

PHARMACEUTICAL REVERSE PAYMENT SETTLEMENT AGREEMENTS AND A PROPOSAL FOR CLARIFYING THE APPLICATION OF ANTITRUST LAW RULE OF REASON ANALYSIS TO THESE AGREEMENTS

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I. INTRODUCTION

Rising health care costs, especially in relation to prescription drugs, have been major concerns in the United States for several years. The media has recounted numerous stories of Americans forced to choose between buying food for their families or needed medicine. In 2012, Americans spent approximately \$325.8 billion dollars on medications.¹ However, in the same year some brand-name drugs lost patent protection or exclusivity, and consumers saved \$28.9 billion by using generic drugs instead of brand-name medicines.² For over a decade, there has been controversy concerning patent infringement disputes wherein patent-holding pharmaceutical companies pay generic drug manufacturers to refrain from marketing their generic drugs in exchange for payments of millions of dollars annually.³ These agreements, called reverse payment settlements, not only result in consumers overpaying for prescription drugs, but they also raise the question of whether such anticompetitive agreements violate antitrust laws.⁴

In late June 2013, the Supreme Court considered the issue in the case *FTC v. Actavis, Inc.*, and held that reverse payment settlements were not immunized from antitrust scrutiny and that rule of reason analysis is the appropriate standard for reviewing the legality of these settlements.⁵ However, rule of reason analysis is incredibly broad in application and could yield the same mix of results obtained before the Court decided *Actavis*. The following comment reviews the issues surrounding reverse payment settlement agreements.

First, the comment begins by providing background information on antitrust law, patent law, and the Hatch-Waxman Act, which was created to expedite generic drug entry into the pharmaceutical market. Next, the comment examines the major circuit cases that reviewed

¹ IMS INSTITUTE FOR HEALTHCARE INFORMATICS, *Declining Medicine Use and Costs: For Better or Worse? A Review of the Use of Medicines in the United States in 2012* (May 2013) at 1, <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=5b21ee0a8e631410VgnVCM10000076192ca2RCRD&vgnnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnnextfmt=default>.

² *Id.* at 8.

³ Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 255, 255 (2009).

⁴ *Id.*

⁵ *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2227, 2237 (2013).

reverse payment settlements, which demonstrate how these settlements have affected the pharmaceutical industry, and how competing policies in antitrust law and patent law led circuits to apply divergent analytical approaches when assessing the legality of these settlements. The comment then provides an explanation of the Supreme Court's decision in *F.T.C. v. Actavis* and why the Court's decision fails to correct the issues surrounding reverse payment settlements, and illustrates the need for Congress to provide clarity on how broadly or narrowly to apply rule of reason analysis. Lastly, the comment proposes content to be included in new statutory language.

II. OBJECTIVES IN OPPOSITION: ANTITRUST & PATENT LAW

Antitrust law and patent law seemingly have polar opposite objectives: promoting competition on the one hand and protecting exclusivity on the other. With regard to the former, among the various concerns of antitrust laws are: "(1) insuring the dispersion of economic power to protect legal, social, and political processes from undue economic power; (2) promoting freedom and opportunity to compete on the merits; (3) fostering the satisfaction of consumers and protecting their property and contract rights; and (4) protecting the competition process as market governor."⁶ Congress enacted the Sherman Act⁷ in 1890 to deter anticompetitive conduct such as price fixing, restricting the production or supply of goods, and market divisions among rivals.⁸ Other significant antitrust legislation followed: the Clayton and Federal Trade Commission Acts (1914), the Robinson-Patman Act (1936), and the Cellar-Kefauver Amendments to the Clayton Act (1950).⁹

Additionally, the antitrust laws seek to: foster equal market access;; ensure procedural due process in the relationships between market distributors and suppliers;; prevent monopolization and monopoly pricing;; prevent collusion among competitors regarding prices or restricting output;; redress possible imbalances in bargaining

⁶ John J. Flynn, *The Role of Rules in Antitrust Analysis*, 2006 UTAH L. REV. 605, 621 (2006)(internal citations omitted).

⁷ See 15 U.S.C. §§ 1-8 (2004).

⁸ PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW 13, 43-44 (4th ed., Vol. 1 2013).

⁹ HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 50 (3rd ed. 2005).

relationships; and decrease unjustified wealth transfers from consumers to producers.¹⁰

Patent law, a subset of the intellectual property laws, is concerned with conferring an entity with the sole right to make, use, or sell something.¹¹ The purpose of the intellectual property laws, as set forth by Article I, § 8 of the United States Constitution, is “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹² Patents are often in the public’s best interest because they promote new methods, ideas, and products by rewarding innovation and risk.¹³

Without patents, inventors have little incentive to spend the time and money necessary for the research and development of new works because imitators can copy; therefore, reducing or eliminating an invention’s profitability.¹⁴ However, too much protection can negatively affect a market: monopolies may develop; inventors may have to license or innovate around a patent-holder’s exclusive rights; and innovation may slow down because the barriers inventors face trying to improve upon and advance existing works.¹⁵ Pharmaceutical companies patent new advances in medicines in order to restrict competition and to recoup as much money as possible from their research efforts. However, the need to be competitive in a risky and costly industry can lead pharmaceutical companies to engage in practices that violate antitrust laws.

A. Antitrust Issues in the Pharmaceutical Industry

Several characteristics of the pharmaceutical industry make it highly susceptible to collusion, horizontal market allocation, and other antitrust violations.¹⁶ First, consumers buying prescription drugs generally have

¹⁰ Flynn, *supra* note 6, at 624 n.53.

¹¹ See ABA SECTION OF ANTITRUST LAW, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK 81 (2009)[hereinafter ABA, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK].

¹² HERBERT HOVENKAMP, THE ANTITRUST ENTERPRISE 249 (2005)(citing U.S. CONST. art. I, § 8).

¹³ HERBERT HOVENKAMP, THE ANTITRUST ENTERPRISE 249 (2005).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV.

serious conditions that make drug treatment a necessity, not a choice.¹⁷ Thus, demand in the market is relatively inelastic,¹⁸ meaning consumer demand changes little whether the price for a prescription drug is \$10 or \$100. Second, individuals with health insurance often only pay a portion of the cost of drug, which tends to obfuscate drug retail price.¹⁹ Third, pharmaceutical drugs are a highly specialized product, and there are usually only a few suitable substitutes, if any, for a specific ailment or condition.²⁰

Lastly, the barriers to enter the pharmaceutical market are substantial in that research and development costs are extremely high, and the risk-to-reward ratio is often unfavorable.²¹ Inevitably, many pharmaceutical companies engage in improper use of their patents or anticompetitive settlements or other license agreements with generic manufacturers in order to lessen competition²² for the purpose of extending their time in which to gain a return on investment.²³

B. Drug Regulation and the Hatch-Waxman Amendments

The Federal Food, Drug, and Cosmetic Act gives authority to the Food and Drug Administration (“FDA”) to regulate the manufacture, sale, and labeling of drugs.²⁴ To market a new drug, a manufacturer must first submit a New Drug Application (“NDA”) to the FDA for approval.²⁵ The NDA process is incredibly time-consuming and

11, 11 (2004).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.* at 18.

²³ Fed. Trade Comm’n Brief as Amicus Curiae, In re Effexor XR Antitrust Litig., No. 3:11-cv-05479, 2013 WL 5183029 at *5 (D.N.J. Sept. 13, 2013) (citing *Actavis*, 133 S. Ct. at 2234-35).

²⁴ 21 U.S.C.A. § 301 *et seq.* (West 2012).

²⁵ 21 U.S.C.A. § 355(b) (West 2012). Among the list of requirements, a NDA must contain: (A) reports of investigation to show whether the drug is safe and effective for use; (B) a list of the articles the drug’s components; (C) a statement of the drug’s composition; (D) a description of the methods, and facilities, and controls used for manufacturing, processing, and packing the drug; (E) drug samples; and (F) the proposed drug’s labeling. *Id.* at § 355(b)(1). Additionally, the application must state any patents issued on the drug’s composition or methods of use for which an applicant could assert a claim of patent

expensive, often taking several years and costing millions of dollars to complete the requisite clinical trials.²⁶ On average, pharmaceutical companies spend approximately five to ten years developing a new drug and the cost to develop one new medicine is roughly \$1.3 billion.²⁷ Moreover, “[f]or every 5,000 to 10,000 compounds tested, 250 undergo preclinical testing. Of these, five will go into clinical trials, and only one ultimately will receive approval from the [FDA].”²⁸

Further, generic drug manufacturers had an additional hurdle in that preclinical and clinical testing often required the patented drug ingredient be used in trials, and this testing often resulted in infringing conduct.²⁹ If the generic manufacturer could not conduct mandatory FDA testing until a brand name drug’s patent expired without risk of an infringement suit, no generic product would be able to enter the market until two or more years after the patent expired.³⁰ Recognizing the substantial barriers for generic manufacturers, Congress enacted the Drug Price Competition and Patent Term Restoration Act in 1984.³¹ The Act, known as the Hatch-Waxman Amendments, eased the market-entry process for generic drug manufacturers by establishing an expedited FDA approval process.³² The generic manufacturer may file an Abbreviated New Drug Application (“ANDA”) in which it establishes that its generic drug is the bioequivalent to the previously approved

infringement if an unlicensed person engaged in the manufacture, use, or sale of the drug. *Id.* The FDA publishes the patent information provided in NDAs in a publication entitled, “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as the “Orange Book,” which is available online at <http://www.fda.gov/cder/ob/default/cfm>. C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 951-52 (2011).

²⁶ Hemphill & Lemley, *supra* note 25, at 951 (internal citations omitted).

²⁷ ABA, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK, *supra* note 10, at 3 (citing PHARM. RESEARCH & MFRS. OF AM. (PHRMA), PHARMACEUTICAL INDUSTRY PROFILE 2008 2 (2008), available at <http://www.phrma.org/files/2008%20Profile.pdf>).

²⁸ ABA, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK, *supra* note 10, at 3.

²⁹ *Id.* at 82.

³⁰ *Id.*

³¹ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)(codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.); Hemphill & Lemley, *supra* note 25, at 989 n.1.

³² Hemphill & Lemley, *supra* note 25, at 947.

brand name drug.³³ Further, instead of requiring the generic manufacturer to perform clinical trials, the FDA relies on its prior determinations regarding the brand name drug's safety and efficacy when reviewing the generic drug's ANDA.³⁴

In addition, per Section 355(j)(2)(A)(vii), the generic manufacturer must certify that to its knowledge, the proposed generic drug did not infringe the brand name drug's patent(s).³⁵ There are four possible certification options: (I) the patent information has not been filed, (II) the patent has expired, (III) the date such patent will expire, or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.³⁶

If the generic manufacturer chooses the paragraph IV certification, it must provide notice to each listed patent owner that it is attempting to obtain approval from the FDA to manufacture, use, or sell its generic drug before the expiration of the patent(s) referred to in the certification.³⁷ The filing of the paragraph IV certification is considered an act of patent infringement,³⁸ which grants the patent holder(s) a 45-day window to file a patent infringement suit.³⁹ Filing a patent infringement suit triggers an automatic stay of the FDA approval process for either thirty months or until the court deciding the patent litigation rules the challenged patent is invalid or not infringed.⁴⁰

Further, the Hatch-Waxman Amendments encourage generic drug manufacturers to challenge existing drug patents by providing a reward to the first generic manufacturer who submits an ANDA and a paragraph IV certification: a 180-day exclusivity period beginning the first day it starts to commercially market its drug.⁴¹ During this time, the first ANDA applicant competes only with the brand name firm's drug

³³ *Id.* at 951 (citing 21 U.S.C. §§ 355(j)(8)(B), 355(j)(2)(A)).

³⁴ Hemphill & Lemley, *supra* note 25, at 951.

³⁵ 21 U.S.C. § 355(j)(2)(A)(vii); Hemphill & Lemley, *supra* note 25, at 952.

³⁶ 21 U.S.C. § 355(j)(2)(A)(vii).

³⁷ *Id.* at § 355(j)(2)(B)(iii)(I).

³⁸ Hemphill & Lemley, *supra* note 25, at 952 (citing 35 U.S.C. § 271(e)(2)(A)).

³⁹ 21 U.S.C. § 355(j)(5)(B)(iii).

⁴⁰ *Id.* at § 355(j)(5)(B)(iii)(I).

⁴¹ *Id.* at § 355(j)(5)(B)(iv); Hemphill & Lemley, *supra* note 25, at 953.

and no other generic drugs may enter the market.⁴² The only time the exclusivity period is granted to more than one company is if both companies are the first filers of a substantially complete ANDA containing a paragraph IV certification against any patent listed in the Orange Book for a product on the same day.⁴³ This is referred to as “shared exclusivity.”⁴⁴ However, subsequent filers, even though they may be the first to file paragraph IV certifications on other patents listed for the same product, are not entitled to exclusivity.⁴⁵

The Hatch-Waxman Amendments’ goals were to make lower-costing generic drugs more widely available,⁴⁶ and “to assure that there were adequate incentives to invest in the development of new drugs’ by extending the term of the innovator’s patent-protected exclusivity.”⁴⁷

There have been arguments that these incentives have increased pharmaceutical innovation, thereby benefitting consumers.⁴⁸ For instance, due to the threat of impending patent expiration and the possibility of easy generic entry into the market, brand name manufacturers research, develop, and market increasing numbers of new, improved drugs.⁴⁹ Further, without patents, people don’t appropriate returns on their innovation.⁵⁰ But patent rights can be used to stifle competition, which can adversely affect innovation in the long run.⁵¹

Balance between monetary incentives for patent owners and fostering innovation and competition is, indeed, key. Maintaining monetary incentives for patent owners is important because “[e]conomic theory predicts that the expectation of profits from new discoveries will

⁴² *Id.*

⁴³ ABA, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK, *supra* note 10, at 92.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ H.R. Rep. No. 98-857, pt. 1, at 14 (1984).

⁴⁷ David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 324 (2000)(citing Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389 (1999)).

⁴⁸ Balto, *supra* note 47, at 324.

⁴⁹ *Id.*

⁵⁰ *Id.* at 324-25 (citing *Hearings Before the FTC on Global and Innovation-Based Competition*, at 24-25 (Oct. 12, 1995) (testimony of Joseph E. Stiglitz)).

⁵¹ Balto, *supra* note 47, at 324-25.

induce investment in research, development, and testing. The available empirical evidence suggests that higher drug profits are indeed correlated with greater research and development efforts."⁵²

On the other hand, since the Hatch-Waxman Amendments went into effect, pharmaceutical patent owners have engaged in numerous questionable acts including: filing several patents on variations of the same drug, listing patents with the FDA that have no relation to the drug, exploiting litigation rules to delay generic entry, and making inconsequential changes to a drug timed specifically to create a barrier to impede a generic competitor's entry.⁵³ Most significantly, pharmaceutical patent owners have engaged in reverse payment settlements wherein they pay potential generic competitors to abandon their challenges.⁵⁴ These reverse payment settlements inevitably preserve weak patents and constrain competition.⁵⁵

Typically, these settlements also include exclusive licenses, field-of-use provisions,⁵⁶ and cross-licensing arrangements; agreements to prohibit licensing to third parties or in the alternative, to license only jointly; or horizontal territorial division.⁵⁷ Often, two potential competitors join together to control a market and keep prices inflated which harms competition and consumers.⁵⁸ Additionally, colluding reduces expensive litigation, the patent owner and accused infringer both share monopoly profits, and it keeps other potential competitors out of market.⁵⁹

The motivation to block new competitors from the market is tremendous because each additional generic that enters the market

⁵² C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1563 (2006) (citing Carmelo Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 195 (2005) (reporting positive correlation between profit and research spending)).

⁵³ Hemphill & Lemley, *supra* note 25, at 948.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ A field-of-use restriction is "[a] license provision restricting the licensee's use of the licensed property to a defined product or service market or to a designated geographic area." BLACK'S LAW DICTIONARY 702-703 (9th ed. 2009).

⁵⁷ Herbert Hovenkamp, Mark Janis, & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1721 (2003).

⁵⁸ *Id.* at 1721-22.

⁵⁹ *Id.* at 1722.

progressively brings down drug prices.⁶⁰ The first generic is priced at approximately 94% of the brand drug's price; a second generic reduces the price of the generics to roughly 52% of the brand drug's price; and with multiple generics, the price drops as low as 20% of the brand drug's price.⁶¹ Additionally, another significant problem with reverse payment settlements is that the first generic drug entrant retains their 180-day period of exclusivity, and no other generic drugs may enter the market until after the exclusivity period expires or is forfeited.⁶² The unused exclusivity period creates bottlenecks that are expensive and difficult for subsequent drug manufacturers to remove.⁶³

In 2012, the FTC reported forty settlements in which patent owners paid generic competitors to delay entering the market.⁶⁴ The FTC has filed numerous lawsuits to contest agreements wherein a generic manufacturer agrees not to compete in exchange for payments from a patent owner as unfair methods of competition, which has resulted in mixed outcomes largely due to the circuit courts applying varying antitrust analysis or no antitrust analysis when reviewing these agreements.⁶⁵ Eventually, a divergence emerged between the circuit courts, and it became apparent that the venue in which a lawsuit was filed was basically outcome-determinative.⁶⁶

⁶⁰ ABA, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK, *supra* note 10, at 7.

⁶¹ *Id.*

⁶² Hemphill & Lemley, *supra* note 25, at 948. Moreover, the ability to use the exclusivity period to exclude rivals often encourages generic manufacturers to enter into agreements that harm consumers. *Id.* at 948-49, 962-63.

⁶³ *Id.* at 963.

⁶⁴ Brief Amici Curiae Of 118 Law, Economics, and Business Professors and The American Antitrust Institute In Support Of Petitioners, Fed. Trade Comm'n v. Watson Pharm., Inc., et al., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 391001 at *4 (citing Bureau of Competition, FTC, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012, <http://www.ftc.gov/os/2013/01/130117mmareport.pdf>).

⁶⁵ Brief for Petitioner at 12-14, Fed. Trade Comm'n v. Watson Pharm., Inc., et al., 133 S. Ct. 2223 (2013) (No. 12-416), 2012 WL 4750283.

⁶⁶ Petition for Writ of Certiorari at 13, Watson Pharm., Inc., et al., 133 S. Ct. 2223 (2013) (No. 12-416), 2012 WL 4750283.

III. CIRCUITS WERE SPLIT REGARDING THE APPROPRIATE LEGAL STANDARD TO APPLY WHEN EVALUATING REVERSE PAYMENT SETTLEMENTS

A. Antitrust Standard

Section 1 of the Sherman Act prohibits contracts, combinations, and conspiracies that unreasonably restrain competition.⁶⁷ More specifically, this involves cartels and market division agreements, boycotts, and vertical restrictions often imposed from an upstream firm such as a manufacturer on downstream firms like dealers. Section 2 prohibits monopolization, attempted monopolization, and conspiracies to monopolize.⁶⁸ Although Section 1 of the Sherman Act prohibits “[e]very” agreement “in restraint of trade,” the Supreme Court has held that this provision outlaws only “undue” or “unreasonable” restraints on competition.⁶⁹ To determine whether a reverse settlement agreement has an adverse effect on competition, the courts may apply one of three traditional analytic standards: (1) the rule of reason, (2) the per se rule, or (3) the “quick look” rule of reason standard.⁷⁰ The modes of analysis are on a continuum: “[E]ach intended to require only the amount of examination and proof necessary to determine or predict the challenged conduct’s effect on competition.”⁷¹

B. Rule of Reason Analysis

Most agreements challenged under Section 1 of the Sherman Act are evaluated under the rule of reason analysis.⁷² Relevant factors include: (1) information regarding the business market in question; (2) competitive conditions in the market before and after the restraint was imposed; and

⁶⁷ ABA SECTION OF ANTITRUST LAW, ANTITRUST HANDBOOK 15 (4th ed. 2010)[hereinafter ABA, ANTITRUST HEALTH CARE HANDBOOK]; 15 U.S.C. § 1 (2004).

⁶⁸ ABA, ANTITRUST HEALTH CARE HANDBOOK, *supra* note 67, at 15; 15 U.S.C. § 2 (2004).

⁶⁹ ABA, ANTITRUST HEALTH CARE HANDBOOK, *supra* note 67, at 48; Standard Oil Co. of N.J. v. United States, 221 U.S. 1, 59-60, 87 (1911).

⁷⁰ ABA, ANTITRUST HEALTH CARE HANDBOOK, *supra* note 67, at 48.

⁷¹ *Id.* at 49.

⁷² In re K-Dur Antitrust Litig., 686 F.3d 197, 209 (2012) (citing State Oil v. Kahn, 522 U.S. 3, 10 (1997)).

(3) the restraint's history, nature, purpose, and effect.⁷³ There is a three-part test to determine whether a restraint is unreasonable: (1) a plaintiff must show that the challenged conduct has produced anti-competitive effects within the market; (2) the burden then shifts to the defendant to show that the challenged conduct has a procompetitive objective; and (3) a plaintiff can rebut the defendant's purported procompetitive justification by showing the restraint is not reasonably necessary.⁷⁴

To prove that the restraint has the requisite anticompetitive effect, the plaintiff must usually first show that the defendant has market power.⁷⁵ The plaintiff may prove market power either by direct evidence that the challenged conduct resulted in higher prices or lower quality, or by circumstantial evidence of market power—that the defendant's market share is large and that entry and expansion barriers prevent other potential and actual competitors from constraining the defendant's anticompetitive conduct.⁷⁶ However, a patent alone does not demonstrate market power over a commodity.⁷⁷ A patentee will not have market power if there are suitable substitutes for the patented product.⁷⁸ Additionally, patents are often "limited to a unique form or improvement of the product and the economic power resulting from the patent privileges is slight."⁷⁹ Therefore, courts must analyze facts on a case-by-case basis to determine whether a patentee indeed has market power over a commodity.⁸⁰

⁷³ *Id.*

⁷⁴ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 209 (2012) (citing *United States v. Brown Univ.*, 5 F.3d, 658, 668-69 (3d Cir. 1993)).

⁷⁵ ABA, ANTI-TRUST HEALTH CARE HANDBOOK, *supra* note 67, at 52. However, in *Actavis*, the Supreme Court stated that in the context of pharmaceutical reverse payment settlement agreements, market power may be inferred: "[T]he size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power . . ." Aaron Edlin et. al, *Activating Actavis*, 28 ANTI-TRUST 16, 17 & 21 n.20 (Fall 2013) (citing *Actavis*, 133 S. Ct. at 2236).

⁷⁶ ABA, ANTI-TRUST HEALTH CARE HANDBOOK, *supra* note 67, at 52-53.

⁷⁷ *Indep. Ink, Inc. v. Trident, Inc.*, 210 F. Supp. 2d 1155, 1163 (C.D. Cal. 2002) *aff'd in part, rev'd in part and remanded sub nom. Indep. Ink, Inc. v. Illinois Tool Works, Inc.*, 396 F.3d 1342 (Fed. Cir. 2005) *vacated and remanded sub nom. Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 126 S. Ct. 1281, 164 L. Ed. 2d 26 (2006)(citing *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 37 n.7 (1984)).

⁷⁸ *Id.*

⁷⁹ *Id.* (citing *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 10 (1958)).

⁸⁰ *Indep. Ink*, 210 F. Supp. at 1165.

C. Per Se Analysis

The second form of analysis, per se analysis, is applied to a specific group of anticompetitive conduct because “[s]ome types of restraints . . . have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit, that they are deemed unlawful per se.”⁸¹ “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.’”⁸² Price fixing, horizontal territorial division, output limitations, market allocation, and concerted refusals to deal (boycotts) are analyzed under the per se rule.⁸³

D. “Quick Look” Analysis

The last form of analysis, the “quick look” or “truncated rule of reason” is used when the plaintiff has shown that the defendant has engaged in a restraint similar to per se violations.⁸⁴ “If a plaintiff meets his initial burden of adducing adequate evidence of market power or actual anti-competitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective.”⁸⁵ The quick look is used where “the conduct entails concerted action among competitors that directly limits output or price competition—the type of agreements to which the per se rule would usually apply. The court will consider plausible procompetitive justifications for the conduct put forth by the defendants . . .”⁸⁶ If the defendant fails to show there is a substantial benefit, the per se rule is applied. However, if the defendant is successful, then the restraint is analyzed under the rule of reason.⁸⁷ “To rebut, the plaintiff must

⁸¹ *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (citing *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)).

⁸² *Khan*, 522 U.S. at 10 (quoting *Ariz. v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 344 (1982)).

⁸³ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 209 (2012) (citing *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *N. Pac. Ry. v. United States*, 356 U.S. 1, 5 (1958)).

⁸⁴ *In re K-Dur Antitrust Litig.*, 686 F.3d at 209.

⁸⁵ *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993).

⁸⁶ ABA, *ANTITRUST HEALTH CARE HANDBOOK*, *supra* note 67, at 54.

⁸⁷ *Id.* at 54-55.

demonstrate that the restraint is not reasonably necessary to achieve the stated objective.”⁸⁸

IV. THE CIRCUITS’ APPLICATION OF ANTITRUST STANDARDS UPON REVERSE PAYMENT SETTLEMENTS CASES

In total, six circuits have reviewed reverse payment settlement agreements and approached the competing policy issues in antitrust law and patent law in a variety of ways. The circuits’ reasoning ranged from reverse payments cannot be characterized as an attempt to enforce patent rights and are therefore subject to antitrust scrutiny, to agreements falling within the scope of valid patents protect patentees from antitrust scrutiny. The circuit courts’ differing analytical approaches to assessing the legality of these settlements have led to divergent case results. These circuit cases will be discussed, in turn.

A. The D.C. Circuit and *Andrx Pharmaceuticals v. Biovail Corp.*: “Biovail’s Alleged Injury is the Type the Antitrust Laws Were Designed to Prevent.”

The D.C. Circuit was the first Court of Appeals to address the issue of reverse payment settlement agreements. In that case, Hoechst Marion Roussel, Inc. (“HMRI”) sued *Andrx Pharmaceuticals, Inc.* (“*Andrx*”) for patent infringement after *Andrx* filed an ANDA seeking to sell a generic form of *Cardizem CD*.⁸⁹ Additionally, *Biovail Corp. International* (“*Biovail*”) filed an ANDA and a paragraph IV certification for its own generic version of *Cardizem CD*; however, HMRI did not sue *Biovail* for patent infringement.⁹⁰

On September 24, 1997, HMRI and *Andrx* entered into an agreement in which *Andrx* agreed to refrain from selling its allegedly infringing product during the pendency of patent infringement litigation.⁹¹ In return, HMRI agreed to pay *Andrx* \$40 million per year beginning the date *Andrx* received final approval from the FDA and ending either on

⁸⁸ *Brown Univ.*, 5 F.3d at 669 (7 P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 1507, at 397 (Supp. 1986)); *Bhan v. NME Hospitals, Inc.*, 929 F.2d 1404, 1413 (9th Cir.), cert. denied, 502 U.S. 994 (1991)).

⁸⁹ *Andrx Pharm., Inc. v. Biovail Corp., Int’l*, 256 F.3d 799, 803 (D.C. Cir. 2001).

⁹⁰ *Id.*

⁹¹ *Id.*

the date Andrx began selling generic Cardizem CD or was adjudged liable for patent infringement.⁹²

In early 1998, Andrx sued the FDA and ANDA applicants such as Biovail to clarify its status as the first generic manufacturer to file an ANDA for Cardizem CD.⁹³ The suit also requested injunctive relief prohibiting the FDA from approving Biovail's generic version of Cardizem CD until the earlier of either: 180-days after Andrx begins marketing its generic formulation of Cardizem CD or a judgment is entered in patent litigation brought by HMRI.⁹⁴ Biovail counterclaimed, and in July 1998, the FDA granted final approval to Andrx's ANDA.⁹⁵

However, after the Hatch-Waxman Amendments' 30-month waiting period had expired, Andrx did not begin selling its generic version of Cardizem CD, thereby delaying the triggering of Andrx's 180-day period of exclusivity, and in turn, delaying competition from other generic manufacturers.⁹⁶ Pursuant to their agreement, HMRI began paying Andrx quarterly payments of \$10 million.⁹⁷ Approximately one year later, Andrx and HMRI settled their patent infringement case and terminated the agreement.⁹⁸ On June 23, 1999, Andrx finally began selling its generic version of Cardizem CD, triggering the 180-day exclusivity period.⁹⁹ Six months later, the FDA approved Biovail's ANDA.¹⁰⁰

The D.C. Circuit reversed the district court's dismissal of Biovail's antitrust claims and allowed Biovail the opportunity to replead,¹⁰¹ reasoning that a payment from the patent holder to the challenging generic firm strongly suggests the anticompetitive intent of the parties in entering the agreement.¹⁰² Further, Andrx's pledge to continue to pursue

⁹² *Id.*

⁹³ *Id.* at 803-04.

⁹⁴ *Id.* at 804.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 819.

¹⁰² *Id.* at 809 (quoting David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 335 (2000)).

its ANDA in order to postpone other applicants from receiving final FDA approval, were not necessarily ancillary restraints, and could be viewed as an attempt to allocate market share and preserve monopolistic conditions.¹⁰³ If Biovail's allegations were correct, "Biovail's alleged injury is the type the antitrust laws were designed to prevent," as the Agreement preserved HMRI's monopoly and excluded Biovail from the market, both of which are illegal restraints of trade.¹⁰⁴

As the Court pointed out, these agreements potentially allow firms to engage in horizontal market allocation and monopolization, violations which antitrust law applies per se rule. This is the first indication that a per se rule might be applicable when reviewing reverse payments.

**B. The Sixth Circuit and *In re Cardizem CD Antitrust Litigation*:
"A Classic Example of a Per Se Illegal Restraint of Trade."**

The aforementioned agreement between Andrx and HMRI also instigated a class action suit brought by purchasers of both the brand and generic forms of Cardizem CD.¹⁰⁵ The Sherman Act class plaintiffs and individual class plaintiffs brought suit against Andrx and HMRI ("defendants") alleging the defendants violated Section 1 of the Sherman Act and were seeking treble damages under Section 4 of the Clayton Act.¹⁰⁶ The state law class plaintiffs brought claims under antitrust laws from seven states and the District of Columbia.¹⁰⁷ Specifically, the plaintiffs allege that but for the defendants' agreement, Andrx (after receiving final FDA approval) would have promptly sold its generic form of Cardizem CD at a lower price than the brand version sold by HMRI.¹⁰⁸ Additionally, the plaintiffs alleged they were overcharged as a result of: (1) the absence of competition due to the agreement that postponed Andrx's entry into the market; and (2) the delay in other generic manufacturers market entry while waiting for expiration of the 180-day exclusivity period.¹⁰⁹

¹⁰³ *Andrx Pharm., Inc.*, 256 F.3d at 811.

¹⁰⁴ *Id.* at 813.

¹⁰⁵ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 899-900 (6th Cir. 2003).

¹⁰⁶ *Id.* at 904.

¹⁰⁷ *Id.* at 904 n.8.

¹⁰⁸ *Id.* at 904.

¹⁰⁹ *Id.* at 904-05.

The Sixth Circuit concluded that the Agreement was a horizontal agreement to eliminate competition in the U.S. market for Cardizem CD; thus, “a classic example of a per se illegal restraint of trade.”¹¹⁰ Moreover, the Agreement could not be “characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation.”¹¹¹ Further, although HMRI may take advantage of the natural monopoly afforded to a patent that does not permit it “to bolster the patent’s effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market.”¹¹²

Thus, the Sixth Circuit, similarly to the D.C. Circuit, likened the Agreement to a horizontal market allocation agreement; therefore, a per se illegal restraint of trade. However, the Sixth Circuit’s approach to reviewing reverse payments is in sharp contrast to the Eleventh Circuit’s approach, as seen in the next few cases.

C. The Eleventh Circuit and the Protections Afforded to a Patent

Instead of applying antitrust law to review a reverse payment settlement, the Eleventh Circuit determines patent law considerations should lead the analysis. In its first influential case, *Valley Drug Company v. Geneva Pharmaceuticals, Inc.*, the Eleventh Circuit creates its own test for reviewing reverse payment settlements.¹¹³

1. Valley Drug Company v. Geneva Pharmaceuticals, Inc.

In *Valley Drug*, private plaintiffs brought suit against three pharmaceutical drug manufacturers alleging that two agreements, one between Abbott Laboratories (“Abbott”) and Geneva Pharmaceuticals (“Geneva”), and the second between Abbott and Zenith Goldline Pharmaceuticals (“Zenith”) violated Section 1 of the Sherman Act.¹¹⁴ Abbott patented Hytrin, a brand-name drug containing dihydrate terazosin hydrochloride.¹¹⁵ Later, generic drug manufacturers Geneva and

¹¹⁰ *Id.* at 908.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

¹¹⁴ *Id.* at 1296.

¹¹⁵ *Id.* at 1298.

Zenith filed multiple ANDAs to produce generic versions of Hytrin.¹¹⁶ In 1998, Abbott entered into two separate settlement agreements with Geneva and Zenith.¹¹⁷ Rather than certifying, Zenith instead filed suit against Abbott attempting to impel Abbott to delist two of its patents from the Orange Book, seeking a declaratory judgment that Zenith's drug did not infringe those patents, and alleging that Abbott listed two patents "knowing that the patents did not claim Hytrin or a method of using Hytrin."¹¹⁸ Abbott subsequently counterclaimed for infringement.¹¹⁹

Abbott and Zenith settled, entering into an agreement whereby Zenith agreed to not sell or distribute any terazosin hydrochloride drug until Abbott's patent expired or another manufacturer's generic entered the market; and Zenith agreed not to sell or transfer its rights under any ANDA application relating to a terazosin hydrochloride drug.¹²⁰ In return, 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 was terminated.¹²¹

The following day, Abbott and Geneva entered into a settlement agreement wherein Geneva agreed not to sell or distribute any terazosin hydrochloride drug until either Abbott's Patent No. 4,215,532 expired, another entity introduced a generic terazosin hydrochloride drug, or Geneva obtained a final judgment either invalidating Abbott's patent or declaring that Geneva's terazosin products did not infringe Patent No. 5,504,207 ("207 patent"); Geneva agreed not to sell or transfer its rights under its ANDAs, including its right to the 180-day exclusivity period; and Geneva would assist Abbott in any attempt for an extension of the 30-month stay of FDA approval on Geneva's tablet ANDA.¹²² In exchange, Abbott paid Geneva \$4.5 million monthly until either another manufacturer began marketing a generic terazosin hydrochloride drug or Abbott prevailed with its infringement claims in district court; Abbott could terminate its payments to Geneva if no other generic terazosin

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 1299.

¹¹⁹ *Id.*

¹²⁰ *Id.* at 1300.

¹²¹ *Id.*

¹²² *Id.*

hydrochloride product had entered the market as of February 8, 2000; and if Abbott terminated payments, it would execute a release in favor of Geneva's infringement claims regarding the '207 patent.¹²³

In the infringement case, the district court held Abbott's '207 patent invalid and that the agreements were per se unlawful horizontal geographic market allocation agreements which would allow Abbott to collect monopoly profits in the U.S. terazosin drug market which it would subsequently share with other cartel members.¹²⁴ The Eleventh Circuit reasoned that the essence of a patent grant is the right to exclude; thus, a firm excluding others by choosing to be the sole supplier of a product, granting exclusive territorial licenses, or subdividing markets is permissible as long as it is within the scope of the patent.¹²⁵ Therefore, in the instant case, there was no horizontal market allocation antitrust violation because Abbott, as a patent-owner, had a lawful right to exclude Zenith and Geneva from competing in the relevant market.¹²⁶

Rejecting both per se and rule of reason analysis, the Eleventh Circuit stated antitrust analysis cannot ignore the scope of the patent exclusion.¹²⁷ The Court created its own standard of review referred to as the "Scope of the Patent" test, which considers the scope of the exclusionary potential of the underlying patent, whether the Agreement's provisions extend beyond the scope, and the resulting anticompetitive effects on the relevant market.¹²⁸ Applying this standard, the Eleventh Circuit held that the Agreements appeared to have no broader exclusionary effect than that of the disputed patents; therefore, they were not per se unlawful.¹²⁹

2. *Schering-Plough Corp. v. FTC*

In its second influential case, the Eleventh Circuit again applied its scope of the patent test and afforded the patentee immunity from antitrust scrutiny. Schering-Plough Corporation, ("Schering") produces

¹²³ *Id.* at 1300-01.

¹²⁴ *Id.* at 1301.

¹²⁵ *Id.* at 1304-05.

¹²⁶ *Id.* at 1304.

¹²⁷ *Id.* at 1310-11 & n.27.

¹²⁸ *Id.* at 1312.

¹²⁹ *Id.* at 1306.

and markets an immediately dispersing potassium chloride extended release 20 mEq (millequivalent) product, K-Dur 20.¹³⁰ Potassium chloride, the active ingredient in K-Dur 20, is unpatentable; however, Schering patented the extended-release coating that surrounds the potassium chloride.¹³¹ Upsher-Smith Laboratories (“Upsher”) sought FDA approval to market a generic version of K-Dur 20, “Klor Con M20” (“Klor Con”), which prompted Schering to sue Upsher for patent infringement.¹³² In 1997, the companies settled, agreeing that Upsher’s generic could enter the market on September 1, 2001.¹³³ Additionally, the companies entered into a three-part licensing agreement: Schering would pay (1) \$60 million in initial royalty fees, (2) \$10 million in milestone royalty payments, and (3) 10% or 15% royalties on sales.¹³⁴ Further, Schering received licenses to market five Upsher products including Niacor.¹³⁵ However, the Niacor license (and possibly other licenses) was never used as Schering and Upsher later abandoned any development of the product.¹³⁶

In 1995, another pharmaceutical manufacturer, ESI Lederle, Inc. (“ESI”) sought FDA approval to market its own generic of K-Dur 20, “Micro-K 20.”¹³⁷ The settlement allowed ESI’s Micro-K 20 to enter the market three years ahead of K-Dur 20’s patent expiration date.¹³⁸ Additionally, the parties agreed to a variable payment up to \$10 million dollars depending upon the FDA’s final approval date of Micro-K 20.¹³⁹

In 2001, the FTC filed an administrative complaint against Schering, Upsher, and ESI’s parent company alleging violations of Section 5 of the Federal Trade Commission Act, and a violation of Section 1 of the

¹³⁰ Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1058 (11th Cir. 2005).

¹³¹ *Id.*

¹³² *Id.* at 1058-59.

¹³³ *Id.* at 1059.

¹³⁴ *Id.* at 1060.

¹³⁵ *Id.* at 1059.

¹³⁶ *Id.* at 1060.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.* at 1060-61.

Sherman Act.¹⁴⁰ After the FTC appealed the initial decision, the Commission determined that the settlements violated the both Acts.¹⁴¹

However, the Eleventh Circuit vacated the Commission's decision and again followed the Valley Drug Scope of the Patent standard, reasoning patents are exclusionary and naturally limit competition during the patent's duration.¹⁴² The Court stated appropriate analysis considers "the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects."¹⁴³

Schering's licenses with Upsher and ESI allowed the two companies to begin selling their microencapsulated forms of potassium chloride five years and two years, respectively, before the expiration of Schering's patent.¹⁴⁴ The Court felt that the FTC's inability to prove that Upsher and ESI could have entered the market on their own prior to Schering's patent expiring validated the strength of the patent.¹⁴⁵ Additionally, because there had not been a challenge to the patent's validity or allegations that the infringement suits were shams, the Court would presume that Schering's patent was valid.¹⁴⁶ Therefore, the Court's analysis focused on whether the agreements' provisions restrained competition beyond the exclusionary scope of Schering's patent.¹⁴⁷ After reviewing the Upsher settlement, the Court determined it is common in the pharmaceutical industry for licenses to be granted for drugs that are never marketed, and the evidence demonstrated that Schering's up-front royalty payments of \$60 million to Upsher were fair-value payments.¹⁴⁸ Thus, Schering's agreement with Upsher was not illegal.¹⁴⁹

Regarding the ESI settlement, the Eleventh Circuit found the ESI settlement to be within the patent's exclusionary power and a reasonable

¹⁴⁰ *Id.* at 1061.

¹⁴¹ *Id.* at 1062.

¹⁴² *Id.* at 1065-66.

¹⁴³ *Id.* at 1066.

¹⁴⁴ *Id.* at 1067-68.

¹⁴⁵ *Id.* at 1068.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* at 1071.

¹⁴⁹ *Id.*

implementation of the protections afforded by patent law.¹⁵⁰ Further, the efficiency enhancing objectives of patent settlements and public policy strongly support settling disputes without litigation.¹⁵¹ Additionally, settling preserved public and private resources, and provided certainty that the Court believed would lead to increased competition.¹⁵²

The Eleventh Circuit reasoned that reverse payments are a natural result of the Hatch-Waxman Act's process.¹⁵³ Moreover, if settlement negotiations fail and the patent holder has a successful outcome of its infringement suit, competition is prevented to the same or to a greater degree because the generic cannot enter the market until after the patent expires.¹⁵⁴ The Court reiterated its position that settlements provide private and social benefits, that litigation decreases product innovation, and that settlements introduce new rivals in the market.¹⁵⁵ Finding the agreements fell within the protections of Schering's patent, the Court concluded they were therefore, not illegal.¹⁵⁶

3. Andrx Pharmaceuticals, Inc. v. Elan Corporation, PLC

The Eleventh Circuit's third case demonstrates how reverse payment settlements often impede later generic drug manufacturers seeking to enter a market subsequent to the first ANDA filer. Defendant-Appellee Elan Corporation, PLC ("Elan") owned a patent that gave it the exclusive right in the U.S. to manufacture and market a controlled release naproxen medication.¹⁵⁷ In 1998, SkyePharma, Inc. ("SkyePharma") filed an ANDA to manufacture and sell a generic version of Elan's medication, Elan countered with a patent infringement suit, and the parties settled by entering into an agreement wherein SkyePharma admitted to infringing Elan's patent in exchange for a

¹⁵⁰ *Id.* at 1072 (citing *Valley Drug*, 344 F.3d at 1312).

¹⁵¹ *Schering-Plough*, 402 F.3d at 1072-73 (internal citations omitted).

¹⁵² *Id.* at 1073.

¹⁵³ *Id.* at 1074.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at 1075.

¹⁵⁶ *Id.* at 1076.

¹⁵⁷ *Andrx Pharmaceuticals, Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1231 (11th Cir. 2005).

license to manufacture a generic controlled release naproxen medication.¹⁵⁸

Andrx Pharmaceuticals, Inc. (“Andrx”), another manufacturer interested in marketing a generic naproxen medication, alleged the Elan-SkyePharma agreement constituted a conspiracy to restrain trade.¹⁵⁹ As the first filing ANDA applicant, SkyePharma was given an exclusive 180-day period to market a generic naproxen medication; however, Andrx alleged SkyePharma had no intention of marketing its generic drug.¹⁶⁰ Therefore, the 180-day exclusivity period would never be triggered, preventing any other generics from entering the controlled release naproxen market.¹⁶¹

After Andrx tried to introduce its generic naproxen into the market, Elan initiated a patent infringement suit against the company.¹⁶² Andrx filed suit against Elan and SkyePharma alleging violations of the Section 1 and 2 of the Sherman Act, and Florida antitrust laws.¹⁶³ Specifically, Andrx alleged Elan “sought to monopolize the controlled release naproxen market and prevent competition by: (1) initiating a sham patent infringement suit against Andrx; and (2) entering into a settlement agreement with SkyePharma which granted SkyePharma exclusive licensing rights to manufacture and sell a generic controlled release naproxen medication” which SkyePharma would never produce, thereby excluding other generic manufacturers from the market indefinitely.¹⁶⁴

The Eleventh Circuit, applying its scope of the patent test, held that Andrx sufficiently pled the Elan-SkyePharma agreement violated Section 1 of the Sherman Act because the Elan-SkyePharma licensing agreement combined with SkyePharma’s putative arrangement not to market a generic controlled release naproxen medication, would effectively block any generic competitors from entering the market, and thus was beyond

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.* at 1232.

¹⁶⁴ *Id.* at 1233.

the scope of Elan's patent.¹⁶⁵ Also, there were possible anticompetitive effects in the relevant market, because Elan, as the sole naproxen supplier in the U.S., could control the entire market and deprive the public of a cheaper, generic alternative.¹⁶⁶

Further, the Court found Andrx had a cause of action under Section 2 of the Sherman Act because Andrx alleged that Elan had the specific intent to be the sole Naproxen supplier in the U.S.; therefore, Elan had a dangerous probability of successfully monopolizing the market.¹⁶⁷ The Court remanded the case for further proceedings on Andrx's allegations.¹⁶⁸

As this case demonstrates, reverse payments settlements also create bottlenecks wherein generic drug manufacturers trying to enter the market after the first ANDA filer are barred from entering when the first ANDA filer fails to market its drug and exhaust its 180-day exclusivity period. This is problematic because if subsequent generic drugs are barred from the market, consumers will continue to be overcharged for drugs similar to the plaintiffs in the *In re Cardizem CD* case.¹⁶⁹

4. FTC v. Watson Pharmaceuticals, Inc.

Once again, the Eleventh Circuit applies the scope of the patent test and rejects the FTC's allegation that the reverse payments at issue violate antitrust law.¹⁷⁰ Solvay Pharmaceuticals, Inc. ("Solvay") owns a license to sell AndroGel, a topical gel that provides sustained release of synthetic testosterone.¹⁷¹ Two generic manufacturers filed ANDAs in May 2003, first-filer Watson Pharmaceuticals, Inc. ("Watson") and Paddock Laboratories, Inc. ("Paddock").¹⁷² Solvay promptly filed patent infringement suits against both companies.¹⁷³ Par Pharmaceutical

¹⁶⁵ *Id.* at 1235.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 1236.

¹⁶⁸ *Id.*

¹⁶⁹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 904-05.

¹⁷⁰ *F.T.C. v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012) *cert. granted*, 133 S. Ct. 787 (2012) and *rev'd and remanded sub nom.* *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

¹⁷¹ *Id.* at 1303-04.

¹⁷² *Id.* at 1304.

¹⁷³ *Id.*

Companies, Inc. (“Par”) later partnered with Paddock, sharing litigation costs in exchange for part of the potential profits from Paddock’s generic AndroGel assuming the product later received FDA approval.¹⁷⁴

The parties settled and entered into multiple settlement agreements.¹⁷⁵ Watson, Paddock, and Par agreed to refrain from marketing generic versions of AndroGel until August 31, 2015, as long as no other manufacturer launched a generic prior to that date.¹⁷⁶ Additionally, Watson and Par agreed to promote branded AndroGel to urologists and primary care doctors, respectively.¹⁷⁷ Par also consented to serving as a backup supplier for branded AndroGel, but later assigned the duty to Paddock.¹⁷⁸ In exchange, Solvay agreed to pay Par and Paddock \$10 million a year for six years, as well as \$2 million per year for the companies’ backup manufacturing assistance.¹⁷⁹ Further, Solvay agreed to share AndroGel profits with Watson through September 2015, estimating those payments to be approximately \$19 million to \$30 million per year.¹⁸⁰ Lastly, the parties terminated the patent infringement lawsuit.¹⁸¹

After reviewing the agreements, the FTC filed suit against Solvay, Watson, Paddock, and Par alleging they violated Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1), by postponing their generics from competing with AndroGel for nine years, unlawfully agreeing to share in Solvay’s monopoly profits, and abandoning their patent challenges.¹⁸² However, the FTC’s key allegation was that “Solvay was not likely to prevail” in the patent infringement litigation because the generic manufacturers had compelling arguments and considerable evidence that their products did not infringe on Solvay’s patent and Solvay’s patent was invalid or unenforceable.¹⁸³ Further, the FTC

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 1305.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.* at 1305-06.

contended that because Solvay was unlikely to prevail in the infringement suit, Solvay's reverse payments made to the generic manufacturers continued and extended Solvay's monopoly and unlawfully restrained competition.¹⁸⁴

The district court held that these allegations did not set forth an antitrust violation, and the Eleventh Circuit affirmed relying on its prior case precedent stating: "Absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."¹⁸⁵

Additionally, the Eleventh Circuit declined to adopt the FTC's argument that Solvay's patent had no exclusionary potential because Solvay was not likely to succeed in the underlying infringement suit against Watson, Paddock, and Par; thus, Solvay's reverse payments to the generic manufacturers to keep them from competing in the market exceeded the potential exclusionary scope of the patent.¹⁸⁶ Further, the Court stated its analysis focuses on the "potential exclusionary effect of the patent, not the likely exclusionary effect."¹⁸⁷ Lastly, the Eleventh Circuit maintained that reverse payments to a few infringing firms will not likely have significant anticompetitive effects because other generic manufacturers will likely emerge to challenge the patent.¹⁸⁸

D. The Second Circuit: Tamoxifen

Following the Eleventh Circuit's reasoning, the Second Circuit adopted the scope of the patent test and held that with the exception of patents procured by fraud and sham litigation, reverse payment settlements cause "no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent."¹⁸⁹

¹⁸⁴ *Id.* at 1306.

¹⁸⁵ *Id.* at 1306, 1312.

¹⁸⁶ *Id.* at 1312.

¹⁸⁷ *Id.* at 1312-13.

¹⁸⁸ *Id.* at 1315 (citing Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competitions*, 39 U.S.F. L. REV. 11, 25 (2004)).

¹⁸⁹ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006).

Zeneca, Inc., AstraZeneca Pharmaceuticals, L.P., and AstraZeneca PLC ("Zeneca") own the patent for tamoxifen (trade name Nolvadex), which at that time was the most widely prescribed drug for the treatment of breast cancer in the world.¹⁹⁰ Barr Laboratories, Inc. ("Barr") filed an ANDA relating to Zeneca's patent for tamoxifen, and Zeneca responded by suing for patent infringement.¹⁹¹

While waiting for the outcome of the appeal of a separate suit declaring the tamoxifen patent invalid, the parties to the instant suit entered into a settlement agreement wherein Zeneca would pay Barr \$21 million and provide a non-exclusive license to sell Zeneca-manufactured tamoxifen in the U.S. under Barr's label, rather than Zeneca's trademark Nolvadex, and in exchange, Barr would change its ANDA paragraph IV certification to a paragraph III certification, and agree to forgo marketing its own generic version of tamoxifen until Zeneca's patent expired.¹⁹² Further, Zeneca and Barr agreed that if the tamoxifen patent were later declared invalid or unenforceable in a final and unappealable judgment, Barr would be permitted to revert to a paragraph IV ANDA certification.¹⁹³

The plaintiffs alleged that Barr prevented any generic manufacturer attempting to market a version of tamoxifen from doing so by invoking the 180-day exclusivity right possessed by the first "paragraph IV" filer.¹⁹⁴ In support of their argument, they showed that five years later, only a few weeks before other generic manufacturers could market their own versions of tamoxifen, Barr enforced the exclusivity period and prevented those manufacturers from entering the tamoxifen market until 180 days after Barr began marketing its own generic drug.¹⁹⁵

However, despite the Settlement Agreement enabling Zeneca and Barr to revive a patent that the district court had found invalid and unenforceable, and perpetuating Zeneca's monopoly and delaying entry of other generic manufacturers in tamoxifen market, the Second Circuit held that to the extent the Agreement was anticompetitive, it "did not extend the patent monopoly by restraining the introduction or marketing

¹⁹⁰ *Id.* at 193.

¹⁹¹ *Id.*

¹⁹² *Id.* at 193-94.

¹⁹³ *Id.* at 194.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

of unrelated or non-infringing products.”¹⁹⁶ Because the Court found the Agreement to be within the scope of the tamoxifen patent, “it was not an unlawful anticompetitive agreement.”¹⁹⁷

E. Federal Circuit: Cipro

When faced with its first case involving reverse payments, the Federal Circuit followed the lead of the Eleventh and Second Circuits and applied the scope of the patent test to determine that the reverse payment settlements at issue did not violate antitrust law.¹⁹⁸ The suit involved brand-name drug manufacturers, Bayer AG and Bayer Corp. (“Bayer”) and generic drug manufacturers, Barr Labs, Inc. (“Barr”), Hoechst Marion Roussel, Inc. (“HMR”), The Rugby, Inc. (“Rugby”), and Watson Pharmaceuticals, Inc. (“Watson”) (“generic Defendants”).¹⁹⁹ In October 1991, Barr filed an ANDA for its generic version of Cipro²⁰⁰ which included a paragraph IV certification challenging Bayer’s patent as invalid based on obviousness (35 U.S.C. § 103), obviousness type double patenting (35 U.S.C. § 101), and unenforceability due to inequitable conduct.²⁰¹ Bayer filed a patent infringement suit against Barr, and Barr answered and counterclaimed.²⁰²

Prior to trial, Bayer, Barr, HMR, and Rugby entered into four Settlement Agreements.²⁰³ In the first three agreements, Barr, HMR, Rugby, Apotex, and Bernard Sherman agreed not to challenge the validity and enforceability of the Bayer’s patent.²⁰⁴ In Barr’s respective Agreement, Barr consented to changing its paragraph IV ANDA to a paragraph III ANDA, and certified it would not market its generic version of Cipro until after Bayer’s patent expired.²⁰⁵ In return, Bayer

¹⁹⁶ *Id.* at 213.

¹⁹⁷ *Id.* at 218.

¹⁹⁸ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008).

¹⁹⁹ *Id.* at 1327.

²⁰⁰ Cipro’s active ingredient is the patented compound ciprofloxacin hydrochloride. *Id.* at 1328.

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.* at 1328-29.

agreed to pay Barr \$49.1 million.²⁰⁶ Additionally, Bayer agreed to either provide Barr with Cipro for resale, or make quarterly reverse payments to Barr until December 31, 2003, in return for Barr's promise not to manufacture Cipro in the U.S. until six months before Bayer's patent expired.²⁰⁷ Bayer and Barr entered into a consent judgment in which Barr admitted patent infringement and affirmed the validity and enforceability of Bayer's patent.²⁰⁸

Four other companies filed paragraph IV ANDAs for generic versions of Cipro, and Bayer subsequently sued each of them for infringement.²⁰⁹ Bayer was successful in two of the cases; in the third case a bench trial ended with the its patent being upheld; and the fourth case was dismissed after the company withdrew its paragraph IV certification.²¹⁰ In 2000 and 2001, patient advocacy groups and direct and indirect Cipro purchasers filed antitrust actions challenging the aforementioned agreements, which were eventually consolidated.²¹¹ The Complaint alleged an illegal market allocation in violation of the Sherman Act Sections 1 & 2, and violations of various state antitrust and consumer protection laws.²¹² The district court applied rule of reason analysis and determined that: the relevant market was ciprofloxacin, Bayer had market power within that market, and any adverse effects on competition stemming from the Agreements were within the exclusionary scope of Bayer's patent.²¹³ Additionally, the court reasoned that Bayer's success in the litigation of three patent infringement suits foreclosed any argument that the litigation was a sham.²¹⁴

Plaintiffs appealed arguing the Agreements allowed Bayer to eliminate a horizontal competitor from the market, not by enforcing its rights as a patent owner, but by paying the competitor \$398 million.²¹⁵

²⁰⁶ *Id.* at 1329.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.* at 1330.

²¹⁴ *Id.*

²¹⁵ *Id.* at 1331.

Upon reviewing the district court's findings, the Federal Circuit upheld the lower court's determination that any adverse effects on competition stemming from the Agreements were within the exclusionary scope of Bayer's patent; therefore, the Agreements did not violate antitrust law.²¹⁶

Like the Eleventh Circuit, The Federal Circuit stressed the long-standing policy in the law favoring settlements, and that case law supports parties in a patent dispute exchanging consideration to settle their litigation.²¹⁷ Further, the Federal Circuit joined the Eleventh and Second Circuits in placing patent protections ahead of antitrust concerns by applying a presumption of the validity of the patent in the absence of evidence of fraud before the PTO or sham litigation.²¹⁸

G. Third Circuit: In re K-Dur Antitrust Litigation

In *In re K-Dur Antitrust Litigation*, the Third Circuit reviews the same settlement at issue in the Schering-Plough case, although this time suit was brought by wholesale and retail pharmacies.²¹⁹ However, the Third Circuit declined to follow the Eleventh, Second, and Federal Circuit's application of the scope of the patent test.²²⁰

Instead, the Court applied a quick look rule of reason analysis in which "the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."²²¹ Further, the Court stated there was "no need to consider the merits of the underlying patent suit because '[a]bsent 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.'"²²²

²¹⁶ *Id.* at 1333.

²¹⁷ *Id.* at 1333 (citing *Standard Oil Co., Ind. v. United States*, 283 U.S. 163, 171 & n.5 (1931)).

²¹⁸ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d at 1336.

²¹⁹ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 202 (3d Cir. 2012).

²²⁰ *Id.* at 218.

²²¹ *Id.*

²²² *Id.* (citing *In re Schering-Plough Corp.*, Final Order, 136 F.T.C. at 988).

The Third Circuit's decision was a drastic departure from prior circuit decisions that found antitrust law did not apply unless a settlement had exceeded the exclusionary potential of the patent. This decision created a circuit split which inevitably prompted the Supreme Court to review the applicability of antitrust law to reverse payment settlement agreements.

V. THE SUPREME COURT AND *FTC v. ACTAVIS, INC.*: "PATENT-RELATED SETTLEMENT AGREEMENTS CAN SOMETIMES VIOLATE THE ANTITRUST LAWS."²²³

After granting certiorari in *FTC v. Actavis, Inc.*, the Supreme Court held that reverse payment settlements can violate antitrust laws, and rule of reason analysis is the appropriate standard to apply when reviewing their legality.²²⁴

First, the Supreme Court agreed that if Solvay's patent was valid and infringed, then the anticompetitive effects of the reverse payment fell within the exclusionary scope of the patent; however, the Court reasoned this fact alone would not immunize the settlement from antitrust scrutiny.²²⁵ The Court rejected the idea that antitrust analysis is not applicable to reverse payment settlements because a valid patent holder has a right to exclude.²²⁶ Justice Breyer stated the "patent here may or may not be valid, and may or may not be infringed," and Solvay's patent infringement suit placed its patent's validity and scope at issue.²²⁷ Further, he pointed out settlements wherein the patent holder pays the alleged infringer millions of dollars to stay out of the market are atypical and can have significant anticompetitive effects that should be analyzed not only against patent law policy, but against antitrust procompetitive policies, as well.²²⁸

²²³ *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2232 (2013) (citing *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963)).

²²⁴ *Actavis*, 133 S. Ct. at 2227, 2237.

²²⁵ *Id.* at 2230.

²²⁶ *Id.* at 2230-31.

²²⁷ *Id.* at 2231.

²²⁸ *Id.*

Citing *U. S. v. Line Material Co.*, the Court stressed it is necessary to look at whether the statute anticipates anticompetitive effects yet, nevertheless allows the patent holder to restrain competition.²²⁹ After reviewing the Hatch-Waxman Act, the Court found the Act's "general procompetitive thrust" and "its specific provisions facilitating challenges to a patent's validity" suggest that Congress did not intend for patents to have antitrust immunity.²³⁰

Additionally, the Supreme Court provided multiple reasons to support its conclusion that Solvay's reverse payment agreements should be reviewed to determine whether they violate antitrust law.²³¹ First, the settlements have potentially adverse effects on competition because they basically allow a patentee to purchase patent protection regardless of the fact that its patent's validity is in question.²³² Patentees continue to charge monopoly prices and divide the extra money between itself and the generic challenger, meanwhile charging consumers more than necessary.²³³ Moreover, patentee's reverse payment settlements with first ANDA filers eliminate the most motivated and capable challengers from the market.²³⁴

Second, the anticompetitive effects will occasionally prove unjustified.²³⁵ Third, the fact that a patentee is comfortable paying a generic challenger an extremely large settlement payment to keep them out of the market suggests it has the ability to exercise the market power suggested by the existence of the anticompetitive settlement.²³⁶ Fourth, the Eleventh Circuit's concerns that antitrust actions are administratively difficult are unfounded because it is unnecessary to fully litigate a patent's validity to resolve the antitrust question; an inexplicably large reverse payment can assist a court in deducing a patent's invalidity.²³⁷ Fifth, there are ways to settle a patent infringement suit other than large

²²⁹ *Id.* (citing *U. S. v. Line Material Co.*, 333 U.S. 287, 311 (1948)).

²³⁰ *Actavis*, 133 S. Ct. at 2234.

²³¹ *Id.*

²³² *Id.*

²³³ *Id.* at 2234-35.

²³⁴ *Id.* at 2235.

²³⁵ *Id.* at 2235-36.

²³⁶ *Id.* at 2236.

²³⁷ *Id.* at 2236-37.

reverse payments, such as allowing a generic drug to enter the market prior to the name brand drug's patent expiring.²³⁸ Next, the Supreme Court rejected the FTC's suggestion that reverse payments should be *per se* illegal and that the quick look approach is appropriate to review settlements. Instead, the Court held a rule of reason analysis should be applied.²³⁹

However, the Court failed to correct the problems associated with reverse payment settlements for three reasons: (1) the Court failed to provide guidance insofar as how to apply the rule of reason; (2) the rule of reason is incredibly broad in application and could yield the same mix of results obtained before the case was decided by the Court; and (3) with a wide range of possible outcomes, it is questionable whether patentees and generic manufacturers will be deterred from entering into these agreements in the future.

First, the Court failed to provide guidance insofar as how to apply the rule of reason. Therefore, lower courts have tremendous room for interpretation. "The establishment of legal standards, either by statute or judicial opinion, should be understood as creating tools for the analysis of future disputes involving the legal concepts established as relevant to the dispute."²⁴⁰ The Court's failure to supply guidance to the lower courts leads to the next problem.

Second, the rule of reason is incredibly broad in application and could yield the same mix of results obtained before the court decided the case. The options range from finding that any benefit generic manufacturers receive from patent holders may warrant antitrust scrutiny, to the other extreme: that cash payments for delay are inappropriate, but payments for licenses, backup manufacturing, or other benefits will not violate antitrust law. Future cases will likely result in a variety of outcomes, similarly to the time period before the Supreme Court's Actavis decision.

Third, with a wide range of possible outcomes, it is questionable whether patentees and generic manufacturers will be dissuaded from entering into these agreements in the future. The knowledge that there will be some amount of antitrust scrutiny will have little deterrence effect because at this point, it is unclear what is permissible and

²³⁸ *Id.* at 2237.

²³⁹ *Id.*

²⁴⁰ John J. Flynn, *The Role of Rules in Antitrust Analysis*, 2006 UTAH L. REV. 605, 615 (2006).

impermissible behavior. Further, unless additional changes are implemented, bottlenecks created by first-filers' unused 180-day exclusivity periods will continue to block subsequent generic drugs from entering the market. Thus, consumers will unnecessarily pay higher prices for many drugs²⁴¹ similar to the plaintiffs in the *In re Cardizem CD* case who were overcharged because the first generic manufacturer agreed not to relinquish or transfer its 180-day exclusivity period, which blocked other potential generic competitors from entering the market.²⁴²

Accordingly, Congress needs to enact legislation to clarify how broadly or narrowly to interpret the Supreme Court's decision and to address the bottleneck created by first-filers' unused exclusivity period. In his dissent Justice Roberts points out, "Indeed, for whatever it may be worth, Congress has repeatedly declined to enact legislation addressing the issue the Court takes on today."²⁴³ Clarification regarding the application of rule of reason analysis will help lower courts to determine the difference between settlement agreements that violate antitrust laws and the ones that are permissible.

VI. PROPOSED SOLUTION

First, Congress should provide tools to define what is an impermissible agreement. This author proposes that a settlement agreement with a reverse payment is an unreasonable restraint of trade in violation of Sherman Act Section 1 if it: (1) contains a payment from the patentee to the generic manufacturer in the settlement of a patent infringement suit totaling ten million dollars or more (this figure includes money designated for licenses, backup manufacturing, and other benefits, and will be adjusted annually for inflation); and (2) restrains the generic manufacturer from marketing its medication for over a year when there is no available bioequivalent substitute on the market as of the time of the settlement.²⁴⁴ However, similarly to the Third Circuit's test in *In re K-Dur*, this presumption can be rebutted by

²⁴¹ Hemphill & Lemley, *supra* note 25, at 962.

²⁴² *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 904-05 & 910.

²⁴³ *Actavis*, 133 S. Ct. at 2242.

²⁴⁴ *See generally* 15 U.S.C. § 1 (2004).

showing the payment: (1) was for a purpose other than delayed entry, and (2) the procompetitive benefit outweighs the anticompetitive effect.²⁴⁵

The \$10 million dollar limit is based upon a review of the reverse payment settlement terms in the aforementioned circuit cases. The following table demonstrates that the payments in those cases ranged from \$10 million dollars per year for several years to over \$60 million dollars:

Case	Terms of Agreement
Andrx Pharm., Inc. v. Biovail Corp., Int'l	HMRI agreed to pay Andrx \$40 million per year.
Valley Drug Company v. Geneva Pharm., Inc.	Abbott agreed to pay Zenith \$3 million up front, \$3 million after three months, and \$6 million every three months until 3/1/2000, or until the Agreement was terminated. (Approximately \$42 million total.) Abbott agreed to pay Geneva \$4.5 million each month.
Schering-Plough Corp. v. F.T.C.	Schering agreed to pay Upsher (1) \$60 million in initial royalty fees; (2) \$10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales. Schering agreed to pay ESI a variable payment up to \$10 million dollars.
Andrx Pharm., Inc. v. Elan Corp.	The parties entered into an agreement wherein SkyePharma admitted to infringing Elan's patent in exchange for a license from Elan to manufacture a generic controlled release naproxen medication.
F.T.C. v. Watson Pharm., Inc.	Solvay agreed to pay Par and Paddock \$72 million (\$12 million per year for six years.) Solvay agreed to share AndroGel profits with Watson through 9/2015, estimating those payments to be approximately \$19 million to \$30 million per year.
In re Tamoxifen Citrate Antitrust Litig.	Zeneca agreed to pay Barr \$21 million.
In re Ciprofloxacin Hydrochloride Antitrust Litig.	Bayer agreed to pay Barr \$49.1 million. Further, Bayer agreed to either provide Barr with Cipro for resale, or make quarterly reverse payments to Barr until 12/31/2005.
In re K-Dur Antitrust Litig.	Same settlement at issue as the Schering-Plough case.

²⁴⁵ *In re K-Dur Antitrust Litig.*, 686 F.3d at 218.

The reasoning behind the proposed language is that any settlement larger than the lowest annual reverse payment is likely a patentee attempting to share monopoly profits in exchange for a competitor staying out of the market or delaying its entry. The burden will then be placed on the parties to the settlement (who are the people with the most access to information) to show that the settlement has some procompetitive justification and that its effects will not unreasonably harm third parties. Additionally, this method of including all payments, whether for infringement damages or licenses and other benefits, addresses behavior in prior cases where patentees paid generic manufacturers millions of dollars to promote products to doctors, provide backup manufacturing,²⁴⁶ or paid for licenses the patentees never used.²⁴⁷

Moreover, the proposed method helps identify the common characteristics of harmful reverse payment settlements, and draws a line that those agreements fitting this description will have a rebuttable presumption of illegality. The proposed language will guide lower courts in their rule of reason analysis, while also allowing enough flexibility to consider any procompetitive justifications for the agreement. Implementing the proposed language will prevent lower courts from issuing contradictory opinions in the future, while also identifying what constitutes an impermissible reverse payment agreement, which will deter future infractions.

Additionally, as previously mentioned, the Hatch-Waxman Amendment's 180-day exclusivity period creates a bottleneck problem wherein subsequent generic drug manufacturers are barred from entering a market if the first ANDA filer fails to market its drug and exhaust its 180-day exclusivity period. The bottleneck effectively keeps any new generic drugs from entering the market until the original patent expires, which in turn, hurts consumers by maintaining the cost of drugs at monopoly prices. Congress needs to address this problem, and the author proposes that the first ANDA filer must exhaust its 180-day exclusivity period within four years from the date it files its paragraph IV certification. Further, if the first-filer later changes to another paragraph certification, the exclusivity period is permanently forfeited and may not be recovered at a later date. This protects later generic

²⁴⁶ *Watson Pharm.*, 677 F.3d at 1305.

²⁴⁷ *Schering-Plough Corp.*, 402 F.3d at 1060 & 1071.

manufacturers from abuses similar to those in the Tamoxifen case, when a few weeks prior to generics entering the market, Barr enforced the exclusivity period and delayed those manufacturers from entering until 180-days after Barr began marketing its own generic drug.²⁴⁸

This four-year deadline takes into consideration that the majority of patent infringement suits reach trial within three years,²⁴⁹ plus allows enough time for a generic manufacturer to exhaust the 180-day exclusivity period. This reasonable timeline will ensure generic manufacturers do not stall litigation, and incentivizes bringing new drugs to market in an expeditious manner. Not only is a four-year deadline simple and cheap to implement, it guarantees that no matter if the parties to a suit settle, use delay tactics during litigation, or if the FTC's resources are stretched and they cannot bring suit on every questionable reverse payment agreement, that subsequent generic manufacturers, and in turn consumers, will have relief from the bottleneck.

After a decade of circuit courts weighing in on the issue of whether pharmaceutical reverse payment settlement agreements violate the antitrust laws, and the Supreme Court's recent opinion, the issue is in almost the same state that it started. The Supreme Court's holding in *FTC v. Actavis, Inc.* that reverse payment settlement agreements sometimes violate the antitrust laws, and that the incredibly broad rule of reason analysis applies when reviewing these agreements sheds little light on how lower courts should analyze the issue in the future. Without clarification regarding the application of rule of reason analysis, it is possible that Americans will face another decade of mixed court opinions, meanwhile continuing to overpay for prescription drugs at a cost of billions of dollars a year. Accordingly, Congress should adopt the aforementioned proposed language to guide lower courts in their rule of reason analysis, to deter pharmaceutical companies from engaging in reverse payment settlements in the future, and to cure the bottleneck problem that is a side effect of an unused 180-day exclusivity period.

²⁴⁸ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 194.

²⁴⁹ "The overall time-to-trial distribution indicates that about 70% of cases reached trial within three years from the filing of the initial complaint." PRICEWATERHOUSECOOPERS, L.L.P., *2013 Patent Litigation Study: Big Cases Make Headlines, While Patent Cases Proliferate* 20 (2013).