I. INTRODUCTION

A name-brand pharmaceutical company filed a patent infringement suit against a would-be generic drug manufacturer and then settled the suit with a payment to the generic manufacturer in a settlement agreement—known as a reverse payment. In a reverse payment settlement, a generic drug manufacturer will often receive tens, or even hundreds, of millions of dollars after the generic company promises, among a variety of other provisions, to withhold its generic product from the market. The Federal Trade Commission (FTC) estimated that reverse payment settlement agreements cost American consumers over $3 billion through higher prescription drug costs in 2011. The Supreme Court recently reviewed the legality of a reverse payment settlement that protected the name-brand
drug manufacturer’s market monopoly granted by its patent. This Note examines the Court’s opinion in that case—FTC v. Actavis, Inc.—and presents an argument that the Court missed an opportunity to protect consumers from higher drug prices caused by reverse payment settlements.

Reverse payment settlements often have devastating results for consumers. Mike Russo, the Federal Program Director of the U.S. Public Interest Research Group, explained those effects to the Senate Judiciary Committee with a story about Karen Winkler. Karen suffers from multiple sclerosis, and her symptoms were so severe that she was only able to take care of her three children because of her prescription medication. That medication cost her $500 per month after insurance paid its share. Although Karen tried to adjust her doses to stretch out the prescription, she finally could not afford it any longer and was forced to live with her pain without any medication. Karen received relief when a generic form of the drug entered the market. Now she can take care of her children again because she only pays $16 every three months for her generic prescription. A reverse payment settlement agreement had delayed the entry of her generic medication on the market for six years. During that six-year delay, the name-brand pharmaceutical company that sold her medication generated $4 billion in sales.

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4 Actavis, 133 S. Ct. at 2227.
5 See infra Part II.
6 See infra Part VII.
8 Id.
9 Id.
10 Id.
11 Id.
12 Id.
13 Id.
14 Id.
Pharmaceutical companies invest an enormous amount of time and money before receiving patents for newly developed drugs. The average drug takes ten to fifteen years to develop, but only five out of 5,000 drugs that enter preclinical testing receive approval from the Food and Drug Administration (FDA). A new drug application (NDA) to the FDA can potentially cost over $1 billion.

Competition for prescription drugs has dramatic results on profits for pharmaceutical companies. The cost of Karen Winkler’s multiple sclerosis medication is just one example of the extreme drop in price that occurs when competition enters the market. In another example from 2003, drug manufacturer Schering-Plough, the patent holder for drugs including Claritin and Nasonex, reported massive losses of profit as a result of “the loss of exclusive selling rights for big selling drugs.” Generic versions of Schering-Plough’s drugs that entered the market between 2002 and 2003 sold for around 10% of the name-brand price, destroying Schering-Plough’s control of the market and drastically lowering profits.

Schering-Plough’s competitors that entered the market in 2002 and 2003 entered with the assistance of the Drug Price Competition and Patent Term Restoration Act of 1984 (Act or Hatch-Waxman Act). The Hatch-Waxman Act has become an extremely valuable tool in making medications more affordable to American citizens. To date, FDA has approved more than 10,000 generic drug products, providing high-quality, lower-cost prescription drugs to millions of consumers.

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17 Id.
18 Id.
19 Id.
20 See George, supra note 15, at 1.
21 Pay-for-Delay Deals Hearing, supra note 7.
22 Gardiner Harris, Schering-Plough Is Hurt by Plummeting Pill Costs, N.Y. Times, July 8, 2003, at C1.
23 Id.
24 Id.
The Hatch-Waxman Act tried to balance the competing policy goals of patent and antitrust laws.\textsuperscript{28} The patent-antitrust tension exists because patent law grants a period of time when the new patent holder owns exclusive rights to profit from the patented product, while antitrust law combats monopolistic practices.\textsuperscript{29} For twenty years, the patent holder controls its product’s price and restricts the supply of its product on the market.\textsuperscript{30} The Patent Act grants this exclusive control of the market to reward a patent holder for taking the financial risk to develop a new product.\textsuperscript{31}

Patent law and antitrust law pursue conflicting goals.\textsuperscript{32} The prescription drug market magnifies the conflict because of the $1 billion disparity between the cost of research and development for a new drug and the cost of a single pill.\textsuperscript{33} Antitrust law protects American consumers, like

\textsuperscript{26} Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368, 1370–71 (Fed. Cir. 2002).

\textsuperscript{27} See Hutt, Merrill & Grossman, supra note 16, at 577 (describing the enormous costs incurred by drug companies in order to obtain an approved NDA); see also Harris, supra note 22, at C1 (describing the profits required by Schering-Plough).


\textsuperscript{31} See Patlex Corp. v. Mossinghoff, 758 F.2d 594, 599 (Fed. Cir. 1985) (“The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.”).

\textsuperscript{32} Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1307–08 (11th Cir. 2003) (“[P]atent and antitrust laws necessarily clash . . . .[.] At the same time, the two regimes seek the same object: the welfare of the public.” (internal quotation marks omitted)).

\textsuperscript{33} See Hutt, Merrill & Grossman, supra note 16, at 577 (describing the high cost of research and FDA approval for pharmaceuticals); Harris, supra note 22, at C8 (noting a single pill could cost as little as $0.10).
Karen Winkler, from unfairly high prices caused by restraints of trade. In 2003, Congress enlisted the FTC, which already held jurisdiction to enforce antitrust claims, to review all pharmaceutical patent settlements.

The FTC has become very concerned about reverse payment settlements. In fiscal year 2012, the FTC reported that the number of reverse payment settlements rose from twenty-eight to forty. Of those forty, nineteen bore characteristics that the FTC believed stifled competition against name-brand drugs. FTC Chairman Jon Leibowitz expressed the concern of many when he stated that “[t]he increasing number of these deals is a win-win proposition for the pharmaceutical industry, but a lose-lose for everyone else.

The issue before the Court in FTC v. Actavis, Inc. was whether a reverse payment settlement “can sometimes unreasonably diminish competition in violation of the antitrust laws.” The FTC asked the Court if reverse payment settlements are “per se lawful” or per se illegal, referencing the two prevailing tests used by courts in reverse payment settlement agreement cases. The question the FTC presented to the Court centered on the age-old conflict between the policies of antitrust and patent

34 See Pay-for-Delay Deals Hearing, supra note 7 (describing Karen Winkler’s struggle to afford prescription drug costs).
35 See Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 538 (1983) (“[T]he Sherman Act was enacted to assure customers the benefits of price competition . . . .”).
40 Id.
41 See FTC Staff Report, supra note 38 (internal quotation marks omitted).
42 133 S. Ct. 2223 (2013).
43 Id. at 2227.
45 Id. (“The question presented is as follows: Whether reverse-payment agreements are per se unlawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the [Eleventh Circuit] held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held.”).
laws, and an answer from the Court resolved a conflict between six federal circuits about whether to protect reverse payment settlements using patent law or to subject them to antitrust scrutiny. The Actavis decision reversed and remanded a ruling by the Eleventh Circuit in FTC v. Watson Pharmaceuticals, Inc., which had dismissed an FTC complaint that a reverse payment settlement agreement violated antitrust law.

The issue of reverse payment settlements involves major corporations and national economic markets, but, as this Note discusses, Congress made it clear that it is important to consider individual consumers in the context of prescription drugs. The Court’s decision in Actavis placed some pressure on pharmaceutical companies to justify the effects of reverse payment settlements, but this Note argues the Court should have placed more pressure on pharmaceutical companies by making reverse payment settlements presumptively illegal. The Court’s rationale could have led to this decision, but it fell short, and instead it imposed a test on the lower courts that will almost certainly allow pharmaceutical companies to continue using reverse payment settlements to keep prescription drug prices higher than necessary.

First, this Note briefly explains the factual and legal context for Actavis decision. Second, this Note explains the policy conflict between patent and antitrust law that the Court granted certiorari to address. Third, this Note explains key provisions of the Hatch-Waxman Act that increase the policy tension and contribute to reverse payment settlement agreements. Fourth, it discusses the circuit split as to the proper test for reverse payment settlement agreements. Fifth, this Note discusses the holding in Actavis. Finally, this Note explains why the Court should

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46 Id. at 12–14.
48 Watson Pharm., 677 F.3d at 1312.
49 See infra Part IV.
50 Actavis, 133 S. Ct. at 2225.
52 See infra Part II.
53 See infra Part III.
54 See infra Part IV.
55 See infra Part V.
56 See infra Part VI.
have adopted the FTC’s “quick look” approach to reviewing reverse payment settlements.\textsuperscript{57}

II. HISTORY OF THE ANDROGEL SETTLEMENT

In 2000, Solvay Pharmaceuticals, Inc. received approval from the FDA for a medication for men with low testosterone: AndroGel.\textsuperscript{58} Then, in 2003, Solvay received a patent from the Patent and Trademark Office (PTO) that would expire in August 2020.\textsuperscript{59} By 2007, Solvay’s profit from U.S. sales of AndroGel “exceeded $1.8 billion.”\textsuperscript{60} Actavis, Inc. (then known as Watson Pharmaceuticals, Inc.) and Paddock Laboratories, Inc. filed an abbreviated new drug application (ANDA) with the FDA for a generic form of AndroGel in May 2003, along with a paragraph IV certification\textsuperscript{61} that their generic product would not infringe on Solvay’s patent for AndroGel.\textsuperscript{62} Solvay responded by filing an infringement action against both Actavis and Paddock, which initiated an automatic thirty-month stay in the FDA approval process for applications by Actavis and Paddock.\textsuperscript{63}

The infringement suit continued for three years and the FDA approved Actavis’s generic AndroGel the same month that the thirty-month stay expired.\textsuperscript{64} Solvay faced two choices. If it continued the infringement suit, it faced the possibility of a judicial determination that Actavis’s generic AndroGel did not infringe its patent.\textsuperscript{65} That judicial determination would free Actavis to place its generic product on the market, potentially replacing 90% of Solvay’s AndroGel market and profits.\textsuperscript{66} The second option involved reaching a settlement with Actavis and Paddock. Solvay decided to settle.\textsuperscript{67}

In the settlement, Solvay retained its exclusive rights to sell AndroGel until August 2015, five years before its patent actually expired.\textsuperscript{68} Actavis

\textsuperscript{57} See infra Part VII.

\textsuperscript{58} FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1303–04 (11th Cir. 2012).

\textsuperscript{59} Id. at 1304.

\textsuperscript{60} Id.


\textsuperscript{62} Watson Pharm., 677 F.3d at 1304.

\textsuperscript{63} Id.

\textsuperscript{64} Id.

\textsuperscript{65} Id.

\textsuperscript{66} Id. at 1304–05.

\textsuperscript{67} See id. at 1305.

\textsuperscript{68} Id.
agreed to promote AndroGel to urologists, and Paddock agreed to promote AndroGel to primary care physicians and to provide additional manufacturing of AndroGel.\textsuperscript{69} In return, Actavis received profit shares estimated to be between $19 million and $30 million annually.\textsuperscript{70} Paddock received $12 million per year.\textsuperscript{71} The parties dismissed their infringement suit and reported the settlement agreement to the FTC.\textsuperscript{72}

The FTC reviewed the settlement and then filed an antitrust suit against the parties, alleging the settlement violated antitrust law because the parties “unlawfully agree[d] ‘to share in Solvay’s monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.’”\textsuperscript{73} The FTC alleged the settlement agreement deferred generic competition, thereby protecting Solvay’s monopoly at the expense of American consumers.\textsuperscript{74} The Eleventh Circuit dismissed the FTC’s complaint and upheld the settlement agreement using the “scope of the patent” test.\textsuperscript{75} The Supreme Court granted certiorari and, in June 2013, reversed the Eleventh Circuit and remanded the case for an analysis of the settlement under the “rule of reason.”\textsuperscript{76}

III. THE POLICY CONFLICT BETWEEN ANTITRUST AND PATENT LAW AND HOW THESE AREAS OF LAW COLLIDE IN THE CONTEXT OF PHARMACEUTICAL DRUGS

The Court’s opinion in Actavis addressed a circuit split over which law to apply to reverse payment settlement agreements.\textsuperscript{77} Patent law and antitrust law are often in conflict and, over the past century, courts have

\textsuperscript{69} Id.  
\textsuperscript{70} Id.  
\textsuperscript{71} Id.  
\textsuperscript{72} Id.  
\textsuperscript{73} \cite{FCC}  
\textsuperscript{74} \cite{Watson Pharm.}  
\textsuperscript{75} Id. at 1306 (quoting \textit{Androgel Antitrust Litig.}, 687 F. Supp. 2d at 1379).  
\textsuperscript{76} \textit{Actavis}, 133 S. Ct. at 2230, 2238.  
\textsuperscript{77} See \textit{id.} at 2230.
commonly needed to find a balance between the policies of the two bodies of law.\textsuperscript{78} This Part discusses antitrust and patent law policy and the opposing types of scrutiny used in reverse payment settlement cases.\textsuperscript{79}

\textit{A. The Sherman Act}

The Sherman Act\textsuperscript{80} forbids “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several [s]tates.”\textsuperscript{81} The Supreme Court has interpreted this statute to prohibit only “unreasonable”\textsuperscript{82} restraints of trade, which “may suppress or even destroy competition.”\textsuperscript{83} Antitrust analysis enforces this standard by determining whether a restraint of trade creates an unreasonable anticompetitive effect.\textsuperscript{84} “[T]here are certain [restraints of trade,] which[,] because of their pernicious effect on competition and lack of any redeeming virtue[,] are conclusively presumed to be unreasonable . . . .”\textsuperscript{85} This category of agreements “often prove[s] so harmful to competition and so rarely prove[s] justified that the antitrust laws do not require proof that an agreement of that kind is, in fact, anticompetitive in the particular circumstances.”\textsuperscript{86} Once a court determines that a trade restraint is within the class of per se illegal conduct, “further inquiry into the merits of that particular restraint is unwarranted.”\textsuperscript{87}

However, in most circumstances, there is no bright line between intuitively anticompetitive effects and effects that require an in-depth

\textsuperscript{79} See infra Part III.A–B.
\textsuperscript{81} Id. § 1.
\textsuperscript{82} State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).
\textsuperscript{83} Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918) (analyzing whether the Board of Trade’s trading schedule unreasonably restricted trade while the exchange was closed for business during certain hours each day).
\textsuperscript{86} NYNEX Corp. v. Discon, Inc., 525 U.S. 128, 133 (1998). The per se rule did not apply because of the “presence of other potential or actual competitors,” which indicated “against the likelihood of anticompetitive harm.” \textit{Id.} at 139.
\textsuperscript{87} \textit{In re} Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682, 694 (E.D. Mich. 2000). The court went on to grant partial summary judgment after finding that the reverse settlement agreement per se violated the Sherman Act. \textit{Id.} at 706–07.
market analysis88 to determine “the competitive significance of the restraint.”89 The Court developed the rule of reason analysis to determine whether a challenged restraint is sufficiently anticompetitive to be considered unreasonable or even presumptively illegal.90 The rule of reason considers “whether the anticompetitive effects of a restraint are outweighed by some procompetitive justification.”91 The Court has acknowledged that “there is often no bright line separating per se from [r]ule of [r]eason analysis” because “considerable inquiry into market conditions” may be necessary before a determination can be made as to whether specific conduct qualifies as per se illegal conduct.92 Instead of thinking of two separate tests, it is better to imagine a spectrum of anticompetitive conduct with per se illegal conduct at one end and legal trade practices on the other.93

The rule of reason “focuses . . . on the challenged restraint’s impact on competitive conditions”94 by “analyzing the facts peculiar to the business, the history of the restraint, and the reasons why [the restraint] was imposed.”95 A court conducts “an enquiry [appropriate] for the case, looking to the circumstances, details, and logic of a restraint.”96 Due to the complexities of some businesses, some competitive restraints may be reasonable because they are necessary to make a commercial transaction productive.97 A restraint that promotes competition through regulation can also sometimes be a reasonable restraint.98 Additionally, “special characteristics of [an] industry may provide a justification” for agreements that trigger antitrust analysis.99

89 Pro'f'l Eng'rs, 435 U.S. at 692.
90 See NCAA, 468 U.S. at 103–04.
92 NCAA, 468 U.S. at 104 n.26 (emphasis omitted).
94 Pro'f'l Eng'rs, 435 U.S. at 688.
95 Id. at 692.
96 Cal. Dental Ass’n, 526 U.S. at 781 (“[T]here is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment.” Id. at 780–81.).
98 Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918).
99 Am. Needle, Inc. v. Nat’l Football League, 560 U.S. 183, 202 (2010) (“Football teams that need to cooperate are not trapped by antitrust law.”). Although the Court (continued)
1. The Sliding Scale of Antitrust Scrutiny

Ultimately, the object of the rule of reason analysis is to distinguish restraints on one end of the spectrum that “may suppress or even destroy competition” from restraints on the spectrum’s other end that “merely regulate[] and perhaps thereby promote[ ] competition.”100 In National Professional Society of Engineers v. United States, the Court provided an example of an acceptable restraint:

Mitchel [v. Reynolds] involved the enforceability of a promise by the seller of a bakery that he would not compete with the purchaser of his business. The covenant was for a limited time and applied only to the area in which the bakery had operated. It was therefore upheld as reasonable, even though it deprived the public of the benefit of potential competition. The long-run benefit of enhancing the marketability of the business itself—and thereby providing incentives to develop such an enterprise—outweighed the temporary and limited loss of competition.101

An abbreviated, or quick-look, rule of reason emerged from instances in which a detailed analysis was not necessary to determine where a restraint of trade fell on the anticompetitive spectrum.102 The plaintiff successfully triggers the quick-look rule of reason when “no elaborate industry analysis is required to demonstrate the anticompetitive character.”103 Unlike the rule of reason analysis, the quick-look application need not be an intense, lengthy process.104 Justice Stevens went so far as to say the quick-look application “can sometimes be applied in the twinkling of an eye.”105 Courts use the quick-look rule of reason “when the great acknowledged that the NFL industry bore characteristics that could lessen an antitrust burden, it still found that the licensing activities at issue in this case were not immune to the Sherman Act. Id. 100 Bd. of Trade of Chi., 246 U.S. at 238.
103 Prof’l Eng’rs, 435 U.S. at 692.
likelihood of anticompetitive effects can easily be ascertained, even in the absence of a detailed market analysis. Sometimes “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.” Under this test, a case “can be disposed of merely on the basis of the parties’ pleadings or arguments [or] . . . on the basis of a limited summary judgment record,” eliminating the need for a long and costly trial.

The rule of reason and the quick-look approach both rely on a burden-shifting framework. A defendant fights antitrust allegations in the following way:

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.

Due to the rule of reason’s burden shifting, “defendant[s] invoke[] the rule of reason in order to maximize the plaintiff’s burden and its own chances of prevailing on the merits or of outlasting plaintiffs lacking the energy,

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106 Cal. Dental Ass’n, 526 U.S. at 770.
107 NCAA, 468 U.S. at 110. The NCAA limited the number of college football games that ABC and CBS could broadcast. Id. at 92. The Court found that the NCAA agreement was a horizontal output limitation, normally per se illegal, but applied the rule of reason because horizontal restraints are essential in the NCAA’s industry. Id. at 99–101. However, the NCAA failed to provide a procompetitive justification for its price and output’s unresponsiveness to consumer preference, so the Court affirmed the lower court’s application of the rule of reason. Id. at 117–20.
108 Cal. Dental Ass’n, 526 U.S. at 770.
109 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 1508, at 435 (3d ed. 2010).
110 In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332 (Fed. Cir. 2008) (quoting Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir. 1997)) (internal quotation marks omitted).
time, or money for a lengthy inquiry into reasonableness.” 111 The rule of reason analysis is costly and time consuming, which favors defendants, but the test’s abbreviated version—the quick-look rule of reason—favors plaintiffs by placing the initial burden on the defendant to show a procompetitive effect. 112

When a court finds an obvious anticompetitive effect that triggers a quick look, the conduct in question is presumed to be illegal, but defendants have an opportunity to explain their actions to the court. 113 Defendants bear the burden of proof to rebut a presumption of illegality because a “naked restraint on price and output requires some competitive justification.” 114 The quick-look test grants an antitrust defendant an opportunity to justify its apparently obvious tampering with the competitive market. 115

2. Supreme Court Precedent for Abbreviating the Rule of Reason

The Court has applied the abbreviated, or quick-look, rule of reason on multiple occasions. This Note discusses several prior opinions regarding anticompetitive conduct below, which relate to the Actavis rationale. 116 This Part demonstrates how the Court’s abbreviated rule of reason analysis parallels the quick-look test proposed by the FTC. 117

In some circumstances, the Court has held that the anticompetitive character of a settlement may preclude the need for an elaborate rule of reason analysis. 118 For example, the Court found antitrust violations in FTC v. Indiana Federation of Dentists, 119 although the Court refrained

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112 See id. at 735 (describing the difficult and time-consuming process of bringing a plaintiff’s antitrust action); see also Carrier, supra note 51, at 830 (“[P]laintiffs almost never win under the rule of reason.”).
114 Id. at 110.
115 In re Ciprofloxacin, 544 F.3d at 1332 (explaining the rule of reason burden-shifting scheme).
116 See infra notes 119–38 and accompanying text.
117 See infra notes 128–31 and accompanying text.
from conducting a full rule of reason analysis. The Court held that the agreement to withhold X-rays from insurance providers suppressed trade to such an extent that further economic justification provided by the federation did not necessitate judicial scrutiny. The Court established “the potential for genuine adverse effects on competition” from the circumstances that made an “elaborate market analysis” unnecessary. Indiana Federation of Dentists shows that the Court, at times, will abbreviate the rule of reason analysis when the anticompetitive effect is obvious.

When presented with a facial restraint of trade in NCAA v. Board of Regents of University of Oklahoma, the Court ruled that the defendant had “a heavy burden of establishing an affirmative defense.” In that case, the NCAA restrained the quantity of television rights available for sale, and the restraints were found facially unreasonable. There, the Court affirmed the lower court’s application of the rule of reason because the NCAA’s restraint on televised games raised prices and lowered output while both remained “unresponsive to consumer preference.” The NCAA decision sounds remarkably parallel to the quick-look rule of reason recommended by the FTC. In NCAA, the Court found a facially unreasonable restraint and rejected the NCAA’s justification for restraining the televising of college football games. Similarly, the quick-look test

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120 Id. at 461. The Indiana Federation of Dentists “conspired . . . to withhold x rays” in order to suppress competition from responding to insurance companies requests. Id. at 455. “A ‘reasonable mind’ could conclude on the basis of this evidence that competition for patients . . . would tend to lead dentists . . . to cooperate with requests for information by their patients’ insurers.” Id. at 456.

121 Id. at 461–62. The federation’s policy, along with the substantial evidence, was “sufficient as a matter of law to establish a violation of § 1 of the Sherman Act.” Id. at 465–66.

122 Id. at 460–61.

123 See id. at 460 (“[T]he FTC’s failure to engage in detailed market analysis is not fatal to its finding of a violation of the [r]ule of [r]eason.”).


125 Id. at 113.

126 Id. at 99.

127 Id. at 107 (“Restrictions on price and output are the paradigmatic examples of restraints of trade that the Sherman Act was intended to prohibit.” Id. at 107–08.).


129 NCAA, 468 U.S. at 120.
“treat[s] 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.”\textsuperscript{130} This presumption is rebuttable if the defendant can show “that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”\textsuperscript{131}

In \textit{Actavis},\textsuperscript{132} Justice Breyer extensively referenced a prior opinion—\textit{California Dental Ass’n v. FTC}.\textsuperscript{133} In that case, the California Dental Association restricted its members from certain types of advertising “to the detriment of both dentists and consumers of dental services.”\textsuperscript{134} There, the Court stated restraints that warrant a quick-look analysis include “‘an absolute ban on competitive bidding’”\textsuperscript{135} and “‘a horizontal agreement . . . to withhold from their customers a particular service.’”\textsuperscript{136} The restraint at issue in \textit{California Dental} failed to meet that standard because the issue in the case centered around the difficulty in quantifying the effect of advertising restrictions on the market.\textsuperscript{137} Because the anticompetitive effects were not facially obvious, the Court remanded for a more detailed rule of reason analysis.\textsuperscript{138}

\textbf{B. The Patent Act}

The Constitution grants Congress the power “[t]o promote the Progress of Science . . . by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”\textsuperscript{139} Under that authority, Congress enacted the Patent Act to provide an incentive for innovators to research, develop, and market new products.\textsuperscript{140} Patent laws are “a careful balance between the need to promote innovation and the

\textsuperscript{130} \textit{K-Dur}, 686 F.3d at 218 (emphasis omitted).
\textsuperscript{131} \textit{Id.}
\textsuperscript{132} \textit{See FTC v. Actavis, Inc.}, 133 S. Ct. 2223, 2226, 2236–38 (2013).
\textsuperscript{133} 526 U.S. 756 (1999).
\textsuperscript{134} \textit{Id.} at 762.
\textsuperscript{135} \textit{Id.} at 770 (quoting Nat’l Soc’y of Prof’l Eng’rs v. United States, 435 U.S. 679, 692 (1978)).
\textsuperscript{136} \textit{Id.} (quoting FTC v. Ind. Fed’n of Dentists, 476 U.S. 447, 459 (1986)).
\textsuperscript{137} \textit{Id.} at 771–72.
\textsuperscript{138} \textit{Id.} at 778, 780–81.
\textsuperscript{139} U.S. CONST. art. I, § 8, cl. 8.
\textsuperscript{140} Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989); see 35 U.S.C. § 101 (2012) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . . .”).
recognition that imitation and refinement through imitation [(generic products)] are both necessary to invention itself."141 The Supreme Court has described these laws as “the very lifeblood of a competitive economy.”142 Patent laws spur and promote innovation by granting a patent holder a lawful right to exclude others from the use of the holder’s invention.143 This constitutionally and statutorily protected monopoly is “an incentive to induce investment in innovation.”144

The exclusion of others from using a patented product necessarily restrains trade,145 but this anticompetitive effect is not unreasonable under the Sherman Act because the exclusivity period encourages and finances ongoing new product development, which ultimately benefits consumers.146 The tension between patent and antitrust law arises from this restriction of competition.147 Acknowledging antitrust policies, the Patent Act places boundaries on the monopoly created by a patent.148 “[T]he precise terms of the [patent] grant define the limits of [the] patentee’s monopoly and the area in which the patentee is freed from competition of price, service, quality[,] or otherwise.”149 A patent holder’s

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141 Bonito Boats, 489 U.S. at 146.
142 Id.
143 35 U.S.C. § 271(a) (2012) (“Whoever without authority makes, uses, offers to sell, or sells any patented invention . . . during the term of the patent therefor, infringes the patent.”); see also Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (“The essence of a patent grant is the right to exclude others from profiting by the patented invention.”).
145 Id. at 1305 (“[A] patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself . . . .” Id. (citing In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1328 (Fed. Cir. 2000))).
146 Id. (“Patent law also serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.” Id. at 1308 (internal quotation marks omitted)).
147 See id. at 1307.
148 Id. at 1304–05.
149 United States v. Line Material Co., 333 U.S. 287, 300 (1948) (“If the patentee . . . licenses the selling of the articles [by a license to make], [he] may [also] limit the selling by limiting the method of sale and the price . . . , provided the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee’s monopoly.” Id. at 299 (quoting United States v. Gen. Elec. Co., 272 U.S. 476, 490 (1926)) (internal quotation marks omitted)); see also 35 U.S.C. § 154(a)(1) (2012) (“Every patent shall contain . . . the right to exclude others from . . . using . . . [the patented] product[].”).
rights include the power to “grant and convey an exclusive right under his application for patent . . . to the whole or any specified part of the United States,” but the exclusion may never extend outside the scope of protection created by the Patent Act.

Courts use the scope-of-the-patent test to ensure that patent holders only restrict the price and production of the patented product within the bounds of the patent. This test protects the patent holder’s exclusive right to control the product. Within the patent’s scope, a patent holder can defeat an antitrust claim if it can show good faith procurement of the patent. When a patent holder alleges infringement against another party, the patent’s market monopoly will be upheld as long as “(1) the exclusion [of competition] does not exceed the patent’s scope, (2) the patent holder’s claim of infringement is not objectively baseless, and (3) the patent procured by fraud on the PTO.” Stated more simply, the scope-of-the-patent test examines whether, absent sham, litigation, or fraud in obtaining the patent, the settlement agreement exceeds the scope of the patent.

The Patent Act states: “A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent . . . shall rest on the party asserting such invalidity.” Relying on precedent from the Federal

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151 See In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006) (“[T]here is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.” (internal quotation marks omitted)).
152 See id.
154 Walker Process Equip., Inc., v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965). The case was remanded to the district court to analyze whether the defendant “illegally monopolized interstate and foreign commerce by fraudulently and in bad faith obtaining and maintaining . . . its patent . . . well knowing that it had no basis for . . . a patent.” Id. at 174 (internal quotation marks omitted).
155 In re K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012); see also 35 U.S.C. § 2(a)(1) (2012) (charging the PTO to examine patent applications); id. § 131 (2012) (noting the PTO issues patents if the application appears to entitle a patent to the patentee).
156 FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012).
Circuit, the Supreme Court recently reaffirmed the presumption of a patent’s validity, stating that a patent infringer must present clear and convincing evidence of the patent’s invalidity. Some courts view a patent’s statutory monopoly, coupled with an unrebutted presumption that the patent is valid, as sufficient justification to dismiss antitrust allegations.

The tension between the policies of antitrust and patent law has not been resolved for nearly a century. In 1984, Congress enacted the Hatch-Waxman Act in an attempt to overlay the two areas of law so as to maximize their potential to benefit consumers of prescription drugs. Although the law achieved its primary goals, the Act has increased the tension between patent law and antitrust law.

IV. THE HATCH-WAXMAN ACT: CONGRESS’S RESPONSE TO BALANCE THE POLICY TENSION REGARDING PRESCRIPTION DRUGS

Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, to balance the conflicting policies of patent and antitrust law to the advantage of both the American consumers and the drug manufacturers. This Part

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158 Microsoft Corp. v. i4i Ltd. P’ship, 131 S. Ct. 2238, 2242 (2011) (“[The Court] consider[ed] whether § 282 requires an invalidity defense to be proved by clear and convincing evidence.”); see also ACS Hosp. Sys., 732 F.2d at 1574–75 (“The presumption is never annihilated, destroyed, or even weakened, regardless of what facts are of record.”).

159 See In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208–09 (2d Cir. 2006).

160 See discussion supra Part III.A–B.


briefly summarizes the Hatch-Waxman Act’s attempt to balance the conflicting policies while also achieving the goal of facilitating generic competition to lower prescription drug costs.  

A. The Abbreviated New Drug Application Process

The Hatch-Waxman Act encouraged competition from generic drug manufacturers by creating a shorter application process for generic firms seeking to enter the market. The ANDA process shortened the time necessary to receive FDA approval and greatly decreased the cost of applying for FDA approval for a generic drug. The lower costs and shortened timelines successfully encouraged the entrance of more generic drugs into the market, and the ANDA process ultimately provided consumers with low-cost prescription drugs years earlier than before the creation of the ANDA process. With the shortened process, a generic drug now only takes three to five years to proceed from development to FDA approval, and the generic can cost as little as $500,000.

The Hatch-Waxman Act rewards the first filer of an ANDA with a 180-day exclusivity period during which time only the generic version of a drug may be available to consumers. Until this exclusivity period expires, the FDA will not approve any subsequent ANDAs filed by other generic drug manufacturers. The first filer receives the right to the exclusivity period at the time it files the ANDA, but it is important to note that the first filer controls when the period begins. The exclusivity period can be triggered when a court rules that the original patent for that product is invalid or when the generic manufacturer begins to commercially market its generic drug. After the exclusivity period

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165 See infra notes 167–70, 183–85, 195–200 and accompanying text.
167 See id.
173 See id.
174 Id. § 355(j)(5)(B)(iii)(I).
175 Id. § 355(j)(5)(B)(iv)(I).
expires, the FDA may finally approve ANDAs for additional generic versions of the drug.\textsuperscript{176} Congress provided this incentive to award generic companies for quickly challenging brand-name companies’ patents and lowering prescription drug prices for consumers.\textsuperscript{177} The exclusivity period provides a substantial share of market profits for taking the financial risk of engaging the name-brand pharmaceutical company in expensive litigation to challenge the original patent.\textsuperscript{178}

The Hatch-Waxman Act’s two goals were to encourage the development of new drugs while increasing the availability of low-cost generic prescription drugs for consumers.\textsuperscript{179} The Act made it easier for generic drugs to receive approval to enter the market from the FDA, but it also sought to protect the holders of name-brand drug patents by withholding FDA approval for alleged generic infringers during pending infringement suits.\textsuperscript{180} The Hatch-Waxman Act also grants patent term extensions,\textsuperscript{181} while facilitating generic competitors’ entry into the marketplace.\textsuperscript{182}

\textsuperscript{176} See id. § 355(j)(5)(B)(iv).
\textsuperscript{178} Id.
\textsuperscript{182} 15 U.S.C. § 1 (2012); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) (Generics are the “lifeblood of a competitive economy.”); see also H.R. REP. No. 98-857, pt. II, at 29 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2713 (“As a result of [§] 202 generic drugs will be able to be placed on the market between [eighteen] months and [two] years earlier than without this provision.”).
Consumers have greater access to low-cost generic drugs since Congress passed the Hatch-Waxman Act. The Congressional Budget Office reported that consumers saved between $8 billion and $10 billion by purchasing generic drugs in 1994. In 2002, Senator Orrin Hatch said he believed the bill was achieving its goals because 47% of prescriptions were filled with generic drugs while accounting for less than 10% of annual drug sales.

B. Abusing the 180-Day Exclusivity Period

The first ANDA filer holds the power to trigger the beginning of the 180-day exclusivity period. Instead of triggering it, the first filer can make the decision to “park” that period by refraining from entering the market, effectively barring additional generic filers from receiving FDA approval for their subsequent ANDAs. The ability to park the exclusivity period grants the first filer significant bargaining power in a settlement agreement with the original drug patent holder.

When submitting an ANDA, the generic applicant must certify the reason the existing patent does not prohibit the product from entering the market. Under 21 U.S.C. § 355(b)(2)(A)(iv), or the “paragraph IV certification,” an applicant certifies that the original patent is either invalid or not infringed by the generic product. A paragraph IV certification is a statutory infringement of the original patent. After a paragraph IV certification is filed, the patent holder has forty-five days to

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184 Kelly, supra note 170, at 426.
187 See id. § 355(j)(5)(B)(iv); FED. TRADE COMMISSION, supra note 177, at 63.
188 See, e.g., Andrx Pharm., Inc. v. Biovail Corp. Int’l, 256 F.3d 799, 803 (D.C. Cir. 2001) (noting that the first filer received $40 million per year in a settlement agreement in which it “parked” its 180-day exclusivity period); see also FED. TRADE COMMISSION, supra note 177, at 58.
file an infringement action against the generic ANDA filer based on that paragraph IV certification.\textsuperscript{193} Filing this infringement action automatically stays FDA approval of the ANDA for thirty months or, if earlier, until the patent expires or there is a judicial determination that the patent is invalid or is not infringed.\textsuperscript{194}

Since it began reviewing settlement agreements under the Hatch-Waxman Act in 2003, the FTC has become greatly concerned that reverse payment settlement agreements may abuse the exclusivity period by paying first filers to park their exclusivity period.\textsuperscript{195} When a generic manufacturer fails to begin commercially marketing its generic product, the patentee drops its infringement suit so the patent’s validity is not ruled on by a court, and the patent holder retains exclusive access to the market and enormous profits while consumers continue paying name-brand prices.\textsuperscript{196} The FTC believes that, by manipulating the statute to retain exclusive access to the market, drug patent holders violate the Sherman Act.\textsuperscript{197} The FTC regularly files suit in response to reverse payment settlement agreements that it believes abuse the Hatch-Waxman Act’s statutory delays to competition.\textsuperscript{198}

When a first filer parks its 180-day exclusivity period, the competitive landscape for that particular drug is significantly altered because other generic drugs cannot enter the market until that period expires.\textsuperscript{199} Although consumers do not see a drug’s price increase after a reverse payment settlement, they also do not see the drug’s price lower.\textsuperscript{200} This anticompetitive result on the market is exactly what the Hatch-Waxman Act tried to avoid.

Before the \textit{Actavis} decision, courts disagreed on the proper way to address reverse payment settlement agreements—whether to analyze the agreements using antitrust or patent law.\textsuperscript{201} Three circuits utilized patent

\textsuperscript{194} \textsuperscript{Id}.
\textsuperscript{195} See \textit{Fed. Trade Commission}, supra note 177, at 1.
\textsuperscript{196} See 35 U.S.C. § 271(a) (2012); see also Harris, supra note 22, at C1 (noting the disparity between name-brand and generic drug prices).
\textsuperscript{197} \textit{See FTC v. Watson Pharm., Inc.}, 677 F.3d 1298, 1307, 1309 (11th Cir. 2012).
\textsuperscript{198} \textit{See, e.g., id. at 1301.}
\textsuperscript{199} \textit{Fed. Trade Commission}, supra note 177, at iv.
\textsuperscript{201} See infra Part V.
law and the scope-of-the-patent test. Three other circuits analyzed anticompetitive effects under antitrust law using the per se rule and rule of reason tests.

V. CIRCUIT COURTS DISAGREE ON THE PROPER TEST TO DETERMINE THE LEGALITY OF REVERSE PAYMENT SETTLEMENT AGREEMENTS

A circuit split developed as the FTC brought suits against patentees for violating the Sherman Act by abusing the Hatch-Waxman Act provisions. Whether a court emphasized patent law or antitrust law was nearly outcome determinative in an analysis of reverse payment settlement agreements. The Federal, Second, and Eleventh Circuits (pro-settlement courts) placed great stock in the strength of a patent’s validity, and these courts upheld settlement agreements in which patent holders paid alleged infringers to delay marketing their products based on the principle that the patent granted certain exclusivity rights. The pro-settlement courts used the scope-of-the-patent test. This test relied heavily on the statutory presumption that the patent was valid and ultimately created a nearly irrebuttable presumption of patent validity. The District of Columbia, Sixth, and Third Circuits (anti-settlement courts) looked past the patent’s presumed validity and tended to find that paying an alleged infringer to retain an exclusive market unreasonably restrained trade under the Sherman Act. The anti-settlement courts used rule of reason analysis or abbreviated quick-look rule of reason to determine if there was an antitrust

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202 Watson Pharm., 677 F.3d at 1307, 1312; In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1335 (Fed. Cir. 2008); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharm. Inc., 344 F.3d 1294, 1308 (11th Cir. 2003).


204 See cases cited supra notes 202–03.

205 See, e.g., K-Dur, 686 F.3d at 218; Valley Drug, 344 F.3d at 1308.

206 See In re Ciprofloxacin, 544 F.3d at 1335; In re Tamoxifen, 466 F.3d at 204, 213; Schering-Plough, 402 F.3d at 1076.

207 See In re Ciprofloxacin, 544 F.3d at 1335; In re Tamoxifen, 466 F.3d at 213; Schering-Plough, 402 F.3d at 1076.

208 See FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012).

violation. The anti-settlement courts sidestepped the patent validity presumption and instead focused their analyses on the anticompetitive effect the settlement would have on the market.

In its petition for certiorari in Actavis, the FTC urged the Supreme Court to adopt a test in which “reverse-payment agreements [are treated] as presumptively anticompetitive.” The FTC believed that this test “reflect[ed] the appropriate balance between the competing interests implicated by such agreements.” The next Part describes how the Court agreed that the Eleventh Circuit’s Watson decision was incorrect, but disagreed that the quick-look rule of reason was the appropriate test for reverse payment settlements.

VI. THE SUPREME COURT’S HOLDING IN ACTAVIS

In Actavis, well-settled precedent from the realms of antitrust and patent law supported the respective arguments from each party, and the opinion specifically addressed each of the three types of analysis explained above. In a 5–3 decision, the Supreme Court held that a reverse payment settlement should receive full rule of reason analysis because a patent does not immunize a reverse payment settlement from antitrust scrutiny. The Court then reversed the Eleventh Circuit’s dismissal of the FTC’s antitrust complaint. The remainder of this Part discusses the analysis of each prong of the rationale in Actavis.

210 K-Dur, 686 F.3d at 218; Cardizem, 332 F.3d at 911; Andrx Pharm., 256 F.3d at 811.
211 K-Dur, 686 F.3d at 218; Cardizem, 332 F.3d at 911; Andrx Pharm., 256 F.3d at 811.
213 Id. at 22.
214 Id. at 21.
215 See infra Part VI.
217 The majority consisted of Justice Breyer, who authored the opinion, joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan. Id. at 2226. The dissenters included Chief Justice Roberts and Justices Scalia and Thomas. Id. Justice Alito took no part in the consideration or decision. Id.
218 Id. at 2237.
219 Id. at 2238.
A. The Scope-of-the-Patent Test Does Not Immunize the Settlement from Antitrust Scrutiny

The Court first reviewed the scope-of-the-patent test in its decision. The Court quickly explained it agreed that the reverse payment settlement’s “‘anticompetitive effects fall within the scope of the exclusionary potential of the patent.’” The very next sentence began with a very significant “but.” The reverse payment settlement, admittedly within the scope of the patent, remained subject to antitrust scrutiny. The Court explained that it previously “indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’ . . . and [the resulting] antitrust immunity.”

The Court refused to grant antitrust immunity for a reverse payment settlement because of the potential risk that the holder of an invalid patent may receive an unreasonable monopoly. An invalid patent does not grant a right to charge “higher-than-competitive price[s].” A reverse payment settlement ends any litigation of a patent’s validity, which raises a concern that the settlement may “have significant adverse effects on competition.” In light of that concern, “it would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy . . . .”

The Court then explored a line of cases in which it used antitrust law to analyze issues relating to the scope of a patent. Whether a patentee fixed prices with its licensees or tried to control production with the patent’s challenger, the Court consistently considered the agreements under the

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220 Id. at 2230.
221 Id. (quoting FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012)).
222 Id.
223 Id.
224 Id. at 2231.
225 Id. at 2230–31
226 Id. at 2231.
227 Id.
228 Id.
229 Id.
Sherman Act.231 These cases emphasized the ever-present balance between patent law policy and antitrust law policy.232

B. The Rule of Reason Analysis Is Necessary to Adequately Assess Whether Reverse Payments’ Anticompetitive Effect Is Reasonable

Justice Breyer then affirmed that the full rule of reason analysis is the appropriate antitrust scrutiny to determine whether a reverse payment settlement agreement is unreasonably anticompetitive.233 Although Justice Breyer concluded that the rule of reason should be used to determine if a reverse payment settlement is unreasonably anticompetitive,234 this Note argues that his conclusion is inconsistent with his analysis and the Court’s rationale actually would have justified imposing a presumption of illegality on reverse payment settlements. Regardless, five antitrust considerations outweighed any patent-related factor and supported the Court’s decision.235

1. Consideration One: The Potential for Genuine Adverse Effects on Competition236

A reverse payment is, in effect, the cost of maintaining the patentee’s monopoly.237 If the patentee fails to reach a settlement with the challenger, and loses the infringement suit, the monopoly will be broken and customers will pay lower prices for the product.238 By making a reverse payment settlement to a patent challenger, the patentee retains its exclusive grasp of the market and continues to determine the market price and receive profits from its product.239 In the Actavis settlement agreement, the reverse payment sum actually exceeded the amount of profit the generic companies anticipated to receive when their generic AndroGel entered the market.240 In these kinds of settlements, “[t]he patentee and the challenger gain; the consumer loses.”241

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231 See cases cited supra note 230.
232 Actavis, 133 S. Ct. at 2231–32.
233 Id. at 2237.
234 See id.
235 See infra Part VI.B.1–5.
236 Actavis, 133 S. Ct. at 2234 (quoting FTC v. Ind. Fed’n of Dentists, 476 U.S. 447, 460 (1986)).
237 Id.
238 Id.
239 Id.
240 See id. at 2229.
241 Id. at 2235.
The Hatch-Waxman Act itself provides the potential for further adverse effects on competition.\textsuperscript{242} In another industry, a massive reverse payment settlement could indicate to other would-be patent challengers that the patentee believes its patent is weak and may not survive patent infringement litigation.\textsuperscript{243} “[I]t is virtually unheard of outside of pharmaceuticals for [a patentee] to pay an accused infringer to settle the lawsuit.”\textsuperscript{244} However, the Hatch-Waxman Act’s 180-day exclusivity period\textsuperscript{245} and thirty-month patent grant stay create an environment that decreases the opportunities for further competition.\textsuperscript{246} Only the first filer receives the 180-day exclusivity period; thus, if the patentee removes the first filer from competition with a reverse payment settlement, future patent challengers will not receive the additional profits provided by the exclusivity period, and later ANDA filers must wait an additional thirty months before receiving FDA approval for their own generic drug.\textsuperscript{247}

The Court recognized that a reverse payment settlement, particularly in the Hatch-Waxman context, is almost inherently anticompetitive, but it recognized that the terms of the settlement can create a procompetitive result.\textsuperscript{248} In some reverse payment settlement agreements, the patentee could, for example, allow the patent challenger to enter the market before the patent expires.\textsuperscript{249} That settlement, the Court concede, would benefit consumers.\textsuperscript{250}

\begin{footnotes}
\footnotetext[243]{See \textit{Actavis}, 133 S. Ct. at 2236.}
\footnotetext[244]{\textit{Id.} at 2235 (quoting 1 \textsc{Herbert Hovenkamp, Mark Janis, Mark Lemley \& Christopher Leslie, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law} § 15.3, at 15-45 n.161 (2d ed. Supp. 2011)) (internal quotation marks omitted).}
\footnotetext[246]{\textit{Id.} § 355(j)(5)(B)(iii).}
\footnotetext[247]{\textit{Actavis}, 133 S. Ct. at 2235.}
\footnotetext[248]{\textit{Id.} at 2235–36.}
\footnotetext[249]{\textit{Id.} at 2234; see also \textit{id.} at 2229 (noting the settlement agreement stipulated that the generic manufacturer could enter the market sixty-five months before the patent term expired).}
\footnotetext[250]{\textit{Actavis}, 133 S. Ct. at 2234.}
\end{footnotes}
2. Consideration Two: The Anticompetitive Consequences Will, at Least Sometimes, Prove Unjustified

The possible reasons for ending patent infringement litigation with a reverse payment settlement are not always anticompetitive. A reverse payment could be considered a lump payment of future litigation costs—without spending the time in court conducting the litigation. Despite the possible justification for the anticompetitive consequences discussed previously, the Court held that a defendant should prove "that legitimate justifications are present."

3. Consideration Three: The Patentee Likely Possesses the Power to Bring That Unjustified Anticompetitive Harm About in Practice

The Court noted two factors that indicate a patentee has the power to bring about the harmful anticompetitive effects. First, the patentee already controls the market with its patent monopoly, naturally receiving "higher-than-competitive profits." Second, the "size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power . . . ." The market power of a patentee to bring about harmful anticompetitive effects with a reverse payment settlement is not really in question.

4. Consideration Four: An Antitrust Action Is Likely to Prove More Feasible Administratively than the Eleventh Circuit Believed

The Eleventh Circuit emphasized its policy to favor settlements instead of costly litigation over a patent’s validity. Without discounting a policy that favors litigation settlement, the Court noted that "it is normally not necessary to litigate patent validity to answer the antitrust question . . . ." A large reverse payment indicates that a patentee may not feel secure in the patent’s strength and would prefer to share monopoly profits than face

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251 Id. at 2235–36.
252 Id. at 2236.
253 Id. at 2236–37.
254 Id. at 2236.
255 Id.
256 Id.
257 Id.
258 Id. (internal quotation marks omitted).
259 Id.
261 Actavis, 133 S. Ct. at 2236.
reduced profits from market competition.262 The Court reasoned that, because a large, unjustified reverse payment “likely seeks to prevent the risk of competition”—which constitutes anticompetitive harm—“the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, . . . without forcing a court to conduct a detailed exploration of the validity of the patent . . . .”263

5. Consideration Five: The Fact that a Large, Unjustified Reverse Payment Risks Antitrust Liability Does Not Prevent Litigating Parties from Settling Their Lawsuit264

Pharmaceutical patent holders can settle patent litigation without a reverse payment settlement.265 It is not hard to imagine why a patent challenger would prefer a reverse payment,266 and it is also not hard to understand why a pharmaceutical patentee would prefer to end the litigation with the first filer.267 The Court emphasized that the important issue is why a reverse payment was included in the settlement agreement.268 The settlement will probably violate antitrust law “[i]f the basic reason is a desire to maintain and to share patent-generated monopoly profits.”269

C. The Court Concluded that the Quick-Look Rule of Reason Failed to Account for the Complexities of Reverse Payment Settlements

After explaining why reverse payment settlements should be subjected to antitrust scrutiny under the rule of reason, the Court addressed the FTC’s argument that reverse payments should be presumptively illegal.270 The majority expressly rejected the FTC’s recommendation to adopt the abbreviated quick-look approach in place of the full rule of reason.271 The Court decided that reverse payment settlements do not meet the obvious

262 Id.
263 Id. at 2236–37.
264 Id. at 2237.
265 Id.
266 See, e.g., id. at 2233 (explaining that the challenger can make more money from the settlement than it would from actually selling its product).
267 See George, supra note 15, at 1 (noting the patent holder continued to generate monopoly profits).
268 Actavis, 133 S. Ct. at 2237.
269 Id.
270 See id. at 2233–38.
271 Id. at 2237.
level of anticompetitive effect necessary to justify an abbreviated look.\textsuperscript{272} The anticompetitive effect was not obvious enough to warrant a quick look because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries.\textsuperscript{273}

Justice Breyer believed that the complexity of each reverse payment settlement precludes the use of the abbreviated test.\textsuperscript{274} However, the Court’s rationale sufficiently justified the FTC’s quick-look test, and that test should have been the standard for future review of reverse payment settlements.

VII. REVERSE PAYMENT SETTLEMENTS SHOULD BE REVIEWED UNDER THE QUICK-LOOK TEST

Up to this point, this Note provided the context and rationale behind the \textit{Actavis} decision.\textsuperscript{275} The opposing policies of patent and antitrust law create a complicated legal background.\textsuperscript{276} The Hatch-Waxman Act adds another layer of complexity by providing an incentive, which pharmaceutical companies converted into an obstacle to competition by paying money to delay generic drugs from entering the market.\textsuperscript{277} After six circuit courts disagreed about how to approach reverse payment settlements, the Court granted certiorari to settle the issue.\textsuperscript{278} Unfortunately, in its \textit{Actavis} decision, the Court missed an opportunity to create a balance between encouraging development of the next wonder

\textsuperscript{272} Id.
\textsuperscript{273} Id.
\textsuperscript{274} Id.
\textsuperscript{275} See supra Parts III–VI.
\textsuperscript{276} See supra Part III.
\textsuperscript{277} See supra Part IV.B.
drug and providing Karen Winkler and others with affordable generic medication alternatives.\textsuperscript{279}

\textbf{A. The Court’s Rationale Supports the Quick-Look Approach}

The quick-look test recommended by the FTC could help to create that balance. The quick-look approach places the initial burden on the defendant “to show empirical evidence of procompetitive effects,”\textsuperscript{280} whereas the rule of reason requires a much more detailed analysis with the burden on the plaintiff (here, the FTC) to show proof of anticompetitive effects on the market.\textsuperscript{281} As the Court summarized its justification for applying antitrust law, it also recognized the strong potential anticompetitive effects of reverse payment settlements:

\begin{quote}
[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.\textsuperscript{282}
\end{quote}

In this summary, the Court stated that reverse payments are not the only way for patentees to settle litigation and they carry a “risk of significant anticompetitive effects” that needs justification.\textsuperscript{283} Under the rule of reason, a plaintiff bears the burden to prove these anticompetitive effects,\textsuperscript{284} but here the Court already recognized that reverse payment settlements naturally carry a high risk of anticompetitive effects.\textsuperscript{285} Requiring the rule of reason analysis seems inconsistent with the Court’s perception of reverse payments. Due to the fact that the Court already

\textsuperscript{279} See \textit{Actavis}, 133 S. Ct. at 2242, 2247 (Roberts, C.J., dissenting).
\textsuperscript{280} Cal. Dental Ass’n v. FTC, 526 U.S. 756, 775 n.12 (1999).
\textsuperscript{282} \textit{Actavis}, 133 S. Ct. at 2237.
\textsuperscript{283} \textit{Id}.
\textsuperscript{284} See Edelman, \textit{supra} note 281, at 198.
\textsuperscript{285} \textit{Actavis}, 133 S. Ct. at 2237.
established the significant potential for anticompetitive effects from a reverse payment, the next logical step in future cases should be for the defendant to explain first how the reverse payment does not create an unreasonable anticompetitive effect. A presumption of illegality from a quick look answers the concerns the Court expressed as it summarized its holding.

The quick-look test rule of reason treats payments from the patent holder to the generic patent challenger as a rebuttable presumption of an unreasonable restraint of trade, which supports the intent of the Hatch-Waxman Act. A “parked” exclusivity period restricts the flow of generic drugs into the market, whereas the Hatch-Waxman Act intended to facilitate the introduction of new drugs to consumers. A misuse of the Act’s provisions, such as parking the exclusivity period, should require additional procompetitive justification by the parties. This approach relieves plaintiffs of the difficult and costly burden of proving anticompetitive effect by first forcing the patentee to justify the settlement.

In reverse payment settlements, patentees choose to make the large reverse payment instead of settling the litigation in a more traditional way. Due to this, the defendant-patentee should bear the initial burden to justify that payment under antitrust scrutiny. If the payment to retain a monopoly cannot be justified by the patentee, why should a court force the FTC to prove that an anticompetitive effect resulted after the Court has already recognized the strong potential for anticompetitive effect? If a company does not believe that it can prove to a court that its reverse payment creates a procompetitive effect, then it will be encouraged to find another means to settle a patent dispute that will not hurt consumers. The Actavis opinion put forward a strong argument for applying antitrust law, and that same reasoning creates a strong argument for using the quick-look test to review reverse payment settlements.

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286 See Edelman, supra note 281, at 198.
287 See discussion supra Part IV.
288 See Actavis, 133 S. Ct. at 2228; Kelly, supra note 170, at 417.
289 See Actavis, 133 S. Ct. at 2235 (citing 12 AREEDA & HOVENKAMP, supra note 109, ¶ 2046, at 341 (3d ed. 2012)) (“[T]hese provisions . . . have created special incentives for collusion.”).
291 See Actavis, 133 S. Ct. at 2227.
292 See id. at 2234–38; discussion supra Part VI.
The quick look’s presumption of illegality is not an insurmountable obstacle that would prevent a reverse payment settlement from surviving antitrust scrutiny. 293 The Court conceded that a reverse payment settlement can have a procompetitive effect. 294 For example, a reverse payment settlement that allows a generic drug to enter the market earlier than a patent’s expiration “bring[s] about [additional] competition, [which is] to the consumer’s benefit.” 295 On the other hand, a reverse payment settlement that simply divides hundreds of millions of dollars of monopoly profits in return for a patent challenger staying out of the market results in a situation in which “[t]he patentee and the challenger gain[, while] the consumer loses.” 296 Higher drug costs naturally result from that type of settlement agreement because the patentee maintains a competition-free market. 297 This anticompetitive effect is obvious, and the Court has previously stated that an obvious anticompetitive effect should trigger a quick-look approach. 298 Why not require the defendant to show a court on which side of the rule of reason spectrum the settlement agreement falls? If a defendant cannot justify the anticompetitive nature of the settlement agreement, why should a court need to conduct any further analysis? 299

Two basic types of reverse payment settlements occur. In one type of reverse payment settlement, the patentee agrees to allow a generic into the market before the patent expires. 300 In the other type of reverse payment settlement, the patentee and challenger split the monopoly profits and the patentee maintains its monopoly until the patent expires. 301 The Court has already conceded that the first type of settlement benefits consumers by

294 Actavis, 133 S. Ct. at 2225–26.
295 Id. at 2234.
296 Id. at 2234–35.
297 See Fed. Trade Comm’n, supra note 3, at 2 (describing the high costs passed on to consumers as a result of pay-for-delay agreements).
299 See Actavis, 133 S. Ct. at 2236 (“[T]he [reverse] payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.”).
301 Id. at 494–95.
prematurely lowering prices. The second type of settlement “keeps prices at patentee-set levels” and, in the Hatch-Waxman context, is only possible because of provisions in the Act that are used contrary to the Act’s purpose. The Court should have placed the burden on the patentee-defendant to justify splitting monopoly profits and maintaining “higher-than-competitive” drug prices, which is in conflict with the purpose of the Hatch-Waxman Act.

The rule of reason will not sufficiently deter further reverse payment settlements from maintaining higher-than-competitive prescription drug prices. As mentioned earlier, defendants nearly always prevail in rule of reason cases. Barring a change in that trend, patent holders will continue to terminate patent infringement suits with reverse payments to patent challengers, as they will most likely prevail if the settlement is challenged by the FTC as an antitrust violation. Alternatively, the quick look’s presumption of illegality would force a patent holder to craft settlement agreements with some procompetitive justification. The procompetitive terms would, in some way, benefit consumers by providing lower prescription drug prices. The quick-look test would encourage lower prescription drug prices, just as the Hatch-Waxman Act originally intended. The next Part of this Note discusses how the intent behind the Hatch-Waxman Act should have factored into the analysis of a reverse payment settlement and supports the application of the abbreviated rule of reason.

B. The Quick-Look Approach Supports the Legislative Intent for the Hatch-Waxman Act

In *Actavis*, Justice Breyer weighed statements from Senator Orrin Hatch and Representative Henry Waxman about how reverse payment settlement agreements violated the purpose of the Hatch-Waxman Act. For example, Senator Hatch made it clear that delaying competition was a

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302 *Actavis*, 133 S. Ct. at 2234.
303 Id.
304 See id. at 2236 (“[R]everse payment agreements are associated with the presence of higher-than-competitive profits . . . .”).
305 Id. at 2231.
306 Id. at 2234.
307 See Carrier, supra note 51, at 830.
308 See infra Part VII.B.
309 *Actavis*, 133 S. Ct. at 2234.
serious affront to the Act. Without treating the statements of the congressmen as dispositive of the issue, the Court recognized the “general procompetitive thrust” of the Hatch-Waxman Act.

The Hatch-Waxman Act encouraged generic drug manufacturers to bring generic drugs to market by challenging patents and filing ANDAs. Settlements that delay generic entry into the market pervert the 180-day exclusivity period by converting the competitive incentive into a roadblock against further generic challengers. The generic’s marketplace entry triggers the 180-day exclusivity period that the FDA requires before approving additional generic ANDAs. Congress did not intend for the first filer’s exclusivity period to be used to prevent FDA approval of ANDAs and to extend the brand-name patent holder’s monopoly on the market. Instead, Congress intended to offer the exclusivity period to incentivize patent challenges, in order that consumers could benefit through the lowering of prescription drug prices. “Parking” the exclusivity period creates a bottleneck that restricts generic access to the market, keeps drug prices high, and defeats the purpose of the Hatch-Waxman Act.

The goals of the Hatch-Waxman Act support treating reverse payment settlements “as prima facie evidence of an unreasonable restraint of trade.” Although reverse payment settlements “are a natural by-product of the Hatch-Waxman process,” Congress did not anticipate that the law would be used to delay generic drug entry into the market. Over the past few years, Senator Hatch and Representative Waxman have continued to speak out against competitive delays resulting from reverse payment settlements. Senator Hatch once called reverse payments “appalling,” and explained that Congress “did not wish to encourage situations [in

311 Actavis, 133 S. Ct. at 2234.
312 See Fed. Trade Commission, supra note 177, at i–ii.
315 Id.
317 In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (discussing how the ANDA and paragraph IV certification lead to reverse payment settlements).
which] payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition.”

In an amicus curiae brief, Representative Waxman told the Court that reverse payment agreements “turn[] the . . . legislation on [its] head.”

C. California Dental Does Not Support the Court’s Rejection of the Quick-Look Approach

Puzzlingly, the Court relied on California Dental as it dismissed the quick-look test. In California Dental, the abbreviated rule of reason was not appropriate because the advertising restraint’s effect on the market was unclear to the Court and the lower court’s analysis of the market effect was incomplete. Similarly, the Federal Circuit later applied California Dental to conclude that the antitrust plaintiff bore the burden to show an actual anticompetitive effect under the traditional rule of reason because the record made it “clear that the [plaintiff’s] technology lacked both the technical and the commercial prospects that would have made it a possible basis for a product that could compete with [defendant].” Once again, the court did not have sufficient evidence that the agreement would produce anticompetitive effects.

Here, however, as in Professional Engineers and Indiana Dentists, the reverse payment settlement ensures that there continues to be no competition for a particular drug, which would ordinarily trigger an abbreviated rule of reason approach. In Indiana Dentists, “no elaborate industry analysis [was] required” to find that “a refusal to compete . . . impair[ed] the ability of the market” to provide reasonable prices to consumers and, therefore, violated the rule of reason. Again, in

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322 Actavis, 133 S. Ct. at 2237.
324 Prince Corp. v. Int’l Trade Com’n, 616 F.3d 1318, 1338 (Fed. Cir. 2010).
325 Id. at 1340.
326 Id.
330 Ind. Dentists, 476 U.S. at 459 (quoting Prof’l Eng’rs, 435 U.S. at 692).
331 Id.
NCAA, the Court held that, despite “the absence of proof of market power[,] . . . an agreement not to compete in terms of price or output” justified an abbreviated rule of reason analysis. The key consideration in both those cases was the absence of price competition—whether the defendant had market power. In Actavis, Justice Breyer stated that a reverse payment indicates that the patentee presumptively possesses market power. He also concluded that there is a strong likelihood that a reverse payment settlement will suppress any competitive pricing for the prescription drug involved in the settlement. The intentional removal of competition by the reverse payment “impede[s] the ordinary give and take of the marketplace,” which the Court has previously held should result in an abbreviated rule of reason analysis.

According to California Dental, a “great likelihood of anticompetitive effect[]” is the trigger for an abbreviated rule of reason analysis. Here, Justice Breyer expressed great concern about the strong likelihood of anticompetitive results that can follow a reverse payment settlement within the Hatch-Waxman context. A person of average economic knowledge could conclude that a lack of competition in the prescription drug market keeps prices high. Therefore, under the California Dental standard, a

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333 Id. at 109.
334 Id. at 109–10; Ind. Dentists, 476 U.S. at 459.
336 See id. at 2234–35.
339 Id. (emphasis added).
340 See Actavis, 133 S. Ct. at 2235 (”First, under Hatch-Waxman only the first challenger gains the special advantage of 180 days of an exclusive right to sell a generic version of the brand-name product. . . . Second, a generic that files a paragraph IV after learning that the first filer has settled will (if sued by the brand-name) have to wait out a stay period of (roughly) [thirty] months before the FDA may approve its application . . . .” (citations omitted)).
341 See Cal. Dental, 526 U.S. at 770 (“In each of these cases, which have formed the basis for what has come to be called abbreviated or ‘quick-look’ analysis under the rule of reason, an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”).
342 Id.
reverse payment settlement agreement should trigger the quick-look approach. *California Dental* actually supports the proposition that the Court should have adopted the quick-look test to analyze reverse payment settlements.

**VIII. Conclusion**

The quick-look rule of reason addresses concerns that the Court expressed in the cases previously mentioned.\(^{343}\) This test would place the burden of proof on the patent holder to show a procompetitive result from the reverse payment and that the patent holder did not unreasonably restrain competition.\(^{344}\) In the past, outside the pharmaceutical industry, the Court often placed the burden of justification on the defendant when it found obviously anticompetitive effects.\(^{345}\) The Court has repeatedly declined to use a full-blown rule of reason analysis when it found such obviously anticompetitive conduct.\(^{346}\) Here, reverse payment settlements have a strong potential to maintain an artificially competition-free market, so past precedent supports placing the initial burden on the defendant with the quick-look approach.

The Court properly held that reverse payment settlements are subject to antitrust law,\(^ {347}\) but it should not have rejected the quick-look rule of reason as the appropriate test to analyze reverse payment settlements. The quick-look rule of reason supports the policy of patent law by allowing the patent holder to profit exclusively from the patented product, as long as it does so in a reasonable way.\(^ {348}\) This test also reinforces the Sherman Act’s policy by presuming an unreasonable restraint of trade when patentees appear to artificially maintain the patent monopoly by buying off statutorily encouraged generic drug manufacturers and maintaining high

\(^{343}\) See cases cited *supra* Part VII.C.


\(^{347}\) See *Actavis*, 133 S. Ct. at 2237–38.

\(^{348}\) See *supra* Part III.B (describing the policy of patent law); *supra* notes 102–15 and accompanying text (describing the quick-look rule of reason).
prescription drug prices for consumers. The quick-look test supports the legislative intent for the Hatch-Waxman Act by discouraging the misuse of Act provisions to sustain high prescription drug prices and to delay generic drugs from the market.

Courts often cite the judicial policy to favor settlements when applying the scope-of-the-patent test and application of the quick-look test would not prevent settlements in paragraph IV certification infringement suits. Professor Hovenkamp points out that removing the reverse payment settlement option “may simply make the settlement take on a different form.” Justice Breyer echoed this idea in Actavis, and history validates that statement. During fiscal year 2005, for example, out of eleven final settlements of drug infringement litigation, only two involved a reverse payment to a generic ANDA filer. The Supreme Court properly subjected reverse payment settlements to antitrust scrutiny, but it should have reinforced Congress’s intent and followed its own precedent by applying the quick-look rule of reason test to the reverse payment settlement agreement in FTC v. Actavis, Inc.

349 See supra Part III.A (describing the Sherman Act).
350 See supra Part IV.
351 See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008) (“[T]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation.”).
352 1 HOVENKAMP, JANIS, LEMLEY & LESLIE, supra note 244, § 15.3a, at 15-53 (2d ed. Supp. 2012).