

NOTES

In re K-Dur Antitrust Litigation—Reverse Payments: Against Prices, Purchasers, and Policy

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I. OVERVIEW OF THE CASE

When manufacturers began producing generic drugs in the 1980s to compete with name-brand medications, patent laws quickly stifled this competition.¹ In response, Congress enacted the Hatch-Waxman Act to increase competition and make it easier for manufacturers to produce generic versions of medication for the benefit of the public.² Companies such as the Schering-Plough Corporation (Schering) found other means to prevent competition from entering the market through settlement agreements, known as “reverse payment agreements,”³ under which the patent holder pays the generic manufacturer to not challenge the patent and abstain from entering the market for a certain time period, typically until the patent expires.⁴ These agreements resulted in monopolies and are now subject to antitrust review by the Federal Trade Commission (FTC).⁵

Schering held a patent on a controlled-release coating, K-Dur 20 (K-Dur), that dissolved slowly on a drug that is used to treat potassium deficiencies.⁶ When two companies, Upsher-Smith Laboratories (Upsher) and ESI Lederle (ESI), both sought approval of generic versions of the drug, Schering began litigation proceedings against both Upsher and ESI.⁷ Eventually, however, Schering entered settlement

1. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 203 (3d Cir. 2012).

2. *See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585-1601 (codified in pertinent part at 21 U.S.C. § 355 (2006)) (allowing a manufacturer of generic medications to file an abbreviated application, known as an ANDA, to get approval from the FDA without long delays or expenses). This procedure is discussed further *infra* Part II.

3. *See In re K-Dur*, 686 F.3d at 204-05.

4. *Id.* at 204.

5. *Id.*

6. *Id.* at 204-05.

7. *Id.* at 205-06.

agreements with both companies.⁸ The agreement provided that Upsher would not market its generic version until September 1, 2001, when Upsher would receive a license under the patent to produce a generic version of the drug.⁹ Furthermore, Upsher gave Schering licenses to produce other drugs that Upsher had created in return for \$60 million, payable over three years.¹⁰ Similarly, Schering granted ESI a license starting January 1, 2004, to refrain from entering the market in exchange for up to \$10 million.¹¹

Private parties then filed antitrust suits that were consolidated, and a Special Master was appointed who certified a class of plaintiffs that bought K-Dur from Schering.¹² In February 2009, the Special Master granted the defendant's motion for summary judgment using the "scope of patent" test and found the patent provided Schering with the right to exclude competing products, including through reverse payments.¹³ The district court adopted the Special Master's report in its entirety.¹⁴ The United States Court of Appeals for the Third Circuit *held* that reverse payments are prima facie evidence of unreasonable restraint of trade and the "scope of patent" test is improper because it allows monopolies to maintain weak patents on the market with no competition. *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir. 2012).

II. BACKGROUND OF THE CASE

The United States Supreme Court has interpreted the Sherman Act,¹⁵ the basis for most antitrust litigation, to prohibit all contracts that unreasonably restrain trade or commerce.¹⁶ As the Supreme Court did not promulgate an exact standard, courts have subsequently developed three rules to determine if the restraint is unreasonable.¹⁷ First, under the most commonly used test, the "rule of reason," the plaintiff must demonstrate that the challenged conduct has created anticompetitive market effects.¹⁸ The defendant must respond by proving that the conduct

8. *Id.* at 205.

9. *Id.*

10. *Id.*

11. *See id.*

12. *See id.* at 218-24. Although the certification of the antitrust plaintiff is a separate issue within the court's opinion, it will not be addressed in this Note.

13. *Id.* at 208.

14. *Id.*

15. Sherman Antitrust Act, 15 U.S.C. §§ 1-7 (2006).

16. *In re K-Dur*, 686 F.3d at 209 (citing *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997)).

17. *See id.*

18. *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993) (citing *Cont'l T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977)).

promotes a “sufficiently pro-competitive objective,” which the plaintiff can rebut by demonstrating that the restraint is not reasonably necessary to reach that objective.¹⁹ Second, courts recognize that some agreements, such as horizontal price-fixing agreements, are always illegal and thus courts apply the “per se rule,” when the agreement “facially appears to be one that would always or almost always tend to restrict competition.”²⁰ Third, courts have adopted a middle ground between the “rule of reason” and “per se rule.”²¹ Under this “quick look” rule, the plaintiff does not need to demonstrate anti-competitive effects if the plaintiff proves that the nature of the defendant’s conduct is typically per se invalid.²² Within the framework of these antitrust standards, Congress further sought to increase competition in the pharmaceutical market.²³

In 1984, Congress wanted to encourage market competition in order to increase the availability of low-priced medication²⁴ and thus enacted the Drug Price Competition and Patent Term Restoration Act, commonly called the Hatch-Waxman Act.²⁵ Before a new prescription drug is marketed, the Food and Drug Administration (FDA) must undergo a lengthy process to evaluate the safety and efficacy of the drug to gain FDA approval.²⁶ The Hatch-Waxman Act allows manufacturers of generic drugs to file an Abbreviated New Drug Application (ANDA) and utilize the FDA’s original findings on safety and efficacy, thereby reducing the lengthy process so consumers can access less expensive drugs more quickly.²⁷ After filing the ANDA, a pharmaceuticals manufacturer has four options to certify that its “proposed generic drug does not infringe any patent.”²⁸ The relevant certification for most patent challenges is a paragraph IV certification, which asserts “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug.”²⁹

For patent challenges, the effects of filing a paragraph IV certification are far-reaching. First, the proposed generic manufacturer

19. *See id.* at 669.

20. *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19-20 (1979).

21. *See, e.g., Brown Univ.*, 5 F.3d at 669.

22. *Id.*

23. H.R. REP. NO. 98-857, pt. 2, at 14-15 (1984).

24. *Id.*

25. Hatch-Waxman Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585-1605 (codified in pertinent part at 21 U.S.C. § 355 (2006)).

26. 21 U.S.C. § 355(a).

27. *Id.* § 355(j)(2)(A).

28. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 203 (3d Cir. 2012).

29. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

must give notice to the patent holder of the challenge.³⁰ The patent holder has forty-five days to file a patent infringement suit, which automatically prevents the FDA from giving final approval to the generic drug until a court declares the patent invalid or not infringed, or until thirty months have passed.³¹ Furthermore, the first to file an ANDA is rewarded with a 180-day exclusivity period in which the FDA cannot approve any subsequent ANDA applications.³² This period begins the day the first ANDA filer with a paragraph IV certification starts to market its generic drug.³³ This benefit is only available to the first ANDA filer and does not pass to future filers.³⁴

As these effects began dramatically altering the pharmaceutical market for brand-name producers, patent holders entered settlement agreements with generic drug manufacturers rather than continuing with litigation against them.³⁵ The patent holders began paying ANDA filers to halt their patent challenges and refrain from producing the generic version often for the life of patent.³⁶ Congress became increasingly concerned that these reverse payments were causing monopolies³⁷ and thus amended the Hatch-Waxman Act so that every settlement agreement resulting from these kinds of pharmaceutical patent challenges is subject to Federal Trade Commission (FTC) antitrust review.³⁸ Reverse payments have been thriving in recent years, costing consumers \$3.5 billion annually through expensive patentable drugs.³⁹ Thus, the FTC has focused heavily on halting the practice, causing courts to split on the standards with which to evaluate reverse payments.⁴⁰

In 2001, the United States Court of Appeals for the District of Columbia became the first circuit court to address the issue of reverse payments.⁴¹ In *Andrx Pharmaceuticals v. Biovail Corp. International*, a would-be generic drug manufacturer filed an ANDA with a paragraph IV

30. *Id.* § 355(j)(5)(B)(iii).

31. *Id.*

32. *Id.* § 355(j)(5)(B)(iv).

33. *Id.*

34. *Id.*

35. FED. TRADE COMM'N (FTC), PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010), available at <http://www.ftc.gov/os/2010/01/10012payfordelayrpt.pdf>.

36. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012).

37. See S. REP. NO. 107-167, at 4 (2002).

38. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in pertinent part as amended at 21 U.S.C. § 355(j)).

39. FTC, *supra* note 35.

40. *Id.*

41. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 803 (D.C. Cir. 2001).

certification, inciting the patent holder to file suit.⁴² The initiation of the suit triggered the thirty-month period in which the FDA could not give final approval to the generic drug or any other ANDAs filed.⁴³ Three months later, the FDA granted a tentative approval of the original ANDA; but nine days after this approval, the patent holder and original ANDA filer entered into a settlement agreement.⁴⁴ The agreement provided that the patent-holder would pay the original ANDA filer \$40 million, beginning the day the generic version received final FDA approval and ending the day the generic drug was marketed.⁴⁵ When the FDA granted final approval, the original filer did not market the drug in order to receive payment.⁴⁶ By not marketing, the original ANDA filer did not trigger its 180-day exclusivity period, thereby preventing the FDA from giving final approval to any other ANDAs and completely eliminating competition.⁴⁷ The court reasoned that because the agreement likely sought to “preserve monopolistic conditions,” the court applied the per se rule of facially illegal conduct to the reverse payment.⁴⁸

Two years later, in *In re Cardizem CD Antitrust Litigation*, the United States Court of Appeals for the Sixth Circuit addressed the same settlement agreement that the D.C. Circuit analyzed in *Andrx*.⁴⁹ However, the plaintiffs were purchasers of the drug, claiming they had suffered antitrust harm due to the delayed-entry agreement.⁵⁰ By differentiating between a typical patent-driven monopoly and a monopoly that arises by “paying the only potential competitor \$40 million per year to stay out of the market,” the Sixth Circuit reached the same conclusion as the D.C. Circuit: that the reverse payment was per se illegal.⁵¹ Only months later did the circuits split on the standard for reverse payments.

The United States Court of Appeals for the Eleventh Circuit first addressed reverse payments in *Valley Drug Co. v. Geneva Pharmaceuticals*, which involved two agreements where the generic manufacturers argued that the name-brand drug patent was invalid.⁵² The name-brand manufacturers then agreed to pay each patent challenger millions of dollars to refrain from entering the market, thereby preventing

42. *Id.* at 803-04.

43. *Id.*; see 21 U.S.C. § 355 (j)(5)(B)(iii).

44. *Andrx Pharms.*, 256 F.3d at 803.

45. *Id.*

46. *Id.* at 804.

47. *Id.*

48. See *id.* at 811-13.

49. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 901-03 (6th Cir. 2003).

50. *Id.*

51. *Id.* at 908-09.

52. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003).

any competition and maintaining their monopoly.⁵³ Although the district court held these agreements were per se invalid, the Eleventh Circuit reversed this decision.⁵⁴ Instead, the court used the “quick look,” middle-ground test to hold that the patent gave the name-brand manufacturers the right to exclude competitors.⁵⁵ The court focused on the policies favoring settlements because “[p]atent litigation is too complex and the results too uncertain,” so that many parties prefer settlement to litigation.⁵⁶ The court held that monetary payments made within a patent litigation settlement did not constitute a per se violation.⁵⁷

Relying on this policy, the Eleventh Circuit addressed reverse payments again in *Schering-Plough Corp. v. Federal Trade Commission*, which arose from the same settlement agreement as the noted case.⁵⁸ Years after the relevant settlements, the FTC filed a complaint alleging that the settlements between Schering, Upsher, and ESI were illegal restraints on trade.⁵⁹ Using the “quick look” analysis applied in *Valley Drug*, the court found that the payments were not per se invalid;⁶⁰ rather, three factors must be considered under a new test: “(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.”⁶¹ Through witness testimony, the court found the payments were made solely to obtain the licenses, rather than delay entry into the market.⁶² Furthermore, the court asserted that even if the reverse payments existed, the policy of favoring settlements was controlling.⁶³ This three-part test was duplicated by the United States Court of Appeals for the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*.⁶⁴

After a competitor filed an ANDA for a generic version of Tamoxifen, the most widely prescribed drug for breast cancer treatment, the brand-name manufacturer filed a patent infringement suit.⁶⁵ While the appeal of the district court’s holding that the patent was invalid was

53. *Id.* at 1301.

54. *Id.* at 1304.

55. *Id.* at 1304-05.

56. *Id.* at 1308.

57. *Id.* at 1309.

58. *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1059-60 (11th Cir. 2005).

59. *Id.* at 1061.

60. *Id.* at 1066.

61. *Id.*

62. *Id.* at 1071.

63. *Id.*

64. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 200 (2d. Cir. 2005) (as amended).

65. *Id.* at 193.

still pending, the parties reached a settlement agreement.⁶⁶ The agreement granted the challenger \$21 million and a license to sell the generic version under the name-brand label in exchange for changing the ANDA paragraph IV certification to a paragraph III certification, thus agreeing to not market the generic version until the patent expired.⁶⁷ The Second Circuit utilized a presumption of patent validity standard and held, “[T]here is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.”⁶⁸ Although the circuit court in *In re Tamoxifen* did not explicitly list the three factors that the Eleventh Circuit used, the underlying premise is identical: the restraint on competition cannot exceed the scope of the patent.⁶⁹ The court provided that the only exceptions to the “scope of patent,” or *Tamoxifen* test, were fraud and if the underlying suit was “objectively baseless.”⁷⁰

This “scope of patent” test was also employed by the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, in which buyers of a drug alleged settlement agreements between the brand-name manufacturer and the generic drug challenger constituted reverse payments and violated antitrust laws.⁷¹ The Federal Circuit refused to find the reverse payments per se invalid.⁷² Rather, the court held the agreements were valid because they did not restrain competition outside of the boundaries of the patent.⁷³

As demonstrated above, circuit courts differ on whether to apply a per se invalid standard to reverse payments or the “scope of patent” test. At the time of the noted case, two circuits relied on the per se invalid standard (D.C. and Sixth Circuits), whereas three circuits relied on the “scope of patent” test (Second, Eleventh, and Federal Circuits). The Supreme Court has yet to rule on the matter or provide a standard.

66. *Id.*

67. *Id.* at 193-94.

68. *Id.* at 213 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Ciprofloxacin I)*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008), and *aff'd in part sub nom. Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010)).

69. *See id.* at 212-13.

70. *Id.* at 213.

71. *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Ciprofloxacin II)*, 544 F.3d 1323, 1327 (Fed. Cir. 2008).

72. *Id.* at 1332.

73. *See id.* at 1339-40.

III. COURT'S DECISION

In the noted case, the Third Circuit applied the per se reasoning of the District of Columbia and Sixth Circuits to analyze whether reverse payments violate antitrust law by illegally restraining the market. The court first questioned the scope of the patent's automatic presumption of patent validity.⁷⁴ Next, the court disagreed with the assertion that subsequent patent challengers will reduce the weak patents held by monopolies that do not wish to lose their patents through litigation.⁷⁵ Third, the court analyzed the underlying goals of the Hatch-Waxman Act to understand how the goals intertwine with reverse payments and patent policy.⁷⁶ Through this analysis, the court asserted that the proper standard should be the "quick look" rule of reason, an "analysis based on the economic realities of the reverse-payment settlement rather than the labels applied by the settling parties," instead of the "scope of patent" test.⁷⁷

Starting with the seemingly un rebuttable presumption of patent validity of the "scope of patent" test, the Third Circuit opposed this requirement, arguing that this standard essentially eliminates the question present in the patent suit.⁷⁸ The court in the noted case disagreed with the Eleventh Circuit on how to interpret 35 U.S.C. § 282, which requires "[a] patent shall be presumed valid."⁷⁹ The court focused on the notion that because many patents are later found to be invalid, a patent "simply represents a legal conclusion reached by the Patent Office."⁸⁰ Thus, the court found that the presumption of validity is a procedural device, rather than substantive law, and as such is easily overturned.⁸¹

Next, the court determined that subsequent patent challengers do not eliminate weak patents through reverse payments to the first challenger.⁸² Typically, the first patent challenger has the greatest motivation to challenge the patent because of the benefits granted under

74. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d Cir. 2012).

75. *Id.* at 215.

76. *Id.* at 217.

77. *Id.* at 218.

78. *Id.* at 214.

79. 35 U.S.C. § 282 (2006 & Supp. V 2011); see *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1066 (11th Cir. 2005); *In re K-Dur*, 686 F.3d at 214.

80. *In re K-Dur*, 686 F.3d at 214-15 (citing *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)); see also FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 16* (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (showing that in 2006, 75% of patent challengers succeeded).

81. See *In re K-Dur*, 686 F.3d at 214-15.

82. *Id.* at 215.

21 U.S.C. § 355, specifically the 180-day exclusivity period.⁸³ Furthermore, the court relied on the assumption that monopolies have extensive sums of money to continue to provide reverse payments to subsequent challengers, causing weak patents to remain in the system.⁸⁴ Thus, reverse payments actually provide strength to monopolies.⁸⁵

Third, the court examined the underlying policies of the Hatch-Waxman Act to analyze reverse payments.⁸⁶ Noting that the purpose of the Act was “to make available more low cost generic drugs,”⁸⁷ the Third Circuit argued that because the “scope of patent” test permits manufacturers to pay competitors not to enter the market, it is in direct conflict with and implicitly undermines this goal.⁸⁸ The court found that this test merely allows name-brand monopolies with weak patents to avoid litigation and the chance of losing their patent.⁸⁹

Relying on the fact that many patents are found to be invalid, the notion that weak patents survive through settlements, and the conflicting policies between reverse payments and the Hatch-Waxman Act, the Third Circuit asserted that the standard should be the “quick look” rule of reason.⁹⁰ The court agreed with the District of Columbia and Sixth Circuits and held that reverse payments are “prima facie evidence of an unreasonable restraint of trade.”⁹¹ The court further held that this can only be rebutted by demonstrating that the payment was for something other than a delayed entry into the market or that the payments provide a competitive benefit.⁹²

IV. ANALYSIS

Currently, three circuits have found reverse payments to be per se invalid (Third, Sixth, and D.C. Circuits)⁹³ and three circuits have found reverse payments valid under the “scope of patent” test (Second,

83. *Id.*; 21 U.S.C. § 355 (2006).

84. *In re K-Dur*, 686 F.3d at 215.

85. *Id.* at 214-15.

86. *Id.* at 217.

87. H.R. REP. NO. 98-857, pt. 1, at 14-15 (1984).

88. *In re K-Dur*, 686 F.3d at 217.

89. *Id.*

90. *Id.* at 218.

91. *Id.*

92. *Id.* (providing as an example a situation where the patent holder provided the challenger a modest sum to prevent bankruptcy).

93. *In re K-Dur*, 686 F.3d 197; *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001).

Eleventh, and Federal Circuits).⁹⁴ The noted court's decision thus deepened the split and furthered the confusion on reverse payments. On August 24, 2012, and August 29, 2012, two petitions for writ of certiorari by defendants Merck & Co. and Upsher-Smith Laboratories, Inc., respectively, were filed appealing the Third Circuit's decision in *K-Dur*.⁹⁵ With the obvious divide between the circuits, the ruling in the noted case makes the topic ripe for Supreme Court review.

Critics of the Third Circuit's recent decision will likely assert that the holding is contrary to policy considerations favoring settlement over litigation.⁹⁶ The court seemingly anticipated such potential criticism and attempted to balance the policy of settlement with the policy of encouraging competition.⁹⁷ Indeed, the *In re K-Dur* opinion is very limited and only applies to "reverse payments between patent holders and would be generic competitors in the pharmaceutical industry."⁹⁸ Although the court only provided a brief defense of this point, the analysis is convincing. The court relied on FTC statistics demonstrating that almost seventy-five percent of Hatch-Waxman Act suits that settled in 2010 did not involve reverse payments.⁹⁹ This statistic is startling and rebuts the notion that competition is stimulated through reverse payments.¹⁰⁰ Obviously, reverse payments are not necessary to stimulate competition or enter encouraged settlement agreements.

If the Supreme Court grants review of the noted case, the Court should address the underlying purpose of the Hatch-Waxman Act and the actual impact reverse payments have on consumers. As a basic economic principle, as prices increase, fewer consumers can afford to purchase the good. Thus, as manufactured drugs became more expensive, fewer

94. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2005); *Schering-Plough Corp. v. Fed. Trade Comm'n.*, 402 F.3d 1056 (11th Cir. 2005); *Ciprofloxacin II*, 544 F.3d 1323 (Fed. Cir. 2008).

95. Petition for Writ of Certiorari, *Merck & Co. v. La. Wholesale Drug Co.*, No. 12-245 (filed Aug. 24, 2012), available at <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-245.htm>; Petition for Writ of Certiorari, *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, No. 12-265 (filed Aug. 29, 2012), available at <http://www.supremecourt.gov/search.aspx?FileName=/docketfiles/12-265.htm>.

96. See, e.g., *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003); *Erheart v. Verizon Wireless*, 609 F.3d 590, 595 (3d Cir. 2010) ("Settlement agreements are to be encouraged because they promote the amicable resolution of disputes . . .").

97. *In re K-Dur*, 686 F.3d at 217-18.

98. *Id.* at 216.

99. *Id.* at 218 (citing BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FTC COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2010, at 2 (2011), available at http://www.ftc.gov/os/2011/05/1105mm_agreements.pdf).

100. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 214 (2d Cir. 2005).

people could afford treatment. The purpose of the Hatch-Waxman Act was to encourage competition to counteract this phenomenon and provide more access to less expensive generic drugs.¹⁰¹ The outcome of reverse payments, preventing generic drugs from entering the market, contradicts the express purpose of the Hatch-Waxman Act. By eliminating competition and preventing consumers from gaining access to less expensive drugs, reverse payments cause harm to both the economy and individual purchasers. The Supreme Court should uphold the Third Circuit holding in the noted case and apply the per se invalid standard.

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101. H.R. REP. NO. 98-857, pt. I, at 14-15 (1984).

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