotation marks omitted).
42. E.g., Klor’s, Inc. v. Broadway-Hale Stores, Inc., 359 U.S. 207 (1959); Fashion Originators’ Guild of Am. v. FTC, 312 U.S. 457 (1941).
43. See Hovenkamp et al., supra note 29, at 1730.
46. See Maricopa County Med. Soc’y, 457 U.S. at 349 n.19 (noting “the established position that a new per se rule is not justified until the judiciary obtains considerable rule-of-reason experience with the particular type of restraint challenged”); id. at 364 (Powell, J., dissenting) (“[T]he per se label should not be assigned without carefully considering substantial benefits and procompetitive justifications. This is especially true when the agreement under attack is novel.”); White Motor Co. v. United States, 372 U.S. 253, 261 (1963).
example, manufacturers and distributors (in a “vertical” relationship). The reason for more stringent treatment of horizontal arrangements is that cooperation between direct competitors is more likely to lead to higher prices and lower output without any concomitant consumer benefit than is cooperation between firms that share a common interest—those in the vertical chain. Only vertical restrictions on minimum resale price fixing are illegal per se, while vertical maximum price fixing, refusals to deal, and territorial restraints are generally analyzed under a full rule of reason.

A “quick-look” analysis lies between the rule-of-reason and the per se rules on the antitrust analysis continuum. This analysis is appropriate when the challenged restraint does not fall into one of the per se categories but the likelihood of anticompetitive effects can easily be ascertained by “an observer with even a rudimentary understanding of economics.” In such cases, the defendant may provide pro-competitive justifications for the restraint, but the court can reject those reasons without undertaking the extensive market inquiry required by a full rule-of-reason analysis.

While these tests can be applied in a fairly straightforward manner in traditional antitrust contexts, there is some question as to whether separate considerations should form part of the analysis in a patent context. Courts addressing antitrust questions in the area of branded and generic pharmaceuticals have used analyses that fall at different points along the analytic continuum. A more consistent approach is needed.

2. Rationale of Antitrust Enforcement

In *Northern Pacific Railway Co. v. United States*, Justice Hugo L. Black articulated the justifications for antitrust law:

The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade. It rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to

55. See id. at 770-71.
the preservation of our democratic political and social institutions. But even were that premise open to question, the policy unequivocally laid down by the Act is competition.58

Although not stated so eloquently or comprehensively as Justice Black’s assessment, commentators and scholars have also offered several policy explanations for the development and enforcement of antitrust laws.

One policy is to protect consumers from artificially high prices.59 The consumer-welfare goals of antitrust doctrine are most commonly viewed through the lens of economic efficiency, an approach that is known as the “Chicago school” of antitrust analysis.60 Chicago school theorists posit that, under monopoly conditions, resources are not allocated efficiently because a consumer who would have purchased the resource at a competitive price may not purchase it at the monopoly price, either foregoing the resource entirely or substituting a less desirable product.61 As such, output is lower and prices are higher than in a competitive market.62

Another consumer-welfare goal, although not a universally accepted one, is the prevention of wealth transfer from the consumer to the monopolist in excess of that which would occur in a competitive market.63

In addition to protecting consumers through maximization of efficiency, antitrust law also protects competition between smaller firms and prevents predatory behavior by dominant firms.64 This limits the concentration of power in a given market, thereby reducing the risk of monopolization.65 Combining the consumer-welfare aspects with seeming favoritism toward small businesses, antitrust laws stimulate competition to benefit both consumers and market participants alike.

A further benefit of competition is increased innovation.66 In a competitive market, firms vie to develop and advance new or improved

61. Sullivan & Grimes, supra note 59, at 3; see Herbert Hovenkamp, Antitrust Policy and the Social Cost of Monopoly, 78 Iowa L. Rev. 371, 371-72 (1993) (defining “deadweight loss” as “a loss caused principally by the fact that consumers make inefficient substitutions for products that would have been their second choices in competitive markets”).
62. Sullivan, supra note 60, at 1215.
63. See Sullivan & Grimes, supra note 59, at 3 (noting that although traditionalists and post-Chicagoans accept the avoidance of wealth transfer as an antitrust goal, many members of the Chicago school reject it as a legitimate concern of antitrust law); see also Easterbrook, supra note 59, at 1703-04 (arguing that Congress intended the judicial system to enforce the Sherman Act with a single goal of efficiency and not redistribution of wealth).
64. See Sullivan & Grimes, supra note 59, at 4; Gladieux, supra note 30, at 475.
65. See Easterbrook, supra note 59, at 1696.
products in order to gain an edge over their competitors.\textsuperscript{67} By contrast, a monopolist has very little incentive toward innovation and may actually suppress innovation in order to protect its monopoly.\textsuperscript{68} Thus, the basic goals of the antitrust system are to stimulate competition by preventing monopolies and to promote the development of new technologies by encouraging active, competitive markets.

\section*{C. Basic Principles of Patent Law}

\subsection*{1. What Can Be Patented and What Are the Benefits to the Patent Owner?}

An invention may be patented if it is a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”\textsuperscript{69} The claims of a patent define the scope of the invention.\textsuperscript{70} The claims must be novel\textsuperscript{71} and unobvious,\textsuperscript{72} and must be described “in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the [invention], and [must] set forth the best mode contemplated by the inventor of carrying out his invention.”\textsuperscript{73}

A patent does not confer upon its owner the right to practice his invention; rather, the patent owner is granted “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”\textsuperscript{74} If the invention is, or includes, a process, the patent owner can also exclude the importation into the United States of goods made by the claimed process outside of the United States.\textsuperscript{75} A patent is enforceable for twenty years from the earliest filing date in the United States of the patent application or of any U.S. application to which it claims the benefit of a priority date.\textsuperscript{76} By statute, each claim of an issued patent is presumed valid, and the burden of demonstrating invalidity is on the challenging party.\textsuperscript{77} Therefore, a patentee enjoys several benefits once a patent is granted.

\subsection*{2. Rationale for the Granting of Patents}

The Constitution granted Congress the authority to establish an intellectual property system “To promote the Progress of Science and useful

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\item \textsuperscript{67} Id.
\item \textsuperscript{68} Id. at 4.
\item \textsuperscript{69} 35 U.S.C. § 101 (2000).
\item \textsuperscript{70} See id. § 112.
\item \textsuperscript{71} See id. § 102.
\item \textsuperscript{72} See id. § 103.
\item \textsuperscript{73} Id. § 112.
\item \textsuperscript{74} Id. § 154(a)(1).
\item \textsuperscript{75} Id.
\item \textsuperscript{76} Id. § 154(a)(2). The earliest United States filing date does not include provisional applications filed under 35 U.S.C. § 119(e). See id. § 154(a)(3).
\item \textsuperscript{77} See id. § 282.
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Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.\textsuperscript{78} Congress used this power to enact the first federal patent laws, encompassed in the Patent Act of 1790.\textsuperscript{79} The rationale for establishing a patent system is threefold.\textsuperscript{80} First, granting a limited monopoly in the form of a patent rewards the inventor for his efforts in developing a novel product or process.\textsuperscript{81} Second, the reward of a patent provides incentive for individuals to engage in inventive activity.\textsuperscript{82} Finally, in order to secure a patent and the limited monopoly it provides, the inventor must meet statutory requirements for sufficient disclosure of the nature and scope of the invention.\textsuperscript{83} This disclosure places the invention in the public domain and allows others to practice the invention immediately upon expiration of the patent.\textsuperscript{84} Therefore, the goals of the patent system are to promote the development of new technology by protecting the inventor from competition within the scope of his or her claimed invention for a limited amount of time, and to stimulate competition by requiring full disclosure of a new invention so that others can use that knowledge to extend or create alternatives to the invention.

D. Regulatory Requirements for Pharmaceutical Products

1. Introduction

Brand-name pharmaceutical companies spend an estimated $500 million to $1 billion in research and development (R&D) of a new drug.\textsuperscript{85} Only about 0.1\% of new drugs reach the stage of clinical testing in humans, and only 20\% of those (or 0.02\% of the total) are ultimately approved by the Food and Drug Administration (FDA) for marketing.\textsuperscript{86} According to one study, it takes approximately twelve years from the synthesis of a new chemical compound to regulatory approval of the compound.\textsuperscript{87} Consequently, brand pharmaceutical companies seek to recoup not only the financial and time costs of developing a marketable drug, but also the R&D

\textsuperscript{78} U.S. Const. art. I, § 8, cl. 8.
\textsuperscript{81} See id.
\textsuperscript{82} See id.
\textsuperscript{84} See Pritchard, supra note 80, at 293.
\textsuperscript{86} See Sherman & Oakley, supra note 85, at 404.
\textsuperscript{87} See id.
costs of compounds that never make it out of the laboratory. One of the primary ways in which companies do so is by obtaining patent protection of a new drug. Patent protection is valuable because it provides the company with a legal vehicle for excluding competitors who would infringe the patent. Therefore, brand companies have great incentive to enforce and protect their patents.

Conversely, generic companies spend far less time and resources to bring a drug to market. For example, the estimated cost of obtaining regulatory approval of a generic drug, which a brand company has already discovered and tested, is approximately $1 million. In addition, as discussed below, the regulatory scheme governing drug approval provides great incentive, coupled with little risk, for generic companies to challenge patents covering brand-name drugs.

2. The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act

Before a new drug can be marketed or sold in the United States, approval from the FDA is required. A “pioneer drug,” one that has never been approved or marketed previously, must be approved through the new drug application (NDA) process. NDA applicants are required to submit patents covering the drug product, formulation, and/or approved methods of use to the FDA for publication in a listing called Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as “the Orange Book.”

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. One of

89. See id. at 95; Robinson, supra note 85, at 56. Congress has made drug patents even more valuable to their owners by extending patent terms to restore time lost in clinical trials and regulatory approval. See id. at 53-54. In addition, Congress has provided other incentives to drug companies in the form of additional exclusivity benefits for pharmaceuticals that contain a new chemical entity (NCE exclusivity), that have been tested in children (pediatric exclusivity), or that treat a disease occurring in less than 200,000 Americans (orphan drug exclusivity). See 21 U.S.C. §§ 355(c)(3)(E), 355a(b)-(c), 360cc (Supp. III 2003); Robinson, supra note 85, at 54-55.
90. Robinson, supra note 85, at 48; Miller, supra note 88, at 104.
91. See Robinson, supra note 85, at 48; Sherman & Oakley, supra note 85, at 405.
92. See Robinson, supra note 85, at 53; infra note 105.
94. Id. § 355(b).
95. See id. § 355(b); Natalie M. Derzko, The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation, 45 IDEA 165, 169 (2005). Patents submitted by the new drug application (NDA) applicant and listed by the Food and Drug Administration (FDA) are commonly referred to as “Orange Book patents.”
the main goals of the Act was to accelerate the process for getting generic drugs to market.\textsuperscript{97} The primary vehicle that the Act established for doing so is an abbreviated new drug application (ANDA) for regulatory approval of generic drugs.\textsuperscript{98} Unlike an NDA, which must include detailed information on the drug and large-scale clinical studies,\textsuperscript{99} an ANDA need only demonstrate biological equivalence of the proposed drug formulation to the approved product, without the need for extensive (and expensive) safety and efficacy studies.\textsuperscript{100} Therefore, the abbreviated approval process provides an incentive for generic manufacturers by reducing the costs and time required for approval of a new drug.\textsuperscript{101} In filing an ANDA, the applicant must certify that (I) no patent information has been filed with the FDA by the NDA holder; (II) any patent filed has expired; (III) any patent filed will expire on a particular date; or (IV) the ANDA applicant’s product either does not infringe the listed patent(s) or the listed patent(s) is (are) invalid.\textsuperscript{102} An assertion by the ANDA applicant that the Orange Book patents are invalid or not infringed is referred to as a “paragraph IV certification.”\textsuperscript{103}

An ANDA applicant making a paragraph IV certification must notify the patent owner (who is usually the NDA holder).\textsuperscript{104} If the patent owner files a patent infringement action within forty-five days of receiving notice of the paragraph IV certification, the FDA automatically delays approval of the ANDA for thirty months.\textsuperscript{105} In the meantime, if a court finds the patent(s) at issue invalid and/or not infringed, the thirty-month stay is lifted.\textsuperscript{106} Conversely, if a court finds the patent(s) valid and infringed, approval of

\textsuperscript{97} See H.R. Rep. No. 98-857(I), at 14 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2647 (stating that the intention of Title I of the Act was “to make available more low cost generic drugs by establishing a generic drug approval procedure”).


\textsuperscript{99} See id. § 355(b)(1).

\textsuperscript{100} See id. § 355(j); Stephanie Greene, A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs, 30 J. Corp. L. 309, 314-15 (2005); Barbara J. Williams, A Prescription for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry, 40 New Eng. L. Rev. 1, 6-7 (2005).

\textsuperscript{101} See Greene, supra note 100, at 314-15; Williams, supra note 100, at 3.


\textsuperscript{103} Williams, supra note 100, at 7-8.


\textsuperscript{105} See id. § 355(j)(5)(B)(iii). Another provision of the Hatch-Waxman Act states that filing an abbreviated new drug application (ANDA) is an act of infringement on any patent that claims the drug, formulation, and/or method of use, if the purpose of the ANDA is “to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.” 35 U.S.C. § 271(e)(2)(B). This provision allows the patent owner to bring suit before the ANDA applicant has actually made or sold the drug product. Id. Because the infringement involved is statutory rather than actual, there is little financial risk for the generic company in filing an ANDA because it is generally sued prior to the accrual of damages. See id. § 271(e)(4) (providing for only injunctive relief in the absence of actual infringement); Schering I, No. 9297, 2003 WL 22989651, at *17-18 (F.T.C. Dec. 8, 2003), vacated, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).

the ANDA is delayed until the expiration date of the patent(s). If, before the expiration of the thirty-month stay, the patent owner obtains a preliminary injunction prohibiting the ANDA applicant from marketing its product, approval of the ANDA is delayed until the patent is declared by a court to be invalid and/or not infringed, or until the expiration date of the patent if it is declared to be valid and infringed.

An additional provision of the Hatch-Waxman Act grants an exclusivity period to the first applicant to file an ANDA containing a paragraph IV certification for a particular drug. The FDA delays approval of subsequent ANDAs until 180 days after the earlier of (1) the date of the first commercial marketing of the drug under the first-to-file ANDA; or (2) the date a court holds the challenged patent(s) invalid or not infringed by the first ANDA applicant. The exclusivity period allows the first-to-file applicant to compete solely with the brand company for 180 days and provides a strong incentive for generic companies “to challenge weak or narrow drug patents.”

The result of the Hatch-Waxman Amendments has been a dramatic increase in the availability of generic drugs; however, some unintended consequences have accompanied this success. For example, some brand companies developed strategies for staggering the listing of Orange Book patents, which resulted in multiple thirty-month stays when ANDA applicants made paragraph IV certifications against the newly listed patents. Such tactics could be used to delay generic entry for several years. On the generic side, the first-to-file ANDA applicant could prevent all other generic competitors from entering the market by never

110. See id. Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Medicare Act), the 180-day exclusivity period was triggered by the first district court decision, regardless of whether the decision was appealed. See Mylan Pharm., Inc. v. Shalala, 81 F. Supp. 2d. 30, 47 (D.D.C. 2000). The Medicare Act clarified the language of the statute, stating that exclusivity would only be triggered by “a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.” Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102, 117 Stat. 2066, 2458 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.). A generic company that markets its product prior to a final appellate decision is said to “launch at risk” because an unfavorable ruling by an appellate court could result in liability for damages and removal of the product from the market. See Greene, supra note 100, at 349-50. Since the passage of the Medicare Act, generic companies are no longer under pressure to launch at risk, as the 180-day exclusivity period is no longer in jeopardy of expiring during appeal. See id.; infra Part I.D.3.
111. Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1298 (11th Cir. 2003); see Derzko, supra note 95, at 195.
113. Williams, supra note 100, at 9; Derzko, supra note 95, at 176.
114. See Williams, supra note 100, at 9; Derzko, supra note 95, at 176.
marketing the drug itself, thereby never triggering the start of its 180-day exclusivity period.115

These particular aspects of the Hatch-Waxman scheme were of sufficient concern to antitrust enforcers that the Federal Trade Commission (FTC) initiated a comprehensive study to determine the prevalence of abuse of the thirty-month stay and 180-day exclusivity provisions.116 After analyzing such factors as the frequency and results of patent infringement suits between brand and generic pharmaceutical companies, the frequency of district court reversals by the Court of Appeals for the Federal Circuit,117 the choice of venue for patent infringement cases, and market entry by generic companies,118 the FTC made two main recommendations to Congress.119 The first was to allow brand companies only one thirty-month stay against each ANDA applicant.120 The second was to provide for FTC review of settlement agreements in which 180-day exclusivity is involved.121 The FTC also made additional recommendations regarding when the 180-day exclusivity period should be triggered.122 Congress responded with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Medicare Act).123


Congress passed the Medicare Act, in part, to address the perceived deficiencies of the regulatory scheme created under the Hatch-Waxman Amendments.124 The Medicare Act followed the FTC’s first recommendation, allowing only one thirty-month stay per ANDA for patentees.125 In addition, the Act requires forfeiture of the 180-day

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115. See Williams, supra note 100, at 11; Derzko, supra note 95, at 196.
118. See FTC Study, supra note 116, at 21-23.
119. Id. at ii.
120. See id. at ii-v.
121. See id. at vi-viii.
122. See id. at vii-xii; see also supra note 110 (discussing when the 180-day exclusivity period was triggered prior to the passage of the Medicare Act).
124. See Williams, supra note 100, at 59.
exclusivity period under several circumstances. For example, the exclusivity period is forfeited if the first-to-file ANDA applicant does not market its drug within seventy-five days of ANDA approval or of a final, non-appealable court decision that the Orange Book patents are invalid or not infringed. Exclusivity is also lost if the holder enters into an agreement with another ANDA applicant, the NDA holder, or the Orange Book patent owner and a court makes a final, non-appealable determination that the agreement violates the antitrust laws. Perhaps most significantly, the Medicare Act requires that agreements among ANDA applicants or between ANDA applicants and NDA holders must be filed with the Department of Justice and the FTC within ten days of execution. These provisions mitigate some of the antitrust implications that arise in the patent infringement settlement context.

E. Settlements of Patent Infringement Litigation Between Brand-Name and Generic Drug Companies

Against this background, courts have had to consider potential antitrust violations when the NDA holder (i.e., the brand company) and the ANDA applicant (i.e., the generic company) settle a patent infringement dispute. Several types of settlement provisions have been subject to judicial scrutiny. Examples of agreements that the courts have examined for antitrust violations include licensing agreements (such as those creating an "authorized generic"), agreements on market entry date of the generic product, and agreements for generic marketing. Bureau of Competition, FTC, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, at 2 (2006), http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

126. Id. § 1102.
127. Id.
128. Id.
129. Id. §§ 1112, 1113. Twenty such agreements were filed with the FTC in fiscal year 2005, sixteen of which were between brand and generic companies, while the remaining four were among generic companies. Bureau of Competition, FTC, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, at 2 (2006), http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

130. See Williams, supra note 100, at 59.
132. See In re Tamoxifen, 429 F.3d at 377; Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1231 (11th Cir. 2005); Schering II, 402 F.3d at 1060; Cipro II, 363 F. Supp. 2d at 519; In re K-Dur, 338 F. Supp. 2d at 525, 526 (D.N.J. 2004); Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 989 (N.D. Ill. 2003). A drug product licensed by a brand company to a generic company for marketing as a generic is called an “authorized generic.” Understahl, supra note 112, at 357. Because the authorized generic is the identical product to the already-approved brand drug, with the generic company’s label replacing the brand-name label, the authorized generic does not have to be separately approved by the FDA. See id. at 374, 384. As such, it is not subject to the 180-day exclusivity provisions of the Hatch-Waxman Act—it cannot gain 180-day exclusivity, as the authorized generic is not the subject of an ANDA filing, and it cannot be barred from the market during the first ANDA
competitor\textsuperscript{133} and reverse payments from the brand company to the generic company.\textsuperscript{134} These settlements can be interim agreements in the course of the patent infringement litigation or can be final agreements that dispose of the infringement dispute entirely.\textsuperscript{135}

Courts and commentators offer various rationales in favor of settlement agreements. As Judge Posner noted in \emph{Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.}, “The general policy of the law is to favor the settlement of litigation…”\textsuperscript{136} From a public policy perspective, settlement of complex and lengthy litigations, such as patent infringement suits, provides cost savings to the public and courts alike.\textsuperscript{137} In addition to receiving economic advantages, the public also benefits from a less congested court system and from a potential increase in competition if the settlement allows generic drug products to enter the market sooner than if the litigation went forward.\textsuperscript{138} From the perspective of the parties, settlement saves more than just financial resources of the companies.\textsuperscript{139}

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\textsuperscript{133} See \emph{Schering II}, 402 F.3d at 1059, 1060; \emph{Valley Drug}, 344 F.3d at 1300; \emph{In re Cardizem}, 332 F.3d at 902; \emph{In re K-Dur}, 338 F. Supp. 2d at 525, 526; \emph{Asahi Glass}, 289 F. Supp. 2d at 989.

\textsuperscript{134} Schering II, 402 F.3d at 1060-61; Valley Drug, 344 F.3d at 1300; In re Cardizem, 332 F.3d at 903; In re K-Dur, 338 F. Supp. 2d at 525, 526.


\textsuperscript{136} In re Terazosin, 352 F. Supp. 2d at 991; see also \emph{In re Tamoxifen}, 429 F.3d at 386 (“We begin our analysis against the backdrop of our longstanding adherence to the principle that ‘courts are bound to encourage’ the settlement of litigation.” (quoting Gambale v. Deutsche Bank AG, 377 F.3d 133, 142 (2d Cir. 2004))).

\textsuperscript{137} \emph{Valley Drug}, 344 F.3d at 1308 n.20; \emph{In re Terazosin Hydrochloride Antitrust Litig.}, 352 F. Supp. 2d 1279, 1307 (S.D. Fla. 2005); \emph{Schering I}, No. 9297, 2003 WL 22989651, at *22 (F.T.C. Dec. 8, 2003), vacated, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).


Litigation is costly in that it diverts employee focus from the running of the business, creates public relations concerns, and affects shareholder confidence for publicly held companies. Moreover, some patentees may be particularly risk averse and would prefer the certainty of settlement over the possibility, even if small, of having its patent invalidated. Therefore, even if a party is relatively confident in its patent infringement position, it may elect settlement over litigation to avoid both tangible and intangible costs.

This Note focuses on the reverse payment aspect of settlement agreements, with ancillary consideration given to entry date restrictions accompanied by reverse payments. Part II discusses the cases involving reverse payments that have been decided to date and the analysis that each court has employed to evaluate the antitrust claims.

II. DISPARATE ANALYSES BY COURTS EVALUATING THE ANTITRUST EFFECTS OF SETTLEMENT AGREEMENTS BETWEEN BRAND-NAME AND GENERIC DRUG COMPANIES

A. Per Se Approach of the Sixth Circuit: In re Cardizem

The Sixth Circuit was the first federal appellate court to consider the legality of reverse payments. In re Cardizem CD Antitrust Litigation involved an agreement in which a brand company, Hoechst Marion Roussel, Inc. (HMR), paid a generic company, Andrx Pharmaceuticals, Inc. (Andrx), not to enter the market for the cardiovascular drug Cardizem CD. Several lawsuits were filed under state and federal antitrust laws against HMR and Andrx. The plaintiffs were direct purchasers (pharmacies), indirect purchasers (consumers), and class representatives. The suits were consolidated by the Judicial Panel on Multidistrict Litigation, and proceedings commenced in the Eastern District of Michigan.

The district court granted partial summary judgment in favor of the plaintiffs and certified for interlocutory appeal the question of whether the agreement between HMR and Andrx was a per se illegal restraint of trade under section 1 of the Sherman Act. The Court of Appeals for the Sixth Circuit held that the arrangement was a "horizontal market allocation/
“per se” and was therefore illegal per se. The court was unmoved by defendants’ arguments that the agreement was “merely an attempt to enforce patent rights,” that this “novel area of law preclude[d] per se treatment,” and that “the Agreement lacked anticompetitive effects and had procompetitive benefits.” Instead, the court applied traditional antitrust principles, relying heavily on the Supreme Court’s decision in Arizona v. Maricopa County Medical Society, which held a price-fixing agreement between physicians illegal per se.

Of particular note in this case was the fact that Andrx was the first to file an ANDA and thus possessed the 180-day exclusivity period. In a particularly troublesome term of the agreement, Andrx agreed not to relinquish or transfer its exclusivity, effectively prohibiting other generic competitors from the market as well. The court viewed this term eliminating all competition in the market for Cardizem CD as “a classic example of a per se illegal restraint of trade.”

B. Traditional Rule-of-Reason Approach

1. The Eastern District of New York: In re Ciprofloxacin

The district court judge in In re Ciprofloxacin Hydrochloride Antitrust Litigation also relied on traditional antitrust principles; however, unlike the court in In re Cardizem, here the court declined to apply a per se rule in deciding a summary judgment motion by the plaintiffs. Instead, the court granted summary judgment to the defendant pharmaceutical companies based on a rule-of-reason analysis.

As discussed in Part I, the rule of reason requires a three-step inquiry: (1) The plaintiff must demonstrate that the agreement in question “has had an actual adverse effect on competition as a whole in the relevant market;” (2) the defendant has the burden of establishing the agreement’s “pro-competitive redeeming virtues;” and (3) the plaintiff must then “show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.”

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148. Id. at 900.
149. Id. at 908-09.
151. In re Cardizem, 332 F.3d at 902.
152. See id. at 907. After this case was decided, Congress passed the Medicare Act, amending the Hatch-Waxman Act and providing a forfeiture of the 180-day exclusivity period if the possessor has settled its litigation and if the FTC or a court has issued a final decision finding an antitrust violation in the settlement. See 21 U.S.C. § 355(j)(5)(D)(i)(V) (Supp. III 2003).
153. In re Cardizem, 332 F.3d at 908.
156. Id. at 520 (citing K.M.B. Warehouse Dists., Inc. v. Walker Mfg. Co., 61 F.3d 123, 127 (2d Cir. 1995)).
legal monopoly conferred upon patent owners, the court framed the first step as a question of whether the agreement in question led to anticompetitive effects that “were outside the exclusionary zone” of the challenged patent.\(^{157}\) Determining that the plaintiff had not demonstrated such effects, the court did not reach the second and third steps of the test.\(^{158}\)

Several facts of this case were distinguishable from *In re Cardizem*. For example, here the generic company holding the 180-day exclusivity period amended its ANDA certification from a paragraph IV to a paragraph III, clearing the way for other generic companies to enter the market.\(^{159}\) In addition, the agreements here resolved the underlying patent dispute, while the agreement in *In re Cardizem* was an interim agreement.\(^{160}\) Moreover, there was no question in this case that the generic product would infringe the brand company’s patent, as the generic company so stipulated during the course of the litigation.\(^{161}\)

The court refused to undertake an ex post analysis of the patent’s validity or potential invalidity.\(^{162}\) In doing so, the court conceded that a rule discounting the patent’s exclusionary power by its probable invalidity would be more likely to target weak patents.\(^{163}\) However, the court was unconcerned about not adopting such a rule, stating that if a patent were truly vulnerable, there would not be enough economic justification for the patentee to continue to thwart attacks from multiple challengers by issuing reverse payments.\(^{164}\) On the facts of this case, it would appear as though such an analysis would have been unnecessary anyway, as the patent in suit withstood validity challenges by three other generic companies, two of which were affirmed by the Federal Circuit.\(^{165}\) Therefore, even though the

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157. Id. at 523. The court stated that, absent *Walker Process* fraud or the *Noerr-Pennington* sham exception, the primary inquiry for an antitrust violation in a patent case is whether the restraint in question exceeds the scope of the patent. Id. at 535. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, the Supreme Court first recognized an antitrust cause of action in cases in which an asserted patent was procured by fraud on the U.S. Patent and Trademark Office, as long as the other elements of a Sherman Act claim are met. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965). The doctrine of *Noerr-Pennington* immunity was established in two Supreme Court cases, *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). *Noerr-Pennington* immunity provides a safe harbor from antitrust liability to a party pursuing an anticompetitive outcome through litigation. *Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3d 1227, 1233 (11th Cir. 2005). However, the Court provided an exception where the litigation has no objective basis and is merely a sham to conceal an attempt to interfere with a competitor’s business relationships. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, Inc., 508 U.S. 49, 60-61 (1993); *Noerr Motor Freight, Inc.*, 365 U.S. at 144.


159. *Cipro I*, 261 F. Supp. 2d at 204.

160. Id. at 242.


162. Id. at 539.

163. Id. at 534.

164. Id. at 534-35.

165. See id. at 519-20. The third case was not appealed, and a fourth generic company withdrew its validity challenge. See id. at 520.
district court did not undertake an inquiry regarding the challenged patent’s validity, both the strength of the patent, as evidenced by other challenges, and the challenger’s admitted infringement supported the finding that the agreement did not exceed the “zone of exclusion” of the patent.166

2. The Second Circuit: In re Tamoxifen

The Second Circuit also rejected a per se rule in evaluating patent infringement settlements involving reverse payments.167 The test articulated by the Second Circuit is whether “the ‘exclusionary effects of the agreement’ exceed the ‘scope of the patent’s protection.’”168 In performing its analysis, the Second Circuit, like the district court in In re Ciprofloxacin, declined to consider the likelihood of the patentee’s success at trial169 or the size of the reverse payment.170 Rather, the court stated that as long as the infringement suit was not fraudulent or baseless, the primary consideration is whether the agreement extends the patentee’s monopoly beyond the scope of the patent.171 As did the court in In re Ciprofloxacin, the court here applied its test and found that the agreement in question did not reach beyond the scope of patent protection.172 The court did not explicitly state what the proper antitrust analysis would be given a determination that an agreement does exceed the patent scope; however, it did discuss the pro-competitive benefits of the settlement in question173 and largely followed the analysis of the district court in In re Ciprofloxacin,174 indicating that the rule of reason is the law in the Second Circuit for evaluating reverse payment settlements.175

166. Id. at 548.
167. Id. at 396 (quoting In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 538 (E.D.N.Y. 2005)); see also id. at 397 n.27.
168. Id. at 397.
169. Id. at 395.
170. See id. at 397.
171. Id. at 397.
172. Id. This appeal affirmed the district court’s decision to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6). Id. at 374. The Second Circuit denied a petition by the plaintiffs for a rehearing and rehearing en banc of this appeal. In re Ciprofloxacin Hydrochloride Antitrust Litig., No. 03-7641 (2d Cir. Sept. 14, 2006).
173. See In re Tamoxifen, 429 F.3d at 398-400.
174. See, e.g., id. at 396-97.
175. In a lengthy dissent, Judge Rosemary Pooler agreed with the majority that a per se approach was inappropriate. See id. at 405. However, he advocated a balancing test in which the strength of the patent at the time of the settlement and the amount of the reverse payment, among other things, were taken into account when evaluating legality of these agreements. Id. at 412.
C. Alternative Approach of the Eleventh Circuit: Valley Drug Co. and Schering-Plough

The Eleventh Circuit has taken another approach to antitrust liability analysis. The court has rejected traditional antitrust doctrine, stating that “neither the rule of reason nor the per se analysis is appropriate in antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market” and, due to the nature of a patent, “[t]he anticompetitive effect is already present.” Instead, the court developed a novel three-part test that examines “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”

In Schering-Plough Corp. v. Federal Trade Commission, the Eleventh Circuit found that the agreements between Schering-Plough and two generic competitors, Upsher-Smith Laboratories, Inc. (Upsher), and ESI Lederle, Inc. (ESI), did not violate antitrust laws. To the contrary, the court posited that the agreements actually had pro-competitive benefits. For example, one of the agreements involved licenses of five of Upsher’s products to Schering-Plough. The FTC asserted that the royalty payments to Schering-Plough exceeded the true value of the licensed products and were actually reverse payments. However, the court opined that the licensing aspect benefited the public “by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation.” A second aspect of the agreements that the court viewed as pro-competitive was the fact that the agreements allowed Upsher and ESI to enter the market five and two years, respectively, prior to the expiration of Schering-Plough’s patent. In addition, the court considered the public policy arguments in favor of settling litigation and found that the benefits of

177. Id. at 1065-66.
178. Id. at 1086. See Valley Drug Co., 344 F.3d at 1312. The Valley Drug Co. court remanded the case to the district court, which found that the agreements in question did violate the antitrust laws. In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1286 (S.D. Fla. 2005). Interestingly, even after being instructed that another court had found the agreements illegal, a jury in the Southern District of California found no antitrust violations in the California counterpart to the Florida In re Terazosin case. See Erin Marie Daly, Generic Drug Makers Did Not Violate Antitrust Law: Jury, IP Law 360, Apr. 7, 2006, at 1.
179. See Schering II, 402 F.3d at 1076.
180. See id. at 1075.
181. See id. at 1059.
182. See id. at 1068.
183. Id. at 1075 (citing Phillip Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 1780(a) (2d ed. 1999)); Hovenkamp et al., supra note 29, at 1750-51).
184. Id. at 1067-68.
settlement outweighed any ancillary restraints resulting from the agreements. 185 Like the Second Circuit, the Eleventh Circuit declined to impose limitations on the size of reverse payments. 186

D. Suggestions from Outside the Judicial System

1. The FTC’s Approach in Schering-Plough

Initially in the Schering-Plough case, an administrative law judge (ALJ) dismissed the FTC’s complaint, which alleged that settlements between Schering-Plough and two generic companies violated the antitrust laws. 187 The ALJ found that reverse payments did not make an agreement illegal per se; rather, the strength and scope of the patent were the determining factors in assessing the legality of the agreement. 188 The full Commission reversed the ALJ, finding that, absent the reverse payments, generic entry into the potassium chloride supplement market would have occurred sooner, and that the resultant delay injured competition and consumers. 189 In doing so, the Commission prohibited “settlements under which the generic ‘receives anything of value’ and agrees to defer its own research and development, production or sales activities.” 190 The Commission exempted agreements where the reverse payment is “linked to litigation costs,” does not exceed $2 million, and is reported to the FTC. 191

Courts and commentators have subsequently portrayed this aspect of the FTC’s order as an absolute rule to be applied in all cases involving reverse payments. 192 In actuality, the FTC appeared to limit the rule to the particular facts of Schering-Plough. 193 Therefore, while the rule advocated by the FTC in Schering-Plough may look like a per se rule against reverse payments, the FTC has stated that per se treatment is not appropriate, “given the complexities of the patent litigation context.” 194 In fact, the

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185. See id. at 1072-76.
186. Id. at 1075; In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 395 (2d Cir. 2005). In Schering I, the size of the reverse payment was particularly troubling to the FTC. Schering I, No. 9297, 2003 WL 22989651, at *22 (F.T.C. Dec. 8, 2003), vacated, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).
188. See Schering II, 402 F.3d at 1061.
189. Schering I, 2003 WL 22989651, at *46; Schering II, 402 F.3d at 1062.
190. Schering I, 2003 WL 22989651, at *47.
191. Id.; Schering II, 402 F.3d at 1062. In its reversal of the FTC decision, the Eleventh Circuit called this an “arbitrary exception.” Schering II, 402 F.3d at 1062.
193. See Schering I, 2003 WL 22989651, at *18, *46 (“[W]e have crafted an order that is appropriate in the circumstances.”).
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opinion of the Commission in Schering-Plough specifically stated that it had analyzed the agreements in question under the rule of reason.195

2. Views of the Solicitor General

Following the FTC’s petition for certiorari in Schering-Plough, the Supreme Court invited the Solicitor General (SG) to express the views of the United States in a brief as amicus curiae.196 The SG advised against granting certiorari,197 stating, in part, that this case was not the appropriate vehicle to resolve “the difficult and unsettled antitrust issues posed by the FTC” because facts of the case were not representative of reverse payment settlements generally.198 The SG also dismissed the FTC’s concern regarding a circuit split, arguing that the unique circumstances of the In re Cardizem case that prompted the Sixth Circuit’s application of a per se analysis were absent from this and other cases in which courts declined a per se approach.199

Of particular interest is the SG’s suggested approach for evaluating the legality of reverse payments.200 The SG rejected both a per se rule and the FTC’s apparent reliance on the parties’ expectations regarding the outcome of the patent litigations.201 Instead, the SG stated that “an appropriate legal standard should take into account the relative likelihood of success of the

198. Brief for the United States as Amicus Curiae, FTC v. Schering-Plough Corp., No. 05-273 (U.S. May 17, 2006), 2006 WL 1358441, at *14-15. To underscore the unusual circumstances of this case, the amicus brief quoted the FTC’s appeal brief, which complained of “judicial pressure to settle” and admitted that this was a “stand-alone case based on [the] relatively limited evidence.” Id. at *14 (alteration in original).
199. See id. at *16-17.
200. See id. at *11-12.
201. See id. In Schering I, the FTC expressed the view that the very presence of a reverse payment in an agreement indicates that the settlement is inconsistent with the litigation outcome expected by the parties. See Schering I, No. 9297, 2003 WL 22989651, at *17 (F.T.C. Dec. 8, 2003), vacated, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006). However, the Solicitor General counsels against placing “undue weight on the parties’ subjective views of the strength of the [patent] claims.” Brief for the United States as Amicus Curiae, supra note 198, at *12.
parties’ claims, viewed ex ante."202 According to the SG, courts could apply this standard without a full trial on the patent claims; rather, the court could undertake a limited inquiry “into the relative merits of the patent claims and other relevant factors surrounding the parties’ negotiations.”203

3. Various Approaches Suggested by Commentators

Antitrust commentators have generally been less lenient than the courts in formulating an analysis for settlements involving reverse payments.204 Some authors advocate a per se approach. They argue that agreements involving reverse payments are nothing more than market restrictions among competitors and should be analyzed under the per se rules established by the Supreme Court for horizontal allocation of markets.205 According to one author, such agreements frustrate the purpose of the Hatch-Waxman Act, namely the facilitation of generic drug competition.206 Other commentators have suggested some form of a quick-look analysis.207 For example, Professor Herbert Hovenkamp proposes that reverse payments should be presumptively illegal, but allows for rebuttal of the presumption.208 The infringement plaintiff has the burden to defend the antitrust challenge by proving that the plaintiff has a significant likelihood of prevailing in its infringement lawsuit and that the amount of the reverse payment does not exceed the parties’ avoided litigation expenses.209 Unlike

202. Brief for the United States as Amicus Curiae, supra note 198, at *11.
203. Id. at *11 n.1.
204. See In re Tamoxifen, 429 F.3d at 392 n.21; M. Elaine Johnston & Matthew J. Galvin, Antitrust Aspects of Settling Intellectual Property Litigation, 867 PLI/Pat 159, 184 (2006) (suggesting that the absence of argument by the plaintiffs in In re Tamoxifen that reverse payments are illegal per se signifies the perceived acceptance by the courts of such payments).
206. See Lobanoff, supra note 205, at 1354-55. The author’s main objection to reverse payment agreements is their connection to manipulation of the 180-day exclusivity period. See id. at 1355. The passage of the Medicare Act has essentially rendered such objections moot. See supra Part I.D.3.
208. Hovenkamp et al., supra note 29, at 1759.
209. Id. As noted above, at least two federal courts of appeals have rejected limitations on the size of reverse payments. See supra note 186 and accompanying text. Professor Cotter disagrees with Professor Hovenkamp’s requirement regarding litigation expenses, calling it “unnecessarily narrow.” Cotter, supra note 207, at 1802.
the per se approach, the quick-look model concedes that there may be pro-
competitive justifications for reverse payment settlements.210

Fewer scholars appear to promote a rule of reason. Seizing on pro-
competitive justifications, some authors point to the fact that a generic
competitor facing a risk-averse patent owner may negotiate a settlement that
will allow the generic competitor to enter the market sooner than if the
infringement litigation had proceeded.211 Other commentators point to the
benefit of reduced risk of uncertainty for both the parties to the litigation
and the public.212 A settlement allows the parties to move forward with
their business plans free of the cloud of pending litigation and its
accompanying legal and financial risks.213 On the consumer side, a
settlement prevents a scenario in which a generic company has launched at
risk, only to be subsequently enjoined or lose the litigation.214 In such a
case the generic company must withdraw from the market, potentially
harming consumers who have come to rely on the product.215 A favorite
rationale of courts in applying the rule of reason, and one advocated by
some scholars as well, is the efficiency of settlements over litigation.216 A
per se rule or even a presumptive rule against reverse payments might
disourage settlements altogether.217

A survey of the cases decided by various courts demonstrates the
disparate approaches to, and outcomes of, antitrust claims against parties
who enter into patent settlement agreements. Likewise, antitrust
commentators are in disagreement as to the appropriate level of scrutiny
such agreements should receive. The Supreme Court has passed on the
opportunity to establish a standard, leaving the uncertainties created by the
case law unresolved. Part III of this Note evaluates the tests formulated by
courts and suggested by commentators and offers a solution that strikes a
balance between antitrust law and patent law concerns.

210. See Blair & Cotter, supra note 207, at 532-38; Thomas F. Cotter, Antitrust
Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable
Presumption of Illegality in Light of Some Recent Scholarship, 71 Antitrust L.J. 1069, 1082-
83 (2004).
211. Crane, supra note 139, at 705; Marc G. Schildkraut, Patent-Splitting Settlements and
the Reverse Payment Fallacy, 71 Antitrust L.J. 1033, 1034 (2004).
212. See James C. Burling, Hatch-Waxman Patent Settlements: The Battle for a
Benchmark, 20 Antitrust 41, 44 (2006); Melissa R. Leuenberger-Fisher, Case Note, In re
Terazosin Hydrochloride Antitrust Litigation: An Argument for the Rule of Reason, 24
213. See Leuenberger-Fisher, supra note 212, at 425.
214. See id. at 426; supra note 110.
215. See id.
216. See Kristopher L. Reed, A Return to Reason: Antitrust Treatment of Pharmaceutical
Settlements Under the Hatch-Waxman Act, 40 Gonz. L. Rev. 457, 478 (2004-2005); supra
notes 136-142 and accompanying text.
2003). Judge Posner also suggests that a per se rule could result in anticompetitive effects if
it diminishes the incentive to challenge patents “by reducing the challenger’s settlement
options should he be sued for infringement.” Id.
III. DISSECTING THE OPTIONS: A REASONABLE APPROACH

Antitrust law and patent law are generally thought to be at odds with one another.218 While antitrust law is designed to prevent monopolies, patent law is designed to grant a legal, albeit limited, monopoly to an innovator. The chasm may not be as wide as it appears. As discussed in Part I, both systems share the common goals of promoting innovation and competition.219 While each seeks to achieve these goals by seemingly opposite policies, it is possible to develop a rule that promotes the common goals without eviscerating the basic policies of either system.

Per se treatment of reverse payments "give[s] almost no weight to the patent holder’s right to exclude."220 Indeed, some commentators who advocate a strict per se approach appear either to misunderstand or to ignore the patent laws entirely.221 For example, one article opines, “Congress did not provide that a patent is conclusively presumed to be valid,"222 a statement directly in conflict with the U.S. Code, which states that “[a] patent shall be presumed valid."223 The authors explain their deviation from the clear language of the statute with references to case law that gives the courts authority both to enforce a patent and to declare it invalid.224 They go on to characterize patent rights as uncertain in the absence of “a final court resolution of the validity and scope of a patent."225 This is a strained interpretation of patent law. Patentees are granted the power “to exclude others from making, using, offering for sale, or selling the invention” for the term of the patent.226 While any patent is certainly subject to a legal challenge, the statutory presumption of validity means that a challenger bears the burden of proof of invalidity.227 Some commentators point to studies indicating that approximately half of all patents challenged in litigation are invalidated.228 However, as discussed below, it is impractical and speculative to try to predict the outcome of litigations that

218. See In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 386 (2d Cir. 2005).
220. Schildkraut, supra note 211, at 1039. Some commentators, while acknowledging the patentee’s right to exclude, argue that the right to exclude does not encompass “the right to pay a potential competitor to stay off the market.” Abbott & Michel, supra note 219, at 8.
221. See Reed, supra note 216, at 475.
222. Leffler & Leffler, supra note 138, at 35.
224. See Leffler & Leffler, supra note 138, at 35 n.9.
225. Id. at 36; see also Abbott & Michel, supra note 219, at 11-12 (arguing that the uncertain outcome of patent litigation casts doubt on the patentee’s ability to exclude competitors from the market).
227. Id. § 282 (“The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”). Conversely, the patent owner bears the burden of proving infringement. SmithKline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988).
228. Abbott & Michel, supra note 219, at 11-12.
have not occurred, and courts have been reluctant to do so. Therefore, although patent rights are not ironclad, the patentee is in a far less tenuous position than some authors suggest, even in the face of a challenge.

Moreover, the Supreme Court has been reluctant to expand upon the existing per se rules. Specifically, it has eschewed the creation of new per se rules “until the judiciary obtains considerable rule-of-reason experience with the particular type of restraint challenged.” Given the fact that the number of decisions involving reverse payments in a patent context barely reaches double digits for all federal courts and that such cases have only been decided by three federal circuits, it is arguable whether the judiciary has had considerable experience with this particular restraint.

On the other hand, the Eleventh Circuit’s treatment of settlements involving reverse payments has been characterized as “virtual per se legality.” By refusing to apply traditional antitrust principles in a patent context, the Eleventh Circuit has made it very difficult to prevent any anticompetitive effects that may arise in connection with these agreements. This is an unsatisfactory outcome for antitrust enforcement concerns.

The FTC’s rule-of-reason analysis in In re Schering-Plough Corp. is flawed because it frames the issue in a way that does not consider patent rights. The FTC stated that the question was “whether these unconditional [reverse] payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments.” The FTC went on to say that an entry date agreement in the absence of a reverse payment simply reflects the parties’ uncertainties with respect to the outcome of litigation, but that the presence of a reverse payment begs the conclusion that the generic company has agreed to an entry date that is inconsistent with its litigation expectations. This reasoning not only fails to factor patent rights into the equation, it ignores the realities of litigation settlement. The Commission itself acknowledged that there might be situations in which a

229. See infra note 251 and accompanying text.
230. The patent owner enjoys another important advantage, in addition to the presumption of validity: A challenger must demonstrate invalidity by clear and convincing evidence, while the patentee need only prove infringement by a preponderance of the evidence. See Geneva Pharm., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003); Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001). Therefore, the patentee bears the lower standard of proof.
233. Schildkraut, supra note 211, at 1039; see Leibowitz, supra note 197, at 3-4.
235. Id.
236. Id. at *17. The FTC was particularly concerned about the size of the payment in this case as well. Id. at *22. Several courts and commentators have dismissed this as a consideration in evaluating the legality of these agreements. See supra notes 170, 209 and accompanying text.
reverse payment was justified, such as when the generic company is “cash starved” and needs funds up front to enter the market sooner, or in cases where the parties’ risk tolerances are disparate.\textsuperscript{237} While the FTC’s opinion in \textit{Schering I} was comprehensive, it does not provide a good model for evaluating settlements involving reverse payments because it was fact-specific and skipped the step of assessing the relevant patent rights.\textsuperscript{238}

In a recent address, FTC Commissioner Jon Leibowitz spoke of the threat that the \textit{Schering II} and \textit{In re Tamoxifen} decisions pose to the “vitality” of the Hatch-Waxman Act.\textsuperscript{239} He supported his thesis with statistics showing that in fiscal year 2004, prior to either decision, none of the fourteen brand/generic agreements reported under the Medicare Act involved reverse payments, while that number rose to three of sixteen in fiscal year 2005 and seven of ten in the first four months of 2006.\textsuperscript{240} Commissioner Leibowitz attributed these increases to the \textit{Schering II} decision in March 2005 and to the \textit{In re Tamoxifen} decision in November 2005.\textsuperscript{241} It is likely that the Commissioner is correct, and that these decisions did give pharmaceutical companies enough confidence in the legality of reverse payments that they included them in the terms of their settlements. While such settlements may indeed “deny consumers potential access to potentially major savings,” even Commissioner Leibowitz agrees that reverse payments “may be appropriate” in an intellectual property context.\textsuperscript{242} The FTC has taken a position that is consistent with the Sherman Act’s consumer welfare goals; however, the FTC cannot operate on a pure policy basis if, in doing so, it sets aside rights granted under the patent system.

The analysis used in the Second Circuit is the most sensible. The court in \textit{In re Ciprofloxacin} applied an analysis based in traditional antitrust principles, yet considered the unique circumstances that arise in patent cases. Under this test, the patent owner is entitled to the protection provided by its patent, but the owner cannot extend its monopoly beyond the scope of the patent.\textsuperscript{243} Under a traditional rule of reason, the court

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\item \textsuperscript{237} \textit{Schering I}, 2003 WL 22989651, at *22. After acknowledging the possibility that these payments could be justified, the FTC went on to find that the parties in this case did not demonstrate such justifications. See id.
\item \textsuperscript{238} In fact, the author of the FTC’s opinion, Commissioner Thomas B. Leary, admits that “the Commission’s opinion on \textit{Schering} was not driven by any view on the appropriate global balance between the domains of patent law and antitrust law.” Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III, Address at Spring Meeting of the American Bar Association Antitrust Section 15 (Mar. 29, 2006), available at http://www.hhlaw.com/files/News/05ac8357-7511-43e9-a927-2c7e96a0ecde/Presentation/NewsAttachment/fd869e0b-b58a-451d-ad8d-2e110dbb796b/LearyABASpringMeetingSpeech.pdf. Instead, the Commission was concerned with achieving the policy goals of the Hatch-Waxman Act. Id.
\item \textsuperscript{239} Leibowitz, \textit{supra} note 197, at 3.
\item \textsuperscript{240} See id. at 4-5.
\item \textsuperscript{241} See id. at 5.
\item \textsuperscript{242} Id. at 6.
\item \textsuperscript{243} See Image Technical Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1216 (9th Cir. 1997).
\end{itemize}
would first determine the anticompetitive effects of the agreement.\textsuperscript{244} In cases where a patent is involved, anticompetitive effects naturally exist as a consequence of the exclusionary nature of intellectual property.\textsuperscript{245} Therefore, the analysis in a patent case in the Second Circuit starts with an assessment of the patent’s exclusionary power.\textsuperscript{246} Only agreements that restrain competition beyond the scope of the patent will be further scrutinized.\textsuperscript{247} In keeping with its efforts to uphold antitrust principles, the court in \textit{In re Ciprofloxacin} also noted that in cases involving patents procured by \textit{Walker Process} fraud or enforced under the \textit{Noerr-Pennington} sham exception, traditional antitrust analysis would apply.\textsuperscript{248}

Admittedly, there may be cases in which an evaluation of the patent’s exclusionary potential proves to be difficult. For example, in its brief treatment of the patent issues in \textit{Schering I}, the FTC emphasized that the underlying patent litigation in that case concerned infringement by the generic company, which is distinct from cases in which the validity of the patent is challenged.\textsuperscript{249} As discussed previously, the patent owner bears the burden of proof on infringement, whereas the challenger bears the burden on invalidity.\textsuperscript{250} This is significant because there is a statutory presumption of validity, while infringement must be demonstrated on a case-by-case basis. Therefore, in cases where the validity of the patent is not challenged (the number of which is likely to be few), the question of whether the agreement to delay market entry exceeds the scope of patent protection is complicated because it requires some level of inquiry into the infringing nature of the generic company’s activity. Both the courts and the FTC have declined to consider the merits of the patent lawsuit in a validity context,\textsuperscript{251} and it is equally unlikely that an antitrust court would embark upon an infringement analysis. Therefore, for purposes of an antitrust analysis, we are effectively left with the assumption that the patents in question are both

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\item \textsuperscript{244} See \textit{Cipro II}, 363 F. Supp. 2d 514, 520 (E.D.N.Y. 2005).
\item \textsuperscript{245} See \textit{Schering II}, 402 F.3d 1056, 1065-66 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).
\item \textsuperscript{246} \textit{In re Tamoxifen Citrate Antitrust Litig.}, 429 F.3d 370, 397 (2d Cir. 2005); \textit{Cipro II}, 363 F. Supp. 2d at 540. In setting forth the proper analysis, the court tried to tie together some of the jurisprudence in this area, suggesting that the Eleventh Circuit’s test could fit into a rule-of-reason analysis as well. \textit{Cipro II}, 363 F. Supp. 2d at 520 n.8 (“The Eleventh Circuit’s opinion can fairly be read as breaking the first step of a rule of reason analysis—assessing the actual adverse effects on competition—into three steps to determine whether there are any anti-competitive effects that exceed the scope of the patent.”).
\item \textsuperscript{247} \textit{Cipro II}, 363 F. Supp. 2d at 540.
\item \textsuperscript{248} See \textit{Cipro II}, 363 F. Supp. 2d at 535; \textit{supra} note 157 (discussing \textit{Walker Process} fraud and \textit{Noerr-Pennington} sham exception); see also \textit{In re Indep. Serv. Orgs. Antitrust Litig.}, 203 F.3d 1322, 1326 (Fed. Cir. 2000).
\item \textsuperscript{250} See \textit{supra} note 227.
\item \textsuperscript{251} See \textit{Cipro II}, 363 F. Supp. 2d at 524-30 (reviewing the refusals of the Eleventh Circuit, the Sixth Circuit, two federal district courts, and the FTC to undertake a validity analysis). On the other hand, the Solicitor General advocates abbreviated consideration of the merits of the patent suit. Brief for the United States as Amicus Curiae, \textit{supra} note 198, at *11 n.1.
\end{itemize}
valid and infringed. In many cases this is not an erroneous assumption, either because of the nature of the patent or because the generic company actually admits infringement as a term of the settlement. While this is imperfect from an antitrust standpoint, it may not be as problematic under the Second Circuit’s test as it initially appears.

The Second Circuit’s analysis will provide for sufficiently rigorous review because the most objectionable cases involve settlement provisions that are, in fact, outside of the patent’s scope. For instance, one particularly troublesome term of the agreement at issue in the Schering-Plough cases was the term that prohibited the generic company from marketing any competing product, not just a potentially infringing product. Another example of a term that would exceed the patent protection is one in which the generic agrees to stay off the market for a period of time after the patent term has expired. Courts should not have difficulty determining whether agreement terms provide “protection from competition which the patent law, unaided by restrictive agreements, does not afford.” Provisions such as these are clearly outside the scope of the patent, and having so determined, a court using the Second Circuit analysis would then proceed to evaluate the agreement under a traditional rule of reason. Thus, the analysis set forth in the Eastern District of New York and approved by the Second Circuit charts a middle course and provides for a substantial antitrust review after the patent aspect has been given its proper treatment.

CONCLUSION

Courts need a consistent standard for evaluating settlements between brand-name and generic pharmaceutical companies that include reverse payments. A per se rule prohibiting such settlements is too rigid to adequately protect the patentee’s rights. On the other hand, a rule such as the one formulated by the Eleventh Circuit, which approaches per se legality, does not adequately address legitimate antitrust concerns. Therefore, a more moderate rule-of-reason approach, such as that used in the Second Circuit, is the best vehicle for analyzing such agreements because it can be applied in such a way that the objectives and policies of both antitrust law and patent law are preserved.

252. Former FTC Commissioner and author of the Schering I opinion, Thomas B. Leary, notes that “[i]f it ultimately turns out that the patent is indeed valid and infringed, it is hard to see how consumers are harmed by the settlement, regardless of whether the settlement includes a reverse payment.” Leary, supra note 238, at 3.

253. See Cipro II, 363 F. Supp. 2d at 518. The pioneer patent in this case claimed the active ingredient, which was necessarily a component of the generic product. Id.


257. Once the second step of the analysis is reached, the guidelines set forth by the FTC in Schering I would then be applicable and instructive.