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THE USE OF MERGER ANALYSIS TECHNIQUES TO ASSESS THE COMPETITIVE EFFECTS OF REVERSE PAYMENT SETTLEMENTS

I. INTRODUCTION

Reverse payment settlements, in which a brand drug manufacturer makes a payment to a generic drug manufacturer in exchange for the generic manufacturer delaying entry into the market, are a frequent topic of scholarship. Common debates range from favoring either antitrust¹ or patent² laws to analyzing which settlements are most likely to be harmful to competition.³ The Supreme Court partially resolved these issues in *FTC v. Actavis, Inc.*⁴ when it held that lower courts analyzing reverse payment settlements should apply the “rule of reason” in weighing the anticompetitive concerns of the settlement against any procompetitive justifications.⁵ In doing so, the Court left to lower courts the task of structuring the particular rule of reason analyses.⁶

This Note offers a solution for lower courts conducting the rule of reason analysis: consider a reverse payment settlement the functional equivalent of a merger and apply the techniques and case law associated

1. See, e.g., Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009).

2. See, e.g., Tania Khatibifar, Note, *The Need for a Patent-Centric Standard of Antitrust Review to Evaluate Reverse Payment Settlements*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1351 (2013).

3. See, e.g., David W. Opperbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303 (2010).

4. 133 S. Ct. 2223 (2013).

5. *Id.* at 2237. The rule of reason “is not really so much a set standard of behavior as it is a general inquiry into whether, under ‘all the circumstances,’ the challenged practice ‘impos[es] an unreasonable restraint on competition.’” WILLIAM C. HOLMES & MELISSA H. MANGIARACINA, ANTITRUST LAW HANDBOOK § 2:10 (2013) (quoting *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977)). In *Actavis*, the FTC urged the Court to adopt the “quick look” approach to reverse payment settlements, but the Court declined to apply this analysis. *Actavis*, 133 S. Ct. at 2237. Courts sometime adopt a quick look analysis where

the defendant’s conduct is shown to be of a type that . . . appears so likely to have anticompetitive effects . . . that it becomes unnecessary to go through a full-blown analysis of market definition, market power, and anticompetitive effect before shifting the burden onto the defendant to come forward with a plausible, procompetitive justification for its behavior.

HOLMES & MANGIARACINA, *supra*, § 2:10. In *Actavis*, the Court held that the quick look approach “is appropriate only where ‘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,’” and that reverse payment settlements do not present such a situation. *Actavis*, 133 S. Ct. at 2237 (quoting *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999)).

6. *Actavis*, 133 S. Ct. at 2238.

with Section 7⁷ merger cases. As will be explored below, lower courts have attempted many forms of analysis, many of which were rejected in *Actavis*.⁸ Because mergers frequently raise the same anticompetitive concerns as reverse payment settlements, the analyses take place in a common structure, which allows the imputation of merger case law to settlement analysis. Merger analysis is also sufficiently flexible such that only the truly anticompetitive settlements will be prevented. By providing a common framework for assessing reverse payment settlements, merger analysis allows for consistent holdings across the federal circuits—a consistency severely lacking in pre-*Actavis* case law.

This Note proceeds in four parts. Part II examines the history of reverse payment settlements and highlights the need for a consistent analysis structure. Part III compares the anticompetitive concerns of reverse payment settlements and mergers to argue that applying merger analysis is appropriate. Part IV surveys the available tools and relevant case law of merger analysis. Finally, Part V applies these tools to reverse payment settlements.

II. THE HISTORY OF REVERSE PAYMENT SETTLEMENTS

Reverse payment settlements sit at the intersection of patent law and antitrust law. The unique regulatory framework governing the pharmaceutical industry creates a system that encourages these settlements, but federal courts have disagreed over their legality. Although presented with an opportunity to resolve the disagreement, the Supreme Court merely noted the incorrect approaches and left it to the trial courts to establish the proper structure of the analysis.⁹ To fully explore the analyses available after *Actavis*, it is necessary to first review the major legislation governing the introduction of generic pharmaceuticals and the legal tests historically applied to reverse payment settlements.

7. Section 7 of the Clayton Act states that “[n]o person engaged in commerce . . . shall acquire . . . the stock . . . of another person engaged also in commerce or in any activity affecting commerce, where . . . the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.” Clayton Act, 15 U.S.C. § 18 (2012).

8. *Actavis*, 133 S. Ct. at 2238.

9. *Id.* at 2237–38 (“[T]he FTC must prove its case as in other rule-of-reason cases. . . . We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.”).

A. *The Hatch-Waxman Act*

The regulatory framework established by the Federal Food, Drug, and Cosmetic Act requires pharmaceutical manufacturers to engage in a thorough approval process that includes several rounds of clinical testing.¹⁰ The process is both costly and lengthy.¹¹ In fact, the original approval process often took so long that a considerable portion of the patent term expired before the drug even reached the market.¹² Patent laws, however, barred generic manufacturers from beginning the FDA approval process for a generic version of a patented drug while the brand-name patent was still in effect.¹³ The lengthy approval process for a generic drug therefore effectively extended the length of the brand manufacturer's patent.¹⁴ In short, the original process was cumbersome and harmful to both brand and generic manufacturers.

Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, in part to alleviate barriers to generic entry into the market.¹⁵ The Act has two relevant effects. First, conduct by generic manufacturers that would ordinarily be considered patent infringement is exempt from patent liability.¹⁶ Second, a generic manufacturer can “piggyback” off a brand manufacturer's New Drug Application (NDA) data and obtain FDA approval simply by filing an Abbreviated New Drug Application (ANDA) and showing that the generic drug is “bioequivalent” to the patented brand drug.¹⁷ By allowing generic manufacturers to rely on the brand manufacturer's data demonstrating the safety and efficacy of the drug, the Act makes market entry much cheaper and thus has ultimately made generic entry much more feasible.¹⁸

10. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (2012).

11. See generally Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003).

12. FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4* (2002), available at http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf, archived at <http://perma.cc/6DEU-SW72> [hereinafter FTC, *GENERIC DRUG ENTRY*].

13. Beginning the approval process earlier “would typically have infringed the brand-name company's patents.” *Id.*; see also *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

14. FTC, *GENERIC DRUG ENTRY*, *supra* note 12, at 4.

15. Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355(j) (2012).

16. FTC, *GENERIC DRUG ENTRY*, *supra* note 12, at 4.

17. 21 U.S.C. § 355(j)(2)(A)(iv); see also FTC, *GENERIC DRUG ENTRY*, *supra* note 12, at 4–7.

18. See C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 617–18 (2011) (estimating the cost of preparing and filing an ANDA to be \$1 million).

The Act requires that an ANDA contain a “certification” for each relevant patent held by the brand drug manufacturer that would affect the generic drug.¹⁹ Under a “Paragraph IV” certification, the ANDA alleges that the brand manufacturer’s “patent is invalid or will not be infringed by the manufacture, use, or sale” of the generic drug.²⁰ ANDA applicants have strong incentives to claim a Paragraph IV certification. First, an ANDA applicant is “protected from infringement liability so long as it has not begun marketing the drug.”²¹ The generic manufacturer thus faces little risk in filing a Paragraph IV certification.²² Second, the first successful filer of a Paragraph IV certification for the generic version of a particular drug is granted a 180-day exclusive distribution period for the generic drug if the ANDA is ultimately successful.²³ Paragraph IV certifications, therefore, are very appealing to generic manufacturers.

If a generic manufacturer successfully challenges a brand manufacturer’s patent by showing that either the patent is invalid or the generic drug does not infringe upon the patent holder’s rights,²⁴ the generic manufacturer essentially creates, at a minimum, a duopoly with the brand manufacturer.²⁵ The addition of a competitor encourages lower

19. FTC, *GENERIC DRUG ENTRY*, *supra* note 12, at 5–6 (“The statute provides ANDA applicants with four certification options: they may certify (I) that the required patent information has not been filed; (II) that the patent has expired; (III) that the patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (IV) that the patent is invalid or will not be infringed by the generic drug for which the ANDA applicant seeks approval.”); *see also* 21 U.S.C. § 355(j)(2)(A)(vii).

20. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

21. Shannon U. Han, Note *Pay-to-Delay Settlements: The Circuit-Splitting Headache Plaguering Big Pharma*, 15 *VAND. J. ENT. & TECH. L.* 913, 920 (2013).

22. In fact, the patent holder faces a greater risk when pursuing an infringement claim. If the claim is successful, it is likely to result in zero damages because the generic drug is not yet being produced. Conversely, if the claim is not successful, the patent holder has substantially weakened the credibility of its patent. *See* Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 245, 270–71 (2012).

23. 21 U.S.C. § 355(j)(5)(B)(iii)(IV)(iv)(I).

24. For example, a patent may have been improperly granted to a brand drug that is obvious in light of prior art, so the patent is invalid. Alternatively, construction of the claims included in a valid patent may limit the patent such that generic production does not constitute infringement. *See, e.g., In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367, 438 (S.D.N.Y. 2014) (“With respect to every patent-in-suit, either (1) [defendant’s] ANDA does not occupy the technological space where plaintiffs enjoy the right to exclude others or (2) plaintiffs’ right to exclude others is based on an invalid patent.”).

25. Generic drugs generally do “not enter the market until there was a district court holding that the brand-name company’s patent was invalid or not-infringed.” FTC, *GENERIC DRUG ENTRY*, *supra* note 12, at 22. After generic entry, the duopoly exists for the life of the 180-day exclusive distribution period that results from a Paragraph IV filing. After the expiration of this period, the duopoly can grow to a competitive market as more generic manufacturers enter the market. FTC, *PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 3* (2010), available at <http://www.ftc.gov/>

market prices for consumers.²⁶ As a result, Paragraph IV certifications provide brand drug manufacturers with strong incentives to settle with generic manufacturers rather than litigate and risk potential patent invalidity.

These settlements, known as reverse payment settlements, typically involve payments from the brand manufacturer to the generic manufacturer in exchange for the generic manufacturer agreeing to refrain from “purchasing, manufacturing, using, selling, distributing, and shipping to third parties any form of the generic’s drug product until the expiration of the patents.”²⁷ The settlement allows the brand manufacturer to preserve the effect of its patent without the risk of litigation.²⁸ The ultimate effect of such a settlement, however, is that the brand manufacturer continues to charge supracompetitive prices for its product and consumers do not receive the benefit of generic entry.²⁹

B. Differing Legal Standards

Though a patent grants the brand drug manufacturer a certain amount of monopoly power over the production and sale of the patented drug, the field of antitrust law has developed to prevent monopoly power from being used to harm competition and consumers.³⁰ In the context of reverse payment settlements, the antitrust issue arises when the brand manufacturer preserves its monopoly through a large cash payment to a potential competitor.³¹ It is this payment, not the settlement itself, that

sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

26. With the addition of the generic drug into the market, either the manufacturers compete on price, or the brand maintains its price and cedes market to the lower-priced generic. Either scenario results in the reallocation of “billions of dollars from producers to consumers.” C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1557 (2006).

27. FTC, GENERIC DRUG ENTRY, *supra* note 12, at 31.

28. Under the structure of the Hatch-Waxman Act, “[t]he 180-day exclusivity period commences either on the date the [first-filing] generic first begins commercial marketing or on the date a court decides that the patent is in fact invalid or not infringed.” Morris, *supra* note 22, at 264. By settling with the first-filer, the first-filer’s drug is never marketed and a court never rules on the validity of the patent, meaning the 180-day exclusivity period never begins. Because the exclusivity period never begins, generic manufacturers other than the first-filer do not have the opportunity to enter the market until after the patent expires.

29. Hemphill, *supra* note 26, at 1557.

30. *See id.* at 1555–56.

31. “The effect of such pay-for-delay agreements is to remove the possibility of early competition in the drug, and to deny consumers the allocative benefit of low prices, which would have followed with some probability had the litigation proceeded to conclusion.” *Id.* at 1557.

draws scrutiny and renders the transaction potentially anticompetitive.³² Several circuits have considered the issue and reached vastly different conclusions.

1. *Per Se Illegality*

The Sixth Circuit held in 2003 that reverse payment settlements are unreasonable restraints of trade and are thus per se illegal.³³ The court emphasized that the brand manufacturer effectively eliminated its only potential competitor through the settlement, explaining, “[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent’s effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market.”³⁴ The court found no justification for the settlement other than keeping the generic drug out of the market, and thus found the per se rule appropriate.³⁵

2. *Scope of the Patent Test*

The Second Circuit declined to apply the per se rule.³⁶ The court reasoned that reverse payment settlements should not be considered per se illegal because “reverse payments are particularly to be expected in the drug-patent context because the Hatch–Waxman Act created an environment that encourages them.”³⁷ Instead, the court adopted the “scope of the patent” test.³⁸ Under this test, “[w]hatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly.”³⁹ The Second Circuit further held that “until

32. Han, *supra* note 21, at 915.

33. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

34. *Id.* (citations omitted).

35. The Sixth Circuit further opined on the per se rule, noting that “the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case.” *Id.* at 909.

36. In rejecting the per se rule, the Second Circuit differentiated the matter from the Sixth Circuit case by explaining that “the Settlement Agreement did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products.” *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *abrogated by* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

37. *Id.* at 206 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003)).

38. *Id.* at 213.

39. *Id.* at 212–13.

the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.”⁴⁰

In the case that the Supreme Court later heard as *FTC v. Actavis*, the Eleventh Circuit echoed the Second Circuit’s scope of the patent reasoning in 2012.⁴¹ The court explained that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”⁴² The Eleventh Circuit reasoned that the scope of the patent test will not overprotect weak patents because

[i]f the patent actually is vulnerable, then presumably [additional] generic companies . . . will attempt to enter the market and make their own challenges to the patent. . . . Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent.⁴³

The opportunistic generic manufacturers, according to the Eleventh Circuit, thus ensure that any anticompetitive behavior outside the scope of the patent will be punished under the antitrust laws.

The Federal Circuit has also adopted the scope of the patent test.⁴⁴ The court noted that “there is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation.”⁴⁵ Further, “[s]ettlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition.”⁴⁶

40. *Id.* at 213 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005)).

41. *See* *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312–15 (11th Cir. 2012), *rev’d sub nom.* *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

42. *Id.* at 1312.

43. *Id.* at 1315.

44. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *abrogated by* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

45. *Id.* at 1333.

46. *Id.* (citing *Standard Oil Co. v. United States*, 283 U.S. 163, 171 n.5 (1931)).

3. *Two New Standards For One Settlement*

The settlement that perhaps best illustrated the varying standards among the circuits was the K-Dur settlement. Two circuits had the opportunity to analyze the same settlement, and not only did they apply tests different from the per se test and the scope of the patent test, each applied a different form of the rule of reason than the other. Despite analyzing the same transaction, the circuits came to different conclusions about its legality.

In 1997 and 1998, K-Dur manufacturer Schering-Plough settled with two generic K-Dur manufacturers.⁴⁷ Each settlement's terms included the generic manufacturer delaying entry into the market, and Schering making payments to the generic manufacturer.⁴⁸ The FTC filed a complaint against Schering in 2001, alleging that the settlements "were illegal agreements in restraint of trade" that violated both the Federal Trade Commission Act and the Sherman Act.⁴⁹ Initially, the Commission rejected the settlements as unreasonable restraints of trade.⁵⁰ The Eleventh Circuit, in turn, rejected the Commission's decision, explaining that patents naturally include potentially anticompetitive results.⁵¹ In fact, the court rejected both per se and rule of reason analyses.⁵² Because prior analyses were thus inappropriate, the Eleventh Circuit created a new test requiring "examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."⁵³ Under this test, the Eleventh Circuit found no violation of antitrust law.⁵⁴

In 2008, the District of New Jersey certified a class of K-Dur purchasers who alleged that the K-Dur reverse payment settlements constituted unreasonable restraints of trade in violation of Section 1 of the Sherman Act.⁵⁵ The district court applied the scope of the patent test and,

47. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058-61 (11th Cir. 2005).

48. *Id.*

49. *Id.* at 1061.

50. *Id.* at 1062 (declaring as anticompetitive a settlement "under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities").

51. *Id.* at 1065-66 ("By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present.").

52. *Id.* (citing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003)).

53. *Id.* at 1066.

54. *Id.* at 1076.

55. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 207-08 (3d Cir. 2012), *cert. granted, judgment vacated sub nom.* *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013), and

after finding the settlement did not exceed the patent's scope, granted the defendants' motion for summary judgment.⁵⁶ On appeal, the Third Circuit rejected the scope of the patent test, and held that "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable restraint of trade"⁵⁷ and the finder of fact should apply a quick look rule of reason analysis.⁵⁷ The Third Circuit then reversed lower court's opinion and remanded the case for further proceedings.⁵⁸

C. Actavis and Partial Split Resolution

After having its K-Dur victory reversed by the Third Circuit's rule of reason approach, Merck⁵⁹ filed a petition for a writ of certiorari to the Supreme Court on August 24, 2012.⁶⁰ Three days later, the Eleventh Circuit denied the FTC's petition to rehear a different reverse payment settlement case, *FTC v. Watson Pharmaceuticals*.⁶¹ Shortly thereafter, the FTC petitioned the Supreme Court for a writ of certiorari to review the Eleventh Circuit's decision.⁶² In December 2012, the Supreme Court granted the FTC's petition and agreed to hear the case as *FTC v. Actavis*.⁶³

In *FTC v. Actavis*, Solvay Pharmaceuticals obtained a patent for its FDA-approved, brand-name drug AndroGel.⁶⁴ Thereafter, generic manufacturers Actavis and Paddock each filed an ANDA that included a Paragraph IV certification claiming both that Solvay's patent was invalid and, even if it was valid, their drugs did not infringe upon the patent.⁶⁵ Pursuant to the procedure established by the Hatch-Waxman Act, Solvay initiated Paragraph IV litigation against the generic manufacturers.⁶⁶ The FDA approved Actavis' first-to-file product, but the parties settled soon

cert. granted, judgment vacated sub nom. Merck & Co. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013), and *reinstatement granted*, Nos. 10-2077, 10-4571, 2013 WL 5180857 (3d Cir. Sept. 9, 2013).

56. *Id.* at 208.

57. *Id.* at 218.

58. *Id.*

59. Merck & Co. acquired Schering and the K-Dur patent after the settlements, but prior to the Third Circuit litigation. *Id.* at 203 n.2.

60. Petition for Writ of Certiorari, *Merck & Co. v. La. Wholesale Drug Co.*, (2012) (No. 12-245), 2012 WL 3645102.

61. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1303–05, 1315 (11th Cir. 2012), *cert. granted sub nom.*, *FTC v. Actavis, Inc.*, 133 S. Ct. 787 (2012) (No. 12-416).

62. Petition for Writ of Certiorari, *Watson*, 677 F.3d 1298 (No. 12-416), 2012 WL 4750283.

63. *Actavis*, 133 S. Ct. 787 (No. 12-416).

64. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013).

65. *Id.*

66. *Id.*

thereafter.⁶⁷ The settlement required that Actavis refrain from introducing its generic drug until sixty-five months prior to the expiration of Solvay's patent and that Solvay pay each generic manufacturer millions of dollars.⁶⁸ The FTC alleged that payments were intended to "compensate the generics for agreeing not to compete against AndroGel."⁶⁹

The Supreme Court declined to follow the Eleventh Circuit's conclusion that the scope of the patent prevented the FTC from trying its case, finding that the "patent-related factor should not determine the result."⁷⁰ The Court identified five "considerations" that necessitated its conclusion: (1) the restraint at issue had the potential to adversely affect competition; (2) any resulting anticompetitive consequences will sometimes be unjustified; (3) the patent holder likely possesses the power to bring about anticompetitive harm; (4) antitrust actions are generally feasible; and (5) the risk of antitrust liability does not prevent parties from settling.⁷¹ Further, the Court specifically noted that

the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries.⁷²

Such complexities require that plaintiff "must prove its case as in other rule-of-reason cases."⁷³

This reasoning led the Court to two holdings. First, "reverse payment settlements [in patent infringement suits] can sometimes violate the antitrust laws."⁷⁴ This holding required the abrogation of the Federal Circuit's endorsement of the scope of the patent test in *In re Ciprofloxacin Hydrochloride*⁷⁵ and the Second Circuit's holding in *In re Tamoxifen*

67. *Id.*

68. "Solvay agreed to pay millions of dollars to each generic—\$12 million in total to Paddock; \$60 million in total to Par; and an estimated \$19–\$30 million annually, for nine years, to Actavis." *Id.*

69. *Id.*

70. *Id.* at 2234.

71. *Id.* at 2234–37.

72. *Id.* at 2237.

73. *Id.*

74. *Id.* at 2227.

75. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332–37 (Fed. Cir. 2008) *abrogated by Actavis*, 133 S. Ct. 2223 (holding that Hatch-Waxman-related settlements are generally immune from antitrust attack as "there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement"); *see supra* text accompanying note 44.

Citrate that there is no cognizable antitrust claim unless the patent was procured by fraud.⁷⁶ Second, reverse payment settlements are not immune from antitrust attack even if the anticompetitive effects fall within the scope of the patent.⁷⁷

The Court's holdings demonstrate a preference for antitrust analysis in areas of overlap between patent and antitrust law. However, they also eliminated precedent without providing a clear analytical framework for future reverse payment settlement cases. Throughout the opinion, the Court rejected the idea that these settlements are either per se anticompetitive⁷⁸ or per se legal,⁷⁹ and also severely undercut, if not outright eliminated, the scope of the patent test.⁸⁰ It instead noted the existence of "a sliding scale in appraising reasonableness [and] the quality of proof required should vary with the circumstances."⁸¹ However, the Court provided little guidance for "appraising reasonableness," instructing only that "trial courts can structure antitrust litigation" so as to achieve the appropriate balancing of interests.⁸² Accordingly, the Court "[left] to the lower courts the structuring of the present rule-of-reason antitrust litigation."⁸³ With little guidance and undercut precedents, courts have a dangerous probability of producing another circuit split on reverse payment settlements.

III. COMPETITIVE CONCERNS OF REVERSE PAYMENT SETTLEMENTS AND MERGERS

Because the Court expressed elevated concerns for antitrust violations in *Actavis*,⁸⁴ any proposed analysis framework must consider the entire scope of antitrust issues. As such, the necessary first steps are identifying

76. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006) *abrogated by Actavis*, 133 S. Ct. 2223 ("Whatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder . . . unless the terms of the settlement enlarge the scope of that monopoly."); *see supra* text accompanying note 40.

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

78. *Id.* at 2235–36 ("Anticompetitive consequences will at least sometimes prove unjustified. . . . [O]ffsetting or redeeming virtues are sometimes present.")

79. *Id.* at 2232 ("[T]his Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws.")

80. *Id.* at 2230 ("And we are willing to take . . . as evidence that the agreement's anticompetitive effects fall within the scope of the exclusionary potential of the patent. But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack.") (citations omitted) (internal quotation marks omitted).

81. *Id.* at 2237–38 (citation omitted) (internal quotation marks omitted).

82. *Id.* at 2238.

83. *Id.*

84. *Id.* at 2230.

the anticompetitive concerns involved in reverse payment settlements and identifying an analysis framework that can properly evaluate those concerns.

A. *Anticompetitive Concerns of Reverse Payment Settlements*

The most prevalent anticompetitive concern of reverse payment settlements is that such settlements constitute an unreasonable restraint of trade in violation of Section 1 of the Sherman Act.⁸⁵ These settlements eliminate a competitor and axiomatically reduce (or at least significantly delay) competition in the market.⁸⁶ Consumers consequently do not receive the benefit of the competition (in the form of lower prices) that would have been available but for the settlement.⁸⁷

Reverse payment settlements also elicit scrutiny because a large cash payment from the brand manufacturer to the generic manufacturer can be viewed as a *de facto* profit sharing arrangement.⁸⁸ In return for agreeing to refrain from (or to delay) entering the market, the generic manufacturer receives a share of the branded manufacturer's monopoly profits—a share that is likely larger than the profits the generic manufacturer would realize if it actually entered the market.⁸⁹ A payment to a competitor with the purpose of preventing competition directly contravenes Section 1 of the Sherman Act.⁹⁰

Congress recognized the potential for anticompetitive effects in reverse payment settlements. In response, it included a provision in the Medicare Modernization Act requiring that any agreement between a brand drug company and a generic drug company relating to the manufacturing, marketing, or sale of a drug be submitted to the Federal Trade Commission and Antitrust Division of the Department of Justice for antitrust review.⁹¹ This provision allows the agencies to continually and effectively monitor the pharmaceutical industry for anticompetitive

85. Khatibifar, *supra* note 2, at 1374; *see also* Sherman Act, 15 U.S.C. § 1 (2012).

86. Han, *supra* note 21, at 915.

87. *Id.*

88. *Id.* at 915–16.

89. *See* Hemphill, *supra* note 26, at 1580–81. Hemphill further explains that such payments result in harm to consumers. *Id.* at 1572–73 (“Economic modeling has shown formally that settlements that include a cash payment from the patentee to the infringer provide consumers with less welfare, on average, than seeing the litigation to completion.”).

90. 15 U.S.C. § 1 (2012) (“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”).

91. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003); *see also* Carrier, *supra* note 1, at 49.

settlements and puts the settling parties on notice that any settlement reached may be subjected to antitrust scrutiny. Notably, this requirement parallels the requirement that the parties to a merger notify the FTC and DOJ of the proposed merger under the Hart-Scott-Rodino Antitrust Improvement Act of 1976.⁹²

B. Anticompetitive Concerns of Mergers

The Antitrust Division of the Department of Justice and the Federal Trade Commission each have the authority to review mergers between firms to see if the merger poses a risk of anticompetitive effects that will harm consumers.⁹³ A horizontal merger⁹⁴ has two potential types of anticompetitive effects: coordinated effects and unilateral effects.

Coordinated effects are “cartel-like” effects.⁹⁵ If a merger has coordinated effects, “the merger will produce a change in market structure or environment that will probably lead the firms to behave less rivalrously or more cartel-like.”⁹⁶ The implication of coordinated effects is that tacit cooperation, if not outright agreements, between the remaining firms regarding pricing and production levels becomes much easier.⁹⁷ These restraints harm consumers in the form of increased prices, lower supply of products, lower quality products, and a smaller variety of products from which to choose.⁹⁸

Unilateral effects are “[t]he elimination of competition between two firms that results from their merger [that] may alone constitute a substantial lessening of competition.”⁹⁹ These effects are most prevalent in a merger to monopoly, though such a merger is not required.¹⁰⁰ Common unilateral effects include increased prices, decreased output, diminished innovation, and a reduction in product variety—concerns mirroring those emanating from a monopolist.¹⁰¹ Unilateral effects are of particular

92. *See infra* Part III.B.

93. ELEANOR M. FOX, *CASES AND MATERIALS ON U.S. ANTITRUST IN GLOBAL CONTEXT* 57 (3d ed. 2012).

94. A horizontal merger is a merger between two firms that are competitors (or potential competitors). *Id.* at 369.

95. *Id.* at 370.

96. *Id.* at 381.

97. DOJ & FTC, *HORIZONTAL MERGER GUIDELINES* § 7 (2010) [hereinafter *HORIZONTAL MERGER GUIDELINES*], available at <http://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf>.

98. *Id.*

99. *Id.* § 6, at 20.

100. *Id.*

101. *Id.* § 6.1–6.4.

concern when a merger takes place within an oligopolistic market—that is, a market in which there are few firms.¹⁰²

Under the Hart-Scott-Rodino Antitrust Improvements Act of 1976,¹⁰³ merging parties must notify the agencies of mergers meeting a set of defined criteria.¹⁰⁴ Such premerger notification filings (“HSR filings”) provide the initial information used by the agencies to determine if the merger has potential anticompetitive effects.¹⁰⁵ These filings also provide a process by which the agencies can gather more information or seek to enjoin the merger if they deem the potential coordinated or unilateral effects to have an adverse impact on competition.¹⁰⁶

Both coordinated and unilateral effects are implicated when a merger takes place within a concentrated industry. However, to determine the extent of these effects and their likely impact on consumers and competition, a full analysis of the market structure is necessary. This analysis is discussed later in this Note.¹⁰⁷

C. Collateral Applications of Antitrust Analyses

Courts do not necessarily restrict the application of a particular type of analysis to the particular problem the analysis was designed to address. Instead, overlaps between statutory purposes and legal concerns may allow the expansion of a particular analysis into new areas of law. For instance, in *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*,¹⁰⁸ the Supreme Court was presented with a predatory pricing case brought

102. FOX, *supra* note 93, at 409.

103. 15 U.S.C. § 18a (2012).

104. The parties must notify the agencies of any merger which would result in the acquirer holding securities of the acquired party in excess of \$303.4 million, or in excess of \$75.9 million if the acquirer meets other criteria described in the statute. 15 U.S.C. § 18a(a); Revised Jurisdictional Thresholds for Section 7A of the Clayton Act, 79 Fed. Reg. 3814 (Feb. 24, 2014) (to be codified at 16 C.F.R. pts. 801-03).

105. An HSR filing must identify and describe the parties involved in the transaction. The reporting parties must provide copies of documents filed with the Securities and Exchange Commission, balance sheets, and other financial data. The parties must also submit forward-looking documents that describe the planning and evaluation of the proposed merger. See FTC, WHAT IS THE PREMERGER NOTIFICATION PROGRAM?: AN OVERVIEW 6 (2009), available at <http://www.ftc.gov/sites/default/files/attachments/premerger-introductory-guides/guide1.pdf>, archived at <http://perma.cc/M376-KE8V>.

106. *Id.* at 9–14.

107. See *infra* Part IV.A.1.

108. 509 U.S. 209 (1993).

under the Robinson-Patman Act.¹⁰⁹ However, the particular analysis set forth by the Court has become the standard framework for assessing predation claims under Section 2 of the Sherman Act.¹¹⁰

The agencies have acknowledged the potential for merger analysis to be applied in non-acquisition contexts. In the Antitrust Guidelines for the Licensing of Intellectual Property,¹¹¹ the agencies explain that merger analysis is appropriate when two firms behave as if combining, but do not enter into a merger.¹¹² Though these guidelines offer two typical scenarios¹¹³ and an example involving two pharmaceutical products¹¹⁴ in which a merger analysis can be applied, neither the scenarios nor the example encompass a standard¹¹⁵ reverse payment settlement.¹¹⁶ However,

109. Generally, the Robinson-Patman Act, which amended Section 2 of the Clayton Act, prohibits a firm from selling its products to similarly situated buyers at different prices where such sales have the effect of lessening competition. FOX, *supra* note 93, at 260.

110. *Brooke Group* was not a Sherman Act Section 2 case because the defendant was not a monopolist, meaning Sherman Act causes of action were not available. However, the goals of analyzing predatory pricing claims are largely the same regardless of the relationship between the parties, so the *Brooke Group* analysis “set the standard for Section 2 predation law.” *Id.* at 266.

111. DOJ & FTC, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995) [hereinafter ANTITRUST IP GUIDELINES], available at <http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/0558.pdf>.

112. *Id.* § 5.7, Example 11.

113. The guidelines allow for a merger analysis to be applied (1) when there is “an outright sale by an intellectual property owner of all of its rights to that intellectual property” or (2) when there is “a transaction in which a person obtains through grant, sale, or other transfer an exclusive license for intellectual property.” *Id.* § 5.7.

114. The example scenario states that

Omega develops a new, patented pharmaceutical for the treatment of a particular disease. The only drug on the market approved for the treatment of this disease is sold by Delta. Omega’s patented drug has almost completed regulatory approval. . . . Omega’s drug would be a significant competitor to Delta’s. However, rather than enter the market as a direct competitor of Delta, Omega licenses to Delta the right to manufacture and sell Omega’s patented drug

. . . .
Id. § 5.7, Example 11. The guidelines explain, “The facts of this example indicate that Omega would be a likely potential competitor of Delta in the absence of the licensing arrangement, and thus they are in a horizontal relationship in the relevant goods market that includes drugs for the treatment of this particular disease.” *Id.* There is a horizontal posture and loss of potential competition, so “[t]he evaluating Agency would apply a merger analysis to this transaction, since it involves an acquisition of a likely potential competitor.” *Id.*

115. Here, “standard” refers to a settlement that includes a payment from the brand manufacturer to the generic manufacturer as compensation for the latter delaying entry into the market.

116. Scenario 1 in note 113 does not apply because the brand manufacturer is not selling its intellectual property to the generic manufacturer. This is true even if a settlement includes the brand manufacturer licensing its intellectual property to the generic because it is not selling “all of its rights to that property.” *Id.* (emphasis added). Scenario 2 in note 113 does not apply because even if the generic is able to negotiate both entry into the market and use of the intellectual property before the expiration of the patent, it will not become the exclusive seller of the drug. For use of the property to trigger a merger analysis under scenario 2, the generic manufacturer must use “a license that precludes all other persons, including the licensor, from using the licensed intellectual property.” *Id.* (emphasis

Section 5.7 of these guidelines provides an important stepping stone toward applying merger analysis to reverse payment settlements.

IV. MERGER ANALYSIS: TOOLS AND CASES

The second step in identifying a proper framework for analyzing reverse payment settlements is identifying a systematic approach that can be applied to address the anticompetitive concerns raised by the settlements. This section explores the techniques used in merger analysis to evaluate if they are suitable for a collateral application to reverse payment settlements.

A. General Overview of Merger Techniques and Analysis

The Department of Justice first issued a set of merger guidelines in 1968.¹¹⁷ These guidelines have been updated several times since, most recently in 2010.¹¹⁸ The 2010 Horizontal Merger Guidelines (hereinafter “Merger Guidelines”) are largely intended to inform businesses of how the agencies are likely to assess horizontal mergers.¹¹⁹ The standard analysis generally involves defining a product market, assessing the level of competition in the market, and predicting the likelihood of anticompetitive effects.¹²⁰

1. Market Definition

When a product sold by one firm competes against a product sold by another firm, those products are considered to be in the same market. According to the Merger Guidelines, market definition plays two roles: it “helps specify the line of commerce and section of the country in which the competitive concern arises” and it “allows the Agencies to identify

added). Though only illustrative, Example 11 does not apply because it involves a market incumbent, Delta, purchasing new intellectual property from a potential competitor, Omega. *Id.* § 5.7, Example 11. This is different from a reverse payment settlement because while an incumbent brand manufacturer buys only a longer exclusive market from a generic manufacturer in a reverse payment settlement, Omega actually purchases new intellectual property from Delta. Such a purchase is more likely to be obviously anticompetitive to “an observer with even a rudimentary understanding of economics” and thus pass the scrutiny of *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999). In short, reverse payment settlements do not fall within the scope of merger analysis under Section 5.7 and thus require a new imputation into cases based on Section 1 of the Sherman Act.

117. FOX, *supra* note 93, at 369.

118. *Id.*

119. *Id.* at 370.

120. HORIZONTAL MERGER GUIDELINES, *supra* note 97, § 1.

market participants and measure market shares and market concentration.”¹²¹ Traditionally, the “outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.”¹²² Thus, market definition focuses on a customer’s ability and willingness to substitute to a different product in response to a price increase.¹²³

To find the point at which customers will substitute products, the agencies employ the “hypothetical monopolist test.”¹²⁴ This test assumes that a single hypothetical monopolist controlling all products in a proposed market imposes a small but significant and non-transitory increase in price (“SSNIP”)¹²⁵ on its products.¹²⁶ If the SSNIP is profitable for the hypothetical monopolist—that is, if consumers do not substitute to other products—the correct market is identified.¹²⁷ If customers are able to substitute to other products, the market is enlarged to include the substitutable products and the process is repeated until the proper market is identified.¹²⁸

2. Market Shares, Concentration, and Presumptions

Once a market has been defined, the agencies measure market shares and market concentration to help determine the likelihood of anticompetitive effects.¹²⁹ Market shares are generally considered useful indicators of a firm’s competitive significance in the relevant market.¹³⁰

121. *Id.* § 4, at 7.

122. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). The Court immediately recognized the potential need for narrower submarkets in some instances: “The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product’s peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.” *Id.*

123. HORIZONTAL MERGER GUIDELINES, *supra* note 97, § 4.

124. *Id.* § 4.1.1.

125. The SSNIP is usually 5%. *Id.* § 4.1.2.

126. *Id.* § 4.1.1.

127. FOX, *supra* note 93, at 370. For example, suppose we want to identify the relevant market for Coke. We observe that if the price of Coke is increased by 5%, customers substitute Pepsi for Coke. If the prices of Coke and Pepsi are increased by 5%, customers do not substitute to a third product (for example, water) and pay the higher price. The relevant market, therefore, is Coke and Pepsi.

128. *Id.*

129. HORIZONTAL MERGER GUIDELINES, *supra* note 97, § 5 (explaining that market shares are important because “if a price reduction to gain new customers would also apply to a firm’s existing customers, a firm with a large market share may be more reluctant to implement a price reduction than one with a small share. Likewise, a firm with a large market share may not feel pressure to reduce price even if a smaller rival does.”).

130. *Id.* § 5.2. Market shares are usually calculated based on revenues rather than unit sales. *Id.*

In combination with the number of participants in a particular market, market shares reveal the market's concentration. The agencies measure market concentration using the Herfindahl-Hirschman Index ("HHI") of market concentration.¹³¹ By calculating a market's HHI both before and after a proposed merger, the agencies can measure the change in market concentration.¹³² By measuring the change in market concentration, the agencies can determine the likelihood of unilateral or coordinated effects of the merger.¹³³

The Merger Guidelines are based on the contention that "mergers should not be permitted to create, enhance, or entrench market power or to facilitate its exercise."¹³⁴ As such, the agencies view mergers showing large HHI increases skeptically. The agencies apply concentration characterizations of "unconcentrated markets,"¹³⁵ "moderately concentrated markets,"¹³⁶ and "highly concentrated markets"¹³⁷ based on the market's pre-merger HHI. In highly concentrated markets, such as those likely to be encountered in the pharmaceutical industry, mergers that increase the HHI by 100 to 200 points "potentially raise significant competitive concerns" and mergers that increase the HHI by more than 200 points are "presumed to be likely to enhance market power."¹³⁸ However, such a presumption "may be rebutted by persuasive evidence showing that the merger is unlikely to enhance market power."¹³⁹ This structure of presumptions and rebuttals mirrors the analysis of the Supreme Court in pre-Merger Guidelines cases.¹⁴⁰

§ 5.2, at 17 ("Revenues in the relevant market tend to be the best measure of attractiveness to customers, since they reflect the real-world ability of firms to surmount all of the obstacles necessary to offer products on terms and conditions that are attractive to customers.").

131. *Id.* § 5.3. An HHI is calculated by summing the square of each firm's market share. For example, an industry with three firms having 50%, 30%, and 20% market shares would have an HHI of 3,800 ($50^2 + 30^2 + 20^2 = 3,800$). The HHI can range from 10,000 (a pure monopolist) to a number approaching zero (an "atomistic market"). *Id.* § 5.3 n.9.

132. *Id.* § 5.3.

133. *Id.*; *see supra* Part III.B.

134. *Id.* § 1.

135. HHI below 1500. *Id.* § 5.3.

136. HHI between 1500 and 2500. *Id.*

137. HHI above 2500. *Id.*

138. *Id.* § 5.3, at 19.

139. *Id.*

140. *See, e.g.,* *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 363 (1963) ("Specifically, we think that a merger which produces a firm controlling an undue percentage share of the relevant market, and results in a significant increase in the concentration of firms in that market, is so inherently likely to lessen competition substantially that it must be enjoined in the absence of evidence clearly showing that the merger is not likely to have such anticompetitive effects.").

B. Analysis of Concentrated Industries

In 1974, the Supreme Court decided *United States v. General Dynamics*.¹⁴¹ The Department of Justice challenged a merger of coal companies based on market concentration as reflected by current market shares.¹⁴² However, the Court reasoned that market shares did not accurately reflect any given coal company's future ability to compete.¹⁴³ The merging companies showed that the structure of the coal industry made current market shares misleading and, contrary to the presumption that mergers in concentrated industries are anticompetitive,¹⁴⁴ the merger would not likely produce an increase in market power.¹⁴⁵ *General Dynamics* marked a shift to "demand[ing] harder proof from the plaintiff that any given merger would probably increase market power, raise price and lower output."¹⁴⁶

C. Analysis of Precluding Competition Through Mergers

As discussed in Part III, merger analysis is concerned with the potential for a substantial lessening of competition when two competitors combine into a single entity. This concern also extends to a merger between an existing firm and a *potential* competitor.¹⁴⁷ Potential competition claims

141. 415 U.S. 486 (1974).

142. *Id.* at 494 (explaining that the government based its challenge on "statistics showing that . . . the coal industry was concentrated among a small number of large producers; that this concentration was increasing; and that the acquisition . . . would materially enlarge the market share of the acquiring company . . .").

143. *Id.* at 501.

144. This merger predated the Horizontal Merger Guidelines in their current form. However, the inference of market power from market share statistics was still the governing merger analysis at the time. *See supra* note 140.

145. In short, the Court found that coal was largely consumed by utility companies. Because the survival of the utility companies depended on an uninterrupted supply of coal, the utilities demanded to purchase coal under long-term contracts. As such, measuring market shares with current revenues did not accurately measure each firm's ability to compete in the future. Even future sales would not be an appropriate measure because much of each company's unmined coal had already been committed to a customer under long-term contracts. Instead, the proper measure of future competitiveness was the uncommitted coal in each company's reserves. Because the reserves of one of the two merging parties were nearly depleted, the merger could not harm future competition and therefore was not divested. *General Dynamics*, 415 U.S. at 501–04.

146. FOX, *supra* note 93, at 369.

147. *See, e.g.*, Darren S. Tucker, *Potential Competition Analysis Under the 2010 Merger Guidelines*, 12 SEDONA CONF. J. 273, 273 (2011). The prevalence of the potential competition doctrine has waned since the Supreme Court's decision in *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602 (1974). There, the Court required a showing that one of the merging firms "has the characteristics, capabilities, and economic incentive to render it a perceived potential *de novo* entrant,

require both a concentrated market and few other competitors with the potential to enter the market—if these conditions are not met, “the elimination of a potential entrant would be competitively irrelevant.”¹⁴⁸ Though some circuits have expressed concern over difficulty of proving anticompetitive harm under the potential competition doctrine,¹⁴⁹ the 2010 iteration of the Merger Guidelines explicitly refers to potential competition,¹⁵⁰ the first time since 1984 that such a reference has been made.¹⁵¹

The Merger Guidelines apply the standard horizontal merger framework to the acquisition of a firm that is outside the market but committed to entering.¹⁵² The Merger Guidelines also note the particularly acute threat to competition when a competitor is prevented from entering the market.¹⁵³ While not devoting the same level of attention as the 1984 Merger Guidelines did,¹⁵⁴ the 2010 Merger Guidelines identify five objective factors to be considered in assessing a horizontal merger with a potential competitor: market concentration, barriers to entry, relative entry capabilities, incumbent market share, and potential efficiencies.¹⁵⁵ These five factors are precisely those that complicate pharmaceutical markets and are thus the factors that must be considered in evaluating potentially anticompetitive behavior by drug manufacturers.

and . . . [its] premerger presence on the fringe of the target market in fact tempered oligopolistic behavior on the part of existing participants in that market.” *Id.* at 624–25.

148. Tucker, *supra* note 147, at 273–74.

149. The First, Second, Fourth, and Fifth Circuits have expressed concerns with implementing the potential competition doctrine and have refused to rule on the doctrine. *See, e.g.*, *Fraser v. Major League Soccer, L.L.C.*, 284 F.3d 47, 70–71 (1st Cir. 2002); *Tenneco, Inc. v. FTC*, 689 F.2d 346, 355 (2d Cir. 1982); *FTC v. Atl. Richfield Co.*, 549 F.2d 289, 293–94 (4th Cir. 1977); *Republic of Tex. Corp. v. Bd. of Governors of Fed. Reserve Sys.*, 649 F.2d 1026, 1048 (5th Cir. 1981). The Eighth Circuit has accepted the potential competition doctrine. *See, e.g.*, *Ginsburg v. InBev NV/SA*, 623 F.3d 1229, 1234 (8th Cir. 2010).

150. HORIZONTAL MERGER GUIDELINES, *supra* note 97, § 1 (“These Guidelines outline the principal analytical techniques, practices, and the enforcement policy . . . with respect to mergers and acquisitions involving actual or potential competitors . . .”).

151. Tucker, *supra* note 147, at 278.

152. HORIZONTAL MERGER GUIDELINES, *supra* note 97, § 9 (“Firms that have, prior to the merger, committed to entering the market also will normally be treated as market participants.”).

153. *Id.* § 5.3 (“A merger between an incumbent and a potential entrant can raise significant competitive concerns. The lessening of competition resulting from such a merger is more likely to be substantial, the larger is the market share of the incumbent, the greater is the competitive significance of the potential entrant, and the greater is the competitive threat posed by this potential entrant relative to others.”).

154. DEP’T OF JUSTICE, 1984 MERGER GUIDELINES §§ 4.131–135 (1984), *available at* <http://www.justice.gov/atr/hmerger/11249.pdf>.

155. HORIZONTAL MERGER GUIDELINES, *supra* note 97, §§ 5.1–3.

V. APPLICATION OF MERGER ANALYSIS TO REVERSE PAYMENT SETTLEMENTS

After confirming the parallel anticompetitive concerns of reverse payment settlements and mergers, and identifying the techniques involved in merger analysis, the next step is to apply merger analysis to these settlements. This Part evaluates the potential for such collateral application.

A. *Application of Merger Analysis Is Appropriate*

The ultimate anticompetitive concerns of reverse payment settlements and mergers are the same: a competitor (or potential competitor) is removed from the market leaving the remaining firm(s) with market power and the ability to charge supracompetitive prices.¹⁵⁶ As discussed in Part III, merger analysis has been imputed to other areas of law—most notably the acquisition of intellectual property rights under the 1995 Antitrust Guidelines for the Licensing of Intellectual Property.¹⁵⁷ While reverse payment settlements are fundamentally different than intellectual property acquisition,¹⁵⁸ a variation of a common logical foundation applies: where there had previously been competition, there is now cooperation.

156. See *supra* Part III.A.

157. ANTITRUST IP GUIDELINES, *supra* note 111, § 5.7.

158. Reverse payment settlements generally involve an intellectual property holder paying a competitor to abandon its pursuit of the property (or its substantial equivalent). Thus, no intellectual property is disclosed and the number of producers is not increased. Contrarily, an intellectual property acquisition increases the number of producers of a given product and has the potential to increase competition. While some reverse payment settlements involve an eventual licensing of intellectual property to the generic manufacturer, the licensing usually occurs after a period of time during which the generic agrees to stay out of the market. The licensing ultimately results in at least the same amount of harm to consumers as an agreement to abandon generic manufacturing. For example, suppose a brand manufacturer has five years remaining on its patent. As part of the settlement, the brand manufacturer may agree to license the intellectual property to the generic manufacturer after three years. This provides the brand manufacturer with three more years of monopoly power and two years of a duopoly likely subject to coordinated effects. The generic manufacturer receives a two-year period as the exclusive generic manufacturer, more than four times the exclusivity period provided by Hatch-Waxman. See *supra* note 23 and accompanying text. Since under Hatch-Waxman settlements can undercut the authority of the FDA to approve subsequent generic ANDAs, the brand manufacturer's patent cannot be challenged again. Hemphill, *supra* note 26, at 1586–88. Consumers thus lose the benefit of having the patent challenged, of potential earlier entry by the first-filing generic, and of entry by additional generics after the statutorily-provided 180-day exclusivity period for the first-filing generic. In short, such licensing arrangements have the potential to inflict the same harm on consumers as settlements in which the brand manufacturer simply pays the generic to delay entry.

The development of merger analysis over the last several decades proves particularly useful in assessing the pharmaceutical industry. By its nature, the industry is segmented into potentially well-defined submarkets.¹⁵⁹ These submarkets are likely to be highly concentrated and require more nuanced analysis than a mechanical application of before-and-after market share statistics.¹⁶⁰ Merger analysis includes techniques¹⁶¹ that address these exact issues and allows for a complete and accurate assessment of the competitive effects of a reverse payment settlement.

B. Industry Analysis and Market Definition

The flexibility of market definition afforded by merger analysis ensures that only those reverse payment settlements that pose threats to competition and consumers are likely to be subjected to intense scrutiny and possible injunction. A properly defined market, an aspect that is problematic in many analyses of the pharmaceutical industry,¹⁶² is the first step toward determining whether a given settlement will harm competition and violate antitrust laws.¹⁶³

Market definition within the pharmaceutical industry is a complicated task. The natural starting point is functionally equivalent drugs. Several branded and generic drugs are often designed to treat the same condition. For example, at least five variations of drugs designed to treat depression are sold under seven brand names.¹⁶⁴ Additionally, four of these drugs are

159. Each pharmaceutical product treats a limited number of conditions or symptoms, so the choices available to consumers are always much narrower than “all pharmaceutical products.” The “practical indicia” of submarkets described by the Court in *Brown Shoe* support narrow market definitions for pharmaceutical products. See *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962).

160. Cf. *United States v. Gen. Dynamics Corp.*, 415 U.S. 486 (1974) (finding that uncommitted coal reserves, not current market shares, accurately measured each firm’s future ability to compete).

161. See *supra* Part IV.

162. See generally Anish Vaishnav, Note, *Product Market Definition in Pharmaceutical Antitrust Cases: Evaluating Cross-Price Elasticity of Demand*, 2011 COLUM. BUS. L. REV. 586.

163. Only per se analyses disregard market definition. LOUIS ALTMAN AND MALLA POLLACK, CALLMANN ON UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES § 4:31, at 4-308 (4th ed. 2009). Because *Actavis* instructs that reverse payment settlements are to be analyzed under the rule of reason, market definition is a necessary step of the analysis. See *id.*; *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

164. Opperbeck, *supra* note 3, at 1334. The generics and their branded versions are citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), paroxetine (Paxil, Paxil CR, Pexeva), and sertraline (Zoloft). Mayo Clinic Staff, *Selective Serotonin Reuptake Inhibitors (SSRIs)*, MAYO CLINIC (July 9, 2013), <http://www.mayoclinic.org/diseases-conditions/depression/in-depth/ssris/art-20044825>, archived at <http://perma.cc/K446-5GWR>.

made with expired patents and thus generics have entered the market.¹⁶⁵ Even when the FDA declares drugs to be “bioequivalent,” however, patients do not necessarily uniformly respond to treatment.¹⁶⁶ Therefore, for the individual consumer, the range of substitutable products may be narrower than “therapeutic equivalence” suggests. Because the boundaries of substitution may vary by the individual consumer, precise market definition may be impossible.¹⁶⁷

However, even “broad” pharmaceutical markets—that is, markets not limited to a brand drug and its equivalent generic¹⁶⁸—are highly concentrated. For example, consider the market for drugs approved by the FDA to treat fibromyalgia as described in Professor Opderbeck’s *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*.¹⁶⁹ The market centers on a brand drug (Lyrica) with no generic competition, but which faces products of potential therapeutic equivalence produced by two brand manufacturers and nine generic manufacturers.¹⁷⁰ Despite the presence of eleven different manufacturers,

165. The patents for Prozac, Paxil, Zoloft, and Celexa expired between 2001 and 2006. Haiden A. Huskamp et al., *Generic Entry, Reformulations and Promotion of SSRIs in the US*, 26 PHARMACOECONOMICS 603, 604 (2008). See also Opderbeck, *supra* note 3, at 1334.

166. Opderbeck, *supra* note 3, at 1334–35.

167. The degree to which consumers can substitute between products places constraints on the pricing of each product. Pharmaceuticals, however, complicate such substitution and constraints. Suppose drugs A and B are therapeutically equivalent and both treat disease C. Drug B, however, causes unpleasant side effects in a large number of patients while drug A does not. These side effects will likely prevent many users of drug A from switching to drug B if the price of A increases (or the price of B decreases). In this case, drug B does not constrain the price of drug A and, because there is little (if any) substitution by patients suffering from disease C, the two drugs may not belong in the same product market. Therefore, the appearance of competition, but not actual competition, may exist.

168. This definition of a “broad” market is undoubtedly narrower than reality. However, the major obstacle of imputing merger analysis into reverse payment settlement evaluation is squaring the presumptive invalidity of mergers in highly concentrated industries, see *supra* note 138 and accompanying text, with the presumptive validity of a patent, see *infra* note 203. If the imputation is successful in narrow, concentrated markets, the analysis will apply equally well to broad, diffuse markets. The conservative approach, therefore, is to test the analysis in markets that may be too narrowly defined.

169. Opderbeck, *supra* note 3, at 1343–44. Opderbeck stresses the importance of market definition in assessing the legality of a reverse payment settlement.

170.

MANUFACTURER	DRUG	GENERIC EQUIVALENT	SALES (MILLIONS USD)	MARKET SHARE
Pfizer	Lyrica	Pregabalin	\$2,573	75%
	Neurontin	Gabapentin	\$387	
	Dilantin	Phenytoin	\$30	
Novartis	Tegretol	Carbamazepine	\$451	11%

the HHI for the market is 5,853—well above the Merger Guidelines’ “highly concentrated” threshold of 2,500.¹⁷¹ This level of concentration is not surprising given the high barriers to entry associated with pharmaceutical markets.¹⁷² The major complication is determining how much of this concentration results from the brand manufacturer holding a lawful patent. Regardless, the concentration of pharmaceutical markets requires careful analysis to minimize the risk of adverse coordinated or unilateral effects of settlements.

Despite the potential difficulties of market definition, the exercise is usually necessary to assess anticompetitive effects. Fortunately, the approach to market definition under merger analysis encourages examination of the “practical indicia” of the relevant submarket¹⁷³ and evidence of competitive effects.¹⁷⁴ Thus, merger analysis renders a more

MANUFACTURER	DRUG	GENERIC EQUIVALENT	SALES (MILLIONS USD)	MARKET SHARE
Teva	Gabapentin	--	\$85	2%
Alpharma	Gabapentin	--	\$85	3%
	Phenytoin	--	\$30	
Ivax	Gabapentin	--	\$85	2%
Glenmark	Gabapentin	--	\$85	2%
Morton Grove	Phenytoin	--	\$30	1%
Precision Dose	Phenytoin	--	\$30	1%
Taro	Phenytoin	--	\$30	1%
UDL	Phenytoin	--	\$30	1%
Xactdose	Phenytoin	--	\$30	1%

Market shares as of 2008. *Id.* at 1344.

171. See *supra* note 137 and accompanying text.

172. See, e.g., David A. Balto & James F. Mongoven, *Antitrust Enforcement in Pharmaceutical Industry Mergers*, 54 FOOD & DRUG L.J. 255, 265 (1999) (noting that in a highly concentrated drug market “[b]arriers to entry were high because of the need to undertake the difficult, expensive, and time-consuming process of researching and developing a new product, obtaining FDA approval, and gaining customer acceptance”).

173. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (“The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product’s peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.”).

174. Vaishnav, *supra* note 162, at 590 (explaining that the 2010 Horizontal Merger Guidelines “allow[] for reliance on direct evidence of competitive effects” which allows for a more flexible approach to market definition than is taken when defining a market for a Sherman Act § 2 monopolization claim).

precise market than a mechanical application of cross-elasticity of demand principles.

C. *Effect on Prices*

The importance of the market definition process is slightly diminished when actions cause observable changes in a market.¹⁷⁵ For example, if a new product enters the market at a lower price and several other products lower their prices to remain competitive, it can be safely assumed that all of the products are in the same market.¹⁷⁶ The effect of a generic entrant on the price of a branded drug has been studied in great detail.¹⁷⁷ The precise price effects are outside the scope of this Note. Pricing is instead relevant to the extent that it helps identify potential anticompetitive effects of a particular reverse payment settlement.

1. *Notable Market Features*

Three features of pharmaceutical markets must be kept in mind when observing actual effects in a given market. First, a brand drug and its generic are identical, so they do not compete on quality.¹⁷⁸ Second, some consumers are loyal to brand drugs and are reluctant to switch to a generic medication.¹⁷⁹ Third, health insurance often covers some, if not all, of the

175. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460–61 (1986) (“Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, proof of actual detrimental effects, such as a reduction of output, can obviate the need for an inquiry into market power . . .”) (citation omitted) (internal quotation marks omitted).

176. Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 337 (1992) (explaining the “negative relationship that states that the higher generic penetration is, the lower the market price will be”).

177. See, e.g., Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75 (1997); Grabowski & Vernon, *supra* note 176; FTC, *AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT* (2011), available at <http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>.

178. Bioequivalence is defined by the FDA as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions.” 21 C.F.R. 320.1(e) (2013). A generic manufacturer must assert that its product is bioequivalent to an approved drug when filing an Abbreviated New Drug Application with the FDA. Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(A)(iv) (2012). Thus, a brand drug and its generic cannot compete on quality.

179. Grabowski & Vernon, *supra* note 176, at 340 (“The strength of brand loyalties is demonstrated by the fact that, on average, pioneers keep about half their market in units despite the fact that generics are roughly one-third the price of pioneers . . .”).

price of pharmaceuticals, so end consumers are not always responsive to prices.¹⁸⁰ The precise implications of these characteristics may not be obvious or constant for all drugs, but the important observation is that many consumers switch to the generic drug once it is available.¹⁸¹

2. Use of Generics

A 2010 FTC study¹⁸² shows that not only do many consumers switch to generics, but that oligopolistic pharmaceutical markets are susceptible to the type of potentially anticompetitive effects discussed in Part III. The study found that a market for generic drugs takes approximately one year to mature.¹⁸³ Thus, it should be expected that the generic will initially charge a supracompetitive price,¹⁸⁴ but then the generic price will decline over time.¹⁸⁵ Once the generic market is mature, the average generic price

180. Vaishnav, *supra* note 162, at 612–13 (“[I]t is likely that . . . the patient . . . will remain insensitive to (and perhaps, completely oblivious of) prices and price changes. The patient will be paying only a fraction of the price of the drug, no matter which drug is prescribed . . .”) (citation omitted).

181. The fact that some consumers choose to continue purchasing the brand name drug even with the availability of a cheaper bioequivalent generic does not indicate that the drugs are in separate markets. Perhaps some consumers feel more comfortable with the brand name drug and the price disparity is not large enough to sway them to the generic. *See supra* note 179. Or perhaps the brand drug has launched an extremely effective marketing campaign and has convinced consumers its product is better. The Supreme Court has held that a lack of switching, even between chemically identical products, is not necessarily an indication that the products are different or belong in different markets. *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 572 (1967) (“Since all liquid bleach is chemically identical, advertising and sales promotion are vital. . . . [T]hese heavy expenditures went far to explain why Clorox maintained so high a market share despite the fact that its brand . . . retailed for a price equal to or, in many instances, higher than its competitors.”).

182. FTC, *PAY-FOR-DELAY*, *supra* note 25.

183. *Id.* at 8.

184. Though a generic may initially charge a price above the competitive level, “[t]he general pattern is that generic products enter at a significant discount to the [brand] product with which they compete.” *Grabowski & Vernon*, *supra* note 176, at 335.

185. The initial supracompetitive price is not necessarily an anticompetitive price. The antitrust laws do not prohibit a firm from charging a price above the competitive price, or even a monopoly price. *Cf. Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (“The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system.”). Even if the generic sets its price based on the brand drug’s price, this is not necessarily indicative of anticompetitive collusion because parallel pricing alone is not sufficient to offend the antitrust laws. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 553–54 (2007) (“Even ‘conscious parallelism,’ a common reaction of ‘firms in a concentrated market [that] recogniz[e] their shared economic interests and their interdependence with respect to price and output decisions’ is ‘not in itself unlawful.’”) (alteration in original) (quoting *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 227 (1993)). Instead, this is another illustration of the structure of pharmaceutical markets potentially facilitating anticompetitive coordinated effects.

is approximately 85% lower than the pre-generic-entry brand drug price.¹⁸⁶ The lower prices help shift consumers to the generic drug—about 90% of prescriptions (for which a generic is available) are filled using a generic drug in mature markets.¹⁸⁷

3. *The Impact of Pricing and Substitution on Settlement Analysis*

The evidence of consumers switching to generic drugs motivates brand manufacturers to prevent generic entry and colors the analysis of reverse payment settlements in three ways. First, it lessens the burden of market definition. Second, it supports the contention that the potential competition doctrine applies to pharmaceutical submarkets. Third, it highlights the anticompetitive effects of reverse payment settlements.

Courts have shown more leniency in accepting a plaintiff's market definition when the plaintiff is able to present evidence of actual anticompetitive effects.¹⁸⁸ While this is not something that can likely be shown in reference to any particular reverse payment settlement,¹⁸⁹ generic entry predictably lowers average¹⁹⁰ drug prices.¹⁹¹ The consistency of this effect suggests that, but for the reverse payment settlement, average drug prices would decrease. The settlements thus keep the available prices artificially inflated and may well be anticompetitive.

The repeated pattern of generic entry followed by lower average prices is strong evidence that the potential competition doctrine applies to reverse payment settlements in the pharmaceutical industry. Once the generic has filed a Paragraph IV Abbreviated New Drug Application with the FDA,¹⁹² it has assumed the posture of a *de novo* entrant into the market and meets

186. FTC, *PAY-FOR-DELAY*, *supra* note 25, at 8.

187. *Id.*

188. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460–61 (1986).

189. In a challenge to a reverse payment settlement, the generic by definition has not entered the market. A showing of lower average prices due to entry of the generic is therefore not possible.

190. This does not necessarily imply that the brand manufacturer lowers, or even maintains, its price. Suppose ten customers buy a brand drug for \$10. Suppose further that a generic enters at a price of \$5, the brand increases its price of \$15, and eight customers switch to the generic. The average price paid fell from \$10 before entry to \$7 after.

191. See Grabowski & Vernon, *supra* note 176, at 335–36; Richard E. Caves, Michael D. Whinston & Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY, MICROECONOMICS 1, 34–35; FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION*, *supra* note 12, at 9.

192. Prior to this filing, the generic drug has not initiated, much less gained, FDA approval, so it cannot enter the market and thus is not a potential entrant. See *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602, 633 (1974) (concluding that National Bank of Commerce could not be a potential entrant in part because “[i]t is undisputed that under state law NBC cannot establish *de novo* branches in Spokane”).

the preconditions for application of the potential competition doctrine.¹⁹³ In fact, pharmaceutical markets closely mirror the markets described by the Court in *Marine Bancorporation* as fit for potential competition analysis.¹⁹⁴ Further, the FTC has used the potential competition doctrine in actions to prevent one brand manufacturer from acquiring a competing brand manufacturer that was developing a competitive product.¹⁹⁵ Consumers will likely benefit from the treatment of generics as potential competitors in assessing whether a reverse payment settlement has an adverse effect on competition.

The declines in average prices after generic entry also show that, prior to generic entry, brand drug manufacturers are usually charging incredibly supracompetitive rates.¹⁹⁶ To properly conceptualize the effect of a reverse payment settlement, it is helpful to think of the events as a merger taking place in the market after generic entry.¹⁹⁷ Comparing projected average prices in a competitive environment with the actual price being charged by the brand manufacturer will likely expose any potentially anticompetitive unilateral effects¹⁹⁸ that result from the settlement.¹⁹⁹

193. Two preconditions must be met before establishing a potential competition claim under Section 7 of the Clayton Act. “It must be determined: (i) that in fact [the potential entrant] has available feasible means for entering the [market]; and (ii) that those means offer a substantial likelihood of ultimately producing deconcentration of that market or other significant procompetitive effects.” *Marine Bancorporation*, 418 U.S. at 633.

194. See *supra* notes 147–55 and accompanying text.

195. HEALTH CARE DIV., BUREAU OF COMPETITION, FTC, OVERVIEW OF FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS 56–61 (2013), available at <http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/rxupdate.pdf> (listing FTC investigations of pharmaceutical mergers that involve the potential competition doctrine), archived at <http://perma.cc/HZU2-J2F3>.

196. The maintenance of such high prices indicates that the existence of generic companies in general is not sufficient “potential competition” to constrain brand drug pricing. Instead, it is only after the generic manufacturer files a Paragraph IV Abbreviated New Drug Application that it becomes a sufficient threat to the brand drug that the brand manufacturer will alter its behavior. This altered behavior often takes the form of pursuing a reverse payment settlement, FTC, PAY-FOR-DELAY, *supra* note 25, at 3, or the introduction of an “authorized generic” produced by the brand manufacturer but sold as a generic drug. See generally FTC, AUTHORIZED GENERIC DRUGS, *supra* note 177.

197. Under a normal merger, two independent firms undergo a transformative event at time *t* and become one firm. In assessing the competitive impact of the merger, part of the agencies’ analyses would include comparing the prices available to consumers in the time periods before and after time *t*.

198. These effects are limited to price effects because the brand and generic drugs are bioequivalent and cannot compete on quality. See *supra* note 178 and accompanying text.

199. This is not necessarily a condemnation of all reverse payments settlements. While FTC research shows that the generic price in a mature market is generally 85% lower than the brand price without generic competition, see *supra* note 186 and accompanying text, this simply recognizes the potential for abuse of consumers through settlement. It is these markets and consumers that are most in need of protection. Consider, instead, the market for fibromyalgia treatments in note 170, *supra*. That market already provides consumers with several alternative drugs that theoretically place downward pricing pressure on Lyrica. If Pfizer, Lyrica’s manufacturer, wanted to enter a reverse payment

D. Presumptions and Burdens in Concentrated Pharmaceutical Markets

Once the market participants have been identified and the market has been defined, a court must determine which party bears the burden of proving whether a particular settlement violates antitrust laws. Under the framework promulgated in the Merger Guidelines, most (if not all) markets in the pharmaceutical industry would have HHIs high enough to place them in the “highly concentrated” category.²⁰⁰ As such, except in the broadest of markets, the Merger Guidelines instruct that the settling parties bear the burden of showing industry characteristics such that the reverse payment settlement is not likely to substantially lessen competition.²⁰¹

However, the position of reverse payment settlements at the intersection of antitrust law and patent law justifies a break from the standard burden presumptions that are generally derived from market shares. Though the Supreme Court indicated a preference for antitrust scrutiny over pure patent application in *Actavis*,²⁰² this was not an instruction to abandon intellectual property rights. Indeed, a brand manufacturer’s patent is presumed to be valid until proven otherwise.²⁰³ Further, the decision to bring a patent infringement claim is not entirely the decision of the brand manufacturer, but is instead a consequence of the structure of the Hatch-Waxman Act.²⁰⁴ Placing a burden on a patent holder to prove the validity of its patent due to legislation that gives the patent holder the choice of either forfeiting its patent or engaging in costly litigation seems at odds with the principles of the patent system. Logic and existing patent presumptions dictate that the party seeking to prevent a reverse payment settlement should bear the burden of proving its anticompetitive effects.

settlement with a new generic that is bioequivalent to Lyrica, the potential price effects, and thus coordinated and unilateral concerns, would likely be substantially weaker. In short, the analysis would treat most harshly the settlements with the greatest potential to harm consumers.

200. *See supra* note 137.

201. In highly concentrated industries, even small increases in concentration are presumptively anticompetitive. *See supra* note 138 and accompanying text.

202. *See supra* Part II.

203. United States Patent Act, 35 U.S.C. § 282(a) (2012) (“A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”).

204. Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012) (“An abbreviated application for a new drug shall contain a certification . . . with respect to each patent which claims the listed drug . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug . . .”). To protect the validity of its patent, the brand manufacturer must assert it has a valid patent upon which the new generic drug infringes.

A strict application of the presumptions of the Horizontal Merger Guidelines is overly harsh. If the rules of thumb provided by the Merger Guidelines were stringently applied, all reverse payment settlements would have to be invalidated.²⁰⁵ However, the discussion of *General Dynamics*²⁰⁶ in Part IV.B provides guidance. Under *General Dynamics*, market shares are helpful to the extent that they illustrate firms' future ability to compete.²⁰⁷ Two intervening parties complicate the pharmaceutical market: physicians and insurance companies. A consumer's choice of which product to purchase²⁰⁸ is often dictated by which product the physician recommends²⁰⁹ and which product is covered by an insurance provider.²¹⁰ The future success of a particular drug is likely linked much more closely to persuading doctors and insurance companies to support its product than it is to the product's current market share.²¹¹ The massive budgets pharmaceutical companies allot to their marketing departments²¹² illustrate the continuous need to persuade consumers and physicians, rather than reliance on fleeting market shares, to ensure future competitiveness and success. If current market share

205. For example, even in the "broad" market for Lyrica described *supra* in note 170, the post-merger HHI of 5,853 would indicate that *any* merger in the market would be presumptively illegal. This HHI measurement is slightly different from Professor Operbeck's HHI calculation (5,777), possibly because Professor Operbeck based his calculation on more precise data.

206. *United States v. Gen. Dynamics Corp.*, 415 U.S. 486 (1974).

207. *Id.* at 501.

208. This involves a choice not only between purchasing a brand drug and a generic drug, but also potentially choosing between several available and therapeutically equivalent products. *See supra* Part V.B.

209. In fact, many courts consider physicians to be the relevant "consumer" of prescription drugs. *See Vaishnav, supra* note 162, at 598 ("While at least one court has considered the role of patients as consumers, the more prevalent view seems to be that the patient's preferences for prescription drugs are irrelevant to the demand for such drugs.") (citing *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003) (focusing on options available to the "consumer patient"); *United States v. Ciba Geigy Corp.*, 508 F. Supp. 1118, 1126 (D.N.J. 1976) (noting that the marketing of drugs "is largely directed at the prescribing physician"); *FTC v. Lundbeck, Inc.*, Nos. 08-6379 (JNE/JJG), 08-6381 (JNE/JJG), 2010 WL 3810015, at *15-19, *21 (D. Minn. Aug. 31, 2010) (explaining that price changes may not affect a physician's prescribing practices)). Despite the physician's role in guiding the choice of the ultimate consumer, the antitrust laws protect the ultimate consumer, not the intervening physician, so the potential price effects on the ultimate consumer must be considered.

210. *See, e.g.*, BlueCross BlueShield of Texas, *Standard Preferred Drug List*, BLUECROSS BLUESHIELD (Jan. 2014), http://www.bcbstx.com/pdf/rx_formulary_std_tx_2014.pdf, *archived at* <http://perma.cc/USJ7-UUPJ>. *See also Vaishnav, supra* note 162, at 603-05, 608-10 (2011) (discussing the roles of third-party payers and pharmacy benefit managers).

211. *See supra* note 209.

212. Eric Palmer, *Top 10 Pharma Advertising Budgets—2012*, FIERCEPHARMA (Feb. 26, 2013), <http://www.fiercepharma.com/special-reports/top-10-pharma-advertising-budgets-2012>, *archived at* <http://perma.cc/V9AF-GUQW>.

accurately indicates future success, these budgets would be a highly inefficient use of resources.

Reverse payment settlements must be presumptively valid and the burden should fall on the opponent of the settlement to show the likelihood of potential anticompetitive effects. Consumers would of course reap great benefits from a generic drug entering the market, but the presumed validity of the patent necessitates the presumptive legality of reverse payment settlements.

E. Rebutting Presumptions and the Elimination of Potential Competition

The presumptive legality of reverse payment settlements is, of course, nothing more than a presumption. Though this presumption is in conflict with the standard presumptive illegality of an increase in concentration in an already concentrated market,²¹³ a plaintiff can still prove the anticompetitive effects of a settlement using merger analysis tools.²¹⁴ By offering proof in the way it would in a less concentrated industry (or perhaps in a concentrated industry in which the merger results in a minimal increase in concentration),²¹⁵ a plaintiff can overcome the presumption of a legal settlement.²¹⁶ This is precisely the type of analysis the Supreme Court imposed on lower courts when it chose to “leave to the

213. *See supra* note 137.

214. The recommended presumptions of legality resulting from HHI statistics are simply useful tools that indicate whether a given merger is likely to produce anticompetitive concerns. Despite the fact that changes in the HHI may indicate that a merger is almost certainly anticompetitive, each merger must still be analyzed on its merits to determine the true potential for anticompetitive effects. This is explicitly stated in the Merger Guidelines:

The purpose of these thresholds is not to provide a rigid screen to separate competitively benign mergers from anticompetitive ones, although high levels of concentration do raise concerns. Rather, they provide one way to identify some mergers unlikely to raise competitive concerns and *some others for which it is particularly important to examine whether other competitive factors confirm, reinforce, or counteract the potentially harmful effects of increased concentration.*

HORIZONTAL MERGER GUIDELINES, *supra* note 97, § 5.3, 19 (emphasis added).

215. Such proof could include a showing of unilateral or coordinated effects insulated by high barriers to entry that prevent new firms from entering the market. High barriers to entry are near ubiquitous in pharmaceutical markets, *see supra* note 172, so the burden of rebutting the presumption is slightly reduced.

216. Placing this burden on the opponent of a settlement is entirely consistent with merger case law. The presumed validity of the patent can be considered evidence sufficient to rebut the presumption of illegality recommended by the Merger Guidelines, which shifts the burden of proof back to the plaintiff. *Cf.* *United States v. Baker Hughes Inc.*, 908 F.2d 981, 983 (D.C. Cir. 1990) (“If the defendant successfully rebuts the presumption [of illegality], the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times.”) (citation omitted).

lower courts the structuring of the present rule-of-reason antitrust litigation.”²¹⁷

The settlement opponent’s burden is not so great as to make proving a settlement is anticompetitive impossible. Instead, at least three specific characteristics of each settlement present opportunities to overcome the presumption of a valid settlement. These characteristics all require the type of fact-intensive inquiries that should be necessary for the plaintiff to meet its burden and overcome the presumption of legality.²¹⁸

First, in *Actavis*, the Court explained that the size of the settlement may indicate anticompetitive harm.²¹⁹ The payment itself is a natural starting point. Does it appear to only cover the brand manufacturer’s anticipated litigation costs?²²⁰ Is it so large that it includes the generic challenger’s expected profits from entering the market?²²¹ Is it so large that it substantially exceeds the generic challenger’s expected profits?²²² While the size of the payment may not be dispositive, it may be an indicator of anticompetitive behavior.

Second, the specific therapeutic effect of the drug can inform the analysis. If the brand drug is the only one available that produces a certain effect, the manufacturer may be willing to protect its product at all costs—including by offending the antitrust laws.²²³ If, however, the brand drug is in a market with many therapeutic equivalents,²²⁴ the brand manufacturer may not have as great of an incentive to keep the generic out and is simply trying to avoid litigation. While part of this inquiry is resolved at the market definition stage, a full analysis will usually be required to

217. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2238 (2013).

218. *See supra* note 216.

219. “[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. . . . [T]he size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power.” *Actavis*, 133 S. Ct. at 2236 (citation omitted) (internal quotation marks omitted).

220. *Id.* (“Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”).

221. Brief for 118 Law, Economics, and Business Professors and the American Antitrust Institute as Amici Curiae Supporting Petitioners at 25, *Actavis*, 133 S. Ct. 2223 (No. 12-416) (“Under the settlement, Solvay paid the generics between \$29 million and \$42 million per year to stay off the market, meaning that the payment at least approached the amount the generics would have made even if they were completely sure they could enter the market.”).

222. *Id.* at 24 (noting that even when applying “a very deferential scope-of-the-patent test,” the Second Circuit was concerned by a settlement in which the brand manufacturer paid the generic more than either party expected the generic would make by winning the suit and entering the market).

223. Protection through anticompetitive means assumes that the firm is not engaged in legal conduct pursuant to a valid patent.

224. For example, see *supra* note 170 for the market for Lyrica and its therapeutic equivalents.

accurately predict the brand manufacturer's possible settlement motivations.²²⁵ This analysis will require a fact-intensive inquiry but may help a plaintiff overcome a presumptively legal settlement.

Third, the pricing level of the branded drug relative to the manufacturer's other products may reveal the manufacturer's motivation to settle. This analysis can be performed in a variety of ways²²⁶ which may lead to a variety of conclusions about the anticompetitive effects of the settlement. Again, this requires a fact-intensive inquiry into the particular drug at issue.

F. Systematic Analysis of Reverse Payment Settlements

The procedures necessary for regulatory authorities to perform a systematic and fact-intensive review of reverse payment settlements are already, at least partially, in place. Just as merging parties are required to submit an HSR filing to the FTC and DOJ,²²⁷ parties entering into a reverse payment settlement are required to submit a similar filing to the agencies.²²⁸ Just as with ordinary merger review, this serves an excellent starting point for a fact-intensive investigation of whether the agencies can rebut the presumption of a legal reverse payment settlement. As the regulating agencies are well versed in assessing the competitive effects of

225. Consider again the Lyrica market described in note 170, *supra*. Despite facing competition from thirteen other drugs, Lyrica does not face competition from a bioequivalent generic and has retained a 75% market share. Combined with the trend of brand manufacturers continuing to charge pre-entry rates after generic entry and conceding market share and thus lowering profits, *see supra* note 179, the brand manufacturer may well attempt to block generic entry even in these "broader" markets. In fact, the FDA approved three applications for a generic form of Lyrica in 2012. FDA, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD AND DRUG ADMINISTRATION (July 28, 2014), <http://www.accessdata.fda.gov/scripts/Cder/ob/docs/tempai.cfm>, archived at <http://perma.cc/PV9R-5WWR>; *Generic Lyrica Availability*, DRUGS.COM, <http://www.drugs.com/availability/generic-lyrica.html> (last visited July 28, 2014), archived at <http://perma.cc/BA88-V9CJ>. Pfizer chose to litigate the validity of its patent and the United States District Court for the District of Delaware upheld the validity of Pfizer's Lyrica patent, blocking generic entry into the market. *Pfizer Inc. v. Teva Pharm. U.S.A., Inc.*, 882 F. Supp. 2d 643, 731 (D. Del. 2012).

226. For example, if the manufacturer charges more for the particular drug involved in the settlement than for other drugs that it produces, this may suggest an above-normal profit margin for the drug which would provide an incentive to keep the generic out of the market as illegal maintenance of monopoly power. *Cf.* Sherman Act, 15 U.S.C. § 2 (2012) ("Every person who shall monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony . . ."). Contrarily, if a time sequence analysis shows a declining brand drug price, the brand manufacturer may simply want to avoid the cost of litigation (and potential, however slight, exposure as the holder of weak or invalid patents). This would be an ordinary settlement and would not raise anticompetitive concerns.

227. *See supra* Part III.B.

228. *See supra* note 91 and accompanying text.

mergers,²²⁹ they can efficiently apply merger analyses to the reported reverse payment settlements and filter out those that pose potential anticompetitive threats.

VI. CONCLUSION

The common anticompetitive concerns of reverse payment settlements and mergers allow the imputation of merger analysis to settlement analysis. This is particularly helpful because the Supreme Court's holding in *Actavis* undercut many of the prior reverse payment settlement analyses.²³⁰ By appropriating analytical tools and case law from an analogous area of law, lower courts can immediately begin evaluating cases with a method that is consistent across jurisdictions. This immediate consistency is necessary to avoid relapsing into the circuit split that has plagued the history of reverse payment settlement cases.

Though reverse payment settlements exhibit the natural tension between antitrust law and patent law, the presumptive validity of a patent requires that a given settlement be presumed valid. The Supreme Court recognized as much by rejecting the FTC's request to apply a "quick look" analysis in *Actavis* and instead requiring a full rule of reason analysis.²³¹ Applying merger analysis techniques allows for the assumption of validity as a starting point, and then applies a consistent and fact-intensive inquiry to the settlements. Such a structure ensures that the presumption of legality is rebutted only when the settlement is truly anticompetitive. This framework balances the ultimate needs of consumers: it allows for the lawful maintenance of a patent that is necessary for pharmaceutical manufacturers to invest in and develop new drugs, but prevents customers from being hurt by the prevention of lawful generic competition.

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229. FTC, *Mergers*, FTC, <http://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers> (last visited Feb. 8, 2013) ("Each year, the FTC and Department of Justice review over a thousand merger filings."), *archived at* <http://perma.cc/584X-4TL4>.

230. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2238 (2013).

231. *Id.* at 2237.

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