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REVERSE PAYMENT SETTLEMENTS: THE U.S. SUPREME COURT HAS FINALLY AGREED TO
RESOLVE THE ISSUE.

TYLER CHO

ABSTRACT

Paragraph IV of the Hatch-Waxman Act provides a mechanism for litigating pharmaceutical patent infringement disputes. Many of these cases have been settled with “reverse payments” from the brand to the generic in return for delayed generic entry. The U.S. Federal Trade Commission (FTC) has contested a number of these settlements with mixed results. On July 16, 2012, the U.S. Court of Appeals for the Third Circuit issued a decision holding that pharmaceutical patent settlements that restrict generic entry and contain a payment to the generic company are presumptively unlawful under U.S. antitrust laws. By holding that a patent settlement can violate antitrust laws without proof that it affected competition outside the scope of a valid patent, the decision directly conflicts with the holdings of three other U.S. Courts of Appeals, and sets up a strong debate across the nation. On December 7, 2012, the U.S. Supreme Court finally agreed to review an antitrust challenge to reverse payment settlements and granted a writ of certiorari. This comment analyzes the conflict among the U.S. Courts of Appeals involving differential applications of either patent law or antitrust law to address reverse payment settlements. After analyzing the conflict, this comment offers a set of rules to guide the U.S. Supreme Court and legislators in determining the legality of such reverse payment settlements.

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INTRODUCTION

Our legal system encourages parties to settle out of court.¹ Settlements of patent disputes often take the form of unrestricted or restricted licenses, cross-licensing arrangements, market division agreements, or field-of-use agreements.² These settlements are encouraged in part because they produce more competition in the market than a judgment establishing the validity of a rival's claim and excluding a competitor from the market.³ However, some settlements require a party's delayed entry into the market. Such settlements may be problematic because they seem to violate antitrust law, even if they may still be valid under the exclusionary right of a patent.⁴

Over the past decade, this type of settlement has emerged in litigation over pharmaceutical patents.⁵ The settlements are known as "reverse payment" or "pay-for-delay" settlements.⁶ Unlike traditional pharmaceutical patent infringement settlements, all reverse payment settlements share a unique feature: the payment goes from the patent holder to the alleged infringer.⁷

Reverse payment settlements occur in the unique setting of the Drug Competition and Patent Term Restoration Act of 1984, also known as the Hatch-

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¹ See Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1721 (2003).

² *Id.* at 1721.

³ *Id.* at 1722.

⁴ *Id.* at 1723–24.

⁵ See Gregory Dolin, *Reverse Settlements As Patent Invalidation Signals*, 24 HARV. J.L. & TECH. 281, 293 (2011) (stating that as with any litigation, settlement of patent suits is not unusual; however, reverse payments are unusual that the patentee pays the challenger while simultaneously preserving its patent monopoly); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1304 (2010) (describing reverse payment settlements as a unique system for the branded manufacturer to buy off the generic company's challenge).

⁶ See, e.g., Opderbeck, *supra* note 5, at 1304 (referring to the agreements both as "reverse payment settlements" and "reverse settlements"); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 632 (2009) (referring to the agreements as "pay-for-delay" settlements).

⁷ Dolin, *supra* note 5, at 293–94 ("[U]nlike usual patent litigation . . . Hatch-Waxman litigation occurs prior to the generic drug actually entering the market. . . . [T]he patentee often pays amounts far exceeding the cost of litigation to the challengers.").

Waxman Act.⁸ The Act provides incentives for a generic manufacturer to challenge a branded pharmaceutical manufacturer's existing patents by creating a 180-day marketing exclusivity period for the first challenger of an issued patent.⁹ This provision was designed to help eradicate weak patents and facilitate competition with generics.¹⁰ Instead, the Act has enabled branded pharmaceutical companies to buy off the generic companies' challenges.¹¹

These reverse payment settlements have created significant antitrust concerns.¹² For years, the Federal Trade Commission ("FTC"), the Department of Justice ("DOJ"), and numerous private plaintiffs have challenged these settlements.¹³ The FTC has been largely unsuccessful in the courts, and its efforts have resulted in a conflict within the United States Courts of Appeals over whether reverse payment settlements warrant antitrust scrutiny.¹⁴ Denials of petitions for certiorari by the U.S. Supreme Court have helped maintain this tension between the exclusivity arising under patent law and the prohibitions against restraint of free competition under antitrust law.¹⁵

Recently, the Third Circuit held that reverse payment settlements are presumptively unlawful under U.S. antitrust laws.¹⁶ By holding that a reverse payment settlement can violate antitrust laws without proof of its effect on competition outside the scope of a valid patent, the decision directly conflicts with the holdings of three other U.S. Courts of Appeals.¹⁷ Due to the inconsistencies in holdings, the U.S. Supreme Court finally agreed to review an antitrust challenge to reverse payment settlements and granted certiorari on December 7, 2012.¹⁸ Part I of this comment describes the regulatory context and the nature of reverse payment settlements. Part II discusses the direct conflict between the decisions of the U.S. Courts of Appeals, and the effects of FTC challenges on reverse payment settlements. Part III then proposes a solution to the problem of reverse payment settlements.

⁸ Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman), Pub. L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of 15, 21, 28, and 35 U.S.C.).

⁹ 21 U.S.C. § 355(j) (2012).

¹⁰ *Id.*

¹¹ Dolin, *supra* note 5, at 283 (defining reverse settlement agreements).

¹² See Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1061 (11th Cir. 2005).

¹³ Opperbeck, *supra* note 5, at 1305.

¹⁴ *Id.* at 1308. For example, the Sixth Circuit has focused on antitrust law to hold that reverse payment settlements are *per se* illegal, while the Second, Eleventh, and Federal Circuits have focused on patent law's exclusionary right, resulting in minimal exposure to antitrust liability. Compare La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re Cardizem CD Antitrust Litig.*), 332 F.3d 896, 900 (6th Cir. 2003) ("*per se* illegal"), with Joblove v. Barr Labs. Inc. (*In re Tamoxifen Citrate Antitrust Litig.*), 466 F.3d 187, 214–15 (2d Cir. 2006) ("minimal exposure to antitrust liability").

¹⁵ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 214–15, *rehearing en banc denied*, Ciprofloxacin Hydrochloride Antitrust Litig. v. Bayer Ag, No. 2008-1097, 2008 U.S. App. LEXIS 27711 (Fed. Cir. 2008), *cert. denied*, Ark. Carpenters Health & Welfare Fund v. Bayer AG & Bayer Corp., 129 S. Ct. 2828 (2009).

¹⁶ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d Cir. 2012).

¹⁷ *Id.* at 218.

¹⁸ Fed. Trade Comm'n v. Watson Pharms., Inc., 133 S. Ct. 787 (2012), *petition for cert. granted*, 81 U.S.L.W. 3324 (U.S. Dec. 7, 2012) (No. 12-416).

I. BACKGROUND

A. History of The Hatch-Waxman Act

Prior to the Hatch-Waxman Act, a generic manufacturer was required to conduct its own tests and studies to prove a drug's safety and efficacy, even if the drug contained exactly the same components as the brand-name counterpart.¹⁹ At the time, the Food and Drug Administration ("FDA") conducted its clinical review and approval process of generics in the same way it did for any other new drug.²⁰ Because of this lengthy and expensive approval process without the reward of a patented product, generic manufacturers were reluctant to proceed with the development of generic drugs.²¹ Further, the Patent Act prohibited generic manufacturers from using a patented drug as a template for developing their own generic equivalents, thereby forcing generic manufacturers to wait until the patent expired.²² This effectively extended the branded manufacturers' exclusive period for years by creating a *de facto* term extension that further sustained high drug costs.²³ As a result, 150 branded drugs with expired patent protection lacked generic equivalents when the Hatch-Waxman Act passed in 1984.²⁴

The Hatch-Waxman Act sought to adjust patent policy by amending both the Food, Drug, and Cosmetic Act and the Patent Act.²⁵ As to the former, the Hatch-Waxman Act introduced a new process called the Abbreviated New Drug Application ("ANDA").²⁶ Under ANDA, the generic manufacturer can rely on the safety and efficacy data used in the FDA approval process for the branded drugs by showing that the generic and branded drugs are bioequivalents.²⁷ This process was designed

¹⁹ Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C.); Jeff Thomas, *Schering-Plough and In re Tamoxifen: Lawful Reverse Payments in the Hatch-Waxman Context*, 22 BERKELEY TECH. L.J. 13, 18 (2007) (stating that prior to the passage of the Hatch-Waxman Act, "the generic manufacturer was required to undertake full clinical trials to prove safety and efficacy").

²⁰ Opderbeck, *supra* note 5, at 1306.

²¹ See FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at viii (2002) [hereinafter FTC GENERIC DRUG ENTRY STUDY], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

²² See *id.* at 4; 35 U.S.C. § 271 (2012).

²³ See Joyce Wing Yan Tam, *Biologics Revolution: The Intersection of Biotechnology, Patent Law, and Pharmaceutical Regulation*, 98 GEO. L.J. 535, 540 (2010) ("[F]orcing generic drug makers to wait until after patent expiration to commence the lengthy FDA approval process, in effect, created a *de facto* term extension that further inhibited the public's access to affordable medicine.").

²⁴ See Thomas, *supra* note 19, at 18.

²⁵ Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, 1585 (1984) ("An Act To amend the Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.").

²⁶ *Id.* § 101, 98 Stat. at 1585–92.

²⁷ See 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv) (2012). As the *Caraco* court explained:

Those amendments allow a generic competitor to file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA. Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the

to eliminate the need for duplicative tests and to speed up the introduction of low-cost generic drugs to market.²⁸ The Hatch-Waxman Act amended the Patent Act so that it is no longer “infringement to make, use, offer to sell, or sell . . . a patented invention” if the uses are “reasonably related to the development and submission . . . under a Federal Law which regulates the manufacture, use, or sale of drugs.”²⁹ This has allowed generic manufacturers to develop bioequivalents during the patent life of branded drugs, and further, it has allowed them to market these low-cost drugs as soon as the branded drug’s patent protection expires.³⁰

B. The Framework of the Hatch-Waxman Litigation

For a new drug, an applicant must submit a New Drug Application (“NDA”), which requires multiple clinical trials for safety and efficacy.³¹ The holder of an approved NDA must provide to the FDA the patent number and expiration date of every patent covering the brand-name drug for the FDA’s approval.³² Upon approval, the FDA lists each patent submitted on a website called “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.”³³ To secure FDA approval in light of these listings, an ANDA applicant must certify to the FDA that its version of the approved drug will not interfere with any of the “listed” patents.³⁴ That is, a generic manufacturer seeking ANDA application must certify to one of the following: “(I) that such patent information has not been filed; (II) that such patent has expired; (III) the date such patent will expire; or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.”³⁵

With a Paragraph I, II, or III certification, no issues of patent law arise because the patents at issue are either expired or will expire on a certain date.³⁶ A Paragraph IV certification, on the other hand, triggers a series of events that usually lead to litigation of the underlying patent.³⁷

An ANDA filer with a Paragraph IV certification must explain why such a patent is invalid and notify the patent holder of its ANDA application.³⁸ Then, the

generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug.

Caraco Pharm. Lab., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012).

²⁸ *Id.*

²⁹ 35 U.S.C. § 271(e)(1).

³⁰ *Id.*

³¹ See 21 U.S.C. § 355(b) (2012).

³² See *id.* § 355(b)(1).

³³ See Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 638 (2007); *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (last updated Nov. 16, 2012).

³⁴ See 21 U.S.C. § 355(j)(2)(A)(vii).

³⁵ *Id.*

³⁶ See *id.* § 355(j)(2)(A)(vii)(I)–(III).

³⁷ See *id.* § 355(j)(2)(A)(vii)(IV).

³⁸ *Id.* § 355(j)(2)(B).

patent holder has the option to bring an infringement action against the ANDA filer or to waive his right to the patent.³⁹ If the patent holder elects to file the lawsuit within forty-five days after receiving such notice, the effective date of any FDA approval of the ANDA application is delayed for thirty months or until the resolution of the lawsuit, whichever comes first.⁴⁰ This thirty-month stay period provides ample time for the ANDA approval process and any subsequent litigation.⁴¹ However, only a single thirty-month stay is available.⁴²

The Hatch-Waxman Act provides incentives for potential competitors to challenge drug patents before they expire.⁴³ More specifically, the first ANDA filer is awarded a 180-day period of market exclusivity beginning either (1) from the date it begins commercial marketing of the generic drug product or (2) from a court decision ruling that the patent is invalid or not infringed, whichever is earlier.⁴⁴ The purpose of the 180-day exclusivity provision is to insure that the first ANDA filer has a fair opportunity to recover its litigation costs.⁴⁵ However, if the litigation is resolved in the ANDA filer's favor, the ANDA filer must market its generic drug within seventy-five days or forfeit its 180-day exclusivity period.⁴⁶ Even if the Paragraph IV challenge fails, the challenger still receives the 180-day exclusivity period for being the first filer; it only needs to wait until the patent expires.⁴⁷

C. Overview of Reverse Payment Settlements

A typical reverse payment settlement between the first ANDA filer and the patent right holder arises from two provisions of the Hatch-Waxman Act: (1) the retention of the 180-day market exclusivity provision, and (2) the "Failure to Market" provision.⁴⁸

³⁹ See 21 U.S.C. § 355(j)(5)(B)(iii) (2012) ("[A]pproval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice . . . is received, an action is brought for infringement of the patent . . .").

⁴⁰ *Id.* ("[T]he approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice.")

⁴¹ Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 422 (1999).

⁴² See 21 U.S.C. § 355(c)(3)(C). Before the 2003 amendments to the Hatch-Waxman framework, an NDA holder could amend its Orange Book entries to list new patents. See FTC GENERIC DRUG ENTRY STUDY, *supra* note 21, at 43. Thus, such an amendment would require new Paragraph IV certifications, which would in turn trigger a new thirty-month stay. *Id.*

⁴³ See C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 634–35 (2009); 21 U.S.C. § 355(j)(5)(B)(iv)(I).

⁴⁴ 21 U.S.C. § 355(j)(5)(B)(iv).

⁴⁵ Engelberg, *supra* note 41, at 423.

⁴⁶ Hemphill, *supra* note 43, at 634.

⁴⁷ *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998) (holding that the successful-defense is not a prerequisite to the invocation of the 180-day exclusivity rule by a first applicant under 21 U.S.C. § 355(j)(5)(B)(iv)).

⁴⁸ See 21 U.S.C. § 355(j)(5)(B)(iv) (2012) ("180-day exclusivity period"); 21 U.S.C. § 355(j)(5)(D)(i)(I) ("failure to market").

The first ANDA filer solely holds the 180-day market exclusivity, and it cannot be transferred to any later filers even if the first filer forfeits this right.⁴⁹ Thus, there is no incentive for later filers to carry the burden of litigation costs.⁵⁰ Further, the interpretation of the forfeiture provision may lead to a situation where the 180-day exclusivity will almost never be forfeited.⁵¹

For example, suppose the first ANDA filer obtains its 180-day exclusivity period, and as the 30-month stay period expires, it obtains the right to market its generic drugs. A failure to market its generic drugs after the FDA's approval will lead to the forfeiture of its 180-day exclusivity period, unless one of the following occurs: (1) a court enters a final decision from which no appeal can be taken that the patent is invalid or not infringed; (2) a court signs a settlement order or consent decree entering a finding of an invalid patent or non-infringement; or (3) the patent holder delists the patent from the Orange Book.⁵² Accordingly, a settlement will allow the first ANDA filer to maintain its 180-day exclusivity period and avoid forfeiture because there will be no court ruling.⁵³ This structural "loophole" provides the basis for a reverse payment settlement to occur between the first ANDA filer and the patent holder because the settlement benefits both parties.⁵⁴ The first ANDA filer will retain the exclusivity period and will receive payments, including the costs of patent litigation, while the branded company enjoys its monopoly over the patented product.⁵⁵

D. Antitrust Law vs. Patent Law

In general, an agreement between competitors to allocate market share is deemed anticompetitive because it has a tendency to diminish output and raise prices.⁵⁶ Accordingly, Section 1 of the Sherman Act prohibits "every contract,

⁴⁹ See *Mova Pharm. Corp.*, 140 F.3d at 1076 (stating that a 180-day exclusivity period is available only to the first ANDA filer to challenge a patent holder for the validity of its patent, regardless of the success on the merits).

⁵⁰ Letter from Gary J. Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation & Research, to Marc A. Goshko, Exec. Dir., Teva N. Am. 4, at 5 (Jan. 17, 2008), available at <http://www.fda.gov/ohrms/DOCKETS/DOCKETS/07n0389/07n-0389-let0003.pdf>.

⁵¹ *Id.* at 4–5.

⁵² *Id.*

We find that under the plain language of the statute, 180-day exclusivity is not forfeited for failure to market when an event under subpart (aa) has occurred, but—as in this case—none of the events in subpart (bb) has occurred. The "failure to market" provision results in forfeiture when there are two dates on the basis of which FDA may identify the "later" event as described in section 505(j)(5)(D)(i)(I). The provision does not effect a forfeiture when an event under subpart (aa) has occurred, but no event under subpart (bb) has yet occurred.

Id. at 5.

⁵³ *Id.* at 5 n.6.

⁵⁴ Hemphill, *supra* note 43, at 635.

⁵⁵ Dolin, *supra* note 5, at 293 (stating that generic companies can avoid the costs of patent litigation, \$5 million on average, by settling the lawsuit).

⁵⁶ *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003).

combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations.”⁵⁷ Although by its terms the Act prohibits any “restraint of trade,” the Supreme Court “has long recognized that Congress intended to outlaw only unreasonable restraints.”⁵⁸ Some types of agreements are so obviously anticompetitive that they are “*per se*” violations.⁵⁹ In most cases, however, courts presumptively apply a “rule of reason” analysis to determine whether an agreement 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.⁶⁰ If one party makes certain payments to potential competitors in return for their delayed market entry, the agreement will likely violate antitrust law.⁶¹

However, problems arise when the agreements involve patents because patents grant their owner the lawful right to exclude others.⁶² This exclusionary right provides a patentee control over its patent.⁶³ For example, a patentee could choose to exclude everyone from producing the patented article, could choose to be the sole supplier itself,⁶⁴ or could grant exclusive territorial licenses among its licensees.⁶⁵ For these reasons, courts and scholars have suggested that the traditional “rule of reason” analysis is not a good fit for practices that would be unlawful *per se*, but for the presence of a patent claim.⁶⁶ Others, including the FTC and other scholars,⁶⁷

⁵⁷ 15 U.S.C. § 1 (2012). Section 2 further states that “every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nation, shall be guilty of a felony.” *Id.* § 2.

⁵⁸ *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *Texaco, Inc. v. Dagher*, 547 U.S. 1, 5 (2006).

⁵⁹ *Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 344 (1982) (stating that a finding of *per se* unlawfulness “is appropriate once experience with a particular type of restraint enables the Court to predict with confidence that the rule of reason will condemn it”); *see also* *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972) (observing that an agreement between competitors to allocate territories is a *per se* violation of the Sherman Act).

⁶⁰ *Texaco*, 547 U.S. at 5. Under the law of the Second Circuit, the rule of reason analysis is a three-step process:

First, the plaintiff bears the initial burden of showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. Then, if the plaintiff succeeds, the burden shifts to the defendant to establish the pro-competitive redeeming virtues of the action. Should the defendant carry this burden, the plaintiff must then show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.

Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir. 1997).

⁶¹ *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003).

⁶² *See* 35 U.S.C. § 154(a) (2012); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) (“[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.”).

⁶³ *See* 35 U.S.C. § 271(a).

⁶⁴ *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000).

⁶⁵ *See* 35 U.S.C. § 261 (providing that a patent is assignable in law).

⁶⁶ Hovenkamp, Janis & Lemley, *supra* note 1, at 1725.

⁶⁷ Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 60 (2010) (explaining that reverse payment settlements have been

have vigorously argued for scrutiny of these settlements under antitrust law. Although such settlements may induce earlier patent expiration, they also “reduce expected static consumer welfare.”⁶⁸

II. ANALYSIS

While each settlement has different terms, the general parameters are quite similar across all settlements. This section discusses the conflict among the Federal Courts of Appeals in reaction to such settlements, and analyzes how the FTC antitrust challenges to those settlements were unsuccessful.

A. The Sixth Circuit (2003): Per Se Illegal

The United States Court of Appeals for the Sixth Circuit addressed the issues involving one of the first reverse payment settlements that attracted significant public scrutiny.⁶⁹ Hoechst Marion Roussel, Inc. (“HMR”) was the licensee of the formulation patent that describes the “dissolution profile” of Cardizem CD, a prescription drug used for treating angina and hypertension and preventing heart attacks.⁷⁰ The dissolution profile claimed by this formulation patent was for zero to forty-five percent of the total Cardizem CD to be released within eighteen hours (“45%-18”).⁷¹

Andrx Pharmaceuticals, Inc. (“Andrx”) filed an ANDA application with a Paragraph IV certification as a first filer, stating that its generic product did not infringe any of HMR’s patents listed in the FDA.⁷² Specifically, the dissolution profile for Andrx’s generic product was not less than fifty-five percent of total Cardizem CD released within eighteen hours (“55%-18”).⁷³ Despite the differences in the dissolution profile for each product, HMR nonetheless continued its patent infringement litigation against Andrx.⁷⁴

During the thirty-month stay period, HMR and Andrx entered into a settlement agreement.⁷⁵ In exchange for Andrx’s delayed market entry, HMR agreed to pay Andrx \$40 million per year, paid quarterly, beginning from the date when the statutory thirty-month stay expired to the date when such a final unappealable

challenged by private litigants, the FTC, and the DOJ, and that reverse payment settlements are agreement that unreasonably restrain trade in violation of Section 1 of the Sherman Act).

⁶⁸ See *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1061 (11th Cir. 2005) (“The FTC alleged that Schering’s settlement . . . were illegal agreements in restraint of trade, . . . in violation of Section 1 of the Sherman Act, . . . [and] also charged that Schering monopolized and conspired to monopolize the potassium supplement market.”); Hemphill, *supra* note 43, at 652–53 (finding that the 18 of 25 generic manufacturers retained their full 180-day exclusivity period by agreeing to pre-expiration entry date of more than 180 days).

⁶⁹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 869, 901–02 (6th Cir. 2003).

⁷⁰ *Id.* at 901.

⁷¹ *Id.* at 902.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

ruling was rendered in Andrx's favor.⁷⁶ The agreement further provided that Andrx would receive a final payment of \$100 million, less any interim payments, if the litigation were terminated without a finding of infringement.⁷⁷ About a year after the thirty-month stay expired, the litigation was finally settled without a finding of infringement, and Andrx received \$89.83 million in total while retaining the benefit of the 180-day market exclusivity.⁷⁸

The direct and indirect purchasers and other putative class representatives challenged the legality of the agreements under antitrust law.⁷⁹ According to the Sixth Circuit, the agreement guaranteed HMR exclusive access to the market even after Andrx obtained the FDA's final approval of its generic drugs.⁸⁰ As such, the court upheld the district court's ruling 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."⁸¹

B. The Eleventh Circuit (2003): Not Per Se Illegal

At about the same time the Sixth Circuit reviewed the agreements between HMR and Andrx, the Eleventh Circuit reviewed settlements between Abbott Laboratories ("Abbott") and a generic manufacturer, Geneva Pharmaceuticals ("Geneva"), concerning the hypertension and prostate drug Hytrin.⁸² Geneva filed a Paragraph IV certification as a first ANDA filer with respect to Abbott's patents and Abbott subsequently sued Geneva for infringement.⁸³ The parties eventually settled.⁸⁴

⁷⁶ *Id.*

Andrx would not market a bioequivalent or generic version of Cardizem CD in the United States until the earliest of: (1) Andrx obtaining a favorable, final and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; or (3) HMR entering into a license agreement with a third party. Andrx also agreed to dismiss its antitrust and unfair competition counterclaims, to diligently prosecute its ANDA, and to not "relinquish or otherwise compromise any right accruing thereunder or pertaining thereto," including its 180-day period of exclusivity.

Id.

⁷⁷ *Id.* at 903.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 907.

⁸¹ *Id.* at 908 (emphasis in original). The petition for certiorari was subsequently denied by the U.S. Supreme Court. *Andrx Pharms., Inc. v. Kroger Co.*, 125 S. Ct. 307 (2004), *petition for cert. denied*, 73 U.S.L.W. 3236 (Oct. 12, 2004) (No. 03-779).

⁸² *Valley Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294, 1298–99 (11th Cir. 2003).

⁸³ *Id.* at 1298–99. Another party, Zenith Goldline Pharmaceuticals ("Zenith"), was involved in the lawsuit. *Id.* at 1299. Eventually, Zenith agreed not to sell or distribute its generic version of Hytrin "until someone else introduced a generic [Hytrin] product first or until Abbott's patent . . . expired." *Id.* at 1300.

⁸⁴ *Id.* at 1300.

In the settlement, Geneva agreed not to sell or distribute any product containing Abbott's patented forms of Hytrin until the patents expired, another party introduced a generic drug, or a final unappealable judgment issued that the patents were invalid.⁸⁵ In return, Abbott would pay Geneva \$4.5 million each month until the agreement terminated by its own terms.⁸⁶

A group of plaintiffs filed an antitrust action against these agreements.⁸⁷ While recognizing that an agreement between competitors to allocate markets is clearly anticompetitive, the Eleventh Circuit rejected the district court's (as well as the Sixth Circuit's) characterization of the agreements as illegal *per se* because one of the parties owned a patent.⁸⁸ The court rested its decision on patent law's grant to the patent owner the right to exclude others.⁸⁹ Thus, the exclusionary effects of the agreements "cannot trigger the *per se* label because these are at the heart of the patent right."⁹⁰

In so holding, the court emphasized that "the mere subsequent declaration of invalidity [did] not render the patent irrelevant to the appropriate antitrust analysis" as long as a settlement was made "reasonably within the scope of the patent."⁹¹ Even a large reverse payment would not necessarily suggest a weak patent because, "[g]iven the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement."⁹² The court remanded the case for the lower court to consider these issues.⁹³

C. The Second Circuit (2006): Presumptively Lawful

In 2006, the Second Circuit faced the reverse payment settlement that involved a blockbuster cancer drug, tamoxifen.⁹⁴ Zeneca, Inc. sued in response to Barr's Paragraph IV certification, but lost in the district court, which declared the patent invalid.⁹⁵

⁸⁵ *Id.* A final unappealable judgment included not only the judgment from the district court, but also the petition for certiorari to the Supreme Court. *Id.*

⁸⁶ *Id.* Ultimately, Abbott lost the suit against Geneva when Federal Circuit affirmed the district court's judgment of invalidity, and the Supreme Court subsequently denied Abbott's petition for certiorari. *Abbott Labs. v. Geneva Pharms., Inc.*, Nos. 96 C 3331, 96 C 5868, 97 C 7587, 1998 U.S. Dist. LEXIS 13864, at *24 (N.D. Ill. Aug. 28, 1998) (declaring the '207 patent invalid); *Abbott Labs. v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999) (upholding the invalidity).

⁸⁷ *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1301 (11th Cir. 2003).

⁸⁸ *Id.* at 1304.

⁸⁹ *Id.*

⁹⁰ *Id.* at 1306.

⁹¹ *Id.* (recognizing, however, that prohibiting the marketing of non-infringing products would expose the patent holder to antitrust liability).

⁹² *Id.* at 1310.

⁹³ *Id.* at 1312.

⁹⁴ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193 (2d Cir. 2006).

⁹⁵ *Id.* at 193. The district court held that tamoxifen patent was invalid because ICI had deliberately withheld "crucial information" from the USPTO regarding the clinical test results. *Imperial Chem. Indus., PLC v. Barr Labs., Inc. (Tamoxifen I)*, 795 F. Supp. 619, 626-27 (S.D.N.Y. 1992). ICI subsequently appealed the district court's ruling to the United States Court of Appeals

While the appeal was pending, Zeneca and Barr entered into a settlement agreement.⁹⁶ Similar to other reverse payment settlements, Barr agreed to not market its own generic version of tamoxifen until Zeneca's patent expired in 2002. An unappealable judgment was rendered in favor of Barr, with Barr retaining the 180-day exclusivity period.⁹⁷ In return, Barr was not only paid \$21 million, but also received a non-exclusive license to sell Zeneca-manufactured tamoxifen.⁹⁸

The parties further filed a "Joint Motion to Dismiss the Appeals as Moot and to Vacate the Judgment Below," which was granted by the Federal Circuit.⁹⁹ Consequently, Zeneca's patent remained valid.¹⁰⁰ Thereafter, three other generic manufacturers filed ANDAs with Paragraph IV certifications to challenge the validity, but the courts upheld the validity of Zeneca's tamoxifen patent.¹⁰¹

Unlike the plaintiffs in *Valley Drug* and *In re Cardizem*, the plaintiffs here did not argue that the agreements were *per se* illegal.¹⁰² Rather, they argued that the tamoxifen patent was unenforceable at the time of the settlement because the district court declared it invalid, and the payment offered by Zeneca to Barr was "excessive," and therefore, anti-competitive.¹⁰³

The Second Circuit disagreed.¹⁰⁴ First, the agreement made after the district court's ruling against Zeneca was legitimate because the risk of losing on appeal may induce both parties to settle before the appeal is decided.¹⁰⁵ Next, the court held the agreement was not excessive because under the circumstances of a Paragraph IV certification, "the ANDA filer might well have the whip hand."¹⁰⁶

Further, the court rejected the notion that reverse payment settlements are *per se* violations of the Sherman Act, and agreed with the Eleventh Circuit that those settlements do not violate antitrust law "unless the 'the exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'"¹⁰⁷ The court ruled that the agreement between Zeneca and Barr did not exceed the scope of the patent because the agreement: (1) did not restrain Barr's marketing of non-infringing products

for the Federal Circuit. *In re Tamoxifen Citrate Antitrust Litig. (Tomoxifen II)*, 277 F. Supp. 2d 121, 125 (E.D.N.Y. 2003).

⁹⁶ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 193.

⁹⁷ *Id.* at 193.

⁹⁸ *Id.* at 193. Under this agreement, Barr was licensed to sell Zeneca-manufactured tamoxifen under its own label, rather than Zeneca's trademark Nolvadex®. *Id.*

⁹⁹ *Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, No. 92-1403, 1993 U.S. App. LEXIS 14872, at *1-3 (Fed. Cir. Mar. 19, 1993). Such a vacatur was shortly thereafter held to be invalid in nearly all circumstances by the Supreme Court. *See U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 27-29 (1994). However, the *U.S. Bancorp* rule does not apply retroactively, meaning that it did not apply in this case. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 194.

¹⁰⁰ *Imperial Chem. Indus.*, 1993 U.S. App. LEXIS 14872, at *3.

¹⁰¹ *Zeneca Ltd. v. Novopharm Ltd.*, No. 96-1364, 1997 U.S. App. LEXIS 6634, at *4-11 (Fed. Cir. Apr. 10, 1997); *Zeneca Ltd. v. Pharmachemie B.V.*, No. 96-12413, 2000 U.S. Dist. LEXIS 22631, at *51-53 (D. Mass. Sept. 11, 2000); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 196.

¹⁰² *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208 (2d Cir. 2006).

¹⁰³ *Id.* at 202-08.

¹⁰⁴ *Id.* at 202-20.

¹⁰⁵ *Id.* at 205. Further, the subsequent validation of the tamoxifen patent supported the court's ruling. *Id.* at 204.

¹⁰⁶ *Id.* at 210.

¹⁰⁷ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212 (2d Cir. 2006).

because it was a composition patent;¹⁰⁸ (2) did not prevent other generic manufacturers from challenging the patent;¹⁰⁹ and (3) did not entirely foreclose competition for tamoxifen because it had added a competitor to the market by licensing tamoxifen to Barr.¹¹⁰ Accordingly, it upheld the district court's judgment that the agreement did not violate antitrust law.¹¹¹

D. The Federal Circuit ("Ciprofloxacin I") and the Second Circuit ("Ciprofloxacin II"): Presumptively Lawful When Within Patent's Exclusionary Power

Plaintiffs consisting of direct and indirect purchasers of Bayer's patented ciprofloxacin hydrochloride ("Cipro") alleged that an agreement between Bayer AG and Barr violated antitrust law.¹¹² The United States District Court for the Eastern District of New York found no violation, and the plaintiffs appealed. The Second Circuit retained jurisdiction over the direct purchaser plaintiffs' appeals ("Ciprofloxacin II"), but transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit due to amendments in their complaints ("Ciprofloxacin I").¹¹³ Thus, the facts involving the reverse payment settlements at issue were the same in both cases.¹¹⁴

In response to Barr's ANDA application with Paragraph IV certification, Bayer brought the patent infringement action against Barr.¹¹⁵ Just before trial, Bayer and Barr entered into a settlement agreement.¹¹⁶ In that settlement, Bayer agreed to pay Barr \$398.1 million in exchange for Barr's agreement that it would delay its market entry until at least six months before the Cipro patent expired.¹¹⁷ Subsequently, Bayer filed for reexamination with the USPTO, which reaffirmed the Cipro patent's validity.¹¹⁸ Thereafter, Bayer defeated four other generic manufacturers' Paragraph IV certification challenges to its Cipro patent.¹¹⁹

¹⁰⁸ *Id.* at 213–14.

¹⁰⁹ *Id.* at 214–15.

¹¹⁰ *Id.* at 215.

¹¹¹ *Id.* at 220.

¹¹² See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 740, 745 (E.D.N.Y. 2001).

¹¹³ Ark. Carpenters Health & Welfare Fund v. Bayer AG (*Ciprofloxacin II*), 604 F.3d 98, 103 (2d Cir. 2010). "The Indirect purchaser plaintiffs amended their complaint to add . . . Walker Process antitrust . . . which recognized an antitrust claim when patents are obtained by fraud." *Id.* Because the Walker Process claims are subject to exclusive federal court jurisdiction under 28 U.S.C. § 1338(a), these claims were transferred to the Federal Circuit. *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Ciprofloxacin I)*, 544 F.3d 1323, 1330 (Fed. Cir. 2008).

¹¹⁴ *Ciprofloxacin II*, 604 F.3d at 103.

¹¹⁵ *Ciprofloxacin I*, 544 F.3d at 1328.

¹¹⁶ *Id.* at 1328.

¹¹⁷ *Id.* at 1329.

¹¹⁸ *Id.* Reexamination of an issued patent during its effective term is available so long as a "substantial new question of patentability" exists. 35 U.S.C. § 303(a) (2012).

¹¹⁹ Bayer AG v. Schein Pharm., Inc., 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002) (finding the Cipro patent not invalid); Bayer AG v. Carlsbad Tech., Inc., No. 01CV0867-B, 2002 U.S. Dist. LEXIS 27830, at *54 (S.D. Cal. Aug 7, 2002) (holding in favor of infringement).

In Ciprofloxacin I, the Federal Circuit, considering the indirect purchasers' appeal, rejected the Sixth Circuit's *per se* illegal approach to reverse payment settlements, and adopted the Second Circuit's view that "the presence of a reverse payment, or the size of a reverse payment, alone is not enough to render an agreement violative of the antitrust laws unless the anticompetitive effects of the agreement exceed the scope of the patent's protection."¹²⁰ It further agreed with the Second and Eleventh Circuits that, "in the absence of evidence of fraud . . . or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a [reverse payment settlement]."¹²¹ Accordingly, the Federal Circuit affirmed the district court's judgment by holding that the agreements between Bayer and Barr did not violate antitrust law because all anticompetitive effects were within the exclusionary power of the Cipro patent.¹²²

In Ciprofloxacin II, the Second Circuit, considering the direct purchasers' appeals, also upheld the district court's ruling that there was no violation of antitrust law in the agreement between Bayer and Barr.¹²³ By analyzing under the standard adopted in *In re Tamoxifen*, the Ciprofloxacin II court found that the agreement: (1) did not restrict the marketing of non-infringing products because Bayer had a compound patent;¹²⁴ (2) allowed other generic manufacturers to subsequently challenge the Cipro patent, all of which Bayer had defeated;¹²⁵ and (3) did not entirely foreclose competition because it had guaranteed Barr a license beginning at least six months before the Cipro patent expired.¹²⁶ Accordingly, this court held that the agreement did not violate antitrust law because it did not exceed the scope of the Cipro patent.¹²⁷ At the end of the opinion, the panel "invite[d] plaintiffs-appellants to petition for . . . rehearing [en banc]"; nonetheless, the Second Circuit declined to reconsider its decision.¹²⁸

E. The Third Circuit (2012): Rejecting the "Scope of the Patent" Test

The Third Circuit's decision of *In re K-Dur Antitrust Litigation* concerned the same agreement considered by the Eleventh Circuit in *Schering-Plough Corporations v. Federal Trade Commission*.¹²⁹ Schering had a formulation patent on a controlled release coating which is applied to potassium chloride crystals. Generic manufacturers Upsher and ESI Lederle ("ESI") filed separate ANDA applications with Paragraph IV certifications. They claimed their generics would not infringe

¹²⁰ *Ciprofloxacin I*, 544 F.3d 1323, 1335–36 (adopting the *In re Tamoxifen* standard).

¹²¹ *Id.* at 1336.

¹²² *Id.* at 1340.

¹²³ *Ciprofloxacin II*, 604 F.3d 98, 106 (2d Cir. 2010).

¹²⁴ *Id.* at 106.

¹²⁵ *Id.* at 107.

¹²⁶ *Id.* at 102.

¹²⁷ *Id.* at 110.

¹²⁸ *Ciprofloxacin II*, 604 F.3d 98, 110 (2d Cir. 2010), *rehearing en banc denied*, *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011).

¹²⁹ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 207 (3d Cir. 2012).

Schering's patent because their products contained a different chemical composition of the controlled release coating than Schering's patented product.¹³⁰

The generic manufacturers settled with Schering separately, but with similar terms: In exchange for cash, they would refrain from marketing their generic version of K-Dur or any similar product until a certain period, at which point they would receive a royalty-free non-exclusive license from Schering.¹³¹

Unlike the recent approaches from most of the U.S. Courts of Appeals, the Third Circuit squarely rejected the "scope of the patent" test and held that reverse payment settlements are presumptively unlawful under U.S. antitrust laws, subject to two exceptions.¹³² Such settlements are only lawful if: (1) parties show that the payment was for a purpose other than delayed entry or (2) the agreement offers some pro-competitive benefit.¹³³

According to the court, the problem of the "scope of the patent" test was its "almost un rebuttable presumption of patent validity."¹³⁴ It reiterated that "a patent [is] simply . . . a legal conclusion reached by [sic] Patent Office" that could be invalidated easily by the court.¹³⁵ Further, it reasoned that the "scope of the patent" test undermined the goal of the Hatch-Waxman Act because it reduced the availability of low cost generic drugs.¹³⁶ The court remanded for further proceedings.¹³⁷

F. The FTC's Rationale and the Responses from the U.S. Courts of Appeals

In *Schering-Plough Corp. v. Federal Trade Commission*, the FTC directly challenged the legality of several reverse payment settlements between brand-name and generic manufacturers.¹³⁸

¹³⁰ *Id.* at 205–06. Upsher argued that its product did not infringe Schering's patent because its generic product's chemical composition of the controlled release coating is different from that of Schering's patent. *Id.* at 205. Meanwhile, ESI argued that, unlike K-Dur, its generic product was made by a "different technology with produces a multi-layered coating with each layer comprised of a separate material having only a single ingredient." *Id.* at 206.

¹³¹ *Id.* at 205–06. Schering promised to pay Upsher \$60 million over three years, and promised to pay ESI an amount ranging from \$5.625 million to a maximum of \$15 million. *Id.*

¹³² *Id.* at 218.

¹³³ *Id.*

¹³⁴ *Id.* at 214.

¹³⁵ *Id.* at 215. A FTC study conducted in 2002 showed that about seventy-three percent of the generic manufacturers prevailed in the Hatch-Waxman litigation with the Paragraph IV certifications. See FTC GENERIC DRUG ENTRY STUDY, *supra* note 21, at 16.

¹³⁶ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (3d Cir. 2012). Further, the court recognized the judicial preference for settlement; however, it concluded that the reverse payment settlements are the only patent settlement that requires antitrust scrutiny. *Id.* at 218.

¹³⁷ *Id.* at 218. The Third Circuit directed the District Court on remand to apply a "quick look rule of reason" analysis. *Id.*

¹³⁸ *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1061 (11th Cir. 2005).

The Commission prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities. Nevertheless, the Commission carved out one arbitrary exception for payments to the generic: beyond a "simple compromise" to the entry date, if payments can be linked to litigation costs (not to exceed \$2 million), and

The Eleventh Circuit criticized the FTC's low threshold for demonstrating the anticompetitive nature of the agreements, which only required evidence of a detrimental market effect.¹³⁹ Because both the rule of reason and the *per se* analysis seek to determine whether the challenged conduct had an anticompetitive effect on the market, it held "both approaches to be ill-suited for an antitrust analysis of patent cases."¹⁴⁰

Further, the Hatch-Waxman process has enabled generic manufacturers to challenge the validity of a patent "without incurring the cost of entry or risking enormous damages flowing from any possible infringement."¹⁴¹ As such, the court concluded that "reverse payments are a natural by-product of the Hatch-Waxman process."¹⁴² "If settlement negotiations fail and the patentee prevails in its suit, competition would be prevented to the same or an even greater extent because the generic could not enter the market prior to the expiration of the patent."¹⁴³ As discussed above, other U.S. Courts of Appeals have adopted the reasoning of this case.¹⁴⁴

Recently, the Eleventh Circuit denied another FTC challenge to a reverse payment settlement that involved a formulation patent for synthetic testosterone.¹⁴⁵ The Eleventh Circuit rejected the FTC's argument that the settlement violated antitrust law because the patent owner was "not likely to prevail" in the underlying infringement action, and reasoned, "it is simply not true that an infringement claim that is 'likely' to fail actually will fail."¹⁴⁶ It further stated that "Congress has given . . . the Federal Circuit exclusive appellate jurisdiction over patent cases" and the Eleventh Circuit and other non-specialized circuit courts are "ill-equipped to make a judgment about the merits of a patent infringement claim."¹⁴⁷ Lastly, the court suggested that "[i]f the patent actually is vulnerable, then presumably other generic companies . . . will attempt to enter the market and make their own challenges to the patent."¹⁴⁸

the Commission is notified of the settlement, then the parties need not worry about a later antitrust attack.

Id. at 1062.

¹³⁹ *Id.* at 1065.

¹⁴⁰ *Id.* at 1065.

¹⁴¹ *Id.* at 1074.

¹⁴² *Id.* at 1075.

¹⁴³ *Id.*

¹⁴⁴ See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2003); *Ciprofloxacin I*, 544 F.3d 1323 (Fed. Cir. 2008); *Ciprofloxacin II*, 604 F.3d 98 (2d Cir. 2010).

¹⁴⁵ Fed. Trade Comm'n v. Watson Pharms., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012). A prior patent covering the synthetic testosterone used in AndroGel had expired, but a patent for a particular gel formulation of it was issued. *Id.* This patent is set to expire in August 2020. *Id.* at 1304.

¹⁴⁶ *Id.* at 1312. "Likely" means more likely than not, which includes a 51% chance of a result one way and a 49% chance of a result on the other way. *Id.* The court rejected the FTC's "not likely to prevail" standard because "a chance is only a chance, not a certainty." *Id.* at 1313.

¹⁴⁷ *Id.* at 1314.

¹⁴⁸ *Id.* at 1315.

G. The Scholars' Debate

As the decisions from the U.S. Courts of Appeals suggest, reverse payment settlements have created significant tension between the exclusionary nature of patents and the anti-competitive nature of these settlements.¹⁴⁹ Not surprisingly, the tension due to the lack of consistency afforded by the courts has drawn the attention of a number of prominent intellectual property and competition law scholars.¹⁵⁰

Professors Herbert Hovenkamp, Mark Janis, and Mark A. Lemley have suggested a rule that reverse payment settlements should be “presumptively unlawful, shifting the burden of proof to the [settling parties].”¹⁵¹ Then, the settling patentee must show: (1) “that the *ex ante* likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size for the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.”¹⁵²

However, Professor Thomas F. Cotter suggested the impossibility of assessing patent strength *ex ante*.¹⁵³ While Professor Cotter believes that Professors Hovenkamp, Janis, and Lemley’s test is helpful, “requiring antitrust tribunals to scrutinize the merits of a settled IP dispute threatens to unravel the substantial private and social benefits to which the settlement gives rise, including the reduction in litigation costs that settlement generally promotes.”¹⁵⁴ Further, in some cases, settlements that exceed the value of litigation costs could also be pro-competitive.¹⁵⁵ In Professor Cotter’s view, the validity of a patent could be measured by the use of the settlement amount, thereby subjecting it to antitrust scrutiny, because “higher [reverse] payments are consistent with a high probability of success, and low payments are consistent with a low probability of success.”¹⁵⁶

Professor David W. Opderbeck strongly opposed Professor Cotter’s view on the use of the settlement amount as a proxy for patent validity because: (1) “many reverse payment settlements involve unrelated licenses, authorized generic sales, and other side deals . . . in lieu of monetary payments”; (2) unlike an ordinary patent case, the [ANDA] challenger faces no risk beyond litigation expenses; and (3) there is a possibility of multiple Paragraph IV challenges by different ANDA filers.¹⁵⁷ Instead, he has proposed the “Settlement Competition Index,” which provides a rough empirical gauge of the potential anticompetitive effects of the settlement.¹⁵⁸

¹⁴⁹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 901–02; *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1298–99 (11th Cir. 2003); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193 (2d Cir. 2006); *Ciprofloxacin I*, 544 F.3d 1323, 1330 (Fed. Cir. 2008); *Ciprofloxacin II*, 604 F.3d 98, 103 (2d Cir. 2010); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

¹⁵⁰ See Dolin, *supra* note 5, at 312.

¹⁵¹ Hovenkamp, Janis & Lemley, *supra* note 1, at 1759.

¹⁵² *Id.*

¹⁵³ Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1815 (2003).

¹⁵⁴ *Id.* at 1795.

¹⁵⁵ *Id.* at 1802–09 (“[P]er se treatment of reverse payment settlements is inappropriate, because these agreements also have some potential to enhance rather than impede efficiency.”).

¹⁵⁶ *Id.* at 1814.

¹⁵⁷ Opderbeck, *supra* note 5, at 1325–28.

¹⁵⁸ See *id.* at 1329.

Professor Gregory Dolin took a somewhat different tack after reviewing disagreements between the courts and scholars.¹⁵⁹ Although a valid patent does not give the patentee any exemption from antitrust law, “the essence of a patent grant is the right to exclude others.”¹⁶⁰ According to Professor Dolin, the question “ultimately turns on the validity of a patent, not on any payment from the patentee to the challenger.”¹⁶¹ Thus, he suggested that patent law, instead of antitrust law, would be a far better instrument to address the issues involving reverse payment settlements such as reexamination proceedings.¹⁶²

In theory, reexamination is a cost-effective process with a lower standard of proof to challenge a patent because there is no presumption of validity of the patent.¹⁶³ Further, the Patent Act authorizes “[a]ny person at any time [to] file a request for reexamination by the Office of any claim of a patent on the basis of any prior art.”¹⁶⁴ Accordingly, Professor Dolin proposed that “any reverse settlement where the amount of money paid to the generic challenger exceeds reasonable litigation costs plus reasonable payments for any cross-licenses that are part of the agreement should be referred to the PTO [for reexamination].”¹⁶⁵

While this approach is quite solicitous of reverse payment settlements, it too presents significant problems. First, both *ex parte* and *inter partes* reexamination processes induce a burden on the third party requesters.¹⁶⁶ In *ex parte* reexamination, a third party requester cannot appeal the decision.¹⁶⁷ Although an appeal is allowed in *inter partes* reexamination, the third party is estopped from raising issues in subsequent civil litigation that he “raised or could have raised” in the reexamination.¹⁶⁸ Thus, the process may deter third parties from pursuing these proceedings.¹⁶⁹ Second, the success rate for complete invalidation is very low: only

¹⁵⁹ See Dolin, *supra* note 5, at 318.

¹⁶⁰ *Id.* at 318 (quoting *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980)).

¹⁶¹ *Id.*

¹⁶² *Id.* at 318–19.

¹⁶³ *Id.* at 319. At trial, the patentee enjoys the presumption that the patent at issue is valid. *Id.* In a reexamination proceeding at USPTO, on the other hand, there is no presumption of validity because the reexamination “departs from the same starting point as the original examination.” *Id.* Thus, any person may submit a request for reexamination including the patentee or a third party. *Id.* For example, the patentee may seek reexamination of an issued patent when he is faced with a validity challenge and prefers to litigate the issue before the agency, where the cost is much lower. *Ciprofloxacin I*, 544 F.3d 1323, 1329 (Fed. Cir. 2008) (Bayer cancelled and amended certain claims to re-validate its existing Cipro patent).

¹⁶⁴ 35 U.S.C. § 302 (2012). The person who is challenging the validity of a patent must identify the prior art that he believes is relevant, and that raises a “substantial new question of patentability.” *Id.*

¹⁶⁵ Dolin, *supra* note 5, at 324.

¹⁶⁶ See 35 U.S.C. §§ 301–07 (*ex parte* reexamination); 35 U.S.C. §§ 311–18 (*inter partes* reexamination).

¹⁶⁷ 35 U.S.C. § 306.

¹⁶⁸ 35 U.S.C. § 315(c).

¹⁶⁹ Between the years 1999 and 2009, only seventy-seven *inter partes* reexamination certificates were issued. See COMM’R FOR PATENTS, U.S. PATENT & TRADEMARK OFFICE, INTER PARTES REEXAMINATION FILING DATA (June 30, 2009), available at http://www.uspto.gov/web/patents/documents/inter_partes.pdf. In contrast, 6908 *ex parte* reexamination certificates were issued between 1981 and 2009. See COMM’R FOR PATENTS, U.S. PATENT & TRADEMARK OFFICE, EX PARTE REEXAMINATION FILING DATA 2 (June 30, 2009), available at http://www.uspto.gov/web/patents/documents/ex_parte.pdf.

11% of the 6908 *ex parte* reexaminations resulted in the patent being invalidated,¹⁷⁰ while 60% of the 77 *inter partes* reexaminations resulted in the same.¹⁷¹ Although the vast majority of reexaminations result in amendment of the claims (64% in *ex parte* and 35% in *inter partes*), patentees could easily and readily amend the claims to avoid prior art but still include the challengers' infringing product.¹⁷²

III. PROPOSAL

As the decisions from the U.S. Courts of Appeals and the scholars' debates suggest, courts have consistently struggled to apply appropriate laws or tests when they are confronted with the issues involving reverse payment settlements.¹⁷³ The lack of a national standard has created inconsistencies in court rulings over the past decade. Thus, the U.S. Supreme Court finally agreed to review an antitrust challenge to reverse payment settlements and granted certiorari on December 7, 2012.¹⁷⁴

The inconsistency among the U.S. Courts of Appeals could be resolved by several means. For example, Congress could enact legislation to remove or modify the 180-day exclusivity period for the first ANDA filer.¹⁷⁵ Additionally, the United States Supreme Court could provide effective guidance on which law should govern when it involves reverse payment settlements.

This section proposes a set of rules that may guide the legislative branch and the United States Supreme Court in making decisions on reverse payment settlement issues. A suggestion to Congress is presented, which is followed by a set of rules and accompanying explanations for the U.S. Supreme Court to examine in reconciling differing court decisions.

A. A Suggestion to Congress

The legislature should consider adopting the FDA's former "successful defense" requirement. Complete removal of the 180-day exclusive period has been vigorously criticized.¹⁷⁶ Subsequent reactions from the legislative branch to address reverse settlement problems were also unsuccessful due to the lack of consistency in congressional findings.¹⁷⁷

¹⁷⁰ EX PARTE REEXAMINATION FILING DATA, *supra* note 169, at 2.

¹⁷¹ INTER PARTES REEXAMINATION FILING DATA, *supra* note 169.

¹⁷² EX PARTE REEXAMINATION FILING DATA, *supra* note 169, at 2; INTER PARTES REEXAMINATION FILING DATA, *supra* note 169.

¹⁷³ See Dolin, *supra* note 5, at 312.

¹⁷⁴ Fed. Trade Comm'n v. Watson Pharms., Inc., 133 S. Ct. 787 (2012), *petition for cert. granted*, 81 U.S.L.W. 3324 (U.S. Dec. 7, 2012) (No. 12-416).

¹⁷⁵ Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 516–19 (2007).

¹⁷⁶ *Id.* at 516–19. This complete removal of the 180-day exclusivity period did not attract attention very much because this exclusivity period is the essence of achieving Hatch-Waxman Act's very purpose: to provide incentives to challenge weak patents, thereby, to promote low drug prices to general public. *Id.*

¹⁷⁷ See Dolin, *supra* note 5, at 305–10. For example, Senator Herb Kohl introduced the Preserve Access to Affordable Generics Act. *Id.* at 306. In his newest version of the bill, the reverse

Prior to 1998, the FDA required a “successful defense” to ANDA filers who wanted to take advantage of the 180-day exclusivity period.¹⁷⁸ A first-filer would only retain its 180-day exclusivity period if it successfully defends against an infringement suit.¹⁷⁹ However, the FDA dropped its “successful defense” requirement after it was held to be an unreasonable interpretation of the Hatch-Waxman Act.¹⁸⁰ The court reasoned that the FDA’s “successful defense” requirement did not reflect the “unambiguously expressed intent of Congress.”¹⁸¹ While holding the requirement void, the Court, nonetheless, suggested that the “FDA could have adopted a more narrow solution to the problem of first applicants who are never sued or who lose their suits,” instead of adopting its broad rule.¹⁸²

This “successful defense” requirement would be a great starting point for the legislature to address the reverse payment settlement problems by narrowly tailoring it to specific circumstances. For example, Congress could amend the award of the 180-day exclusivity period contingent upon the “successful defense” of any subsequent ANDA filer. In other words, any ANDA filer who renders the patent at issue either invalid or unenforceable will be able to take the 180-day exclusivity period away from the first ANDA filer. Consistent with the primary purpose of the Hatch-Waxman Act, this proposal will encourage subsequent generic companies to attack the validity of patents that are settled by reverse payments. As the Eleventh Circuit stated, “[b]lood in the water can lead to a feeding frenzy.”¹⁸³

B. A Suggestion to the U.S. Supreme Court

The U.S. Supreme Court could provide a rigid rule on which law should govern in reverse payment settlement cases. Instead, the U.S. Supreme Court should reconcile the decisions from the U.S. Courts of Appeals by scrutinizing the details of the settlements because every settlement is different and should be decided on a case-by-case analysis.¹⁸⁴

For example, in *In re Cardizem*, the Sixth Circuit rendered the settlement illegal *per se* because it had prevented the generic manufacturer from marketing non-infringing products of a formulation patent, an agreement that clearly could be anticompetitive.¹⁸⁵ In contrast, the Second Circuit in *In re Tamoxifen* distinguished

payment settlements would be presumptively unlawful and anti-competitive, but the settling parties would be permitted to rebut the presumption by demonstrating the pro-competitive benefits by clear and convincing evidence. S. 369, 111th Cong. § 3(a)(2) (2009). Further, the Act suggested that any payment that does not exceed \$7.5 million is allowed to reimburse the ANDA filer “for reasonable litigation expenses.” *Id.*

¹⁷⁸ See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069–70 (D.C. Cir. 1998).

¹⁷⁹ 21 C.F.R. § 314.107(c)(1) (2013). In drafting the regulations implementing § 355(j)(5)(B)(iv), the FDA added its own requirement that the first applicant must have “successfully defended against a suit for patent infringement” before the exclusivity period can begin to run. *Id.*

¹⁸⁰ See *Mova Pharm.*, 140 F.3d at 1069–70 (D.C. Cir. 1998) (holding that the FDA’s “successful defense” requirement is inconsistent with the unambiguously expressed intent of Congress).

¹⁸¹ *Id.* at 1068.

¹⁸² *Id.* at 1069–70.

¹⁸³ *Fed. Trade Comm’n v. Watson Pharms., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012).

¹⁸⁴ See *supra* Part II.

¹⁸⁵ *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 908 (6th Cir. 2003).

the Sixth Circuit's decision and upheld the settlement because the tamoxifen patent was not a formulation patent; "rather, it [was] a patent on a compound that, by its nature, excludes all generic versions of the drug."¹⁸⁶ Further, by including a license from Zeneca to Barr, it actually added a competitor in the market.¹⁸⁷ Subsequent reverse settlements in Ciprofloxacin cases were held valid where the settlement not only involved a compound patent, but also gave licenses to generic companies.¹⁸⁸ Lastly, the Third Circuit held the settlement illegal in *In re K-Dur*.¹⁸⁹ The court voided the settlement that had prevented the generic company from marketing non-infringing products of a formulation patent, even though the settlement contained a licensing agreement.¹⁹⁰

Therefore, the U.S. Supreme Court should consider these differences in determining the legality of reverse payment settlements, and should consider the following set of rules.

First, a reverse payment settlement is presumed legal if it involves a licensing agreement on a compound patent. The only way to rebut this presumption of legality is to invalidate the patent under patent law.

Second, a reverse payment settlement is presumed illegal where it involves a formulation patent and entirely forecloses competition by preventing the generic manufacturers from marketing non-infringing products. A licensing agreement may rebut the presumption of illegality so long as marketing non-infringing products is not material to the parties or non-parties.

CONCLUSION

Tension between patent law and antitrust law surrounding reverse payment settlements is a natural by-product of the Hatch-Waxman Act. Patent law's right to exclude will likely clash with the pro-competitive nature of antitrust law. Although the Hatch-Waxman Act was enacted to eliminate weak patents and to bring cheaper drugs to the general public, this goal may be hindered by such settlements. Solely applying either patent law or antitrust law may result in harsh punishment for patent holders, competitors, and consumers. An ideal solution involves the accommodation of both laws by balancing the effects more appropriately among the parties. Thus, this comment offers a set of rules to guide the legislature and the Supreme Court in determining the legality of such reverse payment settlements.

¹⁸⁶ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 214 (2d Cir. 2006).

¹⁸⁷ *Id.* at 215.

¹⁸⁸ *Ciprofloxacin I*, 544 F.3d 1323, 1330 (Fed. Cir. 2008); *Ciprofloxacin II*, 604 F.3d 98, 103 (2d Cir. 2010).

¹⁸⁹ *In re K-Dur Antitrust Litig.*, 686 F.3d at 205–06 (3d Cir. 2012) (precluding "any sustained-release microencapsulated potassium chloride").

¹⁹⁰ *Id.*