

REVERSE PAYMENTS: WHEN THE FEDERAL TRADE COMMISSION CAN ATTACK THE VALIDITY OF UNDERLYING PATENTS

INTRODUCTION

Settlements between brand-name and generic pharmaceutical companies that delay generic entry into the market are estimated to cost American consumers \$35 billion over the next ten years.¹ With spiraling healthcare costs and an aging population, the public deserves an explanation for the inordinate amount drug companies pay one another to stay off the market because the effects of this egregious conduct are ultimately passed on to them. In recent years, the Federal Trade Commission (FTC) has sought to protect consumers from these dubious payments by arguing they violate antitrust law but to no avail.²

These questionable agreements typically arise from patent infringement cases between a brand-name pharmaceutical company and a generic drug producer. Under the provisions of the Hatch-Waxman Act, a generic company can allege a brand-name's patent is invalid or will not be infringed upon by the generic's new drug when it seeks

¹ FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), *available at* <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

² *See, e.g.,* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065-66 (11th Cir. 2005) (The FTC argued the "reverse payments" were an illegal restraint of trade in violation of antitrust law. The court, however, found that neither the rule of reason or *per se* analysis was applicable, noting "both approaches [are] ill-suited for an anti-trust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market.... By their nature, patents can create an environment of exclusion, and consequently, cripple competition."); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008) (upholding the district court's finding that the agreement was not *per se* illegal and acknowledging that these types of agreements are within the patentee's rights); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206 (2d Cir. 2006) (finding that settlements to protect the patent monopoly, without more, does not establish an anti-trust violation).

approval from the Food and Drug Administration (FDA).³ But prior to an FDA review of the generic's application, a brand-name can elect to sue the generic if it believes the generic will infringe upon its own patent.⁴ To avoid the cost of litigation, parties usually settle; however, it is the patent holder, not the alleged infringer, who ultimately pays to settle. This practice is commonly known as providing a "reverse payment," because the alleged infringer who normally pays to settle a case is being paid by the patent holder instead. In these agreements, the patent holder pays the generic ostensibly for the generic's promise not to enter the market in order to protect its monopoly in the market.⁵ These agreements are particularly problematic because the disputed patents may actually be invalid, an issue that is never debated, since a settlement is often reached prior to trial. This fear increases when one considers that from 1992 to 2002, generics prevailed in 73% of the patent infringement cases that were resolved by a court decision.⁶ Because the frequency of these settlements continues to steadily increase it is imperative to consider the legality of this behavior in order to protect those most affected by this—the consumers.⁷

In reviewing the most recent decisions involving "reverse payments," where these settlements have been increasingly upheld, the need for the FTC to change its tactics becomes evident. Legal commentators, though, have struggled to develop a better alternative to using antitrust laws to combat this practice. This Note proposes that the FTC stop working within the traditional antitrust framework and force the pharmaceutical companies to justify that these agreements

³ See Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat 1585 (1984) (codified as amended at 21 U.S.C.A. § 355 (West 2010)).

⁴ *Id.*

⁵ See *In re Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003) ("If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.").

⁶ FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 8 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

⁷ See BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2008 8 fig.3 (2010) [hereinafter FTC SUMMARY OF AGREEMENTS], available at <http://www.ftc.gov/os/2010/01/100113mpdim2003rpt.pdf> (summarizing settlements filed with the FTC and revealing a steady increase from zero settlements restricting generic entry and compensation the generic in 2004 to sixteen settlements of this nature in 2008).

are within the scope of its patent rights. Specifically, this Note argues that the FTC has standing to challenge the validity of the underlying patent and should challenge the brand-name's patent when it charges these companies with antitrust violations. The Supreme Court has long recognized that the Government has a duty to protect the public from anticompetitive behavior and has extended this duty by allowing the Government to challenge a patent when the patent holder was charged with violating antitrust law.⁸ Based upon this precedent and considering that the FTC's Competition Bureau is the government agency that currently investigates antitrust violations in the pharmaceutical industry,⁹ the FTC should have the ability to challenge patents involved in these settlements.

Part I provides a background of Hatch-Waxman Act. Part II provides an introduction to the basic approaches to antitrust violations: the *per se* and rule of reason analyses. Part III discusses various approaches taken by the courts in recent years when dealing with "reverse payments," while part IV provides an overview of the current academic debate about these settlements. Part V discusses case law that supports the conclusion that the Government has the standing to challenge the underlying patent involved in these suspect settlements and details how this power can be an effective tool in preventing abusive pharmaceutical settlements.

Ultimately, this Note offers a novel approach for the FTC to use in its fight against "reverse payments." By sidestepping the debate over how these payments should be treated (i.e., *per se* illegal or reasonable under the rule of reason), the FTC can avoid current judicial opinion and does not have to wait for Congress to enact legislation prohibiting these payments. Instead, the FTC can ensure these agreements do not abuse the exclusionary scope of the patent by forcing the pharmaceutical companies to prove their patents are valid.

⁸ See, e.g., *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 388 (1948) ("In a suit to vindicate the public interest by enjoining violations of the Sherman Act, the United States should have the...opportunity to show that the asserted shield of patentability does not exist."); *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57-58 (1973) (finding the Government has authority to "raise and litigate the validity of...patents in [an] antitrust case.").

⁹ See generally *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the S. Comm on the Judiciary*, 107th Cong. (2001) (statement of James M. Griffin, Deputy Assistant Att'y Gen. Antitrust Division) (describing the shared responsibility of the Department of Justice and Federal Trade Commission to investigate "reverse payment" agreements).

I. REGULATORY BACKGROUND: SUMMARY OF THE HATCH -WAXMAN ACT AND AMENDMENTS

In 1984, Congress enacted the Drug Price Competition & Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act.¹⁰ The idea behind the Act was to make the pharmaceutical market more competitive by facilitating the ability of generics to enter the market, in particular by changing the FDA approval requirements for generics.¹¹ Prior to 1984, every single drug company who wanted to release a new drug, brand-name or generic, had to file a new drug application (“NDA”).¹² An NDA requires each applicant to submit safety and efficacy studies, list the components of the drug, describe the methods used in manufacturing the drug and the “processing and packaging” of the drug, and disclose any patents issued relating to the drug.¹³ Thus, prior to 1984, generics had to submit their own safety and efficacy studies even if similar studies had been performed for drugs comprised of the same ingredients.¹⁴ However, a generic could not even begin performing drug trials until after the relevant patent on the brand-name drug had expired or it risked being sued for patent infringement by a brand-name.¹⁵ This effectively extended the life of the original pharmaceutical patent beyond its term. Therefore in order to facilitate access to the drug market, the Hatch-Waxman Act created an abbreviated new drug application (“ANDA”).¹⁶ This application differs from the traditional NDA because it allows the generics to take advantage of prior safety and efficacy studies conducted so long as the manufacturer can prove that the

¹⁰ Pub. L. No 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C.A. § 355 (West 2010)).

¹¹ See H.R. REP. NO. 98-857, pt.1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

¹² See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190-92 (2d Cir. 2006) (explaining the NDA process and the availability of the ANDA post-1984 to facilitate generic market entry); see also Erica N. Andersen, *Schering the Market: Analyzing the Debate Over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and In re Tamoxifen Citrate Litigation*, 93 IOWA L. REV. 1015, 1018-19 (2008). Today, brand-name companies making an initial market entry still have to file an NDA under 21 U.S.C. § 355(b)(1).

¹³ § 355(b)(1) (requirements of an NDA).

¹⁴ See *Schering Plough Corp. v. FTC*, 402 F.3d 1056, 1058 n.2 (11th Cir. 2005) (describing the purpose and effect of the addition of the ANDA to the Hatch-Waxman Act).

¹⁵ Prior to 1984, the generic may have been liable under 35 U.S.C. § 271(a) (2006); however, the Hatch-Waxman Act created a safe-harbor provision for this practice in 35 U.S.C. § 271(e)(1) (2006). See *Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 195-96 (2005).

¹⁶ 21 U.S.C.A. § 355(j) (West 2010).

generic is bio-equivalent to the brand-name.¹⁷ Additionally, the Act amended what constitutes patent infringement in order to allow safety and efficacy testing of generics before the expiration of the brand-name drug patent.¹⁸

Under the Act, an ANDA filer must certify that to the best of its knowledge that the generic does not infringe on any patent listed with the FDA.¹⁹ The filer can assert: (1) the “patent information has not been filed” on the generic’s bio-equivalent (Paragraph I certification); (2) a “patent [on a bio-equivalent] has expired” (Paragraph II certification); (3) a patent exists however the generic will not market the drug until after the date “such patent will expire” (Paragraph III certification); or (4) “such patent is invalid or will not be infringed by the manufacture, use, or sale of the new [generic] drug for which the application is submitted” (Paragraph IV certification).²⁰ If the generic filing the ANDA makes a Paragraph IV certification, it is required to notify each NDA holder or patent holder affected by its ANDA certification within twenty days of filing, at which point the brand-name drug company has forty-five days to decide if it wants to sue for infringement.²¹ If the NDA or patent holder decides to file suit, then an automatic thirty-month stay goes into effect during which the FDA is not allowed to approve the generic unless a court determines the patent is invalid or not infringed before the stay ends.²² To compensate for the delay in FDA approval, the first entity to file an ANDA application is automatically entitled to a 180-day period of exclusivity.²³ This period begins after the first commercial marketing of the drug, during which the FDA agrees not to approve any subsequent ANDA applications.²⁴

¹⁷ *Schering-Plough Corp.*, 402 F.3d at 1058-59 n.2 (“The Hatch-Waxman’s truncated procedure avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that the drug is bio-equivalent to the already-approved brand-name/pioneer drug.”).

¹⁸ See 35 U.S.C. § 271(e)(1) (safe harbor provision).

¹⁹ 21 U.S.C. § 355 (j)(2)(A)(vii).

²⁰ § 355 (j)(2)(A)(vii)(I-IV).

²¹ § 355(j)(2)(B) (notice requirements); § 355(j)(5)(B)(iii) (timeline for filing an infringement action).

²² § 355(j)(5)(B)(iii).

²³ § 355 (j)(5)(B)(iv).

²⁴ See *id.* (indicating that the exclusivity period only applies to the “first applicant” after the “first commercial marketing of the drug”); see also Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 47 n.62 (2009) (discussing how prior to 2003 the Hatch-Waxman Act contained a “second trigger” for the exclusivity period with a final court decision).

Concerned with abuses stemming from the original Hatch-Waxman Act, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Act).²⁵ For example prior to the revision, a brand-name drug company, in theory, could obtain an unlimited number of thirty-month stays. A brand-name would obtain these multiple stays by first listing other patents relating to its drug with the FDA after the generic filed its ANDA. Once its first thirty-month stay ended, the brand-name would allege the generic potentially infringed one of these newly listed patents, allowing the brand-name to enjoy another thirty-month stay. Using this strategy, GlaxoSmithKline was able to prevent generic companies from competing against its antidepressant drug Paxil for more than five years.²⁶ Congress addressed this issue in the Medicare Act by limiting thirty-month stays to patents on file with the FDA before the ANDA was submitted.²⁷

The Medicare Act also sought to curb the abuse of the 180-day exclusivity period by ensuring that a generic company who was granted the period either used it or was forced to forfeit it.²⁸ For example, a generic would be forced to forfeit the exclusivity period if it: (1) failed to market the drug within seventy-five days of FDA approval; (2) failed to market the drug within seventy-five days of a final judgment finding the patent invalid or not infringed; (3) withdrew its application; (4) failed to obtain tentative FDA approval within thirty months after the application was initially filed; or (5) entered an agreement with another applicant or patent holder that violated anti-trust laws.²⁹ This amendment was designed to prevent the bottlenecks that could occur if the first filer of an ANDA took actions to avoid triggering its exclusivity period, which would prevent other generics from entering the market until the first-filing generic's exclusivity period expired.³⁰

Finally, the amendments to the Hatch-Waxman Act also required the patent holder and first paragraph VI ANDA filer who reach a settlement during litigation to file the agreement with the FTC and the

²⁵ Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21, 26, and 42 U.S.C.).

²⁶ See Carrier, *supra* note 24, at 47-48 (citing FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 51 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>).

²⁷ 21 U.S.C. § 355(j)(5)(B)(iii); see Carrier, *supra* note 24, at 48.

²⁸ See § 355(j)(5)(D); see also Carrier, *supra* note 24, at 48 (discussing the various forfeiture events provided by the statute to curb the abuse of the 180 day exclusivity period).

²⁹ Carrier, *supra* note 24, at 48 (citing § 355(j)(5)(D)(i)).

³⁰ *Id.* at 49.

DOJ within ten days of entering into the agreement.³¹ Arguably, this requirement would make it easier for the FTC and DOJ to review the agreements to verify they did not violate antitrust law.³²

II. APPROACHES TO ANTITRUST LAW

While a patent allows its holder to “exclude others from making, using, offering for sale, or selling the invention,”³³ the Government and private entities argue that “reverse payments” between pharmaceutical companies go beyond the scope of a patent and are illegal restraints of trade in violation of the Sherman Act.³⁴ The Sherman Act states that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”³⁵ The Supreme Court has interpreted this prohibition as only applying to unreasonable restraints of trade.³⁶ In determining whether there is an unreasonable restraint of trade, courts will apply either the *per se* rule or the rule of reason analysis.³⁷ Despite the existence of two approaches, courts generally apply the rule of reason analysis,³⁸ reserving the *per se* rule for agreements that have a “predictable and pernicious anticompetitive effect, and such limited potential for precompetitive benefit.”³⁹

To find an agreement *per se* illegal, a court must have adequate experience with the conduct described and be able to find it yields anticompetitive effects in almost every instance.⁴⁰ If a court deter-

³¹ § 355 (j)(5)(D)(i)(V); *see also* Carrier, *supra* note 24, at 48.

³² *See* Carrier, *supra* note 24, at 48 (discussing how the Hatch-Waxman Act was designed to prevent secret agreements and how the Medicare Act amendments sought to support this objective through required disclosure).

³³ 35 U.S.C. § 154(a)(1) (2006).

³⁴ *See, e.g.*, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006).

³⁵ 15 U.S.C. § 1 (2006).

³⁶ *See* State Oil Co. v. Khan, 522 U.S. 3, 10 (1997) (“Although the Sherman Act, by its terms, prohibits every agreement ‘in restraint of trade,’ this Court has long recognized that Congress intended to outlaw only unreasonable restraints.”) (citation omitted).

³⁷ *Id.*

³⁸ *Id.*; *see also* Texaco, Inc. v. Dagher, 547 U.S. 1, 5 (2006) (noting that the rule of reason “presumptively applies”).

³⁹ *State Oil Co.*, 522 U.S. at 10.

⁴⁰ *Id.* (“*Per se* treatment is appropriate “[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.” (quoting *Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332,

mines that the disputed conduct is *per se* illegal, it can simply condemn the restraint of trade without an inquiry into the defendant's market power, the actual anticompetitive effects of the conduct, or the reasons for the conduct.⁴¹ The Supreme Court, however, has expressed concerns over applying the *per se* analysis, since it "require[s] the Court to make broad generalizations about the social utility of particular commercial practices."⁴² If there are too many *per se* violations, there is a risk that the law will become too rigid and prevent courts from considering the facts in future cases.⁴³ Therefore, the *per se* rule generally applies only to a few types of conduct, such as price fixing, tying agreements, and "naked" exit payments (made only to keep a potential competitor from entering the market).⁴⁴

If a court is unable to find such pernicious conduct, it instead applies the rule of reason analysis.⁴⁵ Under the rule of reason, "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect."⁴⁶ The plaintiff has the initial burden of demonstrating that the defendants have "market power" in a particular market and that their alleged conduct produced adverse, anticompetitive effects within the relevant market.⁴⁷ If the plaintiff is able to demonstrate such effects, the burden shifts to the defendant to justify the conduct by explaining how it is pro-competitive.⁴⁸ If the

344 (1982)); *see also In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 U.S. Dist. LEXIS 11756, at *52 (D. N.J. Feb. 4, 2009).

⁴¹ *In re K-Dur*, 2009 U.S. Dist. LEXIS 11756, at *52; *see also* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 20 (2004) (citing *NCAA v. Bd. of Regents*, 468 U.S. 85, 100-01 (1984)).

⁴² *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 n.16 (1977).

⁴³ *Id.* ("Once established, *per se* rules tend to provide guidance to the business community and to minimize the burdens on litigants and the judicial system..., but those advantages are not sufficient in themselves to justify the creation of *per se* rules. If it were otherwise, all of antitrust law would be reduced to *per se* rules, thus introducing an unintended and undesirable rigidity in the law.").

⁴⁴ *See State Oil Co.*, 522 U.S. at 11 (price fixing as *per se* illegal); *NCAA*, 468 U.S. at 100 ("Horizontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal *per se*' approach because the probability that these practices are anticompetitive is so high..."); Hovenkamp, *supra* note 41, at 20 (discussing the illegality of price fixing, tying agreements, and exit payments).

⁴⁵ *See State Oil Co.*, 522 U.S. at 10.

⁴⁶ *Id.*

⁴⁷ *United States v. Visa U.S.A. Inc.*, 344 F.3d 229, 238 (2d Cir. 2003).

⁴⁸ *Id.* For instance, a pro-competitive justification may include benefits the consumers by reducing marginal costs or increased efficiency of production. *See* Maurice E. Stucke, *Does the Rule of Reason Violate the Rule of Law?* 42 U.C. DAVIS

defendant is able to provide a reasonable explanation for its conduct, the burden shifts back to the plaintiff to demonstrate either that the objectives of the conduct can be achieved in a less restrictive manner or that the restraint is not reasonably necessary to achieve the pro-competitive objectives.⁴⁹ Essentially, the rule of reason analysis asks the trier of fact to weigh the harms and benefits of the challenged conduct to determine if it broadly promotes or hurts competition.⁵⁰

In relation to pharmaceutical settlements, courts have applied both the *per se* and the rule of reason analysis.⁵¹ The disagreement among courts and commentators on how to treat these settlements stems from the tension between antitrust and patent law. Patents are designed to grant the holder a legal monopoly, which seems in direct conflict with the goals of antitrust law, but a patent monopoly is not absolute. Thus, the courts must decide whether these settlements are a legal exercise of the rights granted by a patent or if they go beyond this scope.

III. SUMMARY OF RECENT PHARMACEUTICAL ANTITRUST CASES

Recently, there has been an influx of antitrust cases filed against brand-name pharmaceutical companies and generics over patent settlements, which according to the FTC and consumer groups should be considered illegal restraints of trade under Section 1 of the Sherman Act.⁵² Initially, the courts were more receptive to the arguments anti-

L. REV. 1375, 1385 (2009). However, “[a] restraint on competition cannot be justified solely on the basis of social welfare concerns.” *Schering-Plough, Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005).

⁴⁹ *Visa U.S.A., Inc.*, 344 F.3d at 238.

⁵⁰ *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir. 1993) (citing *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (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.”)).

⁵¹ *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332 (Fed. Cir. 2008) (upholding the district court’s decision the agreement was legal under the rule of reason analysis); *In re Cardizem CD Antitrust Litig.* (Cardizem CD III), 332 F.3d 896, 908 (6th Cir. 2003) (ruling the agreement was *per se* illegal).

⁵² *See, e.g., See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1061 (11th Cir. 2005) (FTC argued that the ESI agreement violated Section 1 of the Sherman Act); *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1340 (holding that the settlement agreements did not violate the Sherman Act and that all anticompetitive effects were within the exclusionary power of the ‘444 patent); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006) (plaintiffs argued that the settlement was an agreement to monopolize the market for Tamoxifen).

culated by the FTC and consumer groups, but courts have increasingly ruled in favor of these agreements.⁵³

A. In re Cardizem

In the first case ruling against “reverse payments,” *In re Cardizem*, the Sixth Circuit determined that the agreement between Hoescht Marion Rouseel, Inc. (HMR) and Andrx Pharmaceuticals, Inc. was *per se* illegal under the Sherman Act.⁵⁴ HMR manufactured Cardizem CD, a drug used to treat angina and to prevent heart attacks and strokes, under a license granted by Carderm Capital, the patent holder.⁵⁵ In 1996, HMR, in conjunction with Carderm, filed suit against Andrx, claiming its generic would infringe upon Carderm’s new patent, which covered the drug’s method of release in the body.⁵⁶ The two parties came to an agreement in 1997, after the FDA had tentatively approved Andrx’ ANDA.⁵⁷ The approval would have allowed Andrx to enter the market once the court ruled that Carderm’s patent was not infringed or the thirty-month waiting period had elapsed.⁵⁸ In exchange for delaying the release of Andrx’s generic until a determination on infringement, HMR agreed to pay \$40 million a year.⁵⁹ If Andrx received final FDA approval, the payment would increase to \$100 million if it was determined the patent was not infringed.⁶⁰ Additionally, Andrx agreed to prosecute its ANDA, securing its 180-day period of exclusivity granted by the Hatch-Waxman Act.⁶¹

In July 1998, the FDA issued its final approval of Andrx’s ANDA, which prompted HMR to increase its payments to Andrx (as provided in the agreement) to prevent its entry into the market.⁶² Meanwhile, in hopes of avoiding further litigation, Andrx amended its ANDA to seek approval for a reformulated version, which it thought

⁵³ See discussion *infra*.

⁵⁴ *Cardizem CD III*, 332 F.3d at 908 (“There is simply no escaping the conclusion that the Agreement...was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.”).

⁵⁵ *Id.* at 901-02.

⁵⁶ *Id.* at 902.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 903.

⁶¹ *Id.* at 902. This strategy is no longer permissible under the Hatch-Waxman Act, which provides that a company cannot hold onto its 180-day exclusivity period if it fails to market the drug within a specified time period after final FDA approval. See 21 U.S.C. § 355(j)(5)(D)(i) (2006); Carrier, *supra* note 24, at 48-49.

⁶² *Id.*

did not infringe Carderm's patent.⁶³ The FDA approved the new version in 1999 and the two parties decided to end their agreement and settle the infringement case.⁶⁴ In total, HMR paid Andrx \$89.83 million (\$50.7 final settlement payment plus prior payments under the agreement) after which, Andrx began to market its generic and, not surprisingly, obtained a substantial share of the market.⁶⁵

Ignoring the argument that the arrangement was within HMR's rights as the patent holder, the court ruled the agreement was *per se* illegal.⁶⁶ Because HMR paid its only known potential competitor to stay off the market, the court found the agreement was analogous to a "horizontal agreement to eliminate competition in the market," which is always treated as *per se* illegal.⁶⁷ This conclusion was supported by the fact the agreement delayed the entry of other generics into the market since Andrx possessed the 180-day exclusivity period granted to the first generic to file an ANDA.⁶⁸ The court noted that it is one thing to use the legal monopoly granted by the patent, but it is another to silence all potential competitors by "paying the only potential competitor \$40 million per year to stay out of the market."⁶⁹ Therefore, despite the traditional patent rights granted to the holder, the court ruled that this agreement was a *per se* illegal restraint of trade.

B. Valley Drug/Schering-Plough

In *Valley Drug Co. v. Geneva Pharmaceuticals Inc.*, the first major case in the Eleventh Circuit concerning "reverse payments," the court refused to follow the Sixth Circuit and rule "reverse payment" agreements were *per se* illegal.⁷⁰ Instead, the court noted that "reverse payments" may be a permissible exercise of the patent holder's rights and thus, they cannot be held to the *per se* illegal standard.⁷¹ At issue were agreements made between Abbott Laboratories and two generic companies that prevented the generics from entering the market.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.* at 908.

⁶⁷ *Id.*; see *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972) (describing how "horizontal territorial agreements" cannot have pro-competitive objectives).

⁶⁸ See *Cardizem CD III*, 332 F.3d at 907. The agreement by Andrx to continue to seek its ANDA effectively meant that other generics could not enter the market until the 180 days expired. *Id.*

⁶⁹ *Id.* at 908.

⁷⁰ *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F. 3d 1294, 1310-11 (11th Cir. 2003).

⁷¹ *Id.*

Abbott manufactures Hytrin (active ingredient: dihydrate terazosin hydrochloride), which is used to treat hypertension and enlarged prostate.⁷² Originally, Abbott held a patent on the major chemical compound in the drug, but it subsequently obtained patents covering different forms and uses of the drug.⁷³ From 1993-1996, Geneva filed six ANDAs based on Hytrin, each time making paragraph IV certifications with respect to the listed patents.⁷⁴ During the same time period, Zenith also filed an ANDA, making a paragraph IV certification to Abbott's Hytrin patent.⁷⁵ As a result, Abbott filed an infringement suit against both Geneva and Zenith.

In 1998, Abbott and Zenith entered into an agreement, where Abbott agreed to pay Zenith \$3 million up front, \$3 million after three months, and \$6 million every three months until March 1, 2000 or until the agreement terminated for another reason.⁷⁶ In exchange, Zenith agreed not to sell or transfer its rights under any ANDA relating to a terazosin hydrochloride drug. Zenith also agreed not to aid anyone in gaining FDA approval for such drug or to aid anyone in opposing or invalidating Abbott's patents relating to Hytrin. Lastly, Zenith agreed not to sell or distribute any drug containing terazosin hydrochloride until Abbott's patent expired or another generic introduced a drug containing the compound.⁷⁷

In 1998, Abbott and Geneva entered into a similar agreement, where Geneva could not sell or distribute any "pharmaceutical product" containing terazosin hydrochloride until Abbott's patent expired, another company introduced a generic form, or Geneva was successful in demonstrating that its product did not infringe Abbott's patents or proving Abbott's patent was invalid.⁷⁸ In return, Abbott agreed to pay Geneva \$4.5 million each month until another company introduced a generic form of terazosin hydrochloride or Abbott won a favorable result the infringement claim against Geneva.⁷⁹

Several various private drug companies sued Abbott, Geneva and Zenith, asserting that the settlement agreements violated antitrust laws.⁸⁰ The District Court ruled that the agreements were *per se* violations of § 1 of the Sherman Act and granted partial summary judg-

⁷² *Id.* at 1298.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 1299.

⁷⁶ *Id.* at 1300.

⁷⁷ *Id.* (detailing the settlement agreement between Abbott and Zenith).

⁷⁸ *Id.* Geneva also agreed as part of the settlement to not sell or transfer its rights under its ANDA. *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 1301; *see* 15 U.S.C. §1 (2006).

ments to the plaintiffs.⁸¹ On appeal, the Eleventh Circuit reversed, finding that the agreements were not *per se* illegal because one of the parties owned a patent.⁸² Since a patent grants the holder a legal monopoly, creating a settlement excluding generics from the market was considered within the patent holder's rights.⁸³ Although the size of the settlement payment did cast suspicion on the patent's validity, the court would not conclude simply from the size of the payment that the agreement was made in bad faith.⁸⁴ The Eleventh Circuit refused to follow the Sixth Circuit in finding these payments were *per se* illegal because in its opinion the Sixth Circuit failed to adequately consider the "exclusionary power of the patent."⁸⁵

In *Schering-Plough v. FTC*, the Eleventh Circuit went even further to describe its stance on "reverse payments," arguing that neither the rule of reason nor *per se* analysis is appropriate when deciding if such payments violate antitrust law.⁸⁶ In 2001, the FTC filed a complaint alleging that the settlements between Schering-Plough and two generic manufacturers, Upsher-Smith and Schering-Plough and ESI Lederle, Inc. (ESI), violated antitrust law.⁸⁷

Upsher-Smith had filed with the FDA to gain approval on its generic version of Schering-Plough's K-Dur 20, a supplement taken in conjunction with other prescriptions for the treatment of high blood pressure or congestive heart disease.⁸⁸ During the patent infringement action, Schering-Plough and Upsher-Smith reached a settlement where Schering-Plough agreed to license other Upsher products in exchange for Upsher agreeing to delay its entry into the market until September 2001.⁸⁹ Similarly, ESI sought FDA approval of its own generic version of K-Dur 20, which prompted Schering-Plough to file an infringement suit.⁹⁰ As part of the settlement, Schering-Plough agreed to pay ESI \$5 million for legal fees, to allow ESI to enter the

⁸¹ See *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1354 (S.D. Fla. 2000).

⁸² *Valley Drug Co.*, 344 F. 3d at 1306.

⁸³ *Id.* at 1304-05 (describing the scope of the patent holder's rights and the inherent market effect of such rights).

⁸⁴ *Id.* at 1309-10. The court did not know what factors, such as lost profits expected from generic competition, the generics' expected profits, or expected savings in litigation costs, went into determining the size of the payment. Without this knowledge, the court could not conclude that the size of the payment reflected the patentee's belief that the patent was invalid. *Id.*

⁸⁵ *Id.*

⁸⁶ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005).

⁸⁷ *Id.* at 1061.

⁸⁸ *Id.* at 1058.

⁸⁹ *Id.* at 1059.

⁹⁰ *Id.* at 1060.

market three years before its patent expired, and to pay an additional \$10 million if the FDA approved ESI's application.⁹¹ In exchange, ESI agreed to remain off the market and granted Schering-Plough licenses on its own drug patents.⁹²

Subsequently, the FTC filed an administrative complaint against all three companies, alleging that the settlements violated Section 5 of the Federal Trade Commission Act (FTC Act) and Section 1 of the Sherman Act.⁹³ After an Administrative Law Judge (ALJ) found these settlements to be lawful, the FTC appealed to the full Commission.⁹⁴ The Commission overruled the ALJ, finding the payments to be illegal because "the *quid pro quo* for the payment was an agreement to defer the entry dates, and...such delay would injure competition and consumers."⁹⁵ The Eleventh Circuit reversed the Commission, finding that there was not enough evidence to support the conclusion that the settlements violated the Sherman and FTC Acts.⁹⁶ In doing so, however, it rejected both the *per se* and rule of reason analysis typically applied in antitrust cases, finding that both approaches were ill-suited to determine the antitrust liabilities of a patent holder.⁹⁷ It noted that because of "their nature, patents create an environment of exclusions, and consequently, cripple competition" and thus, an "anticompetitive effect is already present."⁹⁸ The court proposed to determine antitrust liability by examining: "(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."⁹⁹ Applying its own standard, the court found that the agreements did not exceed the scope of that patent and the anticompetitive effects of the settlement were far outweighed by the benefits, especially considering the potential negative effects caustic patent litigation may have on innovation.¹⁰⁰

C. In re Tamoxifen

In *In re Tamoxifen*, the Second Circuit considered a "reverse payment" settlement between Zeneca and Barr, involving the drug

⁹¹ *Id.* at 1060-61.

⁹² *Id.* at 1061.

⁹³ *Id.*

⁹⁴ *Id.* at 1062.

⁹⁵ *Id.*

⁹⁶ *Id.* at 1071-72.

⁹⁷ *Id.* at 1065.

⁹⁸ *Id.* at 1065-66.

⁹⁹ *Id.* at 1066 (citing *Valley Drug Co. v. Geneva Pharm. Inc.*, 344 F. 3d 1294, 1312 (11th Cir. 2003)).

¹⁰⁰ *See id.* at 1075.

tamoxifen, which is the most prescribed breast cancer drug.¹⁰¹ Unlike prior cases, the district court had already invalidated the tamoxifen patent before the two parties reached an agreement.¹⁰² However, because the judgment was never affirmed, the Second Circuit did not speculate as to the ultimate resolution of the issue and it declined to consider the district court's finding of invalidity as part of its analysis.¹⁰³ The court ultimately found that the agreements were not *per se* illegal and were, in fact, legal.¹⁰⁴

Immediately after the United States Patent & Trademark Office (USPTO) issued the patent in 1985 to Imperial Chemical Industries, PLC, ("ICI"), Barr filed an ANDA with the FDA based on its generic version of tamoxifen.¹⁰⁵ Barr amended its application in 1987 to include a paragraph IV certification, which prompted ICI to file an infringement suit against Barr and its raw material supplier.¹⁰⁶ At trial, the district court invalidated ICI's patent because the company withheld crucial information from the USPTO during patent prosecution.¹⁰⁷ The decision was appealed but before the appeal was considered, the two sides agreed to settle.

The agreement restricted Barr from marketing its generic until after the expiration of Zeneca's patent in 2002 and required Barr to amend its ANDA to a Paragraph III certification in exchange for \$21 million and a non-exclusive license to market Zeneca-manufactured tamoxifen under its own label.¹⁰⁸ Additionally, if Zeneca's patent was invalidated, Barr would be allowed to revert its ANDA certification to a Paragraph IV certification.¹⁰⁹ Pursuant to the settlement, the parties moved to vacate the district court's judgment, which was granted by

¹⁰¹ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193 (2d Cir. 2006).

¹⁰² *Id.* at 202.

¹⁰³ *Id.* at 204-05.

¹⁰⁴ *Id.* at 206. In so holding, the Second Circuit considered *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F. 3d 1294, 1309 (11th Cir. 2003), where the Eleventh Circuit found the mere existence of a reverse payment is not enough to assert an anti-trust violation and *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003), where the court argued that banning reverse payments would disincentive a patent challenger by limiting settlement options.

¹⁰⁵ *In re Tamoxifen Citrate*, 466 F.3d at 193. Zeneca is a former subsidiary of ICI, which succeeded to the rights of the tamoxifen patent.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* (ICI withheld tests that revealed opposite desired hormonal effects than those "sought in humans," which could have "unpredictable and at times disastrous consequences." (citing *Imperial Chem. Indus., PLC v. Barr Labs.*, 795 F.Supp. 619, 622 (S.D.N.Y. 1992)).

¹⁰⁸ *Id.* at 193-94. Barr's raw material supplier was also paid \$9.5 million upfront and \$35.9 million over the course of ten years. *Id.* at 194.

¹⁰⁹ *Id.* at 194.

the Federal Circuit.¹¹⁰ Subsequently, three other generic companies challenged Zeneca's patent; however none were successful, partly because they could not rely on the prior finding of invalidity.¹¹¹ In 2005, consumer groups challenged the validity of the agreement between Zeneca and Barr, alleging that the agreement was illegal because it: (i) allowed the two parties to "resuscitate" a patent that was held to be invalid and unenforceable; (ii) allowed Zeneca to continue its monopoly in the tamoxifen market; (iii) allowed the two to share in the profits of its continued monopoly; (iv) maintained a high price for the drug; and (v) prevented competition from other generic companies.¹¹² According to the plaintiffs, if the settlement had not occurred, then Barr would have likely prevailed in the infringement suit and gained FDA approval to market its generic.¹¹³ FDA approval would have then triggered the 180-day exclusivity period, ultimately allowing other generics to enter the market years before the patent's expiration and this earlier market entry would have driven prices below the levels which existed during the term of agreement.¹¹⁴

The Second Circuit affirmed the lower court's ruling, finding that the settlement was legal.¹¹⁵ It emphasized the importance of encouraging settlement between parties and explained that a ruling against the settlement had the potential to chill innovation.¹¹⁶ The court also refused to believe the plaintiffs' assumption that the invalidity of the patent would have been affirmed, stating that "[w]e cannot guess with any degree of assurance what the Federal Circuit would have done on an appeal from the district court's judgment in *Tamoxifen I*."¹¹⁷

The court also considered whether excessive payments—those that exceed the value a generic could have realized if it entered the market after a successful litigation—were illegal.¹¹⁸ Unlike other courts, which only considered whether the payments themselves were illegal, the Second Circuit went a step further and found that even

¹¹⁰ *Id.* While at the time considered legal, the Supreme Court has subsequently held that a vacatur like in this case is invalid in nearly all circumstances. See U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship, 513 U.S. 18, 27-29 (1994).

¹¹¹ *In re Tamoxifen Citrate*, 466 F.3d. at 194-95 (noting challenges from Novopharm Ltd., Mylan Pharmaceuticals, Inc., and Pharmachemie, B.V.).

¹¹² *Id.* at 196-97.

¹¹³ *Id.* at 197.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 213-16 (discussing how various portions of the settlement agreement were not unlawful).

¹¹⁶ *Id.* at 203. If patent law becomes more uncertain, then those willing to innovate would be less likely to do so out of fear that their investment would not be rewarded. See *id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.* 208.

“excessive” payments were “not necessarily unlawful.”¹¹⁹ It noted that while it may seem suspicious when a generic manufacturer receives a windfall payment for not competing, such suspicion is unfounded.¹²⁰ So long as the litigation was not meritless or made in bath faith, a patentee is allowed to protect his patent, even if this means paying a future competitor to settle an infringement case.¹²¹ The court did not see the value in setting limits for these payments, since it would inhibit the ability to settle¹²² and thus, it concluded that the settlement was not a restraint of trade in violation of the Sherman Act.¹²³

D. In re Ciprofloxacin

The disputed settlement in *In re Ciprofloxacin* involved Bayer, a brand-name pharmaceutical company, and Barr, a generic manufacturer.¹²⁴ Bayer had a patent for the active ingredient, ciprofloxacin hydrochloride, in its drug Cipro used to treat bacterial infections, which was due to expire in 2003.¹²⁵ In 2001, Barr filed an ANDA for its own version of Cipro, including a Paragraph IV certification.¹²⁶ After receiving notice of Barr’s ANDA, Bayer filed suit, at which point Barr made a side agreement with HMR to help fund its litigation costs in exchange for half of any future profits realized from Barr’s sale of its generic.¹²⁷ Prior to trial, the three parties came to an agreement. Barr agreed to change its ANDA from a Paragraph VI to a Paragraph III, thereby certifying that it would not enter the market until the expiration of Bayer’s patent in exchange for \$49.1 million.¹²⁸ Additionally, Bayer agreed to pay Barr quarterly payments or supply Barr with Cipro for resale until the end of 2003 in exchange for Barr promising not to manufacture its generic version.¹²⁹

¹¹⁹ *Id.* at 213.

¹²⁰ *Id.* at 208.

¹²¹ *Id.*

¹²² *Id.* at 211 (“Such a rule would...fail to give sufficient consideration to the patent holder’s incentive to settle the lawsuit without reference to the amount the generic manufacturer might earn in a competitive market, even when it is relatively confident of the validity of its patent—to insure against the possibility that its confidence is misplaced....”).

¹²³ *Id.* at 218.

¹²⁴ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

¹²⁵ *Id.* at 1328.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.* at 1328-29.

¹²⁹ *Id.* at 1329 (“Under the...Agreement, Bayer agreed to either supply Barr with Cipro for resale or to make quarterly payments (referred to as ‘reverse payments’ or ‘exclusion payments’)....”).

Beginning in 2000, purchasers of Cipro and advocacy groups filed antitrust suits arguing that these agreements were illegal.¹³⁰ The district court found that these agreements did not violate the Sherman Act.¹³¹ Applying the rule of reason test, it determined that ciprofloxacin was the relevant market and that while Bayer did have market power, the anticompetitive effects of the agreement were within the scope of its patent; and therefore there could be no unreasonable restraint of trade.¹³²

On appeal, the Federal Circuit upheld the agreements as legal and summarized the approaches taken by the Second and Eleventh Circuits, stating that in these types of cases it did not matter whether a court started by analyzing the issue under antitrust or patent law.¹³³ It found that, consistent with Supreme Court jurisprudence, both the Second and Eleventh Circuits had recognized that “[t]he essence of the inquiry [was] whether the agreements restrict competition beyond the exclusionary zone of the patent.”¹³⁴ The Federal Circuit agreed with this approach and also found that the validity of the patent, in the absence of fraud or sham litigation, need not be considered in order to assess the need to settle the infringement suit.¹³⁵

In this case, Bayer simply exercised its right to prevent Barr from profiting from its patented invention, therefore the settlement did not run afoul with antitrust laws. The Federal Circuit distinguished *In re Cardizem*, where the agreements were found to be *per se* illegal, because in *Cardizem* the generic manufacturer did not relinquish its 180-day exclusivity period, which completely prevented other generics from entering the market.¹³⁶ In the Federal Circuit’s opinion, this was a clear example of anti-competitive effects falling outside the scope of

¹³⁰ *Id.* The challenges were consolidated in the Eastern District of New York in 2001.

¹³¹ *Id.* at 1330.

¹³² *Id.*

¹³³ *See id.* at 1335-36 (In discussing *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) and *Valley Drug Co. v. Geneva Pharm. Inc.*, 344 F. 3d 1294 (11th Cir. 2003), the court noted that “in cases...wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law...or under patent law by analyzing the right to exclude afforded by the patent.”).

¹³⁴ *Id.* at 1336; *see Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965) (recognizing the legal monopoly granted by patents).

¹³⁵ *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1336-37.

¹³⁶ *Id.* at 1335.

a patent.¹³⁷ Bayer's agreement did not go beyond the scope of its patent and thus the settlement did not violate of the Sherman Act.¹³⁸

IV. CURRENT ACADEMIC VIEWS

Today there is a litany of different approaches to the "reverse payment" dilemma. Some advocate treating these agreements as *per se* illegal or, in the alternative, illegal if the settlements greatly exceed potential litigation costs.¹³⁹ Conversely, others favor any patent settlement provided that the infringement suit was not filed in bad faith.¹⁴⁰ In trying to forge a middle ground, some have suggested creating a rebuttable presumption of illegality while others favor applying the antitrust rule of reason analysis, but with some caveats.¹⁴¹ Each approach has its downfalls and without a Supreme Court decision or legislative action the debate continues.¹⁴²

A. Per se Illegal Treatment

In support of the Sixth Circuit's decision in *In re Cardizem*, a few commentators have called for all "reverse payments" to be declared *per se* illegal.¹⁴³ To allay concerns that this will negatively affect innovation and development of new products in several industries at least one commentator argues that the ban should only apply to the pharmaceutical industry.¹⁴⁴ This narrow application would be consistent with the objectives of the Hatch-Waxman Act both in benefiting consumers by facilitating generic entry into the market and in encouraging brand-name drug companies to continue to invest in research

¹³⁷ *Id.*

¹³⁸ *Id.* at 1341.

¹³⁹ See discussion *infra* Section IV.A.

¹⁴⁰ See discussion *infra* Section IV.B.

¹⁴¹ See discussion *infra* Section IV.C.

¹⁴² See discussion *infra* Section IV.D. Currently, there is proposed legislation in Congress, which would make it *per se* illegal. Preserve Access to Affordable Generics Act, S. 369, 11th Cong. (2009). The Supreme Court, however, has declined the opportunity to resolve the issue. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

¹⁴³ See generally Lisa M. Natter, Note, *Infringement Lawsuits: The Continuing Battle Between Patent Law and Antitrust Law in the Pharmaceutical Industry*, 18 LOY. CONSUMER L. REV. 363 (2006); Keith Leffler & Cristofer Leffler, *The Probabilistic Nature of Patent Rights: In Response to Kevin McDonald*, ANTITRUST, Summer 2003, at 77.

¹⁴⁴ Natter, *supra* note 143, at 381. Natter argues that the *per se* analysis is appropriate because: (1) it would apply only to narrow class of cases, (2) it would resolve unclear law regarding these agreements, and (3) it is consistent with the objectives of the Hatch-Waxman Act. *Id.*

and new product development.¹⁴⁵ Additionally, this rule, while admittedly harsh, would provide clarity to the pharmaceutical industry and ultimately reduce costs associated with litigation.¹⁴⁶ In response to the reduced innovation argument, one commentator has noted that statistics have shown since the enactment of the Hatch-Waxman Act, both generic presence in the market and overall investment in research and development have increased.¹⁴⁷ Thus, because the Act itself has arguably not affected innovation it follows that treating pharmaceutical agreements as *per se* illegal would not likely have a great impact since it would be used in a “limited set of circumstances.”¹⁴⁸

Others have argued for *per se* illegality because there is rarely a valid justification for using “reverse payments” to settle infringement actions.¹⁴⁹ Further, in their opinion, these payments are arguably inefficient because a cross-licensing agreement is often the best method to approximate the expected conclusion of a patent infringement case, and also allows for generic entry into the market.¹⁵⁰ This result benefits the consumer as was intended by the Hatch-Waxman Act. However, the idea of limiting parties’ options during litigation, despite some evidence it may not greatly impact the pharmaceutical industry, has gained little support with the majority of commentators advocating a different approach.¹⁵¹

B. Per se Legal Treatment

Per se legal treatment would allow all “reverse payment” settlements so long as the original patent infringement suit was not a

¹⁴⁵ See *id.* at 385-87.

¹⁴⁶ *Id.* at 384 (arguing that using the rule of reason analysis would increase the cost of litigation and may not be properly applied since courts have difficulty untangling the complex economic issues presented in antitrust cases).

¹⁴⁷ See *id.* at 386 (indicating that investment in research increased from \$2 billion in 1980 to \$39 billion in 2004 and generics increased their market share from 19% in 1984 to 57% in 2005) (citation omitted).

¹⁴⁸ *Id.* (“Applying a *per se* analysis to reverse payment agreements... would unlikely have anywhere near the impact that the Hatch-Waxman Act had on increasing the percentage of generic drugs in the marketplace. It is therefore difficult to argue that applying such an analysis in a limited set of circumstances would stifle the investment and innovation so critical to the pharmaceutical industry.”).

¹⁴⁹ See generally Leffler, *supra* note 143 (providing efficiency arguments to demonstrate why the *per se* approach is appropriate for reverse payment settlements in the pharmaceutical industry).

¹⁵⁰ *Id.* at 79-80.

¹⁵¹ See Ronald W. Davis, *Reverse Payment Patent Settlements: A view into the Abyss, and a Modest Proposal*, 21 ANTITRUST, Fall 2006, at 29 (“[T]here is some support among the commentariat for *per se* illegality, but not very much.”) (citation omitted).

sham.¹⁵² Judge Posner articulated this approach in *Asahi Glass* stating that “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,” the settlement is legal.¹⁵³ While in support of this approach, some commentators recognize that this standard is potentially underinclusive by preventing only the worst abusive settlements.¹⁵⁴ For instance, it could “allow[] the patent owner to preserve its economic position, possibly for the entire life of the patent, even if its chances of prevailing in litigation are substantially less than 50 percent, as long as the suit is not objectively baseless.”¹⁵⁵ However, because they fear that an overinclusive standard would negatively affect settlements and that having no recognized standard would only create more uncertainty, the *per se* legal approach is the best solution available.¹⁵⁶ Another supporter of this approach argues that “reverse payment” agreements are not themselves anticompetitive because this type of payment structure is often necessary to settle these disputes, and may ultimately benefit the consumer by facilitating generic entry onto the market.¹⁵⁷ Despite these arguments in favor of the *per se* legal approach, most propose an approach that attempts to balance consumer interest and antitrust goals, while recognizing the rights granted by a patent.¹⁵⁸

¹⁵² See Kent S. Barnard & Willard Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 632 (2006) (proposing *per se* legal approach to reverse payment settlements as long as the agreement is not a “sham settlement”); see also Davis, *supra* note 151, at 28 (noting that the *per se* legal approach has “scant” support among commentators).

¹⁵³ *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003). Judge Posner did not consider whether this standard applied to the “reverse payment” situation because that issue was not before him. However, some commentators argue that its logic is appropriate in these scenarios. See Barnard & Tom, *supra* note 152, at 633.

¹⁵⁴ See Barnard & Tom, *supra* note 152, at 633.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* (“We are better off with a standard that is occasionally underinclusive than we are with the chilling effect on patent settlements that comes with either an overinclusive standard or the uncertainty bred by the search for a *perfect* standard.”).

¹⁵⁷ See Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1034 (2004) (arguing that instead of continued litigation, which is no benefit to the consumer, settlements that split the life of the patent allow generics to enter the market prior to the patent’s expiration, which ultimately favors the consumer).

¹⁵⁸ See discussion *infra* Section IV.C.

C. Compromise Between the Two Extremes: The Middle Ground

To avoid the over- and underinclusiveness inherent in the *per se* approaches, many commentators seek a middle ground that requires a more nuanced analysis of patent settlements and the goals of antitrust.¹⁵⁹ Some argue for a rebuttable presumption of illegality, where the settling parties have the burden of showing that these agreements do not violate antitrust law since they are in the best position to demonstrate that such payments were reasonable.¹⁶⁰ Each commentator, however, proffers his own unique set of factors that can overcome the presumption of illegality. For example, some suggest that the payment size must be limited to “no more than the expected value of litigation and collateral costs attending the lawsuit,” in order to be considered reasonable.¹⁶¹ The reasoning is that if a patent holder truly believed it would prevail in its patent infringement case, it would pay no more than the expected cost of litigation to settle.¹⁶² If the payment exceeds this expectation, the patent holder must have doubts about its patent validity or the “defendant’s status as an infringer,”¹⁶³ therefore the payment reflects a socially costly outcome, allowing the patent holder to preserve its monopoly even though the patent is probably invalid while denying the consumer the benefit of competition.¹⁶⁴

One commentator warns against a ceiling on acceptable payments, voicing concern over a rule which forces parties “into alternative settlement arrangements [that] might, in some cases, materially affect patent owners’ *ex ante* incentives by reducing the expected payoff

¹⁵⁹ See generally Scott A. Backus, *Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has Schering-plough Created the Blueprint for Defensible Antitrust Violations?* 60 OKLA. L. REV. 375, 410-11 (2007) (discussing the different positions in the middle ground approach to reverse payments).

¹⁶⁰ See, e.g., Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759 (2003) (arguing that the infringement plaintiff should bear the burden of demonstrating that the payment was reasonable); Thomas Cotter, *Antitrust Implications of a Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarships*, 71 ANTITRUST L. J. 1069, 1082 (2004) (arguing that the settling parties should bear the burden of persuasion on whether the settlement was lawful); *Carrier*, *supra* note 24, at 76 (arguing that the settling parties should have the opportunity to rebut the presumption of illegality).

¹⁶¹ Hovenkamp et al., *supra* note 160, at 1759 (footnote omitted).

¹⁶² See *id.* at 1759 n. 177.

¹⁶³ Hovenkamp, *supra* note 41, at 25

¹⁶⁴ *Id.*; see also Backus, *supra* note 159, at 405 (explaining the consumer harm from these payments is the difference between what the consumer would gain if the patent infringement case was decided and what the consumer receives as a result of settlement).

from invention.”¹⁶⁵ Another argues that there should not be a particular method of demonstrating the reasonableness of the payment, and instead suggests that the defendants can explain their payments several ways, including that: (1) the generic was cash-strapped; (2) the generic and the brand-name had “informational asymmetries” about the patent; (3) the payment was not larger than litigation costs; (4) other reasonable explanations (i.e., reliance on sales projects, market analyses).¹⁶⁶

Ultimately, the aim of these propositions is to bridge the divide between courts and commentators, however to achieve this compromise, courts would face greater “administrative costs and decreased efficiency due to the requirement for a more thorough investigation of the settlement agreement and the underlying patent infringement claim.”¹⁶⁷ With each new proposal, the search continues for a perfect solution that properly balances the Hatch-Waxman Act’s goal of increasing generic competition, the exclusionary power granted by a patent, and antitrust principles, in the hopes of obtaining the best outcome for consumers and the pharmaceutical industry. Yet, this debate could be avoided if the FTC, in addition to bringing suit against pharmaceutical companies for antitrust violations, could attack the underlying patent to ensure the settlement was based on a valid patent.

V. THE FTC SHOULD CHALLENGE THE UNDERLYING PATENT’S VALIDITY TO ENFORCE THE PUBLIC’S INTEREST IN FREE COMPETITION

In the past, the FTC has only challenged the settlements between pharmaceutical companies based on allegations of antitrust violations.¹⁶⁸ Yet considering the ruling in *United States v. U.S. Gypsum Co.* and *United States v. Glaxo Group Ltd.*, the FTC has standing to challenge the underlying patents involved in these antitrust disputes.¹⁶⁹ This would ensure that there would always be at least one party who has the ability to challenge the patent and cannot be silenced through payment.

A. The Government has Standing to Challenge a Patent’s Validity

The concept that the Government itself could have standing in a patent validity case was first litigated in *United States v. American*

¹⁶⁵ Cotter, *supra* note 160, at 1092.

¹⁶⁶ Carrier, *supra* note 24, at 76.

¹⁶⁷ Backus, *supra* note 159, at 411 (footnotes omitted).

¹⁶⁸ See discussion *supra* Section III.

¹⁶⁹ See discussion *infra* Section V.A.

*Bell Telephone Co.*¹⁷⁰ The Government argued that Bell Telephone fraudulently delayed its application in order to extend its monopoly on a product that was already in the public domain, or in the alternative, that it was not the original inventor and thus, the court should invalidate the patent.¹⁷¹ Ultimately, the Supreme Court found that the delay was not due to the applicant but rather the patent office itself, so there was no fraud on part of Bell Telephone.¹⁷² The Court did not consider the second argument regarding the validity of the patent because it ruled that the Government lacked standing to make such a claim.¹⁷³

The Government is not required to abide by the standing requirements that apply to private patent suits “when it has a proprietary and pecuniary interest in the result” and “when it is necessary in order to enable it to discharge its obligations to the public.”¹⁷⁴ Yet in *Bell Telephone*, no such interest existed.¹⁷⁵ Instead the Court found that the Government was “a mere formal complainant in a suit, not for the purpose of asserting any public right or protecting any public interest, title, or property, but merely to form a conduit through which one private person can conduct litigation against another private person....”¹⁷⁶ The Government was thereby bound to “the rules governing...suits between private litigants,”¹⁷⁷ which at the time meant that only a party charged with infringement could challenge the validity of the patent.¹⁷⁸ However, the Court explained that the Government might have such an interest when prosecuting antitrust violations.¹⁷⁹ It noted that one of the responsibilities of government is to ensure that the public does not endure the evils of a monopoly, especially one “wrongfully created” through an invalid patent. The Court refused to decide whether this was enough to exempt the Government from the standing rules applied in private litigation.¹⁸⁰ It concluded that reviewing simple errors committed by the patent office was inappropriate and would allow courts to have appellate jurisdiction over the organi-

¹⁷⁰ *United States v. Am. Bell Tel. Co.*, 167 U.S. 224 (1897).

¹⁷¹ *Id.* at 227.

¹⁷² *Id.* at 262-63.

¹⁷³ *Id.* at 265.

¹⁷⁴ *Id.* at 264.

¹⁷⁵ *Id.* at 265.

¹⁷⁶ *Id.* (quoting *United States v. Beebe*, 127 U.S. 338, 347 (1888)).

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* (discussing the limitations on standing imposed by the Court in *United States v. Beebe*, 127 U.S. 338 (1888)).

¹⁷⁹ *See id.* at 266 (discussing when the Government has an obligation to protect the public against monopolies).

¹⁸⁰ *Id.* (citing *United States v. Am. Bell Tel. Co.*, 159 U.S. 548 (1885)).

zation, which was never authorized or intended by Congress.¹⁸¹ Thus, the Government had no standing to argue the invalidity of the patent.

In *United States v. U.S. Gypsum Co.*, the Supreme Court was asked to decide the question it had previously declined to address in *United States v. Bell Telephone Co.*—whether the government was allowed to challenge a patent when the patent holder was accused of violating antitrust law.¹⁸² In *Gypsum*, the Government brought suit against U.S. Gypsum Company and others, arguing the companies had an illegal conspiracy to monopolize trade in gypsum products because of various agreements to fix prices on the patented gypsum board and unpatented gypsum products.¹⁸³ After the defendants admitted that the arrangements would be illegal if they did not have a patent, the Government tried to amend their claim to dispute the patent's validity.¹⁸⁴ The lower court did not allow this amendment, ruling the Government lacked the standing to challenge the patent.¹⁸⁵

The Supreme Court, however, overruled the decision, stating that the Government did have standing to challenge the validity of the patents.¹⁸⁶ Although the Court thought that it was clear that the agreements went beyond the scope of the patent and therefore the Government's failed amendment was not dispositive, the Court felt it necessary to directly overrule the lower court's decision concerning standing.¹⁸⁷ Since a licensee in an antitrust suit can challenge the validity a patent because of a "public interest in free competition" and the Government has the same interest to preserve competition, the Court decided that the Government should have the same right to challenge a patent's validity as well.¹⁸⁸

The Court further expanded the Government's ability to challenge a patent in *United States v. Glaxo Group Ltd.* decision.¹⁸⁹ In *Glaxo*, two companies decided to pool their various patents concerning the antibiotic giriseofulvin, which is used to treat external fungal infections.¹⁹⁰ They agreed not to sell the product without consent and then made various licensing agreements that restricted the resale of the

¹⁸¹ *Id.* at 269 ("That would be an attempt on the part of the courts in collateral attack to exercise an appellate jurisdiction over the decisions of the patent office, although no appellate jurisdiction has been...conferred.")

¹⁸² *United States v. U.S. Gypsum Co.*, 333 U.S. 364 (1948).

¹⁸³ *Id.* at 367.

¹⁸⁴ *Id.* at 386-87.

¹⁸⁵ *Id.* at 387.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 387-88.

¹⁸⁸ *Id.*

¹⁸⁹ *United States v. Glaxo Grp., Ltd.*, 410 U.S. 52 (1973).

¹⁹⁰ *Id.* at 53.

drug as well.¹⁹¹ The Government alleged these restrictions on drug sale and resales were in violation of the Sherman Act.¹⁹² The Government also challenged the validity one of the patents, but the district court struck this argument because the companies did not use the patents and the legal monopoly granted by them to defend the agreements.¹⁹³ Even though the district court held that the agreements were illegal, the Government still appealed because it was denied the relief it requested.¹⁹⁴

In its decision, the Supreme Court ruled the Government could challenge a patent's validity even when the patent was not part of a defense.¹⁹⁵ However, in *Glaxo*, it was necessary to decide the validity of the patent in order to decide whether the Government's request for compulsory licensing and mandatory sales was appropriate.¹⁹⁶ Therefore, the Court noted:

we do not recognize unlimited authority in the Government to attack a patent by basing an antitrust claim on the simple assertion that the patent is invalid. Nor do we invest the Attorney General with a roving commission to question the validity of any patent lurking in the background of an antitrust case.¹⁹⁷

This restriction prevents the Government attacking any patent involved in an antitrust litigation, limiting their challenges to the patent, and in particular, the patent's claims that directly concern the antitrust violations.¹⁹⁸ Yet, if the antitrust violation is "sufficiently related" to the patent, then the Government has the ability to challenge its validity.¹⁹⁹

¹⁹¹ *Id.* at 54-55.

¹⁹² *Id.* at 56 (noting that the district court held that the agreements to be a *per se* violation of the Sherman Act).

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 58.

¹⁹⁶ *Id.* at 58-59.

¹⁹⁷ *Id.* at 59 (citation omitted).

¹⁹⁸ See *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1158 n.2 67 (D.N.J. 1979) (discussing and interpreting standing requirements for challenging a patent in the antitrust context).

¹⁹⁹ *Id.*

B. The FTC Can Challenge the Patent in Pharmaceutical Antitrust Cases Because the Pharmaceutical Companies Rely on Their Patents to Justify Their Conduct

While *Gypsum* and *Glaxo* were cases prosecuted by the DOJ, this should not impact whether the precedent can be extended to suits brought by the FTC. *Gypsum* and *Glaxo* clearly established that when a company relies upon its patents to justify its anticompetitive behavior, the United States is allowed to question the validity of these patents.²⁰⁰ In pharmaceutical patent settlements, companies are clearly relying on their patents to defend their conduct. Thus, the government agency tasked with investigating these settlements and preventing unfair competition should be able to question the validity of these patents in order to protect consumers from unjust monopolies.

The FTC has authority under the Federal Trade Commission Act (FTC Act) to prevent companies from engaging in “unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce.”²⁰¹ The Supreme Court has interpreted the unfairness standard as “encompassing not only practices that violate the Sherman Act and other antitrust laws, but also practices that the Commission determines are against public policy for other reasons.”²⁰² The only limitation to this broad standard is that once the Commission concludes a business practice violates one of these rationales, “administrative law dictate[s] that its decision must stand or fall on that basis, and a reviewing court may not consider other reasons why the practice might be deemed unfair.”²⁰³

When the FTC challenges “reverse payment” settlements, it has always argued that the settlements violate antitrust law, and thus violate the FTC Act.²⁰⁴ Since the FTC is challenging these agreements under antitrust law governed by the Sherman Act and forcing the defendants to justify their anticompetitive behavior, if the defendant tries to defend its actions by invoking its patent rights, then FTC should have the opportunity to “show that the asserted shield of patentability

²⁰⁰ See discussion *supra* Section V.A.

²⁰¹ 15 U.S.C. § 45(a)(1) (2006).

²⁰² *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 454 (1986) (citation omitted); see *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 243-44 (1972) (stating that § 5 of the FTC Act does not limit the FTC to attacking practices that only violate antitrust law).

²⁰³ *Ind. Fed’n of Dentists*, 476 U.S. at 455; see *Sperry & Hutchinson Co.*, 405 U.S. at 245-50.

²⁰⁴ See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); see also discussion *supra* Section III.

does not exist,”²⁰⁵ as discussed in *Gypsum*. Courts have recognized this reliance on patents to defend anticompetitive behavior stating, “the right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim.”²⁰⁶ *Gypsum* clearly stated that when a company relies upon its patents to justify its anticompetitive behavior, the Government is allowed to attack the validity of the patents in the name of public interest in free competition.²⁰⁷ Companies themselves have argued that the FTC needs to consider the exclusionary power and not rely solely on the existence and size of the payment when arguing against these payments.²⁰⁸ If these pharmaceutical companies wish to defend their behavior solely on the principle that their patents grant them the power to exclude, the FTC, as the Government’s representative and consumer advocate in these cases, should be able to question the validity of the relevant pharmaceutical patent.

The ability to question the underlying patent in these settlements would transform the FTC’s approach in prosecuting “reverse payment” settlements. If the pharmaceutical companies were required to justify their agreements by demonstrating that they were founded on valid patents, then the public would be protected from abusive agreements. If the FTC adopted this strategy, it would increase the time and resources required to pursue these claims. However, if pharmaceutical companies are aware of the risk involved in structuring settlements that include “reverse payments,” it is likely that the number of these settlements will decrease to avoid the scrutiny of the FTC, ultimately reducing the expected burden on the agency. While it has been argued this type of payment is a necessary option for companies to consider when creating these settlements, this approach could effectively eliminate this as an option.²⁰⁹ Additionally, it is worth noting that because the pharmaceutical companies have been required to file settlement agreements with the FTC and DOJ, the vast majority of these settlements have not included “reverse payments” to generics.²¹⁰ This settlement structure is not the only option available to pharmaceutical companies. Although this approach may be seen as a way to under-

²⁰⁵ United States v. U.S. Gypsum Co., 333 U.S. 364, 388 (1948).

²⁰⁶ Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1307 (11th Cir. 2003).

²⁰⁷ *Gypsum*, 333 U.S. at 387-88.

²⁰⁸ See, e.g., Opening Brief of Schering-Plough Corporation at 38-44, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (2005) (No. 04-10688-AA), 2004 WL 3557974.

²⁰⁹ See *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003).

²¹⁰ See FTC SUMMARY OF AGREEMENTS, *supra* note 7 (indicating that figures from fiscal year 2008 show that approximately 70% of final agreements between brand-generic companies did not involve payment to the generic).

mine the rights granted to a patentee, Congress has recognized the public interest in ensuring that only valid patents are issued by stating “an issued patent carries only a rebuttable presumption of validity, which can be challenged in court.”²¹¹ If the patentee can effectively silence any of its potential competitors, the public would be forced to endure unwarranted patent monopolies. This approach would not be undermining the rights granted to the patentee but rather ensuring that these rights were properly granted in the first place.

C. Lear Supports the Conclusion that the FTC Can Challenge the Patent’s Validity

In *Lear, Inc. v. Adkins*, the Supreme Court recognized that there are few parties truly capable of challenging a patent and explained the negative consequences that would result if these parties were unable to do so.²¹² The Court was asked to reconsider whether a licensee was able to challenge the validity of the licensor’s patent.²¹³ Previously, the Court had held under the principle of estoppel that a licensee was unable to challenge a patent because as a licensee it would be unfair to reap the rewards of a licensed patent but also challenge it.²¹⁴ In deciding to overrule itself and allow a licensee to challenge a patent’s validity, the Court considered who *really* has the ability to make such a challenge: “[l]icensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor’s discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification.”²¹⁵

The courts today need to revisit *Lear*’s public policy argument and apply it in the context of pharmaceutical settlements, remembering who is best able to act as a guardian of the public interest. Often times only generic drug companies are in the position to challenge a brand-name’s patent and when brand-names are able to negotiate generics’ silence, who is left to make sure we, the public, are not required to pay “would-be monopolists” for patents that may or may not be valid? Considering the FTC is the government agency tasked to

²¹¹ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1334 (Fed. Cir. 2008).

²¹² *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

²¹³ *Id.* at 670.

²¹⁴ *Id.* at 656; *see Automatic Radio Mfg. Co. v. Hazeltine Research Inc.*, 339 U.S. 827, 836 (1950) (ruling that the licensee cannot challenge the validity of the patents when the licensing agreement does not result in a misuse of patents or a violation of public policy).

²¹⁵ *Lear*, 395 U.S. at 670.

protect consumers from anticompetitive behavior, courts should have no issue allowing the FTC to challenge the validity of the patents involved in “reverse payment” settlements because without their help, the public may continue to suffer the high cost of brand-name drugs without justification.

V. CONCLUSION

Allowing the FTC to challenge the underlying patents completely changes the FTC’s ability to attack “reverse payment” agreements. While the FTC still needs sufficient evidence to allege an antitrust violation in order to shift the burden to the defendants to explain their conduct, the FTC can simultaneously question the validity of the patent if the defendants choose to hide behind the exclusionary power of their patents. This approach would allow the FTC to effectively advocate the public’s interest in free competition by ensuring these agreements are founded on valid patents. Without FTC action against pharmaceutical patent settlements, the public will be forced to continue paying higher medical expenses without proper justification.

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COLLATERAL DAMAGE: INSECURITY ASSETS IN THE RISING VIRTUAL AGE OF E-COMMERCE

INTRODUCTION

Virtual worlds are computer-based, simulated environments that incorporate real-world representations of objects into an interface where users can interact with one another, typically through the use of an “avatar”¹ that is graphically visible to other users.² Virtual worlds are “persistent and dynamic” because they exist independent of users’ home computers and constantly change even when users are offline.³ At the forefront of innovative virtual realities is the online application Second Life, developed by Linden Labs and launched on June 23, 2003. In Second Life, a resident assumes the role of an avatar in a virtual world where he can personalize his appearance, own property and real estate, shop in a virtual economy, operate a storefront, socialize with other players, and acquire numerous forms of virtual, intangible property that has real value.⁴ To buy land and items in Second Life, players can acquire “Lindens,” Second Life’s currency, with U.S. dollars.⁵ Second Life, unlike its predecessors, is a “non-scripted” world in which users design content and transform the virtual world

¹ An “avatar” is defined as: “An on-line, real-time graphical representation of an interactive computer service user visible to other users accessing (or sharing) the same virtual three-dimensional world. Depending on its implementation, an Avatar may communicate by a combination of body movements (such as walking, gesturing and making facial expressions), text and speech, all of which may be seen and heard by other occupants of the virtual world. Avatars may grasp, possess and exchange objects with other Avatars and entities within the virtual world.” Steven Hetcher, *Virtual China*, 7 J. MARSHALL REV. INTELL. PROP. L. 469, 473 n. 21 (2008) (quoting 2 RICHARD RAYSMAN ET AL., *EMERGING TECHNOLOGIES & THE LAW: FORMS & ANALYSIS* APP. E. (2008)).

² Ned Kock, *E-Collaboration and E-Commerce in Virtual Worlds: The Potential of Second Life and World of Warcraft*, 4 INT’L J. E-COLLABORATION, Jul.-Sept. 2008, at 1 (discussing the emergence of virtual worlds used for entertainment and business purposes).

³ Juliet M. Moringiello, *What Virtual Worlds Can Do for Property Law*, 62 FLA. L. REV. 159, 169 (2010) [hereinafter Moringiello, *Virtual Worlds*].

⁴ What is Second Life?, SECOND LIFE, <http://secondlife.com/whatis> (last visited Oct. 21, 2010).

⁵ *Id.*