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I. INTRODUCTION

When Congress passed the Hatch-Waxman Act of 1984 amending the Federal, Food Drug and Cosmetic Act of 1938, it did so to speed the development and marketing of generic drugs. Congress hoped that increased competition from generic drugs would reduce prices for consumers. Congress streamlined the FDA approval process for generic drugs and created incentives for generics to challenge patents held by manufacturers of "pioneer" drugs.

However, Hatch-Waxman's remedy may prove worse than the "disease" it allegedly treats. One unforeseen consequence of Hatch-Waxman's generic drug approval regime is visible in the settlements of patent infringement suits encouraged by the law's incentives. Hatch-Waxman reduced the financial risk involved for generic drug manufacturers in their attacks on patented "pioneer" drugs. As a result, patented drug manufacturers have been more willing to settle patent infringement suits against their generic challengers, even on terms that appear favorable to the generic manufacturer. An increasingly common term of these patent-generic settlements has been so-called "reverse payments" made by the patent holder to the generic manufacturer. Even more troubling to some critics are so-called "pay for delay" settlements, in which the reverse payments are accompanied by the generic's agreement to postpone entry into the market.

Such settlements have been increasingly challenged in both private and federal antitrust actions as unreasonable restraints of trade in violation of section 1 of the Sherman Act. The Federal Trade Commission (FTC), in particular, has taken a strong stance against settlements involving reverse payments and other allegedly

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4. Id.
anticompetitive terms. Three appellate courts also have ruled on the validity of these settlements, with the Second, Sixth and Eleventh Circuits proposing competing standards by which to evaluate them. Nor has the FTC’s approach been championed by the Department of Justice (DOJ). In fact, the Solicitor General’s office has written amicus briefs at the request of the Supreme Court that successfully argued against the Supreme Court hearing the FTC’s appeal. Finally, even Congress has considered legislation to amend the Hatch-Waxman Act to prohibit such reverse payments. For the moment, the Supreme Court has refused to grant certiorari to address this issue, most recently denying the FTC’s petition for certiorari from the Second Circuit’s decision in *In re Tamoxifen Citrate Antitrust Litigation.*

As an initial matter, Congress should not step in to resolve this situation. As has been the case with antitrust doctrine in general, the solution to this problem should come from the courts. Indeed, the best standard for the courts to adopt is a modification of the one proposed by the Eleventh Circuit. Courts should evaluate the allegedly anticompetitive aspects of patent settlements under a two-step standard: (1) a comparison of the exclusionary scope of the patent and the settlement terms; and (2) a traditional rule of reason treatment that would take into account the first step’s findings. Only such a two-step standard recognizes the value of both the patent and antitrust regimes’ complementary approaches to promoting competition.

Part II of this Comment outlines the regulatory framework for FDA approval under the Hatch-Waxman Amendments and presents the features of common settlements that raise antitrust concerns. Part III of this Comment briefly sketches the applicable federal antitrust standards and describes the tension among the patent and antitrust regimes. Part IV presents the principal cases to have reached the appellate courts and the various standards articulated by these courts, the FTC and recent Congressional bills. Part V analyzes the merits of these proposed solutions and argues for the adoption of a modified two-step version of the Eleventh Circuit’s standard.


10. Tamoxifen, 466 F.3d 187.

11. *Schering-Plough Corp.,* 402 F.3d at 1066.

12. See infra Part II.

13. See infra Part III.

14. See infra Part IV.

15. See infra Part V.
II. HATCH-WAXMAN’S REGULATORY FRAMEWORK

A. The Hatch-Waxman Act Introduces the Abbreviated New Drug Application

The principal goal of Hatch-Waxman was to speed the arrival of generic drugs onto the market in order to increase competition and thereby reduce costs to consumers. To accomplish this goal, the Act streamlined the FDA approval process for generic drug manufacturers by developing the Abbreviated New Drug Application (ANDA). To qualify for this more efficient approval regime, the proposed generic must be “bioequivalent” to the previously approved patented drug. Rather than having to implement and submit costly and time-consuming “safety and efficacy studies,” a generic manufacturer filing an ANDA may rely on the studies previously filed by the patent manufacturer and already approved by the FDA. This reduces costs and time investment on the part of the generic drug manufacturers.

The ANDA filer must also submit a certification that “the proposed generic drug does not infringe any patent listed with the FDA as covering the pioneer drug.” There are four forms this certification may take, but the so-called “Paragraph IV” certification is the only one relevant in the context of the patent settlements. In a Paragraph IV certification, the ANDA filer certifies that the “patent [for which its generic is bioequivalent] is invalid or [would] not be infringed by the manufacture, use, or sale of the new drug.”

The ANDA filer’s election of Paragraph IV certification triggers a crucial series of statutory requirements. First, the ANDA filer must give notice to each and every patent holder affected by the certification. Second, upon receipt of this notice, the patent holder has forty-five days to initiate a patent infringement lawsuit against the generic manufacturer. Should the patent holder decide not to file a lawsuit, the FDA “may immediately approve the ANDA” and the generic subsequently can enter the market.

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17. 21 U.S.C. § 355(j) (2000). All drugs must be approved by the FDA. Id. § 355(a). Prior to the 1984 Hatch-Waxman Act (HWA), there was one method, new drug approval (NDA), for getting FDA approval. Id. § 355(b). The HWA adds the ANDA in § 355(j).
21. Cardizem, 332 F.3d at 901.
22. 21 U.S.C. § 355(j)(2)(A)(vii). The certification may also state that: (1) there was no patent filed for the “listed” drug (a “paragraph I” certification); (2) that the patent has expired (a “paragraph II” certification); or (3) the patent will expire on a specific date, and the generic drug will not be marketed before that time (a “paragraph III” certification). Id.
24. Id. § 355(j)(2)(B).
25. Id. § 355(j)(5)(B)(iii).
26. Id.
If, however, the patent holder elects to file an infringement suit within the forty-five day window, a thirty-month stay goes into effect and prohibits the FDA from approving the ANDA filing within that time. The only way that this stay can be lifted prematurely is if a district court concludes—in a final decision—that the patent has not been infringed or is otherwise invalid. Following such a ruling, the FDA may begin approving ANDA filings as of the date of the court’s decision.

While the thirty-month stay offers patent holders significant protection, ANDA procedures also provide incentives to generic manufacturers. The first ANDA filer receives a 180-day exclusivity period in exchange for taking on the prospective risks of defending a patent infringement suit. During this exclusivity period, the FDA is prohibited from approving any other generic manufacturer’s ANDA until 180 days after the earlier of two events: (1) the date of the first ANDA filer’s commercial marketing of its generic drug; or (2) the date of a “court [decision ruling] that the patent is invalid or not infringed.” This exclusivity period was designed to encourage ANDA filings in the face of a strong disincentive: the first ANDA filer takes the financial burden and risk of defending a potential infringement suit brought by the patent holder. Should the first ANDA filer prevail in the patent infringement suit, a subsequent ANDA filer could otherwise immediately enter the market and “free ride” on the first filer’s efforts.

It is important to point out one other aspect of the Paragraph IV certification that is no longer in effect, but has some bearing on the factual circumstances of the appellate cases discussed below. FDA regulations had required, prior to 1998, that ANDA filers would not get the 180-day exclusivity period unless they had successfully defended the patent infringement suit. This “successful defense” interpretation was found to be unreasonable, and the FDA dropped this requirement in November 1998. The newer interpretation removes any such obstacle to the first ANDA filer receiving the 180-day exclusivity period.

B. Typical Patent Settlements under Hatch-Waxman

Hatch-Waxman’s goal of increasing challenges of weak patents in the pharmaceutical industry has been only partially successful. Paragraph IV certifications have in-

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27. Id.
29. Id. § 355(j)(5)(B)(iv).
30. Id. § 355(j)(5)(B)(iii)(I). Pre-2000, this was calculated from a “final judgment from which no appeal can be or has been taken.” 21 C.F.R. § 314.107(e)(1) (1999). Now, a district court decision is sufficient. Mylan Pharm., Inc. v. Shalala, 81 F. Supp. 2d 30 (D.D.C. 2000).
creased, but so too have settlements of the resulting infringement actions on terms that delay generic entry into the market.\textsuperscript{35} Outside of the Hatch-Waxman regulatory framework, patent settlements often involve the purchase of a license from the patent holder by the generic manufacturer. Such settlements not only reward the patent holder for its innovation, but also increase competition in the marketplace. Under Hatch-Waxman, however, the regulatory framework has created incentives that lead to settlements with the exact opposite results. These settlements have increasingly included so-called “reverse” payments—from the patent holder to the generic manufacturer—and agreements by the generic not to enter the market for a specific period of time.\textsuperscript{36} These are sometimes referred to as “pay for delay” settlements. For the consumer, there is no competition to reduce the price of the pioneer drug.

These settlements often are accompanied by other terms as well. For example, the patent holder may agree to purchase licenses on other products owned by the generic manufacturer. Additionally, the underlying patent settlement may—but is not always—dismissed or otherwise resolved. Finally, a bottleneck can be created which prevents subsequent ANDA filers from entering the market.

This last term particularly has troubled antitrust regulators and consumer advocates. Under normal ANDA procedures, the patent holder will continue to enjoy a monopoly until the approved date on which the generic manufacturer can enter the market. For the next 180 days, the two companies will enjoy duopoly control of the market. Finally, full competition occurs after the expiration of the 180-day exclusivity period, when other generics enter the market. Remember, however, that the exclusivity period is only triggered by one of two events. The settlement is designed such that the 180-day exclusivity period never will be triggered when (1) the generic manufacturer agrees not to enter the market, and (2) it precludes a court decision in the underlying infringement suit. Thus, the “bottleneck” results, because no other generic can enter the market. Consumer advocates and the FTC argue that such terms harm consumers who would have enjoyed fuller competition and lower prices absent these agreements.

III. THE APPLICABLE FEDERAL ANTITRUST STANDARDS AND THE TENSION BETWEEN PATENT AND ANTITRUST REGIMES

A. Federal Antitrust Analysis of Horizontal Restraints of Trade

Patent settlements between generic and drug manufacturers typically have been challenged under the Sherman Act, section 1 of which prohibits agreements in


\textsuperscript{36} Id.
Just What the Doctor Ordered

restraint of trade. Re It is well-settled that the intent behind this sweeping prohibition is to condemn only unreasonable restraints of trade. The FTC may also challenge violations of the Sherman Act under section 5 of the Federal Trade Commission Act.

Courts evaluate restraints of trade using three different standards. Under the first type of analysis, practices that are clearly anticompetitive are declared "per se illegal." Practices such as horizontal price fixing and market allocation are so obviously anticompetitive that judicial economy precludes an investigation into any alleged pro-competitive effects or justifications. In per se treatment, plaintiffs need only show that the restraint occurred, but are not required to demonstrate actual anti-competitive effects in the market. The defendant is barred from offering justifications or demonstrating that actual market effects were pro-competitive. Courts have been reluctant to add to the category of restraints that are deemed per se illegal, limiting this analysis to practices with which the judiciary has long-term experience of the anticompetitive effects.

Under the second analysis, the "rule of reason" treatment, courts "take[e] into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." The framework for this analysis involves a burden-shifting, three-step process. First, the plaintiff has the initial burden to show that the challenged conduct produces anticompetitive effects in the relevant market. If the plaintiff is successful, the second step requires the defendant to demonstrate sufficient pro-competitive justifications. In the third step, the burden returns to the plaintiff to show that the defendant could have accomplished these goals in a less restrictive manner.

Finally, a third type of analysis has evolved: the "quick look" or "truncated rule of reason" treatment. The truncated rule of reason analysis permits the plaintiff to shift the burden more quickly to the defendant, once the plaintiff has shown that the defendant has engaged in conduct similar to those practices falling into the per

37. 15 U.S.C. § 1 (2002) ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."
41. State Oil, 522 U.S. at 10.
43. Id.
44. Id.
45. State Oil, 522 U.S. at 10.
46. Holmes, supra note 42, § 5.5.
47. Id.
48. Id.
49. Id.
se category, e.g., restraints on price, output or customers. The plaintiff need not establish the relevant market nor the defendant’s market power, but the defendant has the opportunity to demonstrate procompetitive justifications and efficiencies. Modern antitrust doctrine has tended to view these three analytical approaches as relative points on a spectrum, rather than discrete categories.

B. The Conflicting Regimes of the Patent and Antitrust Laws

Like the antitrust laws, the patent laws also seek to improve the fate of the consumer in the marketplace, but do so in an opposite manner. While the antitrust laws prohibit restraints of trade in order to increase competition, the patent laws restrict competition in order to encourage innovation. For this reason, intersections of patent and antitrust law have been marked by the need for careful, deliberate analysis by the courts.

A patent grants the patent holder “the lawful right to exclude others.” There are some limits to this exclusionary right, but this right permits the patent holder to do two things: (1) the patent holder can elect not to produce the patented article and thus exclude its use completely, or (2) the patent holder can elect to “be the sole supplier itself.” Crucially, the patent right permits the patent holder to act in ways that otherwise would violate the antitrust laws: (1) the patent holder can divide up the geographical market by granting exclusive territorial licenses; or (2) allocate the market in other ways, such as between retailers and wholesalers. Antitrust doctrine must acknowledge these conflicting circumstances whenever evaluating a patent holder’s conduct.

IV. DIVERGENT STANDARDS FOR THE TREATMENT OF PHARMACEUTICAL PATENT SETTLEMENTS

Settlements under Hatch-Waxman generally did not involve “reverse payments” until the mid-1990’s. As the number of agreements with such payments increased,
the FTC began challenging them and obtained a number of consent orders.\textsuperscript{62} Eventually some cases began to reach the federal district courts,\textsuperscript{63} but the issue did not reach a federal appellate court until 2003 when the Sixth Circuit decided \textit{In Re Cardizem CD Antitrust Litigation}.\textsuperscript{64} In three subsequent cases, both the Eleventh and the Second Circuits also have addressed pharmaceutical patent settlements under Hatch-Waxman.\textsuperscript{65} An examination of the conflicting standards articulated by the courts reveals the difficulty in balancing the competing values of patent and antitrust law, while also respecting the Hatch-Waxman regulatory framework. Finally, a legislative solution to these issues was offered in Senate Bill 316, the Preserve Access to Affordable Generics Act of 2007.\textsuperscript{66}

\textbf{A. The Sixth Circuit Cardizem Decision: Agreements Involving "Pay for Delay" are Per Se Illegal}

In \textit{Cardizem},\textsuperscript{67} a Sixth Circuit panel found an agreement between patent holder, Hochst Marion Roussel (HMR), and generic manufacturer, Andrx, Inc. (Andrx), per se illegal as a “naked, horizontal restraint of trade.”\textsuperscript{68} A brief review of the underlying facts demonstrates how the Hatch-Waxman framework plays out in actual infringement suits and settlements. HMR manufactured and sold a drug, Cardizem CD, that prevented heart attacks and strokes.\textsuperscript{69} HMR’s original patent for dilitazem chloride, the active ingredient of Cardizem CD, expired in late 1992.\textsuperscript{70} In September 1995, Andrx filed an ANDA with the FDA and submitted a Paragraph IV certification, averring that its drug did not infringe on HMR’s patent.\textsuperscript{71} As the first ANDA filer to do so, Andrx earned the right to a 180-day exclusivity period.\textsuperscript{72}

In November 1995, HMR received a new patent for Cardizem CD’s “dissolution profile” (“the ’584 patent”).\textsuperscript{73} HMR subsequently filed a patent infringement suit in January 1996.\textsuperscript{74} This triggered the thirty-month stay, prohibiting Andrx from marketing its generic competitor and prohibiting the FDA from approving a second ANDA filer.\textsuperscript{75} The thirty-month stay did not, however, prevent the FDA from tentatively approving Andrx’s ANDA, subject to the resolution of the infringement suit.

\textsuperscript{62} Id.
\textsuperscript{63} Id.
\textsuperscript{64} 332 F.3d 896 (6th Cir. 2003).
\textsuperscript{65} See supra note 6.
\textsuperscript{66} See supra note 8.
\textsuperscript{67} 332 F.3d 896.
\textsuperscript{68} Id. at 905.
\textsuperscript{69} Id. at 901.
\textsuperscript{70} Id.
\textsuperscript{71} Id. at 902.
\textsuperscript{72} Id.; see also 28 U.S.C. § 355(j) (Supp. V 2006).
\textsuperscript{73} Cardizem, 332 F.3d at 902.
\textsuperscript{74} Id.
\textsuperscript{75} Id.
Shortly after the FDA granted this tentative approval, the two companies entered into the agreement that is the subject of the case. There are four principal terms of the agreement relevant to our analysis. First, the agreement did not settle the patent infringement suit. Second, HMR agreed to pay Andrx $40 million per year in quarterly payments, beginning at the moment of FDA approval of Andrx’s ANDA, which would occur only upon expiration of the thirty-month stay. Third, Andrx agreed to delay marketing any generic version of cardizem in the United States. Fourth, Andrx agreed not to “relinquish or otherwise compromise any right accruing” under its ANDA filing, including the 180-day exclusivity period. The result of these terms was that Andrx received approximately $40 million per year, and HMR continued to enjoy a monopoly in the cardizem market.

On July 9, 1998, one day after the thirty-month stay ended, the FDA approved Andrx’s ANDA, and HMR began making its quarterly payments. For eleven months, HMR continued its quarterly payments, and Andrx did not market its generic, despite FDA approval. Only in June 1999, after the FDA approved a reformulated generic version submitted by Andrx, did the two companies terminate their agreement and enter into a final settlement of the patent infringement suit. Per this settlement, HMR made a further $50.7 million payment to Andrx, which brought the total payments to more than $89 million. On June 23, 1999, Andrx began marketing its generic product, triggering its 180-day exclusivity period. Only in December 1999—more than four years after Andrx’s ANDA and more than eighteen months after the stay ended—were subsequent ANDA filers able to enter the market.

In finding the agreement per se illegal, the Sixth Circuit affirmed both the holding and the reasoning of the district court with relatively little analysis. In its opinion, the panel emphasized the reciprocal nature of two factors: first, HMR agreed to pay $40 million per year to its only potential competitor to stay out of the cardizem market. Second, the court noted that, because Andrx’s entry into the market was delayed, all other competitors were delayed due to the fact that Andrx

76. Id.
78. Cardizem, 332 F.3d at 902.
79. Id. (“[U]ntil the earliest of: (1) Andrx obtaining a favorable, final and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; or (3) HMR entering into a license agreement with a third party.”).
80. Id.
81. Id. at 903.
82. Id.
83. Id.
84. Id.
85. Id.
86. Id. at 906.
87. Id. at 908.
88. Id. at 907.
retained its 180-day exclusivity period. The court was not persuaded by the defendants’ arguments that the agreement was an “attempt to enforce patent rights or an interim settlement of the patent litigation” because it involved an agreement by the generic manufacturer not to enter the market despite FDA approval, in exchange for quarterly payments. Such pay for delay settlements are now per se illegal in the Sixth Circuit.

B. The Eleventh Circuit Declines to Adopt a Per Se Approach

1. Valley Drug Decision: Only Agreements that Exceed the Scope of the Patent are Subject to Antitrust Scrutiny

The Eleventh Circuit’s decision in Valley Drug Co. v. Geneva Pharmaceuticals, Inc. was handed down only three months after Cardizem, but arrived at a starkly different conclusion. As in Cardizem, the case came to the appellate court on interlocutory appeal of the district court’s decision finding the agreements per se illegal under section 1 of the Sherman Act. In Valley Drug, however, the Eleventh Circuit reversed the district court, emphasizing the patent holder’s lawful right to enforce a monopoly and to exclude competitors from the market.

The facts of this case generally are similar to those of Cardizem, but there are a couple of complications worth mentioning. Abbott Laboratories had multiple patents relating to terasozin hydrochloride, the active ingredient in a hypertension drug marketed by Abbott since 1987. The patents covered various forms of the terasozin hydrochloride compound and numerous methods for using it, including tablet and capsule forms. Here, the patents were challenged by two generic competitors, Geneva Pharmaceuticals and Zenith Goldline Pharmaceuticals. Ultimately, Abbott filed suits alleging infringement of its Patent No. 5,504,207 (“the ’207 patent”) against both generics.

Faced with multiple challenges to its terasozin patents, Abbott entered into an agreement with Zenith on March 31, 1998 and with Geneva one day later. The Zenith Agreement contained four principal terms: (1) Abbott agreed to make quarterly payments of $6 million dollars to Zenith until March 1, 2000 or the termination of the agreement; (2) both parties dropped their lawsuit claims; (3) Zenith

89. Id.
90. Id. at 908.
91. Id. at 907–08.
92. 344 F.3d 1294 (11th Cir. 2003).
93. Id. at 1312.
94. Id. at 1309 (“If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court’s order. This is not such a case, however, because one of the parties owned a patent.”).
95. Id. at 1298.
96. Id.
97. Id. at 1296.
98. Id. at 1300.
agreed not to market any product containing terazosin hydrochloride until Abbott’s ’207 patent expired on February 17, 2000; and (4) Zenith agreed not to transfer any of its ANDA rights, including the 180-day exclusivity period it earned as the first ANDA filer.99

The agreement with Geneva was similar: (1) Abbott agreed to pay Geneva $4.5 million per month, until another manufacturer brought a terazosin product to market, or Abbott won the ’207 patent infringement suit; (2) Geneva agreed not to market any terazosin product until a second patent expired in February 2000 or until it obtained a victorious final judgment in the ’207 patent infringement suit; (3) Geneva agreed not to transfer its rights under the ANDA, including its 180-day exclusivity period; and (4) Geneva agreed to challenge any subsequent ANDA filer’s attempt to enforce the “successful defense” requirement.100

The Eleventh Circuit found for the defendants and proposed a new standard to use in evaluating Hatch-Waxman patent settlements. The court emphasized that the “exclusionary potential of the [’207] patent” shielded the agreements’ effects from per se antitrust evaluation.101 Because the ’207 patent would not expire until 2014,102 the effect of the agreements on competition was “no broader than the potential exclusionary effect of the ’207 patent, and was actually narrower to the extent [they] permitted Zenith [and Geneva] to market [their] drug[s] before the ’207 patent expired.”103 Even though the ’207 patent subsequently was deemed invalid,104 the court emphasized that the reasonableness of the agreements must be considered at the time they were entered into.105

While the court noted that the agreement resembled a horizontal market allocation, it recognized that the patent rights held by Abbott changed the evaluation.106 The patent grant involves the right to exclude, which can lead to lawful agreements allocating the market geographically or by customer type.107 Because the district court focused on this market allocation as a basis of its finding of per se illegality, the Eleventh Circuit was forced to reverse.108 Not only did the court reject a per se rule, but it also refused to apply a rule of reason analysis to the agreements.109 In doing so, the court pointed out that rule of reason analysis would be inappropriate, as well, because “the anticompetitive effects of exclusion cannot be seriously de-

99. Id.
100. Id.
101. Id. at 1311.
102. Id.
103. Id. at 1305.
104. Id. at 1306.
105. Id.
106. Id. at 1304.
107. Id. at 1305.
108. Id. at 1304; see also In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003).
109. Valley Drug, 344 F.3d at 1311.
bated.\textsuperscript{110} Thus, the Eleventh Circuit seemed to reject any traditional antitrust analysis of these settlements.

Instead, the Eleventh Circuit remanded the case, providing guidelines to the district court for analyzing the potential anticompetitive effects of the agreements.\textsuperscript{111} The court described a threshold analysis that must take place before any specific antitrust inquiry.\textsuperscript{112} If it is determined that terms of the agreements have effects “beyond the exclusionary effects of Abbott’s patent,” these terms “may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act.”\textsuperscript{113}

The court pointed to a number of factors influencing its reasoning. First, the court emphasized the competing regimes of patent and antitrust law.\textsuperscript{114} Second, the fact that the ’207 patent subsequently was found to be invalid was not dispositive.\textsuperscript{115} Third, in direct opposition to the Sixth Circuit, the mere existence or substantial size of a “reverse payment” was insufficient to trigger per se illegality, especially where the lack of any damages reduces the risk for the generic manufacturers in the infringement suit.\textsuperscript{116} The Eleventh Circuit seems to be in agreement with the Sixth Circuit that these agreements have some anticompetitive effects, but traces them to the exclusionary power of the patent, which shelters them from antitrust liability.

2. The Eleventh Circuit’s Schering-Plough Decision: Rejection of the FTC’s Standard Prohibiting Reverse Payments in Exchange for Delayed Entry

The Eleventh Circuit clarified its reasoning in the subsequent decision of Schering-Plough Corp. v. Federal Trade Commission,\textsuperscript{117} a case in which the FTC also articulated its own standard. In this case, the FTC challenged the settlements between patent holder Schering-Plough and two generic manufacturers, ESI Lederle, Inc. and Upsher Laboratories under section 1 of the Sherman Act and section 5 of the FTC Act.\textsuperscript{118} The agreement between Schering and Upsher settled their patent infringement suit just before trial and included a licensing deal, whereby Schering obtained an exclusive license from Upsher to market Niacor.\textsuperscript{119} Specifically, Schering agreed to pay Upsher $60 million in “initial royalty fees,” $10 million more in...

\textsuperscript{110} Id.
\textsuperscript{111} Id. at 1312.
\textsuperscript{112} Id.
\textsuperscript{113} Id.
\textsuperscript{114} Id. at 1306 (“As one court has concluded, ‘when patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal.’” (citation omitted)).
\textsuperscript{115} Id. at 1308.
\textsuperscript{116} Id. at 1309–10; see also Daniel A. Crane, Ease over Accuracy in Assessing Patent Settlements, 88 MINN. L. REV. 698, 703–04 (2004) (emphasizing asymmetries of risk in HWA litigations).
\textsuperscript{117} 402 F.3d 1056 (11th Cir. 2005).
\textsuperscript{118} Id. at 1061.
\textsuperscript{119} Id. at 1059–60.
milestone royalty payments, and a further $10–15 million royalties on sales. The parties also agreed that Upsher could enter its generic onto the market beginning September 1, 2001, more than five years before Schering’s patent was to expire.

ESI also submitted an ANDA filing with a Paragraph IV certification in December 1995. Schering duly filed a patent infringement suit against ESI. Schering and ESI ultimately agreed to the following settlement terms: (1) ESI could enter the market on January 1, 2004—almost three years ahead of the patent’s expiration date; (2) Schering would pay $5 million to ESI for legal fees; and (3) Schering potentially would make a $10 million payment to ESI, if the FDA approved ESI’s generic within a certain period of time.

In 2001, the FTC brought an administrative complaint against all three companies. Using a full rule of reason analysis, the administrative law judge (ALJ) found both agreements to be lawful patent settlements. In particular, the ALJ found that the patent’s exclusionary power outweighed the FTC’s argument that, absent the reverse payment settlement, the generics could have entered the market earlier.

On appeal to the full Commission, the ALJ’s decision was reversed under a truncated rule of reason analysis. The Commission announced its standard prohibiting any settlement in which a reverse payment is made in exchange for delayed market entry. In Schering’s case, the Commission determined that the reverse payments far exceeded actual consideration for the licenses received. The Commission would allow for agreements on entry date without reverse payments or with payments limited to litigation costs not to exceed $2 million.

The defendants appealed the Commission’s decision, wisely bringing its appeal in the Eleventh Circuit. The Eleventh Circuit reversed and clarified its Valley Drug holding into a three part test: “the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.” Applying that test to the Schering agreements, the Elev-

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120. Id. at 1060.
121. Id. at 1058–59.
122. Id. at 1060.
123. Id.
124. Id. at 1060–61.
125. Id. at 1061.
126. Id.
127. Id. at 1061–62.
128. Id. at 1062.
129. Id.
130. Id.
131. Id.
132. Id.
133. Id. at 1066.
enth Circuit found them well within the scope of the patent and thus legal patent settlements.\textsuperscript{134}

C. The Second Circuit's Tamoxifen Decision: The Supreme Court's Missed Opportunity

The Second Circuit has provided the most recent appellate decision on pharmaceutical patent settlements in In re Tamoxifen Citrate Antitrust Litigation.\textsuperscript{135} In this case, Zeneca, Inc.\textsuperscript{136} held the patent rights to and manufactured tamoxifen citrate, a leading breast cancer drug.\textsuperscript{137} Barr Laboratories, Inc. filed a Paragraph IV certification in an attempt to bring a generic version of tamoxifen to market.\textsuperscript{138} Zeneca brought a patent infringement suit in 1987 ("Tamoxifen I"),\textsuperscript{139} which it subsequently lost in 1989,\textsuperscript{140} and which was on appeal in 1993 when the two companies signed a settlement agreement.\textsuperscript{141}

The agreement's principal terms resemble those of the agreements discussed above. Barr agreed not to market its generic version of tamoxifen until Zeneca's patent expired in 2002 and thus amended its ANDA to a Paragraph III certification.\textsuperscript{142} In exchange, Zeneca agreed to pay Barr $21 million plus an additional $45 million over ten years to Barr's raw material supplier.\textsuperscript{143} Barr also received a non-exclusive license to sell tamoxifen tablets manufactured by Zeneca under Barr's own label.\textsuperscript{144} Furthermore, the two companies agreed that Barr would be permitted to revert to Paragraph IV certification, if a second generic manufacturer successfully challenged the tamoxifen patent as invalid or unenforceable "in a final and unappealable judgment."\textsuperscript{145}

Finally, the two parties also moved the Federal Circuit to dismiss Zeneca's appeal as moot and obtained a vacatur of the district court's Tamoxifen I judgment.\textsuperscript{146} This action was significant for Zeneca because its patent was further challenged by three ANDA filers, who were all unsuccessful in their attempts to rely on the vacated Tamoxifen I decision.\textsuperscript{147} Meanwhile, the "successful defense" rule was held to be

\begin{itemize}
  \item \textsuperscript{134} Id. at 1068.
  \item \textsuperscript{135} 466 F.3d 187 (2d Cir. 2006), cert. denied sub nom., Joblove v. Barr Labs., Inc., 127 S. Ct. 3001 (2007).
  \item \textsuperscript{136} Id. at 190. The defendants were Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC.
  \item \textsuperscript{137} Id.
  \item \textsuperscript{138} Id. at 193.
  \item \textsuperscript{139} Id.
  \item \textsuperscript{140} Id. The patent was declared invalid. See Imperial Chem. Indus., PLC v. Barr Labs., Inc., 126 F.R.D. 467, 469 (S.D.N.Y. 1989).
  \item \textsuperscript{141} Tamoxifen, 466 F.3d at 193–94.
  \item \textsuperscript{142} Id.
  \item \textsuperscript{143} Id.
  \item \textsuperscript{144} Id.
  \item \textsuperscript{145} Id. at 193.
  \item \textsuperscript{146} Id. at 194. Such a vacatur was subsequently held to be invalid. Id. (citing U.S. Bancorp Mortgage Co. v. Bonner Mall P’ship, 513 U.S. 18, 27–29 (1994)).
  \item \textsuperscript{147} Id. at 195.
\end{itemize}
invalid, and Barr then became eligible for the 180-day exclusivity period, which would only be triggered by Barr marketing its own generic version of tamoxifen.\footnote{148} After further proceedings, Zeneca’s patent was upheld against all generic challengers,\footnote{149} and no generic marketing of tamoxifen occurred until after the expiration of the patent in 2002.\footnote{150} The private antitrust plaintiffs challenged three aspects of this settlement agreement: (1) that it was made after the finding of invalidity in the Tamoxifen I decision; (2) that it involved a reverse payment; and (3) that the reverse payments were excessive.\footnote{151}

The Second Circuit upheld the agreement and affirmed the district court.\footnote{152} Two factors were central to the court’s decision. First, the court noted that the plaintiffs’ arguments rested heavily on the contention that the Federal Circuit would have affirmed the invalidity of Zeneca’s patent.\footnote{153} This contention was too uncertain for the court, as evidenced by the subsequent success enjoyed by Zeneca in the later infringement suits. Second, the court held that the mere existence of a reverse payment, especially in the context of HWA, is not enough to trigger per se unlawfulness.\footnote{154} While the court acknowledged that a reverse payment seemed “suspicious,”\footnote{155} it viewed the settlement as an attempt by a patent holder to protect its lawful monopoly, which must be presumed valid.\footnote{156} In this sense, the settlement did not exceed the scope of the patent.\footnote{157} The Second Circuit acknowledged falling in line with the Eleventh Circuit on the importance of analyzing the scope of the patent.\footnote{158} If an agreement does not exceed the patent scope, it will be valid unless the patent infringement suit is itself baseless.\footnote{159}

Dissatisfied with this ruling, the FTC petitioned the Supreme Court for writ of certiorari.\footnote{160} In an interesting move, the Supreme Court requested an amicus brief from the Solicitor General’s office. As it did in the Schering-Plough case, the Solicitor General broke ranks with the FTC and recommended denial of certiorari.\footnote{161} Ultimately, the Solicitor General’s view prevailed with the Supreme Court.\footnote{162}

\begin{footnotes}
\footnotetext[148]{Id. at 195–96.}
\footnotetext[149]{Id. at 196.}
\footnotetext[150]{Id.}
\footnotetext[151]{Id. at 198.}
\footnotetext[152]{Id. at 197.}
\footnotetext[153]{Id. at 203–04. Indeed, the court noted that Zeneca later won lawsuits enforcing the tamoxifen patent. Id.}
\footnotetext[154]{Id. at 206. The plaintiffs themselves did not argue for a standard of per se illegality, as had been adopted by the Sixth Circuit. Id.}
\footnotetext[155]{Id. at 208.}
\footnotetext[156]{Id. at 208–09.}
\footnotetext[157]{Id. at 209 n.22.}
\footnotetext[158]{Id. at 212.}
\footnotetext[159]{Id. at 213.}
\footnotetext[160]{Petition for Writ of Certiorari, Tamoxifen, 127 S. Ct. 3001 (No. 06-830), 2006 WL 3694387.}
\footnotetext[161]{Id.}
\footnotetext[162]{Joblove v. Barr Labs., Inc., 127 S. Ct. 3001 (2007).}
\end{footnotes}
D. The Congressional Response: Senate Bill 316: The Preserve Access to Affordable Generics Act

In January 2007, Senator Kohl, along with other members of the Senate Judiciary Committee, introduced Senate Bill 316 entitled the "Preserve Access to Affordable Generics Act." The bill's principal thrust is to prohibit "reverse payments" that accompany delays of entry by the generic manufacturer. Specifically, the bill would amend the Clayton Act to prohibit an agreement in conjunction with a patent infringement claim in which: "(1) an ANDA filer receives anything of value; and (2) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time." The bill explicitly allows for the patent holder to permit the ANDA filer to enter the market early, but that must be the limit of value given. A violation of this provision will result in a forfeiture of the 180-day exclusivity period. Though this bill stalled in committee, it likely will resurface in some form in the future.

V. THE BEST SOLUTION IS A TWO-STEP STANDARD INCORPORATING PATENT RIGHTS INTO THE RULE OF REASON

A. Proposed Two-Step Standard

The variety of solutions proposed reveals the difficulty in resolving the problem posed by pharmaceutical patent settlements under the Hatch-Waxman regulatory provisions. Given the intricacy of the competing interests among the patent regime, antitrust laws, and the regulatory framework provided by the Hatch-Waxman Act, this variety comes as no surprise. The best solution is one that addresses all these interests, while providing patent and generic drug manufacturers the direction and predictability to craft flexible solutions to complex business issues. Consequently, the ideal standard to use when evaluating these settlements has two steps. First, the court should compare the exclusionary scope of the patent and the settlement terms. Second, the court should perform a traditional rule of reason treatment that takes into account the first step's findings.

The Supreme Court stands in the best position to effect these proposed changes. Had it granted certiorari in Tamoxifen, the Court could have installed a new standard, thereby providing drug manufacturers with the clearest parameters for future settlements. This issue will not disappear, and the Court may yet weigh in on these settlements. For the moment, the Eleventh Circuit's standard likely will become the prevailing test for all pharmaceutical settlements. Because appeals from an FTC decision may be made to any circuit court of appeals, antitrust defendants certainly

164. S. 316 § 3.
165. Id. § 3(b).
166. Id. § 5.
The B. The Advantages of the Proposed Two-Step Standard

The two-step standard is advantageous for three reasons. First, it provides pharmaceutical companies with the most flexibility to craft settlements to costly and unpredictable litigation. Second, it strikes a proper balance between patent and antitrust considerations. Finally, it will provide sufficient antitrust oversight to protect consumers from anticompetitive sham settlements. The two-step standard accomplishes all this while avoiding the pitfalls inherent in the solutions proposed by the Sixth Circuit, FTC, and Congress.

1. The Two-step Standard Avoids the Pitfalls of the Sixth Circuit's Per Se Rule

The Sixth Circuit's per se rule is simply too narrow and limits the options available to parties in patent settlement negotiations. The Sixth Circuit likened the agreement in Cardizem to a "horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade."168 This depiction of the agreement fails to take into account HMR's patent rights, which are designed to permit patent holders to profit from that type of market allocation through licensing agreements.

The Sixth Circuit also fails to give sufficient weight to the fact that the generic manufacturer in Cardizem entered the market before the expiration of the patent term.169 To follow the Sixth Circuit's reasoning would seem to require patent holders to pursue every patent infringement claim against an ANDA filer to its final judicial conclusion. In such a situation, both parties would assume large litigation costs, but the generic manufacturer would face no risk beyond these costs. If the generic manufacturer loses the infringement case, there will be no actual damages available to the patent holder because the generic has not yet marketed its drug.

On the other hand, if the generic manufacturer wins the infringement case, it reaps huge rewards that border on windfall. First, it will enter the market immediately, or upon forthcoming FDA approval, and take a significant portion of the market share in the duopoly situation granted by the 180-day exclusivity period. It cannot be denied that this result is good for consumers, who likely will see de-

167. Private plaintiffs still can bring suit in district courts of other circuits.
169. Id.
creased prices even in the duopoly situation—and certainly after the 180-day exclusivity period expires and other generics enter the market. Nevertheless, the generic's ability to act as a proxy for the consumer with zero risk beyond litigation costs gives them too much bargaining power over the patent holder. Even a strong patent must bear some risk of losing in a patent infringement suit, and a wise company would be willing to pay a reasonable settlement fee to ensure that a patent suit is not lost. Under the Sixth Circuit's per se rule, patent holders are barred from this choice. Such a standard would not give due weight to the policy of innovation underlying the exclusive nature of the patent laws and at the heart of Hatch-Waxman Act itself.

2. The Two-step Standard Avoids the Pitfalls of the FTC's Standard

The FTC's standard attempts to ameliorate the strictness of the per se standard by permitting reverse payments up to $2 million to the generic for litigation costs. The FTC believes that this will not discourage settlements because drug manufacturers still will be free to settle on an entry date before the expiration of the patent.\(^\text{170}\) Given that delayed entry is the principal danger that the FTC wishes to avoid, it seems anomalous to permit settlements that provide for delayed entry without reverse payments. Under Hatch-Waxman, a generic manufacturer has sufficient bargaining power to negotiate entry into the market before the expiration of the patent in addition to payments of millions of dollars. Absent those payments, the generic manufacturer will surely have enough bargaining power to negotiate for an even earlier entry into the market. If the settlement provided anything but an immediate entry date, the FTC would permit the settlement, despite the same anticompetitive effects of a "pay for delay" settlement.

Furthermore, the FTC's championing of the truncated rule of reason will not provide the flexibility pharmaceutical manufacturers need to navigate Hatch-Waxman's complex regulatory scheme. The truncated rule of reason permits plaintiffs to establish a prima facie case without demonstrating any actual adverse effects in a defined relevant market.\(^\text{171}\) In practice, this low threshold means that the burden shifts almost immediately to the defendants to justify the settlement terms with procompetitive effects.\(^\text{172}\) As a result, this standard begins to look like a standard of presumptive invalidity, differing from the Sixth Circuit's standard of per se illegality only to the extent of permitting procompetitive justifications.

The two-step standard would take better account of the patent regime that encourages innovation at the expense of short-term competition. Because pharmaceutical patent settlements take place at the intersection of patent law, antitrust law and a rigorous regulatory framework, the onus needs to be on the antitrust plain-

\(^{170}\) Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005).
\(^{171}\) See 11 Herbert Hovenkamp, ANTITRUST LAW § 1911 (2d ed. 2005).
\(^{172}\) Schering-Plough, 402 F.3d at 1065.
tiffs to establish the anticompetitive nature of the proposed or actual settlement. This can be done only by addressing the nature of the patent grant. Consumers still would be protected from settlements like the one in Cardizem, in which Andrx agreed to delay marketing any generic version of cardizem in the United States, not merely one that infringed HMR’s patent.173

Though less stringent than the per se rule, the two-step standard is not a standard of presumptive validity. If the plaintiff is successful in demonstrating anticompetitive effects or if the settlement terms exceed the scope of the patent, the burden will shift to the defendant manufacturers to show the pro-competitive justifications or corresponding efficiencies. This is a difficult burden for the defendants. Even if the defendants are successful in meeting the burden, the plaintiff has a final opportunity to show that “alternative means” are available to achieve the same desired procompetitive effects.174

3. The Two-step Standard Avoids the Pitfalls of the Preserve Access to Affordable Generics Act

Congress should not seek to impose its will on an uncertain and developing area of law for a number of reasons. First, the courts always have been the traditional forum for the development of antitrust doctrine.175 Second, the two-step test has the added advantage of being a legal standard with which district courts are generally familiar based on other patent and antitrust doctrines. Third, the congressional remedy would still permit delayed entry, even when accompanied by reverse payments. The only proposed sanction for such “pay for delay” settlements under the Preserve Access to Affordable Generics Act is forfeiture of the 180-day exclusivity period. This seems to offer little help to consumers, while stifling the creativity of pharmaceutical manufacturers in devising unique solutions to the complexities of Hatch-Waxman. Like the inadequate solutions proposed by the FTC and the Sixth Circuit, the Preserve Access to Affordable Generics Act also fails to consider the value of the patent holder’s lawful exclusionary rights.

173. Cardizem, 332 F.3d at 902; see supra note 81 and accompanying text.
175. See Standard Oil Co. v. United States, 221 U.S. 1, 63–64 (1911) (“The merely generic enumeration which the statute makes of the acts to which it refers, and the absence of any definition of restraint of trade as used in the statute, leaves room for but one conclusion, which is, that it was expressly designed not to unduly limit the application of the act by precise definition, but, while clearly fixing a standard, that is, by defining the ulterior boundaries which could not be transgressed with impunity, to leave it to be determined by the light of reason, guided by the principles of law and the duty to apply and enforce the public policy embodied in the statute, in every given case whether any particular act or contract was within the contemplation of the statute.”).
JUST WHAT THE DOCTOR ORDERED

* * *

The Hatch-Waxman Amendments have complicated an already difficult and contentious area of law. Nevertheless, the district and appellate courts have begun to develop and articulate the parameters of this complex issue. Given the Supreme Court's reluctance to hear this issue, it is up to the lower courts to develop new standards. A clear and predictable rule such as the two-step standard proposed in this Comment would provide manufacturers and antitrust regulators the predictability and flexibility to protect consumers without sacrificing innovation or increasing costly litigation.