Cornell Law Review

Volume 99
Issue 5 *July 2014*

Article 5

Reanalyzing Reverse-Payment Settlements: A Solution to the Patentee's Dilemma

Zhenghui Wang

NOTE

REANALYZING REVERSE-PAYMENT SETTLEMENTS: A SOLUTION TO THE PATENTEE'S DILEMMA

Zhenghui Wang†

INTRODUCTION

A brand-name drug company invests a considerable amount of money and resources in developing a pioneer drug. It then successfully obtains patents, files with the Food and Drug Administration

† J.D., Cornell Law School, 2014; Ph.D., Chemistry, Washington University in St. Louis, 2011. I would like to thank my Note Editors Steve Ma and Stefanie Williams for their invaluable advice and help; the editors of Volumes 99 and 100 of the *Cornell Law Review* for their friendship and excellent editing skills; and, of course, my family and friends for their love and support. All errors and omissions are mine.

(FDA), and markets the drug. Later, the company files a patent-infringement lawsuit against a company that tries to market a generic form of the drug.[1] Faced with the prospect of a tedious litigation marathon and the risk of losing its patents, the brand-name company often settles with the alleged infringer. Strangely, instead of receiving any compensation from the alleged infringer, the brand-name drug manufacturer pays the alleged infringer to stay out of the market until the patents expire.[2] The problem that this presents is far from being settled: regulatory agencies such as the Federal Trade Commission (FTC) may challenge such settlements as illegal under the antitrust laws.[3] Now what can the brand-name drug manufacturer do? Continue with litigation? Settle with the alleged infringer and subject both of them to the antitrust sanction? Or allow the alleged infringer to market its generic drug? None of these options seem appealing, locking up the company in a predicament.

This oversimplified story depicts what I call the "patentee's dilemma," which was created after Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act (HWA).[4] Under the HWA, a generic pharmaceutical company can challenge a pioneer manufacturer's patents on the brand-name drug by filing an Abbreviated New Drug Application (ANDA) with the FDA.[5]

The HWA was enacted with the primary purpose of promoting generic drugs' entry into the pharmaceutical market so as to increase competition and to lower drug prices.[6] But Congress did not anticipate that the HWA would lead to the creation of "reverse payments."[7] Specifically, the ANDA filing usually triggers a lawsuit brought by the

---

1 *See* Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 60 (2010) (discussing reverse-payment settlements in which the brand-name drug company [the plaintiff] makes payments to the alleged infringer [the defendant]).

2 *Id.*

3 *See infra* Part II (explaining the FTC and DOJ's position on the issue).

4 Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2012)).

5 *See* 21 U.S.C. § 355(j) (listing the requirements for applicants that seek to challenge a pioneer manufacturer's patent).

6 *See* Jon Leibowitz, Commissioner, Fed. Trade Comm'n, Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust: Exclusion Payments to Settle Pharmaceutical Patent Cases; They're B-a-a-a-ck! (Apr. 24, 2006) ("When Hatch-Waxman was enacted it had a few simple goals: 'to make available more low cost generic drugs by establishing a generic drug approval procedure . . . .'" (quoting H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647)), *available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

7 Butler & Jarosch, *supra* note 1, at 87 (stating that the DOJ "assumes that [Congress's scheme under the HWA] does not anticipate, and is upset by, the existence of reverse payments").

brand-name drug company against the generic drug company for patent infringement.[8] Contrary to the common understanding of a judicial settlement, where the infringer pays the patentee to end the lawsuit, the brand-name drug company (the patentee) usually pays a large amount of money to the generic-brand drug company (the alleged infringer) to keep the generic drug out of the market.[9] This practice of settling a patent-infringement lawsuit is called reverse-payment settlement. This allows the brand-name drug company to keep its exclusive monopoly over the patented product.[10]

The practice of making reverse payments raises antitrust concerns.[11] Both consumer groups and the FTC often file antitrust lawsuits against parties that settle in post-HWA litigation.[12] These antitrust lawsuits created a federal circuit split,[13] resulting in the Supreme Court rendering a decision on the issue in June 2013.[14]

On the one side, the Sixth Circuit claimed that such reverse payments are per se illegal.[15] Similarly, the Third Circuit decided that the payments are presumptively illegal unless the defendant can show that "the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."[16] The court held that this presumption of illegality could not be rebutted by proof about the merits of the patent suit because the reverse payment itself indicated that the purpose was to delay entry.[17]

On the other side, the Second, Eleventh, and Federal Circuits recognized the need to evaluate the strength of the patent, holding that reverse-payment settlements violate antitrust law only if the settle-

---

8 *See* 35 U.S.C. § 271(e)(2)(A) (2012) ("It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . .").

9 *See* Butler & Jarosch, *supra* note 1, at 60 (describing reverse-payment settlements as settlements in which a payment is made from the patent holder to the alleged infringer). There can be other types of consideration or side deals as well, such as a nonexclusive licensing. *See id.* at 119.

10 *See id.* at 61 (suggesting side deals between patent holders and ANDA filers have an anticompetitive effect).

11 *Id.* at 60–61.

12 *Id.* at 60.

13 *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 209–15 (3d Cir. 2012) (reviewing courts' decisions regarding reverse-payment settlements and indicating the different treatments), *vacated sub nom.* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013).

14 *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013) (holding that reverse-payment settlements may violate antitrust laws).

15 *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 904 (6th Cir. 2003).

16 *In re K-Dur*, 686 F.3d at 218.

17 *Id.*

ment exceeds the exclusionary "'scope of the patent's protection.'"[18] Unless the patent was a sham or procured by fraud, reverse-payment settlements were illegal only if the settlement extended the patent monopoly, such as by "restraining the introduction or marketing of unrelated or non-infringing products."[19]

The Supreme Court, however, took a middle ground position in *FTC v. Actavis, Inc.* With a heated dissent from Chief Justice John Roberts, the majority rejected the scope-of-the-patent test, announcing that the potential anticompetitive effect of the reverse payment could not be immune from antitrust law scrutiny.[20] The Court adopted a rule-of-reason analysis, leaving the construction of the analysis open to the lower courts.[21]

Reverse payment has also been a popular topic of discussion among scholars.[22] For example, Herbert Hovenkamp, Mark Janis, and Mark A. Lemley propose that reverse-payment agreements are presumed illegal unless the brand-name drug company can prove "(1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit."[23] In contrast, Daniel Crane proposes that such agreements should be presumed lawful and that the burden of proving unlawful conduct should fall on the shoulders of the plaintiff in the antitrust suit.[24] Unsatisfied with both of these approaches, Henry Butler and Jeffrey Jarosch suggest a rule-of-reason analysis and discuss a list of factors that a court ought to balance when analyzing the reverse-payment issue.[25] David Opderbeck advocates the importance of market power in an antitrust analysis and proposes a refined model of a "Settlement Competition Index," which creates a safe harbor for certain agreements and sets a threshold for per se illegal violations.[26]

---

18 FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd*, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008), *abrogated by Actavis*, 133 S. Ct. 2223; *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006) (internal quotation marks omitted), *abrogated by Actavis*, 133 S. Ct. 2223.

19 *In re Tamoxifen Citrate*, 466 F.3d at 213.

20 *See Actavis*, 133 S. Ct. at 2230–31.

21 *See id.* at 2237.

22 *See* Butler & Jarosch, *supra* note 1, at 101–14 (introducing different scholarly views).

23 Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759 (2003).

24 *See* Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements: A Response to Herbert Hovenkamp, Mark Janis, and Mark A. Lemley*, Anticompetitive Settlement of Intellectual Property Disputes, 88 MINN. L. REV. 698, 709 (2003) [hereinafter Crane, *Ease Over Accuracy*].

25 *See* Butler & Jarosch, *supra* note 1, at 114–18.

26 *See* David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1328–35 (2010).

After the *Actavis* opinion, commentators believe that the Court has taken an antitrust-centric approach, brushing away the issue of patent validity.[27] Some commentators go even further, interpreting the opinion as announcing a de facto presumptive illegality rule.[28]

In this Note, I analyze the current debates on the reverse-payment issue and ultimately reject the de facto illegality presumption. In light of *Actavis*, this Note proposes a solution to the predicament that parties face in reverse-payment settlements. The proposed model is distilled from the aforementioned judicial decisions, academic debates, and recent developments in antitrust analysis on tying arrangements. Under the proposed model, an antitrust plaintiff challenging a reverse-payment settlement needs to prove three factors to establish an affirmative case of anticompetitive harm: (1) the patent holder has strong market power; (2) the settlement amount or other considerations are not justified; and (3) the potential enforceability of the patent is low.[29] If a plaintiff meets this burden, a court should then weigh the procompetitive benefits of the settlement against its anticompetitive harm. Even if lower courts read *Actavis* as not requiring plaintiffs to prove lack of patent enforceability, they should allow the antitrust defendants to offer patent strength as a justification for the payment.[30] Part I of this Note introduces the background of the HWA and reverse-payment settlements. Part II analyzes the circuit split and the Supreme Court's opinion in *Actavis*. Part III summarizes some scholarly debates and proposals. Part IV proposes a model to analyze the issue based on the Supreme Court's decision in *Actavis*.

I
Background of the Hatch-Waxman Act

Congress enacted the HWA: "(1) to reduce the average price paid by consumers; (2) [to] preserve the technologies pioneered by the brand-name pharmaceutical companies; and (3) [to] create an abbreviated new drug application ('ANDA') to bring generic drugs to the market."[31] The HWA was designed to strike a balance between encouraging innovation by pioneers and promoting competition by the generic followers.[32] However, its special procedural settings have created particular settlements between brand-name drug companies and generic-brand challengers in patent litigation where the brand-name

---

27 *See, e.g.*, Aaron Edlin et al., *Activating* Actavis, 28 Antitrust 16, 16–17, 19 (2013).

28 *See* Thomas F. Cotter, FTC v. Actavis, Inc.*: When is the Rule of Reason not the Rule of Reason?*, 15 Minn. J.L. Sci. & Tech. 41, 42–43 (2014).

29 *See infra* Part IV.

30 *See infra* Part IV.

31 Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 n.2 (11th Cir. 2005).

32 C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1560 (2006).

drug manufacturers may keep their monopolistic market status by paying the generic-brand drug companies to stay out of the market.[33] As a result, drug prices remains at "supracompetitive" levels, and consumers do not get the benefit of lower prices, raising antitrust concerns.[34]

Under the HWA, the pioneer pharmaceutical company that first launches a prescription drug must obtain FDA approval.[35] In order to do so, it must submit a New Drug Application (NDA) that includes details of efficacy and safety from studies.[36] These clinical studies may take a long time and are very costly for pharmaceutical companies.[37] After approving the application, the FDA publishes the drug's patent information in its famous *Orange Book*.[38] The HWA gives NDA filers certain nonpatent exclusivities, one of which is the New Chemical Entity (NCE) exclusivity,[39] which bars a generic drug company from filing an application for approval of a generic drug until five years after the first approval of the relevant NDA.[40]

The HWA allows a generic pharmaceutical company to file an ANDA without conducting clinical trials.[41] The company only needs to prove bioequivalence between the generic drug and the brand-name drug.[42] The FDA also requires the generic pharmaceutical company filing an ANDA to certify:

> (I) that such patent information has not been filed,
> (II) that such patent has expired,
> (III) of the date on which such patent will expire, or
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .[43]

Most of the reverse-payment cases involve filers who certify that the patent is not valid or not infringed upon, known as a Paragraph IV certification.[44] A generic drug company may file an ANDA with a Par-

---

33 This process is also known as "pay-for-delay." *Id.* at 1557.

34 Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283, 288 (2012).

35 21 U.S.C. § 355(a) (2012).

36 *Id.* § 355(b)(1).

37 For a general discussion about the cost of developing new drugs, see Avik Roy, *How the FDA Stifles New Cures, Part I: The Rising Cost of Clinical Trials*, FORBES APOTHECARY BLOG (Apr. 24, 2012, 5:19PM), http://www.forbes.com/sites/aroy/2012/04/24/how-the-fda-stifles-new-cures-part-i-the-rising-cost-of-clinical-trials/.

38 Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 316–17 (2005).

39 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

40 One exception is Paragraph IV filers, who are barred for only four years. *Id.*

41 Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 n.2 (11th Cir. 2005).

42 21 U.S.C. § 355(b)(3)(D)(i).

43 *Id.* § 355(j)(2)(A)(vii).

44 *See id.* § 355(j)(2)(A)(vii)(IV).

agraph IV certification four years after the first NDA approval, despite the five-year bar provided by the NCE exclusivity discussed above.[45]

Under the HWA, this ANDA filing with a Paragraph IV certification constitutes constructive patent infringement, even if the generic drug has not been marketed for sale.[46] The filer must also notify the patent holder, the brand-name manufacturer, who will usually bring a patent-infringement lawsuit against the ANDA filer.[47] If the patent owner does not bring the lawsuit against the ANDA filer within forty-five days, the FDA can approve the ANDA without further delay.[48] If, however, the patent owner brings the lawsuit, the ANDA is automatically stayed for either thirty months or until a district court renders a decision regarding the validity of the patent.[49]

The HWA awards the first Paragraph IV ANDA filer a 180-day exclusive-entry period, making the market a duopoly of the first ANDA filer and the brand-name drug company.[50] However, subsequent ANDA filers cannot enjoy an equivalent 180-day exclusive-entry period, an effect known as the "bottleneck" effect of approval.[51] This

---

45 *Id.* This provision also creates the possibility of multiple "first filers" on the four-year anniversary of FDA approval of an NDA subject to New Chemical Entity exclusivity. *See infra* note 50.

46 *See* 35 U.S.C. § 271(e)(2)(A) (2012).

47 21 U.S.C. § 355(j)(2)(B)(iii).

48 *Id.* § 355(j)(5)(B)(iii).

49 *Id.*

50 *Id.* § 355(j)(5)(B)(iv); Hemphill, *supra* note 32, at 1560. In fact, "duopoly" may not be an accurate word under certain situations. The term "first ANDA filer" refers to all of the applicants who submit substantially complete ANDAs with Paragraph IV certifications on the same day that is earlier than any other ANDA filing. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). Multiple ANDA applicants may hold exclusivity concurrently on the same drug if they each apply on the same day and file Paragraph IV certifications concerning at least one of the *Orange Book*–listed patents for that drug. This most commonly occurs when multiple applicants file ANDAs on the four-year anniversary of FDA approval of an NDA subject to the NCE exclusivity. *See id.* § 355(c)(3)(E)(ii), (j)(5)(F)(ii) (allowing actions to commence beginning forty-eight months after the approval date of an application filed under § 355); *see also* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2246 (2013) (Roberts, C.J., dissenting) ("[A]ccording to the Food and Drug Administration, all manufacturers who file on the first day are considered 'first applicants' who share the exclusivity period.").

51 When the HWA was originally enacted, it provided two triggers for the 180 days of exclusivity: (1) the ANDA first-filer beginning marketing of its generic drug or (2) a court declaring the patent on the brand-name drug invalid or not infringed. The FDA conditioned the second trigger on the ANDA filer successfully defending against the patent infringement suit. Therefore, as long as the ANDA filer reached an agreement with the patent holder, the 180 days of exclusivity would never be triggered. However, after the D.C. Circuit's 1998 decision in *Mova Pharmaceutical Corp. v. Shalala*, 140 F.2d 1060, 1069–70 (D.C. Cir. 1998), and the 2003 Medicare Modernization Act, the HWA was modified to include a use-it-or-lose-it provision that requires the first ANDA filer to take 180 days of exclusivity before a certain triggering deadline. Otherwise, such exclusivity will be forfeited. *See* 21 U.S.C. § 355(j)(5)(D) (including a forfeiture provision intended to promote more generic entry). For a detailed discussion, see Erica N. Andersen, Note, Schering *the Market: Analyzing the Debate Over Reverse-Payment Settlements in the Wake of the Medicare Moderni-*

lucrative 180 days becomes the main incentive for a generic drug company to be the first to challenge a brand-name drug company's patent.[52]

In general, the brand-name drug company will then file a patent-infringement lawsuit against the Paragraph IV filer to litigate the patent's validity.[53] During the patent litigation, the brand-name company may elect to settle with the challenging generic drug company, offering it more money than it would make during the 180-day exclusive period, inducing the challenger to drop the ANDA filing and keeping the patent intact.[54] Subsequent generic drug companies would not have the benefit of the 180-day exclusive period and would not be approved for entry into the market.[55] After the 180-day exclusive period, subsequent sellers will lack the incentive to file an ANDA because the potential costs associated with a patent-infringement suit outweigh the low profit margins and the consequently low settlement amount.[56] Both the brand-name company and the first ANDA filer benefit from settling the suit; subsequent ANDA filers will be blocked by the bottleneck and discouraged from entering the market for the particular drug, allowing the brand-name company to continue charging monopoly prices for its drug.[57]

Another form of implicit compensation for delay is licensing, where the brand-name companies grant licenses to the generic companies to launch authorized generic drugs. As a result of nonexclusive licensing, the patent remains intact and the generic drug company is compensated through sales of the authorized generic drugs.[58]

---

zation Act of 2003 and In re Tamoxifen Citrate Litigation, 93 IOWA L. REV. 1015, 1021–24 (2008) (indicating that the FTC argued for the potential abuse of the amended Hatch-Waxman provision).

52 David A. Balto, *We'll Sell Generics, Too: Innovator Drug Makers Are Gaming the Regulatory System and Harming Competition*, LEGAL TIMES, Mar. 20, 2006, at 39.

53 *See supra* notes 47–49 and accompanying text.

54 For a general discussion, see Yuki Onoe, Note, *"Pay-For-Delay" Settlements in Pharmaceutical Litigation: Drawing a Fine Line Between Patent Zone and Antitrust Zone*, 9 J. MARSHALL REV. INTELL. PROP. L. 527, 530 (2009) (discussing the context and incentives for the "pay-for-delay" settlement and its predicament under antitrust scrutiny).

55 21 U.S.C. § 355(j)(5)(B)(iv).

56 Scott Bergeson, Note, *A Vaccine Approach to the Reverse Payment Illness*, 18 RICH. J.L. & TECH. 1, 26–30 (2012) (arguing that Congress should amend the HWA to allow the 180 days of exclusivity to transfer to subsequent filers to provide more incentives for the subsequent filers).

57 *See id.* at 15, 23 (discussing the resulting bottleneck effect on competition).

58 *See* BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2010, at 1 (2011), *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-

The agreement between the brand-name company and the generic company give rise to antitrust concerns.[59] Any settlement agreement must be submitted to the FTC, although prior clearance is not required.[60] The FTC and Department of Justice (DOJ) have joined together to argue that these reverse payments are illegal agreements between competitors.[61] However, some federal circuit courts do not endorse the FTC and DOJ's challenge to these settlement agreements.[62] The disagreement among circuits led the Supreme Court to consider the issue of reverse-payment settlements in *FTC v. Actavis, Inc.*[63] Part II of this Note will discuss the conflict among the federal circuit courts and the Supreme Court's decision in *Actavis*.

II
THE CIRCUIT SPLIT AND *ACTAVIS*

Before *Actavis*, the decisions addressing reverse-payment settlements were quite polarized among the federal circuits. The Sixth Circuit once ruled that reverse-payment settlement agreements were per se illegal,[64] and the Third Circuit, adopting the FTC and DOJ's approach, held that reverse-payment settlements were presumptively illegal, subject to limited exceptions.[65] In contrast, the Second, Eleventh, and Federal Circuits adopted the "scope of the patent" test,[66] which states that reverse-payment settlements violate antitrust laws only if the settlements exceed the exclusionary scope of the patent.[67]

In *Actavis*, the Supreme Court rejected the scope-of-the-patent test.[68] The Court held that the fact that a reverse-payment settlement agreement's anticompetitive effects fell within the patent's scope did not immunize the agreement from antitrust attack.[69] At the same time, the Supreme Court refused to embrace the "quick look" ap-

---

and/1105mmaagreements.pdf (showing that certain settlements were reached as implicit compensation).

59 Cory J. Ingle, *Reverse Payment Settlements: A Patent Approach to Defending the Argument for Illegality*, 7 I/S: J.L. & POL'Y FOR INFO. SOC'Y 503, 504 (2012).

60 21 U.S.C. § 355 note.

61 Butler & Jarosch, *supra* note 1, at 61.

62 *See infra* Part II.

63 133 S. Ct. 2223 (2013).

64 *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 907–08 (6th Cir. 2003).

65 *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), *vacated sub nom.* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849, 2849 (2013); Butler & Jarosch, *supra* note 1, at 60.

66 *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212–13 (2d Cir. 2006), *abrogated by Actavis*, 133 S. Ct. 2223; Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075–76 (11th Cir. 2005); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1335–37 (Fed. Cir. 2008), *abrogated by Actavis*, 133 S. Ct. 2223.

67 FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd*, *Actavis*, 133 S. Ct. 2223; *Schering-Plough Corp.*, 402 F.3d at 1065–66, 1075–76.

68 *Actavis*, 133 S. Ct. at 2231.

69 *See id.* at 2232.

proach advocated by the FTC, which would have had the effect of holding reverse-payment settlements presumptively unlawful.[70] Rather, the Court adopted a rule-of-reason analysis, which will be discussed below.[71]

A. The Circuit Split Before *Actavis*

In *In re Cardizem CD Antitrust Litig.*, the Sixth Circuit ruled that a payment-for-delay agreement was per se illegal.[72] The ANDA filer (Andrx) agreed with the brand-name company (HMR) to refrain from marketing its generic drug in exchange for a quarterly payment of ten million dollars, despite the FDA's approval of the generic drug.[73] Andrx also retained the exclusivity period once the patent litigation between Andrx and HMR terminated.[74] The court ruled that the agreement "was, at its core, a horizontal agreement to eliminate competition in the market."[75] Similarly, in *In re K-Dur Antitrust Litigation*, the Third Circuit adopted a quick look method, analyzing "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."[76] The court agreed with the FTC and ruled that there was no need to consider the merits of the patent suit because "the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[77]

These cases set a very high level of judicial scrutiny of parties that settle with reverse payments, while overlooking an important aspect of

---

70 *See id.* at 2237.

71 *See id.*

72 *See* 332 F.3d 896, 915 (6th Cir. 2003).

73 *Id.* at 902–03.

74 *Id.*

75 *Id.* at 908. This is no longer an issue under the current amendment to the Hatch-Waxman Act, however, because under the amendment, a generic company would forfeit the 180-day exclusive award. *See supra* discussion accompanying note 51.

76 686 F.3d 197, 218 (3d Cir. 2012), *vacated sub nom.* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013).

77 *Id.* (internal quotation marks omitted). The FTC and DOJ advocated for a similar approach: reverse payments should be illegal unless the defendant could propose procompetitive effects for the payments. *See* Butler & Jarosch, *supra* note 1, at 61. More specifically, the DOJ would presume that such payments were unlawful unless the defendant could show "either that (1) the reverse payment amount was 'not greatly in excess of avoided litigation costs' or (2) the settlement exclusion period did not exceed the expected litigation exclusion period, given the settlors' contemporaneous estimates of the likelihood that the patent holder would have won the patent litigation." Elhauge & Krueger, *supra* note 34, at 287 (quoting Brief for the United States in Response to the Court's Invitation at 10, 22, 28–32, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (Nos. 05-2851-cv(L), 05-2852-cv (CON), 05-2863-cv (CON)), 2009 WL 8385027, at *10, *22, *28–32) (emphasis omitted).

patent law: its monopolistic nature.[78] Such decisions force the patent holder either to secure the validity of the patent through litigation or allow the alleged infringer to market the generics.[79] While weeding out weak patents, the approach to reverse-payment settlements discussed above may burden pioneer brand-name companies and may discourage innovation in the long run.[80]

On the opposite end of the spectrum was the "scope of the patent" test. In *In re Tamoxifen Citrate Antitrust Litig.*, two parties settled Hatch-Waxman litigation in which the patent was declared invalid by the district court and the case was pending appeal.[81] The ANDA filer agreed to change its Paragraph IV certificate to a Paragraph III certificate in return for a nonexclusive license and a payment of more than forty million dollars from the brand-name drug company.[82] The Second Circuit assumed the legality of the settlement, rejecting the argument that reverse-payment settlements are inherently anticompetitive. The court recognized that "the patent holder [was] seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."[83] Therefore, the anticompetitive effect of the settlement was acceptable unless the terms of the settlement enlarged the monopoly's scope.[84]

As a result of the scope-of-the-patent test,[85] courts have paid more deference to the patent scope and have allowed some blatantly an-

---

78 *See* Shannon U. Han, Note, *Pay-to-Delay Settlements: The Circuit-Splitting Headache Plaguing Big Pharma*, 15 VAND. J. ENT. & TECH. L. 913, 924 (2013) ("The court reasoned that '[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition,' and therefore the anticompetitive nature is present by force of law." (quoting Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065–66 (11th Cir. 2005))).

79 *See* Meredith Bateman, Note, In Re K-Dur Litigation—*Reverse Payments: Against Prices, Purchasers, and Policy*, 15 TUL. J. TECH. & INTELL. PROP. 293, 302 (2012) (stating that critics "will likely assert that the holding is contrary to policy considerations favoring settlement over litigation").

80 *See* Han, *supra* note 78, at 938 ("Though commentators have argued that these settlements could ultimately have some competitive benefits by allowing earlier entry into the market, the standard does not call for an understanding of countervailing procompetitive effects.").

81 *See* 466 F.3d 187, 193 (2d Cir. 2006), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

82 *Id.* at 193–94.

83 *Id.* at 208–09.

84 *Id* at 208.

85 In *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, the court differentiated *Ciprofloxacin* from *In re Cardizem*, in which case the agreement exceeded the exclusionary zone of the disputed patent because the generic drug company agreed not to market the noninfringing drug so as to delay the entry of other generic drugs. 544 F.3d 1323, 1335–36 (Fed. Cir. 2008), *abrogated by Actavis*, 133 S. Ct. 2223. In *Schering-Plough Corp. v. FTC*, the court adopted a three-part test to determine if antitrust analysis was appropriate, examining: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects. 402 F.3d 1056,

ticompetitive reverse-payment agreements that fell within the patent's scope.[86]

B. The Middle Ground: The Supreme Court's Rule-of-Reason Approach in *Actavis*

The Supreme Court appears to settle the issue of reverse payments in *Actavis*. In this case, after the FDA's approval of an ANDA filing, the ANDA filers (Watson and Par/Paddock) reached an agreement with the brand-name drug company (Solvay) where Solvay would pay Par/Paddock ten million dollars per year for six years and an additional two million dollars per year for backup manufacturing assistance.[87] In addition, Solvay would share some profits of the brand-name drug with Watson through September 2015.[88] In return, Watson and Par/Paddock agreed to delay marketing the generic products until August 31, 2015, and to promote the brand-name drug to healthcare professionals and urologists.[89] The parties stipulated to dismiss the pending patent infringement litigation, which involved a patent that expires in August 2020.[90] The Eleventh Circuit affirmed the district court's dismissal of the FTC's complaint, rejecting the FTC's argument that it had sufficiently stated an antitrust claim.[91]

The Supreme Court reversed the Eleventh Circuit's decision by first rejecting the notion that reverse-payment settlements falling within the scope of the patent's exclusionary power are immune from antitrust scrutiny.[92] After the Court summarized controlling law, holding that patent-related settlement agreements can sometimes violate the antitrust laws, the Court noted five sets of considerations that the FTC should have been allowed to prove its antitrust claim:[93] First, "the specific restraint at issue has the potential for genuine adverse effects on competition."[94] Second, "these anticompetitive conse-

---

1066 (11th Cir. 2005). Under this test, as long as the reverse payment did not pertain to products outside the patent's exclusionary scope, such payment would often not be considered anticompetitive. *Id.* at 1067.

86 *See* Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 8 (2012) [hereinafter Carrier, *Why the "Scope of the Patent" Test*]. For further critiques on the scope-of-the-patent test, see *id.* at 5–8.

87 FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1303–05 (3d Cir. 2012), *rev'd*, *Actavis*, 133 S. Ct. 2223.

88 *Id.* at 1305.

89 *Id.*

90 *Id.* at 1303–05.

91 *Id.* at 1312.

92 *Actavis*, 133 S. Ct. at 2230.

93 *Id.* at 2234–37. *But see id.* at 2241 (Roberts, C.J., dissenting) (arguing that each of the cited precedents "stands for the same, uncontroversial point: that when a patent holder acts *outside* the scope of its patent, it is no longer protected from antitrust scrutiny by the patent").

94 *Id.* at 2234 (majority opinion) (internal quotation marks omitted).

quences will at least sometimes prove unjustified."[95] Third, "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice."[96] Fourth, "an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed."[97] Fifth, "the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit."[98]

Although the Court identified these five issues, it rejected the FTC's quick look approach and adopted a rule-of-reason analysis.[99] Quoting *California Dental Ass'n v. FTC*, a case that discussed the quick look approach, the Court concluded that the quick look approach was not appropriate in the reverse-payment-settlement context. Rather, it was only appropriate when "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."[100]

However, the Court gave little guidance on how lower courts should apply the rule of reason.[101] While this gave the lower courts flexibility on how to conduct the rule-of-reason analysis, as the dissenting opinion sarcastically pointed out, the lack of detailed instruction amounted to little more than wishing the lower courts "[g]ood luck" in analyzing the issues that arise with reverse-payment settlements under the rule of reason.[102]

III
Scholarly Views on Reverse-Payment Settlements

The Supreme Court's decision in *Actavis* has settled the debate to some extent. However, some of the concerns and analyses in the following scholarly works will be helpful in constructing a rule-of-reason analysis post-*Actavis*. The theories discussed in this Part are among

95 *Id.* at 2235–36.
96 *Id.* at 2236.
97 *Id.*
98 *Id.* at 2237.
99 *Id.*
100 *Id.* (quoting Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999)) (internal quotation marks omitted).
101 *See id.* at 2238.
102 *Id.* at 2245 (Roberts, C.J., dissenting) ("Good luck to the district courts that must, when faced with a patent settlement, weigh the 'likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances.'" (quoting *id.* at 2231 (majority opinion))).

the most influential analyses[103] found in rich legal treatises that have considered the reverse-payment settlement issue.[104]

Scholars who considered reverse payments prior to the Supreme Court's decision in *Actavis* disagreed sharply on the proper approach. Hovenkamp, Janis, and Lemley suggest that reverse payments should be treated as presumptively unlawful.[105] On the other end of the spectrum, Daniel Crane has argued that reverse-payment settlements should be permitted when the ex ante probability of patent validity is high but not when it is low.[106] He also argues that the burden of proof should not be placed on the settling parties.[107] In contrast to both of the approaches above, Butler and Jarosch argue that since reverse payments are not anticompetitive in nature, the rule-of-reason approach is more appropriate because it balances multiple factors on a case-by-case basis.[108] Alternatively, Opderbeck proposes a quantita-

---

103 Commentators have discussed extensively about the reverse-payment issue. Some are not satisfied with courts' undue deference to the exclusivity power of patent law, claiming that at least some reverse-payment settlements in Hatch-Waxman cases should be presumed illegal. *See* Hovenkamp, Janis & Lemley, *supra* note 23, at 1759. Some criticize the scope-of-the-patent test as incompetent to solve the reverse settlement problem because the test assumes the validity of the patent and is inapplicable to the infringement issue. *See* Carrier, *Why the "Scope of the Patent" Test*, *supra* note 86, at 6–7. On the other hand, many commentators also defend reverse payments. *See* Joe Mullin, *Reversal of Fortune?*, IP L. & BUS., Oct./Nov. 2009, at 34 (listing the names of several attorneys who represent pharmaceutical companies and who favor reverse-payment settlement agreements); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1033–35 (2004) (arguing that reverse payments are not always anticompetitive and may have positive features). For example, one theory treats such payments as insurance paid to avoid the uncertainty of litigation. *Cf.* Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) ("It is not 'bad faith' to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights." (citation omitted)). Others have also proposed novel treatments to the issue; for example, instead of using antitrust analysis, courts could use the patent law doctrine of patent misuse to determine the illegality of the reverse payment. *See* Ingle, *supra* note 59, at 503.

104 Of course, although this Note's framework is not based on them, there are many other influential treatises. *See, e.g.*, ABA SECTION OF ANTITRUST LAW, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK (2009).

105 *See* Hovenkamp, Janis & Lemley, *supra* note 23, at 1759. Other scholars have advocated similar views of presumed illegality with different rebuttal grounds. For a detailed discussion, see Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 77 (2009) (allowing rebuttal based on information asymmetries); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003) (proposing presumed illegality rebutted by proof of varying party estimates or risk aversion).

106 Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 779–96 (2002) [hereinafter Crane, *Exit Payments*].

107 Crane, *Ease Over Accuracy*, *supra* note 24, at 709 (placing the burden of persuasion on the settling parties, however, would chill patent infringement settlements by making them presumptively illegal under section 1 of the Sherman Act).

108 *See* Butler & Jarosch, *supra* note 1, at 113 (indicating that the empirical data did not prove anticompetitive effect of reverse payments and that economic analysis shows both

tive measurement involving a determination of market concentration and the probability of the patent's enforcement.[109]

After the *Actavis* decision, many scholars believe that a full-scale analysis under the rule of reason is not necessary.[110] These scholars have read Justice Stephen Breyer's majority opinion in *Actavis* to presume that the brand-name drug company has market power.[111] One scholar, Thomas Cotter, has gone further, arguing that under the majority's holding, the rule-of-reason standard is functionally no different from the presumptive illegality standard.[112]

A. Presumptively Unlawful

Hovenkamp, Janis, and Lemley suggest that reverse payments should be treated as presumptively unlawful.[113] According to their analysis, in cases where an agreement itself looks like it would fall under an antitrust per se rule but for the presence of intellectual property rights, the traditional rule-of-reason analysis is not appropriate.[114] Specifically, cases challenging reverse-payment settlements center around the validity of the patent and the reasonableness of the settlement, whereas the rule-of-reason analysis assesses whether a practice tends to diminish market-wide output.[115] Therefore, Hovenkamp, Janis and Lemley argue, these cases should be decided on intellectual property grounds and not subjected to antitrust scrutiny if it can be shown that "the patent in question is valid and infringed."[116]

These scholars also argue that there are two components to a reverse payment: "the cost of continued litigation" and "the value of eliminating competition that the patentee could not expect ex ante to exclude after trial."[117] They argue that while it may be rational for a patent holder to enter a reverse-payment settlement to lower litigation costs, reverse payments are clearly anticompetitive because they permit patent holders to exclude potential rivals from the market.[118] To address these two components, they propose that a reverse payment should be presumed unlawful unless the plaintiff can prove "(1) that

---

anticompetitive and procompetitive effect). *But see* Hovenkamp, Janis & Lemley, *supra* note 23, at 1724 (rejecting a rule-of-reason analysis).

109 Opderbeck, *supra* note 26, at 1325–29.

110 *See* Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision*, 15 MINN. J.L. SCI. & TECH. 3, 6 (2014).

111 *See id.* at 6, 23–24.

112 Cotter, *supra* note 28, at 43–46.

113 Hovenkamp, Janis & Lemley, *supra* note 23, at 1759.

114 *Id.* at 1724.

115 *Id.* at 1724–25.

116 *See id.* at 1725.

117 *Id.* at 1758.

118 *Id.* at 1758–59.

the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit."[119]

Hovenkamp, Janis, and Lemley posit that such "a harsh rule will not necessarily impede settlement[,]" as settlements can take other forms such as licensing.[120] Another alternative is a settlement of delayed entry without reverse payments.[121] They also argue that this rule will not "reduce the legitimate value of pharmaceutical patent rights" because the legitimate exclusion value of a pharmaceutical patent is a function of the scope of the patent and its chance of being held valid.[122] The patent rights do not immunize from antitrust scrutiny reverse payments that seek to exclude potential competitors.[123]

B. Presumptively Lawful

Realizing that the presumption of illegality is harsh on antitrust defendants and would "unduly chill patent infringement settlements,"[124] Daniel Crane proposes a standard that places the "burden of persuasion" on the antitrust plaintiff to prove the defendants' unlawful conduct.[125] He also emphasizes the potential validity of the patent at issue: an "optimal rule would permit exit payment settlements when the *ex ante* likelihood of success of the patentee's infringement suit is high and prohibit them when the *ex ante* probability of success is low."[126] If the patent holder can present evidence that it would likely succeed at the infringement trial, then the size of the payment should not trigger antitrust concerns.[127]

Crane also proposes four methods to distinguish between cases that are free from antitrust scrutiny and those where heightened scrutiny is warranted: First, if the patent holder received a preliminary injunction against the alleged infringer, then the patent holder is likely to win its case on the merits.[128] Second, if a preliminary injunction issue was not litigated, then a court could conduct a "quick look" at

---

119 *Id.* at 1759.

120 *Id.* at 1760. Notice, however, that in the same article, the authors also suggest that courts look into the merit of the settlement and caution that parties may conceal those payments by turning them into non-cash compensation. *See id.* at 1760, 1763.

121 *Id.* at 1762.

122 *Id.* at 1761–62.

123 *Id.*

124 Crane, *Ease Over Accuracy*, *supra* note 24, at 709.

125 *Id.* (emphasis omitted).

126 Crane, *Exit Payments*, *supra* note 106, at 750.

127 *Cf.* Crane, *Ease Over Accuracy*, *supra* note 24, at 710–11 ("[T]he strength of the patent infringement suit, not the monetary structure of the settlement, determines whether the settlement is socially beneficial or costly.").

128 *See* Crane, *Exit Payments*, *supra* note 106, at 783–85.

the merits of the patent-infringement suit to determine whether or not to allow the settlement.[129] Third, if a patent holder pays a large proportion of its monopoly rents to the alleged infringer, then the settlement is suspicious, indicating either a low probability that the patent is valid or that the defendant's use actually infringes the patent.[130] Fourth, courts can look at which parties are affected by the reverse payment.[131] For instance, if the settlement blocked a third party from entering the market, it could be anticompetitive.[132]

C. Full-Scale Rule of Reason

Realizing that the presumptive illegality rule can be an overdeterrent, Butler and Jarosch argue for a rule-of-reason analysis.[133] Such an approach could minimize errors that occur when a per se or quick look rule is applied, specifically when challengers to reverse-payment settlements falsely accuse an activity that is procompetitive or antitrust neutral.[134] The authors argue that in order to apply, both per se and quick look rules require an obviously anticompetitive agreement type, which reverse payments lack.[135] Instead, reverse payments are context specific and can be better analyzed under the rule of reason.[136] There are multiple policy concerns and economic incentives behind a reverse-payment settlement, and empirically, such a settlement can be procompetitive.[137]

To operationalize the rule-of-reason analysis, Butler and Jarosch propose six factors that courts should examine: (1) market power—if a brand-name drug does not have market power in its targeted market, the reverse payment will not harm consumers and will not be anticompetitive;[138] (2) the entrance date allowed by the reverse-payment settlement—"[i]f the negotiated entry date is significantly before the date that the patent will expire, the agreement is not likely to be anticompetitive";[139] (3) the relative size of the reverse payment—while a large payment is problematic and potentially signals an agreement not to compete, it can also demonstrate the patent holder's extreme risk-aversion activities;[140] (4) the ANDA filer's ability to market

---

129 *Id.* at 785.
130 *See id* at 788.
131 *See id.* at 792.
132 *Id.*
133 *See* Butler & Jarosch, *supra* note 1, at 61–62.
134 *See id.* at 120–21 (noting the Type I error that would result from the DOJ's per se rule).
135 *Id.* at 85–86.
136 *Id.* at 86.
137 *See id.* at 94–100, 112–13.
138 *Id.* at 116.
139 *Id.*
140 *See id.* at 117–18.

the drug without a reverse payment—a showing that the generic company lacks marketing ability may indicate that the payment has no anticompetitive effect;[141] (5) sham litigation—nonmeritorious litigation strongly indicates anticompetitive effects;[142] and (6) suspicious side deals—"[i]nequitable or severely unbalanced side deals suggest a payment for delay" and can be anticompetitive.[143]

This rule-of-reason analysis, which extensively reviews the reverse-payment issue, may overanalyze certain cases where agreements are clearly not anticompetitive. Therefore, this approach may be too cumbersome for lower courts to carry out on a case-by-case basis.[144]

D. "Settlement Competition Index" Analysis

Acknowledging that previous models might overdeter potentially beneficial settlements or underdeter deleterious settlements, David Opderbeck proposes a more quantitative and easier-to-operate model to analyze the issue, the Settlement Competition Index (SCI).[145] This index is essentially a refinement of Hovenkamp, Janis, and Lemley's theory.[146] Using empirical data and a mathematical model, it creates three zones of antitrust scrutiny: the safety zone with no antitrust liability; the per se illegal zone, and a zone in between, which requires a rule-of-reason analysis.[147]

Opderbeck essentially uses two criteria to compute the SCI: "(1) [t]he difference in product market concentration that would likely result from the agreement; and (2) [t]he probability that the patent will be held to be valid and infringed."[148] The SCI was partly derived from the Herfindahl-Hirschman Index (HHI), which measures market concentrations before and after generic entry.[149] SCI equals the change in HHI divided by the probability of a patent enforcement.[150]

---

141 *Id.* at 118.

142 *See id.*

143 *Id.* at 119.

144 For examples of contexts in which a reverse-payment settlement may be clearly anticompetitive, see Hovenkamp, Janis & Lemley, *supra* note 23, at 1763. Chief Justice Roberts also strongly opposed the rule-of-reason analysis in his dissenting opinion to the *Actavis* case. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2245 (2013) (Roberts, C.J., dissenting).

145 *See* Opderbeck, *supra* note 26, at 1305.

146 Hovenkamp, Janis, and Lemley argue that courts should treat reverse payments that are greater than litigation costs as presumptively illegal. *See* Hovenkamp, Janis & Lemley, *supra* note 23, at 1720. Opderbeck offers a "more refined inquiry into the actual anticompetitive effects" of these payments by considering market power. Opderbeck, *supra* note 26, at 1323.

147 *See* Opderbeck, *supra* note 26, at 1305.

148 *Id.* at 1328–29.

149 *See id.* at 1329.

150 *Id.*

Opderbeck argues that previous approaches overlooked or oversimplified the influence of market power.[151] "Only in the context of per se liability, where the conduct is deemed inherently anticompetitive, is the question of market definition set aside . . . . [H]owever, [the authorities in reverse-payment settlements] do not explain why such agreements are inherently anticompetitive . . . ."[152] The difference in the patented product's market-power concentration is properly reflected in the change in HHI, consistent with the DOJ-FTC intellectual property licensing and merger guidelines.[153]

The second important aspect of the model is the probability of patent enforcement, which is, in effect, an assessment of the patent's scope.[154] Opderbeck argues that a capable expert could offer an opinion about the probability of patent enforcement, allowing a federal court to evaluate properly the merits of the underlying litigation or settlement.[155]

Under Opderbeck's model, then, a settlement that yields high market concentration with a low probability of patent enforcement, meaning that the SCI number is high, is per se illegal.[156] Conversely, a low SCI number creates a safe harbor for a settlement, which occurs when the market concentration, taking the settlement into account, is low and the probability of patent enforcement is high.[157] Any settlements with SCI numbers falling between these two critical levels will be subject to heightened scrutiny, where the court or regulatory agency would inquire into a variety of factors under the rule of reason.[158]

E. Readings of *Actavis*

The Supreme Court's decision in *Actavis* inevitably preempted some scholarly views, but it also adopted certain insights from the aforementioned approaches.[159] Moreover, post-*Actavis*, these schol-

---

151 *Id.* at 1329 n.208 ("[M]ost economists who have attempted to model responses to the reverse payment settlement problem define a relevant product market[ ] but oversimplify their models by assuming the market is either a monopoly or duopoly."); *id.* at 1330 (suggesting that the scope of a patent should be considered in addition to a patent holder's market power).

152 *Id.* at 1330.

153 *See id.* at 1329, 1333.

154 *Id.* at 1336.

155 *Id.* at 1337–39 (noting also that similar to class action cases and bankruptcy proceedings, a federal court could properly evaluate the merits of the underlying litigation or settlement).

156 *See id.* at 1329, 1346.

157 *See id.*

158 *See id.* at 1346.

159 *See, e.g.*, FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) (citing the academic work of Phillip Areeda and Herbert Hovenkamp, two antitrust scholars).

ars' works can still influence how lower courts will conduct their rule-of-reason analyses.[160]

One way of reading the Court's opinion is that the lower courts do not need to launch a full scale rule-of-reason analysis[161] because "the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power."[162] Moreover, competitive harm could be inferred from a large payment where convincing justifications are absent.[163] While Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, and Carl Shapiro propose several justifications for a significant reverse-payment settlement—patent strength, patent law and policy, and risk aversion—they still suggest that courts should reject these explanations under the *Actavis* holding.[164]

Professor Cotter's reading of *Actavis* goes even further. By formulating a flowchart for a rule-of-reason analysis, he argues that when facing a reverse-payment settlement, a plaintiff will easily meet the burden of proof, which will shift the burden to the defendant to prove the payment's procompetitive benefits.[165] Despite the Court's formal adoption of the rule of reason, Cotter asserts that this framework functions like a quick look or a de facto, presumptive illegality approach.[166] To Professor Cotter, the potential risk to competition is obvious in the reverse-payment settlement context.[167] In addressing why the Court adopted the rule of reason, Professor Cotter suggests that the Court's reasons were either political or based on concerns that if the Court adopted a presumptive illegality standard, lower courts would apply such a test in cases outside of the Hatch-Waxman context.[168]

Some of these post-*Actavis* analyses seem to read the opinion as a landslide victory for the FTC and other antitrust plaintiffs in reverse-payment lawsuits.[169] This reading may have gone too far. First, to

---

160 *See id.* at 2238 ("We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.").

161 *See* Hovenkamp, *supra* note 110, at 3, 6.

162 *Actavis*, 133 S. Ct. at 2236 (citing 12 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046 (3d ed. 2010)).

163 *See Actavis*, 133 S.Ct. at 2237 ("[T]he 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."); *see also* Hovenkamp, *supra* note 110, at 25.

164 *See* Edlin et al., *supra* note 27, at 18–20.

165 *See* Cotter, *supra* note 28, at 43–46.

166 *See id.* at 43, 46.

167 *See id.* at 45.

168 *See id.* at 47–48.

169 *See, e.g.*, Alexandra Sklan, *Supreme Court Rules in Favor of "Pay for Delay" Settlements*, 2 PHARMACEUTICAL PAT. ANALYST 582, 583 (2013) ("FTC chairwoman, Edith [Ramirez], said

read the Court's opinion as a functional equivalent to presumptive illegality ignores the Court's clear rejection of presumptive illegality.[170] Second, the de facto, presumptive illegality proposal also counters the Court's holding that the anticompetitive effect of a settlement depends on various factors, including the payment's size, scale, independence from other services, and lack of any other convincing justification.[171] Since the Court leaves the construction of the rule-of-reason analysis to lower courts, it is likely that lower courts will require plaintiffs to make a more rigorous economic showing beyond just the size of the payment to satisfy the burden of proof.[172]

IV
Proposed Model to Analyze Reverse-Payment Settlements

The Supreme Court's holding in *Actavis* leaves the construction of the rule-of-reason analysis to the lower courts.[173] The Court also leaves the door open to "other justifications" for reverse payments.[174] By analyzing the issues left open by the Court, this Note proposes an analytical model based on the Court's holding and the aforementioned theories. In agreement with the notion that a full scale rule-of-reason analysis may not be necessary,[175] this model draws from the recent judicial development of antitrust analysis in tying arrangements, especially the concurring opinion of four Justices in *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*.[176] This framework requires a plaintiff to demonstrate three factors to establish a prima facie case under the rule of reason: (1) the patent holder has strong market power; (2) the settlement amount or other considerations are not justified; and (3) the potential enforceability of the patent is low.[177] If a plaintiff

---

that the decision '*is a significant victory for American consumers, American taxpayers, and free markets.*'").

170 *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) (explaining that "quick-look" review is appropriate only when "an observer with even a rudimentary understanding of economics" could observe that "the arrangements in question would have . . . anticompetitive effect[s]" (quoting Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999)) (internal quotation marks omitted)).

171 *See id.* at 2237; *see also id.* at 2236 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.").

172 Joshua D. Wright, Commissioner, Fed. Trade Comm'n, Remarks at the Concurrences Journal Annual Dinner: *FTC v. Actavis* and the Future of Reverse Payment Cases 9–10 (Sept. 26, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf.

173 *Actavis*, 133 S. Ct. at 2237–38.

174 *See id.* at 2236.

175 Hovenkamp, *supra* note 110, at 3, 6.

176 *See* 466 U.S. 2, 32–47 (1984) (O'Connor, J., concurring).

177 *See* Hovenkamp, *supra* note 110, at 23.

establishes these threshold requirements, then the court can proceed to weigh the procompetitive benefits of the reverse-payment settlement against the anticompetitive harm.[178]

A. Reanalyzing the Issue After *Actavis*: A Comparison of Reverse-Payment Settlements and Tying Cases

Actavis was not the first time the Supreme Court addressed the tension between antitrust and patent law.[179] But one important principle in the Supreme Court's decision in *Actavis* is to strike a balance "between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act."[180]

In analyzing its precedents, the Court concluded that "patent-related settlement agreements can sometimes violate the antitrust laws."[181] However, Chief Justice Roberts forcefully opposed this reasoning in his dissent, claiming that the key word was "sometimes."[182] He argued that only when agreements relating to patents confer benefits beyond the patent's scope are those agreements subject to antitrust scrutiny.[183] A close reading of the Supreme Court's mixed antitrust-patent cases seems to indicate that the Chief Justice was right.[184] Yet the majority in *Actavis* would extend antitrust scrutiny to reverse-payment settlements even if the benefits of the settlements fall within the scope of the patents,[185] possibly because the Court was uncertain about the enforceability of the patents.[186]

---

178 *Id.* at 23–24.

179 *See, e.g.*, Ill. Tool Works Inc. v. Indep. Ink., Inc., 547 U.S. 28, 31–32 (2006) (concerning a patent on special printer components); United States v. New Wrinkle, Inc., 342 U.S. 371, 379 (1952) ("Price control through cross-licensing was barred as beyond the patent monopoly."); United States v. Line Material Co., 333 U.S. 287, 315 (1948) (holding that a patentee's use of control in cross-licensing to fix prices is unlawful); Int'l Salt Co. v. United States, 332 U.S. 392 (1947) (concerning a patent on salt processing machines).

180 FTC v. Actavis, Inc., 133 S. Ct. 2223, 2231 (2013) (internal quotation marks omitted). The Court also considered other aspects such as the long-standing judicial objective to settle lawsuits without wasting judicial resources, *see id.* at 2234 ("The Eleventh Circuit's conclusion finds some degree of support in a general legal policy favoring the settlement of disputes."), but it concluded that other antitrust considerations, taken together, outweigh the single desirability of settlement.

181 *Id.* at 2232.

182 *Id.* at 2242 (Roberts, C.J., dissenting).

183 *See id.*

184 *See, e.g.*, United States v. Gen. Elec. Co., 272 U.S. 476, 494 (1926) (holding that a licensing agreement containing a restriction on sale price of the patented devices is a lawful exercise of the monopoly created by the patent).

185 *Actavis*, 133 S. Ct. at 2230 ("[W]e are willing to take this fact as evidence that the [agreement] . . . fall[s] within the scope of the exclusionary potential of the patent. . . . But we do not agree that that fact . . . can immunize the agreement from antitrust attack." (quoting FTC v. Watson Pharm., Inc. 677 F.3d 1298, 1312 (11th Cir. 2012)) (internal quotation marks omitted)).

186 Although the language in *Actavis* seems to suggest that the Court is willing to extend antitrust scrutiny to agreements that fall within the exclusionary potential of the pat-

Since the Court extended antitrust scrutiny to areas within a patent's scope, it is helpful to look at the Court's analytical framework for issues that fall outside the patent's scope.[187] One particularly probative framework is the Court's analysis in tying arrangements.

A common type of tying case involves a product that has been tied to a patented product through licensing contracts.[188] Of course, tying products do not need to be patented, but for the purposes of this Note, I will discuss cases that involve patented products. In *Illinois Tool Works Inc. v. Independent Ink, Inc.*, an unpatented ink product was tied to a patented ink container designed for a printer.[189] Wholesalers agreed with the manufacturer not to use ink from other competitors to fill the patented ink container.[190]

The Supreme Court had previously held that while a natural monopoly in the tying product is lawful, any attempt to extend monopoly power to a tied market to extract greater profits, thus harming both competition and consumers in the tied market, is anticompetitive and unlawful.[191] The Court had treated tying arrangements as per se unlawful for years.[192] However, realizing that tying schemes might have some procompetitive effects, the Court later declined to apply a strict per se rule and instead adopted a qualified per se rule. Under this new rule, tying arrangements are illegal per se if the plaintiff can show that: (1) purchases of the tying product are conditioned upon purchase of a distinct, tied product;[193] (2) the seller possesses sufficient market power in the tying market to compel acceptance of the tied product;[194] and (3) the arrangement forecloses a not-insubstantial volume of commerce in the tied market.[195] In *Illinois Tool Works*, the Court announced that tying arrangements involving patented products should also be evaluated under the same standard.[196] The

---

ent, a close reading suggests that such extension is premised upon the uncertain enforceability of the patent. *See Actavis*, 133 S. Ct. at 2231 ("The patent here may or may not be valid, and may or may not be infringed."); *see also id.* at 2240 (Roberts, C.J. dissenting) ("The problem, as the Court correctly recognizes, is that we're not quite certain if the patent is actually valid, or if the competitor is infringing it.").

187 *See* Butler & Jarosch, *supra* note 1, at 77–78.

188 Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 33 (2006).

189 *Id.*

190 *Id.* at 31–32.

191 *See* Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 12 (1984) ("Our cases have concluded that the essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the purchase of a tied product . . . .").

192 *See* Int'l Salt Co. v. United States, 332 U.S. 392, 396 (1947); *see also* Standard Oil Co. v. United States, 337 U.S. 293, 305–06 (1949) ("Tying agreements serve hardly any purpose beyond the suppression of competition.").

193 Fortner Enters. v. U.S. Steel Corp., 394 U.S. 495, 507 (1969).

194 Times-Picayune Publ'g Co. v. United States, 345 U.S. 594, 611–13 (1953).

195 *Fortner Enters.*, 394 U.S. at 499.

196 Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 42 (2006).

conclusion that an arrangement is unlawful "must be supported by proof of power in the relevant market rather than by a mere presumption thereof."[197]

The analysis in these cases shifted almost from a per se rule to a rule-of-reason analysis.[198] In *Jefferson Parish*, five Justices in a sharply divided Court upheld the qualified per se rule.[199] However, four Justices issued a separate concurring opinion advocating a case-by-case rule-of-reason application in tying arrangement cases.[200] The concurring Justices proposed three threshold conditions prior to a balancing analysis: (1) market power in the tying product, (2) a substantial threat of market power in the tied product, and (3) a coherent economic basis for treating the products as distinct.[201] If all three conditions are satisfied, they argued, courts should then weigh the economic benefits of the arrangement against its harms.[202]

The Court's analysis of tying arrangements can shed light on the treatment of reverse payments. This analysis has migrated from a strict application of the per se rule to a more relaxed one.[203] Similarly, on the reverse-payment settlement issue, the Supreme Court rejected the quick look analysis in favor of the rule-of-reason analysis, a more relaxed approach.[204] Although developed under different historical settings, the schemes share many similarities. For example, both arrangements are anticompetitive when patent holders are trying to extract benefits that are not conferred by the immunized scope of the patent law.[205] In tying cases, the anticompetitive harm comes from the extension of monopoly power in one market to obtain con-

---

197 *Id.* at 42–43.

198 *See* NCAA v. Bd. of Regents of Univ. of Okla., 468 U.S. 85, 104 n.26 (1984) ("[T]here is often no bright line separating *per se* from Rule of Reason analysis. *Per se* rules may require considerable inquiry into market conditions before the evidence justifies a presumption of anticompetitive conduct."); *see also Ill. Tool Works*, 547 U.S. at 35 ("Over the years, however, this Court's strong disapproval of tying arrangements has substantially diminished."); *cf.* Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 9 (1984) ("It is far too late in the history of our antitrust jurisprudence to question the proposition that certain tying arrangements pose an unacceptable risk of stifling competition and therefore are unreasonable '*per se.*'"); Meribeth Richardt, *Tying Arrangement Analysis: A Continued Integration of the Rule of Reason and the Per Se Rule:* Jefferson Parish Hospital District No. 2 v. Hyde, 104 S. Ct. 1551 (1984), 63 WASH. U. L.Q. 337, 347–49 (1985) ("In *Jefferson Parish Hospital District No. 2 v. Hyde*, the Supreme Court narrowed the distinction between per se and rule of reason analysis of tying arrangements.").

199 466 U.S. at 16–18.

200 466 U.S at 32–47 (O'Connor, J., concurring).

201 *Id.* at 41.

202 *Id.*

203 *See supra* discussion accompanying notes 198–202.

204 *See* FTC v. Actavis, Inc., 133 S. Ct. 2231, 2239 (2013).

205 Again, in tying arrangements, the tying products do not always need to be patented, but for the purpose of this section, I will focus on tying arrangements involving patented products. In tying cases, the patent scope analysis is closely related to the patent misuse doctrine. *See* Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 40–41 (2006)

trol of a second market.[206] In reverse-payment settlements, parties reach agreements to exclude potentially noninfringing products from entering the market.[207] Both arrangements can be anticompetitive if one party has sufficient market power but may also be procompetitive so that the traditional per se treatment (for tying arrangements) or quick look treatment (for reverse payments) would not be appropriate.[208]

Therefore, analogous to the Court's reasoning regarding tying arrangements, this Note posits that in reverse-payment settlement cases, the party who is challenging a settlement must demonstrate the following to satisfy a prima facie case: (1) the patent holder has strong market power; (2) the settlement amount or other considerations are too large to be justified; and (3) the potential enforceability of the patent is low. If the antitrust plaintiff meets this burden, the court should then conduct a balancing analysis to determine whether the procompetitive effects of the settlement outweigh the anticompetitive harm.

B. Analysis Under the Proposed Model

1. *The Patent Holder's Market Power*

In a tying case, a plaintiff must prove that the defendant has monopoly power in the tying product market.[209] Without market power, whatever arrangement the seller makes with regard to the tied product will likely not restrain competition in the tied product's market.[210] For example, if an item can be easily substituted, consumers will not buy the tied product if they are forced to purchase the tying product.[211] To establish market power, antitrust analysis places emphasis on key factors such as market concentration and the fungibility of the product.[212]

(discussing the patent misuse treatment on tying arrangements); *see also* Ingle, *supra* note 59, at 538 (proposing a patent misuse treatment to the reverse payment).

206 *See supra* discussion accompanying notes 191–97; *see also* Richardt, *supra* note 198, at 340–41 ("Tying arrangements fall within the antitrust laws because they extend the seller's power in the tying product's market to the tied product's market." (footnote omitted)).

207 *Actavis*, 133 S. Ct. at 2226.

208 *See Ill. Tool Works*, 547 U.S. at 35–36; Butler & Jarosch, *supra* note 1, at 112–13.

209 *See supra* discussion accompanying note 194.

210 *See* Opderbeck, *supra* note 26, at 1330–32.

211 *Id.* at 1331.

212 *See id.* at 1329–32 (discussing the importance of assessing a product's market concentration); Herbert Hovenkamp, *Market Power in Aftermarkets: Antitrust Policy and the* Kodak *Case*, 40 UCLA L. Rev. 1447, 1450 (1993) ("Market power is a matter of degree. In perfectly competitive markets for fungible products, firms price at marginal cost and market power is said not to exist.").

In cases involving a patent, the antitrust analysis should not be different. In *Illinois Tool Works*, the Supreme Court held that to prove that a tying arrangement involving a patented product is unlawful, the claim "must be supported by proof of power in the relevant market rather than by a mere presumption thereof."[213] The Court ruled that "a patent does not necessarily confer market power upon the patentee."[214] Similarly, in Justice Sandra Day O'Connor's concurrence in *Jefferson Parish*, she argued that while a patent product may help give a seller market power, it is also possible that a seller will not have market power if there are close substitutes for the patented product.[215] "[A] high market share indicates market power only if the market is properly defined to include all reasonable substitutes for the product."[216]

In *Actavis*, the Court seemed to indicate that the threshold for proving market power would be a very low one, stating that "the 'size of the payment from a branded drug manufacturer to a prospective generic is a strong indicator of power.' "[217] However, the Court was probably not proposing that this threshold created a presumption of market power for at least two reasons.

First, the Court states that "where a reverse payment threatens to work *unjustified* anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice."[218] In other words, the plaintiff still has to prove that the anticompetitive harm, such as a price above the competitive level, is unjustified.

Second, the Court says that the size of the payment is "*a* strong indicator of power," not the *only* indicator or a *sufficient* indicator.[219] Thus, factors such as a brand-name drug company's market share of similar drugs or annual profits on these drugs can demonstrate a patented drug's market power.[220] Determining market power should not cause substantial difficulties for courts, as a company's public findings provide a common way to examine a product's market share and corresponding annual revenue.[221]

---

213 *Ill. Tool Works*, 547 U.S. at 42–43.

214 *Id.* at 45.

215 Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 37 n.7 (1984) (O'Connor, J., concurring).

216 *Id.*

217 FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013) (quoting 12 AREEDA & HOVENKAMP, ANTITRUST LAW ¶ 2046 (3d ed. 2010)).

218 *Id.* (emphasis added).

219 *Id.* (emphasis added) (internal quotation marks omitted).

220 *See* Opderbeck, *supra* note 26, at 1329.

221 *See, e.g.*, *id.* at 1339 (explaining courts' ability to calculate a product's HHI measurement); *see also id.* at 1344 n.275 (providing resources for obtaining sales figures and market data).

2. *The Settlement Amount*

In *Actavis*, the Court stated that a reverse payment "may amount to no more than a rough approximation of the litigation expenses saved through the settlement."[222] However, the Court also seemed to accept other types of settlements, such as "compensation for other services that [a] generic [company] has promised to perform,"[223] delayed entry, but before the patent's expiration, of the generic company into the market.[224] This latter type of settlement benefits consumers of the patented drug more quickly, as it cuts the patent holder's monopoly short.[225] The Court did not clarify how to value these types of settlements or how to assess the validity of such settlements; however, to challenge the legality of these settlements, an antitrust plaintiff should nonetheless present evidence of the services' market value[226] or the generic manufacturer's projected profits before the patent expires. The Court also did not mention how to determine the value and legality of settlements that relate to nonexclusive licenses.[227] However, based on the Court's primary emphasis on consumer welfare in the *Actavis* decision,[228] it is likely that the parties to any settlement that limits competition may need to justify the settlement's value to a court.

The *Actavis* decision also suggested that there could be other "justifications"[229] for reverse-payment settlement amounts, as mere litigation costs are not always an accurate indicator of the settlement amounts.[230] For instance, one way of calculating the reverse-payment settlement amount is by adding a generic company's potential earnings to the litigation cost.[231] This approach would be rational for a brand-name company to pursue because once a generic company enters the market, the brand-name company's losses may exceed the generic company's earnings due to a decrease in drug prices.[232]

---

222 *Actavis*, 133 S. Ct. at 2236.

223 *Id.*; *see also In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *7–8 (D.N.J. Jan. 24, 2014) (reading *Actavis* to apply only to "reverse payments" of money).

224 *Actavis*, 133 S. Ct. at 2236.

225 This seems to be consistent with the Supreme Court's emphasis on customer welfare. For a general discussion about customer welfare and total welfare, see Hovenkamp, *supra* note 110, at 7–8.

226 *Id.* at 17 ("[Courts] must defer to the parties' reasonable, good faith assessments of likely outcomes and risk.").

227 *See supra* note 58 and accompanying text.

228 *See Actavis*, 133 S. Ct. at 2235 ("The patentee and the challenger gain; the consumer loses.").

229 *Id.* at 2236.

230 *See supra* Part III (discussing scholars' various approaches to reverse-payment settlements that include litigation costs and other considerations).

231 *See* Crane, *Exit Payments*, *supra* note 106, at 780–82.

232 *See* Andersen, *supra* note 51, at 1059.

Therefore, in order to keep drug prices high and the generic company out of the market, a brand-name company is likely to pay more than the generic company could earn.[233] However, it is not clear whether a court would accept a reverse-payment settlement amount comprised of litigation costs plus potential earnings, as the generic company's delayed entry would harm consumers.

Another reverse-payment settlement amount that may be justified to a court is the patent holder's cost of losing the patent-infringement suit against the generic company—determined by the lost profits of the patent holder from competition with the generic company, plus the patent holder's expected litigation costs, plus any other explained costs.[234] This calculation, however, is inevitably tied to a brand-name company's risk averse nature.[235] Under the current HWA framework, the first generic company that files an ANDA has nothing to lose and much to gain, whereas the brand-name company risks losing the monopoly benefits associated with its patent when it files the patent-infringement suit against the generic company.[236] Even if a brand-name company in a reverse-payment settlement case pays an enormous amount of money to a generic company, this decision is economically rational as long as the settlement amount does not exceed the brand-name company's estimated loss after a patent-infringement trial. The Supreme Court recognized this concern but determined that a payment based on this concern alone, *without other explanations*, likely seeks to prevent competition and is probably not justified.[237]

If lower courts allow these considerations in assessing whether a settlement amount is reasonable, a brand-name company's own estimation of loss after a patent-infringement trial will determine an appropriate settlement amount.[238] This estimation indicates a brand-name company's own confidence in its patent's validity, which supports the previous commentators' argument that in a reverse-payment settlement case, a patent's validity rather than the settlement amount should be the focus of the antitrust inquiry.[239]

---

233 *See id.*

234 *See A Post-*Actavis *Approach to Reverse Payment Settlements*, LAW360 (July 31, 2013, 3:00 PM), http://www.kslaw.com/imageserver/KSPublic/library/publication/2013articles/7-31-13_Law360.pdf.

235 *See* Butler & Jarosch, *supra* note 1, at 95–96.

236 *See id.*

237 *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013) ("[B]e that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition").

238 *See* Crane, *Exit Payments*, *supra* note 106, at 780–82.

239 *See* Crane, *Ease Over Accuracy*, *supra* note 24, at 710–11.

3. *Potential Enforceability of the Patent*

Analyzing the enforceability of the patent will determine the patent's scope, an important consideration when applying antitrust scrutiny to reverse-payment settlement agreements.[240] In *Actavis*, the Court stated that the reverse-payment settlement agreement's "potential for genuine adverse effects on competition" is premised on the hypothetical that, had the patent been invalidated or not infringed, a large sum of revenues would have flowed to consumers in the form of lower drug prices.[241] However, since an antitrust challenge to a reverse-payment settlement occurs after the patent litigation has settled, there arises an issue of second-guessing whether the patent is valid. Thus, determining the patent's validity during an antitrust challenge penalizes the brand-name drug company by having the brand-name company litigate the validity of the patent in both proceedings.[242] The Court addressed this dilemma in *Actavis* and then quickly disposed of it, stating: "it is normally not necessary to litigate patent validity to answer the antirust question . . . [and] [a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."[243] Commentators read this language to suggest that the patent holder cannot raise the patent's validity as a defense in an antitrust suit, as the Court appears to adopt a payment approach rather than a patent approach in assessing the reverse-payment settlement amount.[244]

However, this interpretation seems to contradict the Supreme Court's own view that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent."[245] Moreover, as previously discussed, the anticompetitive effect of the payment seems to be premised on the possible enforceability of the patent.[246]

Therefore, I argue that to establish a prima facie case challenging a reverse-payment settlement, an antitrust plaintiff should provide certain proof, other than the payment itself, to indicate that the likelihood of the patent's enforceability is low. This proposal is consistent with the Supreme Court's holding that an antitrust action should be administratively feasible with no need to litigate the patent-infringe-

---

240 *See Actavis*, 133 S. Ct. at 2231 ("The paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope.").

241 *Id.* at 2234 (quoting FTC v. Ind. Fed. of Dentists, 476 U.S. 447, 460–61 (1986)) (internal quotation marks omitted).

242 *See* Opderbeck, *supra* note 26, at 1322–23.

243 *Actavis*, 133 S. Ct. at 2236.

244 Edlin et al., *supra* note 27, at 17–18.

245 *Actavis*, 133 S. Ct. at 2231.

246 *See supra* discussion accompanying notes 240–42.

ment suit.[247] Rather than the clear-and-convincing evidence standard applied to validity in a patent-infringement case,[248] courts should require a lower burden of proof for the plaintiff in order to minimize the emphasis on the minitrial that determines patent-infringement issues within the antitrust case.[249] For example, courts can require plaintiffs to prove that, more likely than not, the patent is not enforceable—by analyzing the history and records of the patent disputes, obtaining expert-witness testimony, or interpreting settlement amounts and patterns.[250] Courts may also apply the "sliding scale" test, lowering the threshold for proving patent unenforceability if the reverse-payment settlement amount is exceptionally large with few justifications for such an amount.[251]

4. *Balancing the Procompetitive Effects with the Anticompetitive Harm*

Once a plaintiff establishes a prima facie case, a defendant should be allowed to provide procompetitive justifications while the court conducts a balancing test to decide whether the reverse-payment settlement passes antitrust scrutiny.

As the *Actavis* Court correctly points out, the HWA was not designed to allow deals between brand-name and generic companies.[252] Both patent holders and ANDA challengers may abuse this system by colluding with one another to maintain exclusive power on weak patents,[253] which will ultimately harm consumers through drug prices at supracompetitive levels.[254] The "genuine adverse effects on competition" exist because a reverse-payment settlement agreement in effect "amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product."[255] In other words, consumers will "continually be required to pay tribute to would-be monopolists without need or justification."[256]

---

247 *See Actavis*, 133 S. Ct. at 2236.

248 *See* Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2242 (2011). This higher standard derives from a statutory presumption of validity that attaches to patents. *See* 35 U.S.C. § 282 (2006 & Supp. V 2011).

249 *See Actavis*, 133 S. Ct. at 2226; Edlin et al., *supra* note 27, at 19.

250 35 U.S.C. §§ 321–329.

251 *See Actavis*, 133 S. Ct. at 2237–38 (internal quotation marks omitted).

252 *Id.* at 2234.

253 *See* Andersen, *supra* note 51, at 1043.

254 *See* Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 262 (2010).

255 *Actavis*, 133 S. Ct. at 2234 (internal quotation marks omitted).

256 Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969).

While reverse-payment settlements may have their shortcomings, a short-term reduction in competition increases a patent's value, provides more secure protection to a brand-name company, and allows a brand-name drug company to recoup more capital for later research and development.[257] A reverse-payment settlement may also be an incentive for patent holders to be innovative and to file stronger patents,[258] thereby creating procompetitive effects in the long term.[259] Therefore, there is a consumer welfare trade-off between maintaining the prices that consumers pay for existing products and stimulating research and production of new products for future consumption.[260] In addition, some empirical data seem to suggest that at least sometimes, reverse-payment settlements have very minimal or neutral impact on competition.[261] The reverse-payment settlement agreement should be condemned only when its anticompetitive impact outweighs its procompetitive benefits.[262]

C. Limitations

Realizing the complexity of the reverse-payment settlement issue and the arguments from both antitrust law and patent law perspectives, I propose this mechanism to formulating a rule-of-reason analysis that can achieve balanced interests for both sides.

Perhaps the most contentious part of this proposal is the need for an antitrust plaintiff to prove that a patent lacks enforceability. It is unclear if the Supreme Court in *Actavis* suggests that only antitrust law should be utilized to analyze reverse-payment settlements.[263] The Court does state that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."[264] One way to read this opinion is that the enforceability of a patent should count as one explanation for the size of a re-

---

257 James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777, 778 (2003).

258 *See* Butler & Jarosch, *supra* note 1, at 90.

259 Langenfeld & Li, *supra* note 257, at 778.

260 *Id.*

261 *See* Butler & Jarosch, *supra* note 1, at 112–13 (empirical studies show that reverse payments are not necessarily anticompetitive).

262 For a similar proposition in tying analysis, see Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 42 (1984) (O'Connor, J., concurring) ("A tie-in should be condemned only when its anticompetitive impact outweighs its contribution to efficiency.").

263 Again, commentators vary on this issue, and Edlin et al. believe that the strength of the patent is not a valid defense post-*Actavis*. *See* Edlin et al., *supra* note 27, at 19. But FTC Commissioner Joshua Wright holds a different view. *See* Wright, *supra* note 172, at 15 ("[I]t would be surprising if courts summarily did away with the question of patent validity as part of their analysis altogether.").

264 FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236–37 (2013).

verse-payment settlement, of which anticompetitive effect should be weighed against other, procompetitive effects, such as efficiency.[265] Therefore, even if lower courts would not agree that a plaintiff should be required to bear the burden of proof on the patent enforceability issue, they should allow antitrust defendants to provide evidence that, more likely than not, the size of the settlement is justified through the patent's enforceability.[266]

Conclusion

I propose a model for analyzing reverse-payment settlements in the antitrust setting. To strike a balance between patent law's exclusionary exemption and antitrust law's prohibition on anticompetitive agreements, I propose that antitrust plaintiffs bear the burden to prove their prima facie case under the rule-of-reason analysis. Three factors need to be present to prove anticompetitive harm: (1) the patent holder must have strong market power; (2) the settlement amount or other considerations must not be justified; and (3) the potential enforceability of the patent must be low. Only after a plaintiff establishes this prima facie case should a court conduct the more complicated balancing analysis to weigh the procompetitive benefits of the agreement against its anticompetitive harm.

---

265 *See* Wright, *supra* note 172, at 16.

266 *Id.* at 15–16 ("What role patent validity will play within the rule-of-reason is an open question . . . . [O]ne possibility is that after a plaintiff satisfies its prima facie burden[,] . . . the defendant will be able to put on evidence that the strength of its patent justifies the size of the payment or the payment is otherwise not competitively suspect in light of the strength of the patent.").