



1-1-2013

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Recommended Citation

Carl W. Hittinger & Lesli C. Esposito, *In Re K-DUR Antitrust Litigation: The Third Circuit's Controversial Pay-For-Delay Antitrust Decision Splits With Other Circuit Courts*, 58 Vill. L. Rev. 103 (2013).

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IN RE K-DUR ANTITRUST LITIGATION: THE THIRD CIRCUIT'S
CONTROVERSIAL PAY-FOR-DELAY ANTITRUST DECISION
SPLITS WITH OTHER CIRCUIT COURTS

CARL W. HITTINGER & LESLI C. ESPOSITO*

ON July 16, 2012, in a controversial departure from the prevailing standard for analyzing the anticompetitive effects of so-called “pay-for-delay” settlement agreements in prescription drug cases, the Court of Appeals for the Third Circuit, in *In re K-Dur Antitrust Litigation*,¹ rejected the “scope of the patent” test utilized by many of its sister circuits.² Adopting a “quick look” rule of reason analysis, a three-judge panel of the Third Circuit, consisting of Circuit Judges Dolores Sloviter and Thomas Vanaskie, and District Judge Lawrence Stengel (sitting by designation) directed the District of New Jersey on remand to treat any payment from the patent-holder, Schering-Plough Corporation (“Schering”), to the generic drug manufacturers, Upsher-Smith Laboratories (“Upsher”) and ESI Lederle, Inc. (“ESI”), as prima facie evidence of an unreasonable restraint of trade.³ The Third Circuit ruled, in an opinion authored by Circuit Judge Sloviter for the unanimous panel, that Schering, Upsher, and ESI could then try to rebut that evidence by showing that the payments were made for a purpose other than delayed entry into the market, or by offering a pro-competitive benefit.⁴ This precedential decision imposes a formidable hurdle for pharmaceutical companies to clear before their pay-for-delay settlement agreements are found lawful and not in violation of federal antitrust laws.

I. STATUTORY AND REGULATORY BACKGROUND

Any pharmaceutical company wishing to market a new prescription drug to the consuming public must first obtain approval from the Food and Drug Administration (“FDA”) by submitting a New Drug Application,

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1. 686 F.3d 197 (3d Cir. 2012).

2. *See id.*

3. *Id.* at 218.

4. *Id.*

otherwise known as an NDA.⁵ This is an exhaustive, time-consuming, and expensive process that requires the drug manufacturer to produce information and data regarding the method of producing the drug, results of studies and tests, as well as any patents issued for the drug.⁶ Prior to 1984, this was the only method of obtaining FDA approval, regardless of whether the pharmaceutical company was the first to market.⁷ Indeed, every applicant had to submit an NDA, complete with results on the safety and effectiveness of the drug, even if those same studies had already been performed and submitted for drugs with the same or similar active ingredients.⁸ What made this process even more cumbersome was that the very act of performing these studies, if there existed a patent on the drug that was the subject of these studies, would constitute an act of patent infringement on the part of the subsequent filer.⁹

Attempting to ease the headaches caused by this arduous and costly process, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, in 1984.¹⁰ This piece of legislation allowed generic drug manufacturers to file a shortened version of the NDA, known as an Abbreviated New Drug Application, or an ANDA, which relies on the information included in an NDA previously filed for a patented drug, as well as the FDA's determination of that drug's safety and effectiveness.¹¹ When filing an ANDA, a generic drug manufacturer must certify that the proposed generic drug does not infringe the patent on file with the FDA.¹² It can do this in four different ways, one of which is known as a "paragraph IV certification."¹³ Under a paragraph IV certification, a generic drug manufacturer declares that the patent either is invalid or will not be infringed by the generic drug manufacturer's production, use, or sale of the new drug.¹⁴ When a generic manufacturer certifies that its proposed generic drug will not infringe a patent by means of a paragraph IV certification, it must also notify each patent owner that will be affected by the ANDA.¹⁵ Upon receipt of this notice from the generic drug manufacturer, the patent holder has forty-

5. See 21 U.S.C. § 355(a) (2006).

6. See *id.* § 355(b)(1).

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

8. See *id.*

9. See *id.* (citing 35 U.S.C. § 271(a)) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.").

10. See Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of 21, 35, and 42 U.S.C.).

11. See 21 U.S.C. § 355(j); see also *Valley Drug*, 344 F.3d at 1296 (explaining ANDA filing process).

12. See *id.* § 355(j)(2)(A)(vii).

13. See *id.*

14. *Id.* § 355(j)(2)(A)(vii)(IV).

15. *Id.* § 355(j)(2)(B).

five days within which to file an infringement action in federal court.¹⁶ Once an infringement action is filed, the FDA is then barred from approving the generic manufacturer's ANDA for thirty months or until the resolution of the infringement action, whichever occurs first.¹⁷

The primary goal of the Hatch-Waxman Act was to increase the availability of low-cost drugs to the consuming public.¹⁸ This goal was intended to be achieved by increasing competition in the pharmaceutical drug market through incentives provided to generic drug manufacturers.¹⁹ One such incentive is a 180-day exclusivity period provided to the first generic manufacturer to file an ANDA containing a paragraph IV certification.²⁰ During this period, the FDA cannot approve any subsequent ANDAs.²¹

II. PAY-FOR-DELAY

When generic drug manufacturers attempt to enter the market early, lengthy and expensive patent litigation often results. Add to that the risk of losing profits afforded by a patent, and most patent-holders prefer to settle these lawsuits to protect their market share. One such settlement is known as the "reverse payment" agreement, or the "pay-for-delay" agreement. In these types of agreements, a patent holder pays one or more generic drug manufacturers to stay out of the market until an agreed-upon date. Oftentimes, that date may be years prior to the expiration of the patent at issue, but still years after the infringement action is settled.

The Federal Trade Commission ("FTC"), along with direct and indirect purchasers of prescription drugs, advocacy groups, and competitors, has taken issue with pay-for-delay agreements for years, alleging violations of state and federal antitrust laws, including the Sherman Antitrust Act ("Sherman Act"). Section 1 of the Sherman Act generally prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or

16. *Id.* § 355(j)(5)(B)(iii).

17. *Id.* If the court decides that the patent is invalid or not infringed prior to the expiration of the thirty months, approval of the ANDA will be made effective on the date on which the court enters judgment on the decision. *Id.* If, on the other hand, the court finds that the patent is valid and infringed, approval of the ANDA will be made effective on or after the date the patent will expire. *Id.* See also 35 U.S.C. § 271(e)(4)(A).

18. See H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

19. See 21 U.S.C. § 355(j)(5)(B)(iv).

20. *Id.* This 180-day exclusivity period begins to run on the day the first generic drug manufacturer to file an ANDA begins to market its drug, or the day on which a court hearing the underlying infringement action determines that the patent is invalid or was not infringed. *Id.*

21. What this necessarily also means is that, during the thirty-month stay triggered at the filing of an infringement action by a patent holder, the FDA can also not approve any subsequent ANDAs filed by additional generic drug manufacturers.

with foreign nations”²² It is understood that the ban on “contract[s] . . . in restraint of trade” means only those contracts that are unreasonable or impair competition.²³

In determining the unreasonableness of contracts, including pay-for-delay agreements, many courts have applied the “rule of reason” analysis.²⁴ Under this framework, “the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.”²⁵ Courts have simplified this analysis into three steps. First, the challenger must show that the conduct at issue has generated anticompetitive effects.²⁶ The burden then shifts to the defendant to show that the conduct at issue has a pro-competitive effect.²⁷ If the defendant successfully advances a sufficient pro-competitive objective, the plaintiff can then rebut that by showing that the conduct is not necessary to achieve that objective.²⁸

There are some types of agreements that are so obviously anticompetitive, however, that they can be deemed to violate antitrust laws by virtue of the nature of the restraint.²⁹ This occurs when a “practice facially appears to be one that would always or almost always tend to restrict competition or decrease output.”³⁰ These types of agreements have become known as “per se” violations of antitrust laws.³¹

More recently, some courts have taken a different approach when analyzing the lawfulness of pay-for-delay agreements, explaining that patents are, by their very nature, anticompetitive, and, as such, would not survive under the rule of reason analysis. These courts have begun to follow what is called the “scope of the patent” test.³² Taking into account the monopolistic effects of patents, these courts follow a test that requires examina-

22. 15 U.S.C. § 1.

23. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 209 (3d Cir. 2012) (citing *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997)) (interpreting Sherman Act provision).

24. See *id.* (citing *State Oil*, 522 U.S. at 10) (discussing rule of reason analysis).

25. *Id.* (quoting *State Oil*, 522 U.S. at 10).

26. *Id.* (citing *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993)).

27. *Id.* (citing *Brown Univ.*, 5 F.3d at 669).

28. *Id.* (citing *Brown Univ.*, 5 F.3d at 669).

29. *Id.* (citing *State Oil*, 522 U.S. at 10).

30. *Id.* (quoting *Broad Music, Inc. v. CBS, Inc.*, 441 U.S. 1, 19–20 (1979)).

31. See *id.* Still other courts apply a framework that falls between the rule of reason analysis and the “per se” analysis. *Id.* Under this “quick look” analysis, the plaintiff is merely required to show that the defendant’s behavior is similar to that which has been deemed to be “per se” anticompetitive in the past. *Id.* Proof of anticompetitive effects is not required, but the defendant then must present pro-competitive objectives. *Id.*

32. See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

tion 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.”³³ Essentially, these courts determine whether any provisions of the pay-for-delay agreement are more exclusive than the patent at issue, and, if so, subject those provisions to further antitrust scrutiny.

III. NOTEWORTHY PAY-FOR-DELAY CASES

Prior to the Third Circuit’s decision in *In re K-Dur*, the trend among the circuits was to uphold pay-for-delay settlement agreements unless the agreement’s anticompetitive effects extended beyond the scope of the underlying patent. The three circuits to have most recently decided pay-for-delay cases upheld the pay-for-delay settlement agreements at issue in those cases under the scope of the patent test.³⁴ The Third Circuit’s decision in *In re K-Dur* has now created a notable split among the circuits, three of which have adopted the scope of the patent test and three of which seemingly adhere to different variations of the rule of reason analysis.

A. *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International* and *In re Cardizem CD Antitrust Litigation*

In 2001, in an action brought by a competing pharmaceutical company, the D.C. Circuit was one of the first courts to consider a pay-for-delay agreement in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*.³⁵ Unlike *In re K-Dur*, the agreement at issue in *Andrx* was not a litigation-ending patent settlement.³⁶ Instead, the agreement was made between a patent-holder and a generic manufacturer while litigation continued, and simply provided for delayed entry into the market, which manipulated the 180-day exclusivity period, and prevented subsequent generic drug manufacturers from entering the market.³⁷

By way of background, *Andrx Pharmaceuticals* (“*Andrx*”) filed an ANDA and a paragraph IV certification for a generic formulation of the prescription drug *Cardizem CD*, which was manufactured and marketed by the patent holder, *Hoechst Marion Roussel, Inc.* (“*HMRI*”).³⁸ *HMRI* then timely filed an infringement action against *Andrx*.³⁹ Subsequent to the filing of the infringement action, several other generic drug manufac-

33. *Schering-Plough*, 402 F.3d at 1066 (citing *Valley Drug*, 344 F.3d at 1312).

34. See *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

35. 256 F.3d 799 (D.C. Cir. 2001).

36. See generally *id.* at 803–05.

37. See *id.*

38. *Id.* at 803.

39. *Id.*

turers filed ANDAs, including Biovail.⁴⁰ After Biovail filed its ANDA, however, Andrx and HMRI entered into an agreement under which Andrx agreed to keep its generic form of Cardizem CD off the market until a date agreed upon by both parties, and HMRI agreed to compensate Andrx in the amount of \$40 million per year.⁴¹ In July 1998, Andrx's ANDA was approved by the FDA, and, by that time, the thirty month waiting period had expired during which Andrx was prohibited from marketing its generic drug.⁴² Despite the fact that Andrx was now permitted to market its generic drug, it chose not to do so because of the agreement, and HMRI began making payments to Andrx for its compliance with the agreement.⁴³ By choosing to not market its generic form of Cardizem CD, Andrx did not trigger the 180-day exclusivity period, which effectively prevented any subsequent ANDAs from being approved by the FDA.⁴⁴

Biovail filed suit, alleging antitrust violations, and the district court dismissed the claims with prejudice, concluding that Biovail did not and could not plead an antitrust injury that was caused by the agreement between HMRI and Andrx.⁴⁵ The D.C. Circuit, however, reversed the district court's decision, and found that, not only was the payment from HMRI to Andrx prima facie evidence of an illegal agreement in restraint of trade, the agreement could "reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions."⁴⁶ While the court did acknowledge that Biovail failed to allege an injury-in-fact in its complaint, it did not agree that the injury was a result of "the existence of a troublesome statutory scheme."⁴⁷ Indeed, the court stated that but for the pay-for-delay agreement, Andrx would have entered the market upon approval of its ANDA, triggering the 180-day exclusivity period, the end of which would have permitted Biovail's entry into the market.⁴⁸

40. *Id.*

41. *Id.* HMRI's payments to Andrx were to begin on the date Andrx's ANDA was approved by the FDA and end on the date that Andrx began to market the drug or HMRI was successful in its infringement suit. *Id.*

42. *Id.* at 804.

43. *Id.* Prior to its ANDA approval, Andrx filed suit against the FDA seeking clarification concerning its rights as a first filer. *Id.* at 803–04. Specifically, Andrx sought a declaration that stated that the FDA was prohibited from approving any ANDA filed subsequent to Andrx's ANDA until at least 180 days after Andrx began marketing its generic form of Cardizem CD or HMRI was successful in its patent litigation. *Id.* at 804. The FDA provided Andrx the relief it sought in the form of a notice published in July of 1998. *Id.* at 804 n.6.

44. *Id.* at 804.

45. *Id.* Biovail failed to inform the district court that, on December 23, 1999, the FDA gave final approval to its ANDA. *Id.* The district court held that Biovail's alleged injury was caused by its lack of FDA approval, and not the agreement between HMRI and Andrx. *Id.* at 808.

46. *Id.* at 811.

47. *Id.* at 808–09 (quoting *Andrx Pharm., Inc. v. Friedman*, 83 F. Supp. 2d 179, 185 (D.D.C. 2000)).

48. *Id.* at 809.

Similarly, *In re: Cardizem CD Antitrust Litigation*⁴⁹ arose out of the same pay-for-delay agreement that was considered by the D.C. Circuit in *Andrx*.⁵⁰ This action, however, was brought by direct and indirect purchasers of Cardizem CD who alleged that they were harmed by the agreement between HMRI and Andrx.⁵¹ In 2003, the Sixth Circuit issued a decision similar to that issued by the D.C. Circuit in *Andrx*.⁵² The court found that the agreement there was intended to eliminate competition throughout the United States. The Sixth Circuit then went a step further and held the agreement to be a “*per se* illegal restraint of trade.”⁵³ The court added that “it 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.”⁵⁴

B. Valley Drug Co. v. Geneva Pharmaceuticals, Inc.

Also in 2003, in a consolidated action brought by several private antitrust plaintiffs, the Eleventh Circuit strayed from the limited course charted thus far by the D.C. and Sixth Circuits when it issued its decision in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*⁵⁵ The court not only found that the patent-holding drug manufacturers were permitted to exclude generic drug manufacturers from the market, but it suggested that the district court utilize what is now understood to be the beginnings of the scope of the patent test.⁵⁶ This case marks the beginning of the trend which has seen the federal circuits upholding pay-for-delay settlement agreements.

Beginning in 1993, Geneva Pharmaceuticals, Inc. (“Geneva”) and Zenith Goldline Pharmaceuticals (“Zenith”) filed several ANDAs and paragraph IV certifications for generic formulations of Abbott Laboratories’ (“Abbott”) brand-name drug, Hytrin.⁵⁷ Abbott filed several infringement actions against both generic drug manufacturers and the actions were settled as the result of two pay-for-delay agreements.⁵⁸

Specifically, in March 1998, Abbott and Zenith entered into an agreement under which both parties’ claims and counterclaims in the underlying infringement action were dismissed.⁵⁹ Furthermore, Zenith agreed to stay out of the Hytrin market until another generic drug manufacturer

49. 332 F.3d 896 (6th Cir. 2003).

50. *See id.*

51. *Id.* at 900.

52. For a further discussion of *Andrx*, see *supra* notes 34–47.

53. *In re: Cardizem*, 332 F.3d at 908.

54. *Id.* (footnote omitted).

55. 344 F.3d 1294 (11th Cir. 2003).

56. *Id.* at 1306, 1311–12.

57. *Id.* at 1298.

58. *Id.* at 1298–1300.

59. *Id.* at 1300.

entered the market, or a specific Abbott patent expired.⁶⁰ In return, Abbott agreed to pay Zenith \$3 million up front, \$3 million after three months, and \$6 million every three months until an agreed-upon date, or the agreement terminated under its terms.⁶¹

Abbott and Geneva entered into a similar agreement in April 1998, under which Geneva agreed to not sell or distribute any generic form of Hytrin until one of four events occurred.⁶² In return, Abbott agreed to pay Geneva \$4.5 million each month until either another generic drug manufacturer marketed a generic formulation of Hytrin, or Abbott won a favorable decision in the district court on its infringement claim.⁶³

Several private antitrust plaintiffs filed suit, alleging that the agreements were illegal contracts in restraint of trade.⁶⁴ The district court granted the plaintiffs' motion for summary judgment that the agreements were illegal under the Sherman Act.⁶⁵ The court characterized the agreements as "geographic market allocation Agreements between horizontal competitors, essentially allocating the entire United States market for [Hytrin] to Abbott, who shared its monopoly profits with the other cartel members during the life of the Agreements."⁶⁶ As such, the court held the agreements to be per se unlawful.⁶⁷

The Eleventh Circuit, however, reversed the lower court's decision, and, in doing so, emphasized the rights a patent grants to its owner, including the right to exclude others from the market.⁶⁸ Instead of utilizing the per se analysis or the rule of reason analysis, the court developed an analysis that has evolved into the so-called scope of the patent test.⁶⁹ The Eleventh Circuit directed the district court to determine whether any provisions of the agreements went beyond the scope of the patent at issue, and, if so, to apply traditional antitrust scrutiny to only those provisions.⁷⁰

60. *Id.* The Abbott patent at issue expired on February 17, 2000. *Id.* at n.13.

61. *Id.* The agreed-upon date on which the payments would stop, if the agreement had not terminated first, was March 17, 2000. *Id.*

62. *Id.* The four events that would trigger the termination of the agreement between Abbott and Geneva were as follows: 1) Abbott's patent expired; 2) another generic drug manufacturer introduced a generic formulation of Hytrin to the market; 3) Geneva obtained a judgment that its generic formulation of Hytrin did not infringe Abbott's patent; or 4) Abbott's patent was invalid. *Id.*

63. *Id.*

64. *Id.* at 1296.

65. *Id.* at 1301.

66. *Id.*

67. *Id.*

68. *Id.* at 1304.

69. *Id.* at 1311–12.

70. *Id.*

C. *In re*. Tamoxifen Citrate Antitrust Litigation

Three years later, the Second Circuit in *In re: Tamoxifen Citrate Antitrust Litigation*⁷¹ sided with the Eleventh Circuit's reasoning in *Valley Drug*, and the scope of the patent test began to solidify.⁷² In fact, the Third Circuit in *In re K-Dur* refers to the scope of the patent test alternatively as the "*Tamoxifen* test."⁷³ This case, including both the district and circuit court opinions, reflects the migration of the scope of the patent test outside the Eleventh Circuit.⁷⁴

Shortly after Imperial Chemical Industries, PLC ("ICI") was awarded the patent for tamoxifen, Barr Laboratories, Inc. ("Barr") filed an ANDA and a paragraph IV certification.⁷⁵ ICI timely filed a patent infringement suit, and the district court declared ICI's patent invalid.⁷⁶ ICI appealed the district court's ruling, and, while the appeal was pending, ICI and Barr entered into a settlement agreement.⁷⁷ Under the terms of the settlement agreement, Barr agreed to change its paragraph IV certification to a paragraph III certification, effectively agreeing that it would not market its own generic formulation of tamoxifen until the patent expired in 2002.⁷⁸ In return, AstraZeneca PLC ("Zeneca")⁷⁹ agreed to provide Barr with a \$21 million payment and a non-exclusive license to sell Zeneca-manufactured tamoxifen under Barr's label.⁸⁰ This agreement was also contingent on Zeneca obtaining a vacatur of the district court judgment holding the Tamoxifen patent invalid.⁸¹

Plaintiffs, a group of consumers, consumer advocacy groups, and providers of medical benefits, filed suit, alleging that the agreements between the defendants monopolized the United States market for tamoxifen.⁸² The Second Circuit adhered to a presumption of patent validity when it affirmed the district court's dismissal of the plaintiffs' claims, supported the scope of the patent test, and held that there was no antitrust

71. 466 F.3d 187 (2d Cir. 2006).

72. *See id.*

73. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 213 (3d Cir. 2012).

74. Prior to this opinion being issued, the Eleventh Circuit had already issued its opinion in *Schering-Plough*, which had also adhered to the scope of the patent test. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

75. *In re: Tamoxifen*, 466 F.3d at 193.

76. *Id.*

77. *Id.*

78. *Id.* at 193–94.

79. After ICI was awarded the patent, AstraZeneca PLC obtained the ownership rights of the patent. *Id.* at 193.

80. *Id.* at 193–94. Zeneca also agreed to pay Barr's raw material supplier more than \$45 million over the course of ten years. *Id.* at 194.

81. *Id.* Vacatur of the district court's judgment was subsequently obtained. *Id.*

82. *Id.* at 190.

violation because the agreement between Zeneca and Barr “did not unlawfully extend the reach of Zeneca’s tamoxifen patent.”⁸³

Despite its holding, the Second Circuit did acknowledge a potential problem looming on the horizon with regards to pay-for-delay agreements. The court explained that “[t]he less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.”⁸⁴ The court frankly explained, however, that cases like these will continue to be settled so long as there is a judicial preference for settlement.⁸⁵

D. *In re* Ciprofloxacin Hydrochloride Antitrust Litigation

In 2008, the Federal Circuit became the third federal circuit court to adhere to the scope of the patent test when it issued its decision in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.⁸⁶ This decision is particularly noteworthy, as the Federal Circuit has original jurisdiction over patent cases, and at least one other federal court has refused to overturn a pay-for-delay settlement agreement for this very reason.⁸⁷

In October 1991, Barr Labs, Inc. (“Barr”) filed an ANDA and paragraph IV certification for a generic version of Cipro, which was manufactured and sold by the patent holder, Bayer AG and Bayer Corp. (collectively “Bayer”).⁸⁸ Bayer timely filed an infringement action, but just before trial, Bayer entered into agreements with Barr and several other parties.⁸⁹ These agreements provided that, among other things, Barr and the other parties would not challenge Bayer’s patent.⁹⁰ In addition, Barr agreed that it would convert its paragraph IV certification to a paragraph III certification, effectively preventing Barr from marketing a generic form of Cipro until after the expiration of Bayer’s patent.⁹¹ In exchange, Bayer agreed to pay \$49.1 million to Barr.⁹² Bayer also agreed to provide Barr with Cipro for resale or make quarterly payments to Barr until an agreed-upon date.⁹³

83. *Id.* at 213.

84. *Id.* at 211.

85. *Id.*

86. 544 F.3d 1323 (Fed. Cir. 2008).

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

88. *In re Ciprofloxacin*, 544 F.3d at 1327–28.

89. *Id.* at 1328. Rugby Group, Inc. (“Rugby”) entered into an agreement with Barr in which they would share litigation costs and Barr would then provide to Rugby half of any profits realized on the sale of generic ciprofloxacin. *Id.* Rugby is a subsidiary of HMRI. *Id.* Bernard Sherman is Barr’s principal shareholder, and Apotex is a company controlled by him. *Id.*

90. *Id.*

91. *Id.* at 1328–29.

92. *Id.* at 1329.

93. *Id.* The date agreed upon by Bayer and Barr was December 31, 2003. *Id.* The Bayer patent expired on December 9, 2003. *Id.* at 1328.

In 2000 and 2001, plaintiffs, a group of direct and indirect purchasers and advocacy groups, filed several antitrust actions in federal court, alleging that the agreements between Bayer and Barr were illegal market allocations in violation of federal antitrust law.⁹⁴ The district court dismissed the plaintiffs' motion for summary judgment while granting the defendants' motion, and, adhering to the growing trend to follow the scope of the patent test, found that any anticompetitive effects resulting from the agreement were within the exclusionary zone of the patent.⁹⁵

The Federal Circuit affirmed the district court's decision, reiterating that there were "no anti-competitive effects outside the exclusionary zone of the patent."⁹⁶ The court further explained that, as the patent holder, Bayer had the right to exclude the other defendants from profiting from its patented invention.⁹⁷ Finally, the court noted that the settlement of patent claims through settlement agreements, as opposed to litigation, is not automatically precluded by the Sherman Act, even if some anticompetitive effects result.⁹⁸

E. *In re AndroGel Antitrust Litigation and FTC v. Watson Pharmaceuticals, Inc.*

In 2010 and 2012, two separate opinions were issued as a result of challenges to the same pay-for-delay agreements between patent-holder Solvay Pharmaceuticals ("Solvay") and two generic drug manufacturers. In 2010, the District Court for the Northern District of Georgia decided an action filed by the FTC and purchasers of AndroGel in *In re AndroGel Antitrust Litigation*.⁹⁹ Two years later, the Eleventh Circuit issued its opinion in *FTC v. Watson Pharmaceuticals, Inc.*,¹⁰⁰ which began as a complaint filed by the FTC.¹⁰¹ Both decisions adhered to the scope of the patent test originally suggested by the Eleventh Circuit in *Valley Drug*, and seemed to cement the scope of the patent test firmly within the Eleventh Circuit's jurisprudence.¹⁰²

In May 2003, two generic drug manufacturers submitted ANDAs and paragraph IV certifications for a generic formulation of AndroGel, the patent of which was held by Solvay.¹⁰³ Solvay filed timely infringement ac-

94. *Id.* at 1329. The several actions were consolidated in the Eastern District of New York. *Id.*

95. *Id.* at 1330.

96. *Id.* at 1333.

97. *Id.*

98. *Id.*

99. 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

100. 677 F.3d 1298 (11th Cir. 2012).

101. *See id.*

102. *See In re AndroGel*, 687 F. Supp. 2d at 1377; *see also Watson*, 677 F.3d at 1315; *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311–12 (11th Cir. 2003).

103. *In re AndroGel*, 687 F. Supp. 2d at 1374.

tions against both generic drug manufacturers, and, despite going through extensive litigation in both actions, ultimately settled both suits before any court decisions were handed down.¹⁰⁴ Under the agreements, Solvay agreed to voluntarily dismiss its infringement actions, and both generic drug manufacturers agreed to remain off the AndroGel market until an agreed-upon date or the date on which another company began to market a generic formulation of AndroGel.¹⁰⁵ Solvay further agreed to share profits of AndroGel with both generic drug manufacturers if they would promote AndroGel to urologists and primary care physicians.¹⁰⁶

The Northern District of Georgia chose to follow the scope of the patent test established by the Eleventh Circuit when analyzing the lawfulness of the agreements.¹⁰⁷ In doing so, the court explained that “neither the rule of reason nor the per se analysis is appropriate when a patent settlement is involved.”¹⁰⁸ Moving step-by-step through the scope of the patent test, the court found that the agreements provided only for the exclusion of generic AndroGel, and only until August 31, 2015—a full five years less than what is provided for in the patent itself.¹⁰⁹ Additionally, the agreements prevent only the parties to the agreement from marketing the generic formulation of AndroGel prior to the agreed-upon date.¹¹⁰ As a result, the court found that the agreements did not hinder competition any more than the patent already did.

In *Watson*, the FTC asked the Eleventh Circuit to adopt a “rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date.”¹¹¹ The court refused to do so for several reasons. First, the court explained that the suggested rule would require a determination of how likely a patent holder was to succeed in a lawsuit that had already been settled.¹¹² Second, not only would the rule impose heavy burdens on the court, but the Eleventh Circuit said the courts are “ill-equipped to make a judgment

104. *Id.* at 1374–75.

105. *Id.* at 1375. The agreed-upon date for both parties was August 31, 2015 if the first-filer did not assert its 180-day exclusivity period. *Id.* If the first-filer asserted its 180-day exclusivity period, the first-filer could enter the market on that date, and the subsequent filer could enter on February 28, 2016. *Id.*

106. *Id.* Solvay estimated that its payments to the generic drug manufacturers under the agreement to share profits would be anywhere between \$23 million and \$38 million per year. *Id.*

107. *Id.* at 1377. The FTC and purchasers of AndroGel filed the instant action. *Id.* at 1375–76.

108. *Id.* at 1377 (citing *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005)).

109. *Id.*

110. *Id.*

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

112. *Id.* at 1312–13.

about the merits of a patent infringement claim.”¹¹³ Finally, the court deferred to existing precedent in the circuit.¹¹⁴ In doing so, the Eleventh Circuit found that the pay-for-delay agreements at issue did not exceed the scope of the underlying patents, and, as a result, the agreements were not found to be illegal restraints of trade.¹¹⁵ After the court issued its decision, the FTC sought review of the decision, and, on December 7, 2012, the Supreme Court granted certiorari.

IV. THE THIRD CIRCUIT'S CONTROVERSIAL DECISION IN *IN RE K-DUR*

In the face of multiple decisions on both sides of the coin from several circuits, the Third Circuit, in *In re K-Dur*, approached the issue of pay-for-delay settlement agreements differently than any court to date.¹¹⁶ Even with the guidance provided by the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*,¹¹⁷ which considered the legality of the very same pay-for-delay agreement, the court chose to chart a new path.¹¹⁸

Schering manufactures and markets K-Dur 20 (“K-Dur”), which is a sustained-release potassium chloride supplement used to treat potassium deficiency.¹¹⁹ While potassium chloride is a commonly used pharmaceutical ingredient, and, as a result, unpatentable, Schering did receive a patent in 1989 on a process called “microencapsulation,” which allowed the manufacturer to compress an entire day's worth of the supplement into one sustained-release tablet.¹²⁰

In 1995, Upsher filed an ANDA and paragraph IV certification for a generic version of K-Dur called Klor Con M20 (“Klor Con”).¹²¹ Schering timely filed a patent infringement action, but, on the night before trial was to begin, Schering and Upsher reached a settlement.¹²² Under the terms of the settlement agreement, Upsher agreed to keep Klor Con off the market until September 1, 2001.¹²³ In exchange, Schering agreed to a deal under which it would obtain licenses to market five Upsher products, and Schering would pay Upsher \$60 million in “up-front royalties,” \$10 million in milestone payments, and royalties on the net sales of the licensed products.¹²⁴

113. *Id.* at 1314–15 (explaining that Congress has given Federal Circuit exclusive jurisdiction over patent cases, and Eleventh Circuit has no expertise or experience in area).

114. *Id.*

115. *Id.* at 1312–13.

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

117. 402 F.3d 1056 (11th Cir. 2005).

118. *See generally In re K-Dur*, 686 F.3d 197.

119. Brief of Appellees at 8, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (No. 10-2077).

120. *Id.* This patent expired in September 2006. *Id.* at 9.

121. *See Schering-Plough*, 402 F.3d at 1058.

122. *Id.* at 1060.

123. *Id.* at 1059.

124. *Id.* at 1059–60.

At the same time, another pharmaceutical company, ESI, filed an ANDA and paragraph IV certification, seeking FDA approval to market its generic formulation of K-Dur called Micro-K 20 (“Micro-K”).¹²⁵ Schering filed an infringement action, and, after more than a year of court-ordered mediation, Schering and ESI settled.¹²⁶ The agreement provided for Micro K’s entry into the market on January 1, 2004, and, in return, Schering agreed to pay ESI up to \$10 million if ESI received FDA approval by an agreed-upon date.¹²⁷

In March 2002, the FTC filed a complaint against Schering, Upsher, and ESI, alleging that the agreements were illegal restraints of trade.¹²⁸ The Administrative Law Judge held that the settlement agreements were not illegal, and explained that the evaluation should focus on the strength of the patent and its exclusionary power, utilizing the same analysis as the Eleventh, Second, and Federal Circuits used in upholding various pay-for-delay settlement agreements.¹²⁹ Without going as far as calling the payments to Upsher and ESI per se anticompetitive, the full Commission reversed the ALJ, and found that the settlements violated Section 5 of the FTC Act and the Sherman Act.¹³⁰

On appeal, the Eleventh Circuit’s decision in *Schering-Plough* adhered to its precedent and reversed the Commission.¹³¹ While the court agreed with both the ALJ and the Commission that the payments from Schering to Upsher and ESI were not per se anticompetitive, it did find that the rule of reason analysis utilized by both of the lower tribunals was unsuitable in a case such as this.¹³² The court reiterated that the proper framework to be utilized in patent cases is the scope of the patent test suggested in *Valley Drug*.¹³³ The anticompetitive effects of the agreements, as determined by the court in its application of the scope of the patent test, were found to be non-existent. Absent evidence to the contrary, Schering’s patent was presumed valid, which gave Schering the right to exclude infringing competitors from the market until September 5, 2006.¹³⁴ The agreements, however, provided for early entry into the market for both Upsher and ESI.¹³⁵ As negotiated, the exclusionary effect of the agreements was narrower than the patent itself.¹³⁶ As a result, the court found that there were no anticompetitive effects beyond that which the patent already pro-

125. *Id.* at 1060.

126. *Id.* at 1060–61.

127. *Id.*

128. *Id.* at 1061.

129. *Id.*

130. *Id.* at 1062.

131. *Id.* at 1076.

132. *Id.* at 1065.

133. *Id.* at 1066.

134. *Id.* at 1067.

135. *Id.* at 1067–68.

136. *Id.* at 1074.

vided. Thus, the agreements were found legal. The FTC filed a petition for writ of certiorari with the Supreme Court. Ultimately, the petition was denied.

In addition to the complaint filed by the FTC, *In re K-Dur* arose out of the very same pay-for-delay settlement agreements as considered by the Eleventh Circuit in *Schering-Plough* when several private parties filed actions against Schering, Upsher, and ESI, in the District Court for the District of New Jersey, alleging various antitrust violations.¹³⁷ In February 2009, former federal judge Stephen Orlofsky, the assigned Special Master responsible for handling all motions in the consolidated action, issued a Report and Recommendation granting defendants' motions for summary judgment.¹³⁸ In doing so, he relied on the presumption that Schering's patent was valid, enabling it to exclude—even through reverse payment settlements— infringing generic medicines until the expiration of the patent term.¹³⁹ The Special Master further held that the agreements did not exceed the scope of the patent, and the underlying infringement actions were not objectively baseless.¹⁴⁰ Thereafter, Chief Judge Greenaway simply adopted Special Master Orlofsky's Report and Recommendation in its entirety.¹⁴¹

Plaintiffs appealed their case to the Third Circuit, which then reversed the district court's decision.¹⁴² Before beginning its analysis, the Third Circuit noted that “[a]s a practical matter, the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny. As the antitrust defendants concede, no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial.”¹⁴³ The court then asserted that it did not agree with the trend in its sister circuits to follow the scope of the patent test.¹⁴⁴ Supporting its assertion, Circuit Judge Sloviter, writing for the unanimous court, found at odds with antitrust law the “almost unrebuttable presumption” that pat-

137. *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 207 (3d Cir. 2012). These actions were consolidated in the District of New Jersey by the Judicial Panel on Multidistrict Litigation. *Id.*

138. *Id.* at 208.

139. *Id.*

140. *Id.* Hatch-Waxman cases allow antitrust plaintiffs to assert a claim of “sham litigation” in the context of reverse payment agreements. See *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010). To prove an allegation of sham litigation, the plaintiff must demonstrate that the lawsuit is objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits, and the party bringing the allegedly baseless suit did so with the subjective motivation to interfere directly with the business relationships of a competitor. *Id.*

141. See *In re K-Dur Antitrust Litig.*, No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 25, 2010), *rev'd*, 686 F.3d 197 (3d Cir. 2012).

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

143. *Id.* at 214.

144. *Id.*

ents at issue in Hatch-Waxman cases are valid.¹⁴⁵ The court explained that, although the party challenging the validity of a patent bears the burden of proving that the patent is, in fact, not valid, this is merely “a procedural device and is not a substantive right of the patent holder.”¹⁴⁶ Furthermore, the court urged other courts to keep in mind that a patent is nothing more than a “legal conclusion reached by the Patent Office.”¹⁴⁷

The Third Circuit also took issue with the assumption that subsequent challenges by additional generic drug manufacturers will serve to invalidate weak patents that would otherwise remain in effect because of a reverse payment made to the initial challenger.¹⁴⁸ While idealistic, this is not realistic, according to the court, as many patent-holding drug manufacturers reap such great rewards by being the first to market that they are often able to pay several generic drug manufacturers substantial sums to remain off the market.¹⁴⁹

Finally, the court found pay-for-delay settlement agreements, the frequency of which have increased under the Hatch-Waxman Act, to be at odds with the stated goals of the Act.¹⁵⁰ With the goal of increasing the availability of low-cost drugs through increased competition, pay-for-delay agreements have the effect, according to the court, of stifling competition.¹⁵¹ Furthermore, the court found that the application of the scope of the patent test does nothing to rectify the anticompetitive effects of pay-for-delay agreements.¹⁵²

In flatly rejecting the scope of the patent test, the Third Circuit directed the district court to apply a “quick look” rule of reason analysis, not a *per se* standard, but noted that utilization of this test would not preclude patent settlements in the future, and would subject to antitrust scrutiny only reverse payment agreements.¹⁵³ In applying the quick look rule of reason analysis, the court instructed the district court to treat any payment from a patent-holder to a generic drug manufacturer as *prima facie* evidence of an unreasonable restraint of trade.¹⁵⁴ This, the court held, can then be rebutted by a showing that the payment was for a purpose other than delayed entry into the market, or by offering a pro-competitive benefit.¹⁵⁵ The Third Circuit, however, failed to delineate what might be such a legitimate purpose or benefit leaving that for future cases to sort out. After this decision was handed down, the defendant pharmaceutical com-

145. *Id.*

146. *Id.*

147. *Id.* at 215 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

148. *Id.*

149. *Id.*

150. *Id.* at 217.

151. *Id.*

152. *Id.*

153. *Id.* at 217–18.

154. *Id.* at 218.

155. *Id.*

panies filed a petition for writ of certiorari with the Supreme Court without seeking a rehearing en banc by the full Third Circuit. Although the Supreme Court has granted certiorari in *Watson*, it has not yet denied certiorari in this case.

V. CONCLUSION

The Supreme Court has, for years, declined to review pay-for-delay settlement agreements. The time has come for guidance from the Court. Not only is there a clear circuit court split regarding the settlements, generally, but one specific settlement, in particular, was decided differently by two different circuit courts. Additionally, while one standard of analysis has been predominant over the past decade—specifically, the scope of the patent test—the other side of the aisle presents variations on another standard—the quick look rule of reason analysis. Review of this issue is necessary to provide direction on how to proceed in a nationwide pharmaceutical market. The Court's future decision in *Watson* will provide the necessary guidance for both pharmaceutical companies and challengers of pay-for-delay agreements.

While the parties await a decision from the Supreme Court on whether pay-for-delay settlement agreements are legal, it is unclear how pharmaceutical companies wishing to enter into such agreements, in the meantime, should proceed. Various lawsuits challenging pay-for-delay agreements were stayed prior to the Supreme Court's decision granting certiorari on the pay-for-delay issue, while others were not.¹⁵⁶ Now that the Supreme Court has granted certiorari in *Watson*, it would only seem prudent to stay all pay-for-delay cases currently pending until the Court makes a definitive decision on the legality of reverse payment agreements.

Of note is the fact that when the Supreme Court issued its order granting certiorari in *Watson*, not only did Justice Samuel Alito recuse himself from the case, but the Court made no mention of the petitions filed by Merck and Upsher, despite the near identical pay-for-delay agreements at issue in the cases.¹⁵⁷ Given the fact that the Third Circuit is the only court

156. See Ama Sarfo, *Effexor Pay-for-Delay Suit Awaits High Court's K-Dur Answer*, LAW360 (Oct. 23, 2012, 8:44 PM), <http://www.law360.com/articles/389024/effexor-pay-for-delay-suit-awaits-high-court-s-k-dur-answer> (explaining that case involving agreement between Wyeth, LLC, and Teva Pharmaceuticals USA, Inc. ("Teva") has been stayed); see also Alison Frankel, *New Pay-for-Delay Twist: NJ Judge Says If No Pay, Deals Are Legal*, THOMSON REUTERS (Dec. 7, 2012), <http://newsandinsight.thomsonreuters.com/Legal/News/ViewNews.aspx?id=63210&terms=%40ReutersTopicCodes+CONTAINS+'ANV'> (discussing how GlaxoSmithKline and Teva case was dismissed); Django Gold, *GSK, Teva Can't Put Brakes on Pay-For-Delay Challenge*, LAW 360 (Oct. 24, 2012), <http://www.law360.com/articles/389298> (explaining that lawsuit challenging agreement between GlaxoSmithKline PLC and Teva is continuing to move forward despite then-pending grant of certiorari).

157. See *Federal Trade Commission v. Watson Pharm., Inc.*, SCOTUSBLOG, <http://www.scotusblog.com/case-files/cases/federal-trade-commission-v-watson-pharmaceuticals-inc/> (last visited Jan. 12, 2013).

that has strayed from the trend in the federal courts, however, one can assume that the Supreme Court granted certiorari in *Watson* to affirm the reasoning of the court in *In re K-Dur*.¹⁵⁸ Stay tuned.

158. See Daniel Fisher, *Supreme Court Takes Generic “Pay To Delay” Case*, FORBES (Dec. 7, 2012, 5:18 PM), http://www.forbes.com/sites/danielfisher/2012/12/07/supreme-court-takes-generic-pay-to-delay-case/?utm_source=dlvr.it&utm_medium=twitter.