Boston College Law Review

Volume 54
Issue 6 *Electronic Supplement*

Article 4

2-26-2013

Merck-y Standards: The Third Circuit's Diverging Analysis of Reverse Payment Settlements in *In re K-Dur Antitrust Litigation*

Janice Ye
Boston College Law School, janice.ye@bc.edu

Follow this and additional works at: http://lawdigitalcommons.bc.edu/bclr

Part of the Antitrust and Trade Regulation Commons, Health Law and Policy Commons, and the Intellectual Property Law Commons

Recommended Citation
Janice Ye, *Merck-y Standards: The Third Circuit's Diverging Analysis of Reverse Payment Settlements in In re K-Dur Antitrust Litigation*, 54 B.C.L. Rev. E. Supp. 29 (2013), http://lawdigitalcommons.bc.edu/bclr/vol54/iss6/4

This Comments is brought to you for free and open access by the Law Journals at Digital Commons @ Boston College Law School. It has been accepted for inclusion in Boston College Law Review by an authorized administrator of Digital Commons @ Boston College Law School. For more information, please contact nick.szydlowski@bc.edu.

MERCK-Y STANDARDS: THE THIRD CIRCUIT'S DIVERGING ANALYSIS OF REVERSE PAYMENT SETTLEMENTS IN *IN RE K-DUR ANTITRUST LITIGATION*

Abstract: On July 16, 2012, in *In re K-Dur Antitrust Litigation*, the U.S. Court of Appeals for the Third Circuit held that, when challenged as an antitrust violation, a reverse payment settlement constitutes prima facie evidence of an unreasonable restraint of trade. The "quick look rule of reason" analysis articulated by the court represents a well-intentioned divergence from the Second, Eleventh, and Federal Circuits' "scope of the patent" test. It does not, however, fully consider the parties' motivations and the possible public benefit from these settlements. This Comment argues that the court's introduction of an overly restrictive standard introduces uncertainty that may avert the Hatch-Waxman Act's goal of speeding public access to more affordable drugs.

Introduction

Antitrust and patent law both seek to promote competition and innovation, but their methods conflict.[1] Whereas the Sherman Antitrust Act prohibits anticompetitive behavior such as monopolization, patent law fundamentally rewards drug innovators with a temporary monopoly over the patented technology.[2]

When determining whether settlement agreements from patent infringement cases between innovator and generic pharmaceutical companies constitute antitrust violations, the courts have diverged on the appropriate method to analyze these agreements due to the ten-

[1] *See* Sherman Antitrust Act, ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. § 1 (2006)); 35 U.S.C. § 154 (2006 & Supp. V 2011); *see also In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 201–02 (2d Cir. 2006) (noting that tension exists between antitrust and patent law, although their motives are the same); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066–67 (11th Cir. 2005) (highlighting how patents' exclusionary nature seems to conflict with antitrust law).

[2] *See* 15 U.S.C. §§ 1–2; 35 U.S.C. § 154; *see also In re Tamoxifen*, 466 F.3d at 202 (noting the tension between the Sherman Antitrust Act's proscription of anticompetitive behavior and patent law's grant on monopolies); *Schering-Plough*, 402 F.3d at 1065–66 (highlighting that patents naturally create anticompetitive effects); Christina Bohannan & Herbert Hovenkamp, *IP and Antitrust: Reformation and Harm*, 51 B.C. L. Rev. 905, 915–20 (2010) (comparing antitrust and patent law's approaches to economic goals and innovation incentives).

sion between antitrust and patent law.[3] In these cases, the courts not only must balance antitrust and patent law, but they must also consider the Drug Price Competition and Patent Term Restoration Act.[4] Known as the Hatch-Waxman Act, Congress passed this legislation to provide earlier public access to lower-cost generic versions of innovator drugs.[5]

The Hatch-Waxman Act includes incentives for generic drug companies to challenge drug innovators' patents and, if successful, market generic versions before the end of the patent term.[6] When these challenges lead to patent litigation, known as Paragraph IV disputes, the parties have often reached pretrial settlements involving reverse payments to avoid the high costs, lengthy proceedings, and uncertainty associated with litigation.[7] Some circuits have refrained

---

[3] *See In re* K-Dur Antitrust Litig. (*K-Dur II*), 686 F.3d 197, 209 (3d Cir. 2012), *petition for cert. filed*, 81 U.S.L.W. 3090 (U.S. Aug. 29, 2012) (No. 12-245 & No. 12-265); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 Geo. L.J. 1303, 1308 (2010); *see also* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 Harv. L. Rev. 1813, 1815–17 (1984) (highlighting the long-standing confusion and controversy at the intersection of these fields, and stating that the courts approach issues at the patent-antitrust intersection in three general ways, all of which avoid this intersection).

[4] *See* Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments), Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 301, 355 (2006 & Supp. IV 2010)); *K-Dur II*, 686 F.3d at 203.

[5] *See* H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48, 2670. Through the Hatch-Waxman Act, Congress also incentivized drug innovators to produce novel therapies. *See id.*

[6] *See id.* Under the Hatch-Waxman Act, a generic drug company may file an Abbreviated New Drug Application (ANDA) to produce a generic version of an innovator company's drug. 21 U.S.C. § 355(j). Congress included this pathway to expedite consumer access to cheaper drugs. *See* H.R. Rep. No. 98-857, pt. 1, at 14–15. The generic drug company must include a certification that confirms one of four options regarding any patents for the innovator company's drug: (i) that such patent information has not been filed; (ii) that such patent has expired; (iii) the date on which such patent will expire; or (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the ANDA's proposed generic version. 21 U.S.C. § 355(j)(2)(A)(vii). The Paragraph IV certification—that such patent is invalid or will not be infringed—is a technical act of patent infringement. *Id.* § 355(j)(2)(A)(vii)(IV).

[7] *See, e.g.*, *Schering-Plough*, 402 F.3d at 1075; *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003). When the generic drug company files an ANDA with a Paragraph IV certification, the innovator company often sues the generic drug company for patent infringement. *See* 21 U.S.C. § 355. As an alternative to a time-consuming and costly trial, the reverse payment settlement is a common resolution to this type of litigation. *See Schering-Plough*, 402 F.3d at 1075. The settlement often consists of the innovator company's payment to the generic drug company in return for the generic drug company's agreement to refrain from entering the market until a negotiated date prior to the end of the patent term, thereby "splitting" the patent term. *See id.*; Opderbeck, *supra* note 3, at 1307–08.

from deeming these settlements unlawfully anticompetitive because parties should be allowed to contract within the bounds of the patent's exclusionary scope.[8] In contrast, others have considered reverse payment settlements to be per se violations of antitrust law.[9]

When the U.S. Court of Appeals for the Third Circuit addressed the antitrust implications of reverse payment settlements in 2012 in *In re K-Dur Antitrust Litigation* (*K-Dur II*), it introduced greater risk for pharmaceutical companies hoping to resolve patent disputes related to the Hatch-Waxman Act.[10] In adopting a "quick look rule of reason" analysis, the Third Circuit rejected the method of analysis applied by the U.S. Courts of Appeals for the Second, Eleventh, and Federal Circuits.[11] Those circuits have used the "scope of the patent" analysis, which permits settlements so long as the agreement terms fall within the patent's exclusionary scope.[12] In contrast, the Third Circuit's test allows scrutiny of all reverse payment settlements under a presumption of anticompetitive behavior.[13] This approach discourages pharmaceutical companies from reaching settlements in these disputes.[14]

Part I of this Comment introduces the reverse payment settlements that led to the antitrust litigation before the Third Circuit in *K-Dur II*

---

[8] *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig. (*Cipro*), 544 F.3d 1323, 1337 (Fed. Cir. 2008); *In re Tamoxifen*, 466 F.3d at 213; *Schering-Plough*, 402 F.3d at 1066–67; Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003).

[9] *See, e.g.*, *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 909 n.15 (6th Cir. 2003); Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 813–15 (D.C. Cir. 2001). The D.C. Circuit and Sixth Circuit cases involved settlements that included attempted manipulation of the 180-day exclusivity period awarded to the first generic drug company to file an ANDA with the U.S. Food & Drug Administration (FDA). *See In re Cardizem*, 332 F.3d at 909; *Andrx*, 256 F.3d at 813–15; Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 Hastings L.J. 171, 181 (2008). The *K-Dur II* settlements did not manipulate this exclusivity period, so the D.C. and Sixth Circuits' approach to antitrust is not discussed in this Comment. *See K-Dur II*, 686 F.3d at 205–06; Avery, *supra*, at 181.

[10] *See K-Dur II*, 686 F.3d at 217–18; *cf. Valley Drug*, 344 F.3d at 1310 ("Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.").

[11] *K-Dur II*, 686 F.3d at 217–18; *see Cipro*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 213; *Schering-Plough*, 402 F.3d at 1066–67; *Valley Drug*, 344 F.3d at 1312.

[12] *See Cipro*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 213; *Schering-Plough*, 402 F.3d at 1066–67; *Valley Drug*, 344 F.3d at 1312.

[13] *Compare K-Dur II*, 686 F.2d at 217–18 (holding that a reverse payment is a presumptive violation of the Sherman Antitrust Act), *with Cipro*, 544 F.3d at 1337 (concluding that no support exists to state that the Hatch-Waxman Act intended to prevent settlement and that the "scope of the patent" test should apply), *and In re Tamoxifen*, 466 F.3d at 206 (concluding that the "scope of the patent" test should apply).

[14] *See K-Dur II*, 686 F.2d at 217–18.

and a similar case in the Eleventh Circuit.[15] It then addresses the Third and Eleventh Circuits' different approaches to the antitrust claims arising from these settlements.[16] Part II outlines the "scope of the patent" approach to antitrust claims surrounding reverse payment settlements and examines the reasoning underlying the Third Circuit's "quick look rule of reason" test.[17] Part III argues that, although the court attempted to reconcile the competing interests of patent and antitrust law, it did not fully assess the companies' risk allocation and subsequent settlement motivations.[18] By failing to do so, the court also disregarded situations where these settlements provide public benefits.[19] The Third Circuit's overly restrictive standard therefore may deter pharmaceutical companies from engaging in or reaching any settlement in Paragraph IV disputes, which will ultimately harm consumers.[20]

I. *In re K-Dur Antitrust Litigation*: The Clash in Exclusionary Scopes of Antitrust and Patent Law

A. *The Settlement of Schering's Patent Infringement Claims Against Upsher and ESI*

In 1989, Schering-Plough Corporation ("Schering") was granted a patent for the controlled-release coating of its potassium chloride supplement, branded K Dur 20 ("K-Dur").[21] Schering's patent was set to expire in 2006.[22] On December 15, 1995, generic drug companies Upsher-Smith Laboratories ("Upsher") and ESI Lederle ("ESI") each filed Abbreviated New Drug Applications (ANDAs) under the Hatch-Waxman Act to gain approval from the U.S. Food & Drug Administration to market generic versions of K-Dur.[23] Both generic drug companies included Paragraph IV certifications claiming that their proposed generic versions would not infringe on Schering's patents.[24] In re-

---

[15] *See infra* notes 21–34 and accompanying text.

[16] *See infra* notes 35–49 and accompanying text.

[17] *See infra* notes 50–67 and accompanying text.

[18] *See infra* notes 68–93 and accompanying text.

[19] *See infra* notes 68–93 and accompanying text.

[20] *See infra* notes 68–93 and accompanying text; *see also supra* notes 6–7 and accompanying text (describing Paragraph IV disputes).

[21] *K-Dur II*, 686 F.3d at 204–05.

[22] *Id.* at 203.

[23] *Id.* at 205–06; *see supra* notes 6–7 and accompanying text (discussing the ANDA process and how it typically leads to litigation).

[24] *K-Dur II*, 686 F.3d at 205–06; *see supra* note 6 and accompanying text (defining Paragraph IV certification). Under the Hatch-Waxman Act, a Paragraph IV certification for an

sponse, Schering sued Upsher and ESI for patent infringement in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Eastern District of Pennsylvania, respectively.[25]

After nearly two years of pretrial litigation and mediation, Schering eventually reached settlement agreements with both generic drug companies.[26] Schering and Upsher reached an agreement on June 18, 1997, just hours prior to the district court's scheduled ruling on their motions for summary judgment.[27] Upsher agreed not to market a generic K-Dur until September 1, 2001, on which date Schering would grant Upsher a non-exclusive license to make and sell the generic version of the drug.[28] Upsher also agreed to grant Schering licenses to make and sell cholesterol drug products that Upsher had developed in exchange for sixty million dollars.[29]

In Schering's litigation against ESI, the parties finally settled in December 1997 after fifteen months of court-supervised mediation.[30] Schering offered to divide the patent's remaining life, granting ESI a license to start marketing generic K-Dur in 2004, which was nearly three years earlier than the patent's expiration date.[31] In exchange, ESI agreed not to develop any potassium chloride products.[32] Schering also paid ESI five million dollars plus an amount dependent on the approval date of ESI's ANDA.[33] These terms were encouraged and approved by mediation.[34]

ANDA automatically constitutes a cause of action for the patent holder against the infringing party for patent infringement. 21 U.S.C. § 355(j)(2)(A)(vii) (2006 & Supp. IV 2010).

[25] *K-Dur II*, 686 F.3d at 206.

[26] *Id.*

[27] *Id.* at 205.

[28] *Id.*

[29] *Id.* at 205–06. The sixty million dollars was paid over three years, with additional payments based on the sales volume of one of the products, Niacor SR. *Id.*

[30] *Id.* at 206; *see Schering-Plough*, 402 F.3d at 1060. The judge had ordered the parties to participate in mediation in hopes of achieving a settlement and avoiding the substantial time and costs of trial. *K-Dur II*, 686 F.3d at 206; *see Schering-Plough*, 402 F.3d at 1060.

[31] *K-Dur II*, 686 F.3d at 206.

[32] *Id.*

[33] *Id.* Schering's payment to ESI ranged from a maximum of $10 million if ESI's ANDA was approved before July 1999 to a minimum of $625,000 if it was not approved until 2002. *Id.* In May 1999, Schering paid ESI an additional $10 million when the FDA approved ESI's ANDA. *Id.*

[34] *Id.*

B. *Antitrust Suits for the Reverse Payment Settlement*

In 2001, the Federal Trade Commission (FTC) contested the settlement agreements between Schering and Upsher and Schering and ESI as violations of Section 1 of the Sherman Antitrust Act because they were anticompetitive restraints of trade.[35] The FTC asserted that the settlements had unlawfully injured competition and consumers because the companies had agreed to delay generic K-Dur's launch by splitting Schering's patent term as well as exchanging payments and licensing agreements.[36] In 2005, in *Schering-Plough Corp. v. FTC*, the U.S. Court of Appeals for the Eleventh Circuit determined that Schering's reverse payment settlements did not unreasonably restrain trade.[37] Rejecting the FTC's reasoning, the Eleventh Circuit upheld these settlements' validity because they fell within the exclusionary scope of Schering's patent.[38]

In 2010, in *In re K-Dur Antitrust Litigation* (*K-Dur I*), the U.S. District Court for the District of New Jersey also ruled for the drug companies when it evaluated the same settlements.[39] This time, a class of direct purchasers of K-Dur sued Schering, Upsher, and ESI, alleging antitrust injury under Section 1 of the Sherman Antitrust Act.[40] Employing similar arguments to those of the FTC in *Schering-Plough*, the direct purchasers claimed that these agreements were collusive and anticompetitive because they purposefully allowed Schering to maintain its monopoly on the potassium chloride extended-release tablet market.[41] The purchasers asserted that, but for Schering's reverse

---

[35] *Schering-Plough*, 402 F.3d at 1061; *see* 15 U.S.C. § 1 (2006). The Sherman Antitrust Act states: "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." 15 U.S.C. § 1.

[36] *Schering-Plough*, 402 F.3d at 1061–62.

[37] *Id.* at 1076.

[38] *Id.*

[39] *See K-Dur I*, No. 01-1652(JAG), 2010 WL 1172995, at *1 (D.N.J. Mar. 25, 2010). The district court judge in this case adopted the opinion of the Special Master assigned to the case. *K-Dur I*, 2010 WL 1172995, at *1 (citing *K-Dur I*, No. 01-1652(JAG), 2009 WL 508869, at *1, *27 (D.N.J. Feb. 6, 2009)).

[40] *K-Dur II*, 686 F.3d at 202; *see* 15 U.S.C. § 1. The district court certified the plaintiffs as a class of forty-four wholesalers, health maintenance organizations, and retailers who had purchased K-Dur directly from Schering. *K-Dur II*, 686 F.3d at 218–19. These direct purchasers claimed that Schering, Upsher, and K-Dur had violated Section 1 of the Sherman Antitrust Act, several federal and state antitrust and unfair competition statutes, and common law when the drug companies had entered into settlement agreements. *Id.* at 202 n.1; *see* 15 U.S.C. § 1; *In re* K-Dur Antitrust Litig. (*K-Dur I*), 338 F. Supp. 2d 517, 526 (D.N.J. 2004).

[41] *K-Dur I*, 2009 WL 508869, at *1; *see Schering-Plough*, 402 F.3d at 1061.

payments to Upsher and ESI, the generic drug companies would not have settled on the present terms and therefore would have entered the market sooner.[42] This assertion assumed that the generic drug companies would have prevailed in the patent litigation.[43] Accordingly, Upsher and ESI would have marketed generic K-Dur earlier, thereby increasing competition and lowering this drug's price for consumers.[44]

Using the "scope of the patent" test applied by the Second, Eleventh, and Federal Circuits, the District of New Jersey reasoned that the settlements were not subject to antitrust scrutiny because Schering had lawfully contracted within the bounds of its K-Dur patent's exclusionary rights.[45] The direct purchasers appealed, claiming that the court should not have applied this test because it assumed the patent's validity; rather, the court should have applied traditional antitrust standards.[46]

In 2012, in *In re K-Dur Antitrust Litigation* (*K-Dur II*), the U.S. Court of Appeals for the Third Circuit rejected the District of New Jersey's application of the "scope of the patent" test.[47] Instead, it reversed and remanded the case to apply the "quick look rule of reason" analysis.[48] The court reasoned that this analysis properly reinforced—by addressing the interaction of patent law and antitrust law—the Hatch-Waxman Act's goal of providing consumers with access to lower-cost drugs sooner, whereas the "scope of the patent" test had deferred too much to patent law's presumption of patent validity.[49]

---

[42] *K-Dur I*, 2009 WL 508869, at *26.

[43] *See id.*

[44] *Id.*

[45] *See id.* at *27.

[46] Brief of Petitioner-Appellant, *K-Dur II*, 686 F.3d 197 (Nos. 10-2077, 10-2078, 10-2079), 2011 WL 1979816, at *13–*15.

[47] 686 F.3d at 207–08, 211, 218.

[48] *Id.* In December 2012, the Supreme Court granted review of *FTC v. Watson Pharmaceuticals, Inc.* *See* FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1300 (11th Cir. 2012), *cert. granted sub nom.* FTC v. Actavis, 133 S. Ct. 787 (Dec. 7, 2012) (No. 12-416). In that case, the Eleventh Circuit reaffirmed the method of antitrust analysis it applied in *Schering-Plough. Watson*, 677 F.3d at 1310, 1315. The petitioners have asked the Supreme Court to address the issue of whether reverse payment settlements are per se lawful—barring sham patent limitation or a fraudulently obtained patent—or presumptively anticompetitive and unlawful. *See* Petition for a Writ of Certiorari at i, *Watson*, 677 F.3d 1298 (No. 12-416), 2012 WL 4750283, at *1.

[49] *See K-Dur II*, 686 F.3d at 214, 217.

II. Tensions Between Antitrust and Patent Law: Diverging Antitrust Standards for Reverse Payment Settlements

A. *The "Scope of the Patent" Test*

Prior to the Third Circuit's 2012 decision in *K-Dur II*, several other circuit courts had faced antitrust claims concerning reverse payments between innovator and generic companies.[50] The Second, Eleventh, and Federal Circuits chose to evaluate these claims using the "scope of the patent" test.[51] Under this analysis, these courts permitted reverse payment settlements so long as their terms fell within the exclusionary scope of the innovator's patent.[52] These courts reasoned that the patent holder may contract within the patent's term because a patent statutorily gives its owner rights to exclude others from making or selling the invention.[53] They also reasoned that the "scope of the patent" approach aligned with public policy by encouraging settlement and judicial efficiency.[54]

In rejecting the "scope of the patent" test in *K-Dur II*, the Third Circuit asserted that this test did not adequately accommodate the intentions underlying the Hatch-Waxman Act.[55] Congress had passed this legislation to increase consumer access to more affordable drugs sooner by substantially expediting the generic drug approval pathway.[56] The Third Circuit feared that the "scope of the patent" test's

---

[50] *See In re* K-Dur Antitrust Litig. (*K-Dur II*), 686 F.3d 197, 205–06 (3d Cir. 2012).

[51] *See In re* Ciprofloxacin Hydrochloride Antitrust Litig. (*Cipro*), 544 F.3d 1323. 1337 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2005); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066–67 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003).

[52] *See, e.g.*, *Cipro*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 213; *Schering-Plough*, 402 F.3d at 1066–67. This approach also requires that the patent holder did not obtain the patent through fraud and brought the infringement claim in good faith. *See Cipro*, 544 F.3d at 1335.

[53] *See* 35 U.S.C. § 282 (2006 & Supp. V 2011); *see, e.g.*, *Cipro*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 208–09. The "scope of the patent" test allows drug manufacturers to split the patent term, thereby permitting other manufacturers to produce the patented drug. *See Cipro*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 208–09; Opderbeck, *supra* note 3, at 1323–24.

[54] *See Cipro*, 544 F.3d at 1333; *Schering-Plough*, 402 F.3d at 1072–73 ("[P]ublic policy strongly favors settlement of disputes without litigation." (quoting Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1975))).

[55] *See K-Dur II*, 686 F.3d at 217.

[56] *See id.*; H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48, 2670. Under the Hatch-Waxman Act, the generic drug company need only demonstrate bioequivalence between its drug and the branded version. 21 U.S.C. § 355 (2006 & Supp. IV 2010). It is additionally rewarded with a 180-day period of exclusive mar-

reliance on a presumption of patent validity allowed innovator companies wrongfully to protect weak or narrow patents by paying generic challengers to delay market entry and avoid litigation.[57] Without settlement, these weak or narrow patents might otherwise have been invalidated through patent infringement trials, thereby allowing generic drug companies to enter the market earlier and decrease prices for consumers.[58]

B. *The Third Circuit's Application of the "Quick Look Rule of Reason" Test*

After weighing the legislative intent behind the Hatch-Waxman Act and the rationale underlying the "scope of the patent" test, the Third Circuit in *K-Dur II* mandated application of its "quick look rule of reason" test.[59] This test treats a reverse payment settlement as prima facie evidence of an unreasonable restraint of trade.[60] As a result, the pharmaceutical company defendants bear the burden to rebut this presumption by demonstrating that the payment either had a purpose other than delaying generic drug entry or offered some "pro-competitive benefit."[61] Unlike the "scope of the patent" test's deference to patent law's exclusionary rights and presumption of patent validity, the Third Circuit's test relied upon antitrust law's scrutiny of anticompetitive behavior.[62]

In diverging from the test used by other circuits, the Third Circuit concluded that the "quick look rule of reason" test's scrutiny of all reverse payment settlements more appropriately accommodated the Hatch-Waxman Act's policy objectives by protecting consumers from innovator companies' unjustified monopolies.[63] The court determined that addressing reverse payment settlements should outweigh the judicial preference for settlement.[64] Adopting reasoning similar to the FTC's reasoning in the 2005 case before the Eleventh Circuit, *Schering-*

---

keting over other generic versions if it is the first generic drug company to file its ANDA with the FDA. *Id.* § 355(j)(5)(B)(iv).

[57] *See K-Dur II*, 686 F.3d at 215.

[58] *See id.*

[59] *See id.* at 218.

[60] *See id.*

[61] *See id.* The Third Circuit provided an example of a pro-competitive benefit: "a modest cash payment that enables a cash-starved generic drug company to avoid bankruptcy and begin marketing a generic drug." *Id.*

[62] *See id.*; *Cipro*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 213; *Schering-Plough*, 402 F.3d at 1066–67; *Valley Drug*, 344 F.3d at 1312; Kaplow, *supra* note 3, at 1815–17.

[63] *See K-Dur II*, 686 F.3d at 217–18.

[64] *See id.* at 218.

Plough Corp. v. FTC, the Third Circuit considered reverse payment settlements to be presumptively unreasonable restraints of trade,[65] thereby representing the parties' anticompetitive intent to delay the generic drug's market entry.[66] The Third Circuit further asserted that the intent behind the Hatch-Waxman Act overrode the policy encouraging settlements.[67]

III. The Consequences of the Third Circuit's Decision to Adopt a Broader "Quick Look Rule of Reason" Test

Although the Third Circuit in *K-Dur II* correctly recognized that the "scope of the patent" test may wrongfully shield drug innovators who hold weak patents, it over-corrected by applying its "quick look rule of reason" test.[68] The court's consideration of appropriate rebuttals to its presumption that any reverse payment settlement is unlawfully anticompetitive failed to include the reality that some settlements actually align with the Hatch-Waxman Act's goals.[69] As a result, the Third Circuit's "quick look rule of reason" test may deter generic drug companies from challenging innovator companies' patents, thus eliminating consumer benefits arising from these settlements.[70]

Reverse payment settlements can be efficient resolutions to otherwise lengthy and complex trials in Paragraph IV disputes, given the Hatch-Waxman Act's reallocation of litigation risk.[71] Generally, when the litigation outcome is uncertain, a strong preference toward settlement exists because settlement can accommodate not only each party's investment at risk but also their likelihood of a favorable out-

---

[65] *See id.*; *see also Schering-Plough*, 402 F.3d at 1066–73 (following its *Valley Drug* precedent by applying the "scope of the patent" test).

[66] *See K-Dur II*, 686 F.3d at 218.

[67] *See id.* at 217.

[68] *See In re* K-Dur Antitrust Litig. (*K-Dur II*), 686 F.3d 197, 218 (3d Cir. 2012); *infra* notes 69–93 and accompanying text.

[69] *See K-Dur II*, 686 F.3d at 218; *infra* notes 71–85 and accompanying text.

[70] *See infra* notes 86–89 and accompanying text.

[71] *See* 21 U.S.C. § 355(j) (2006 & Supp. IV 2010); FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1300 (11th Cir. 2012) (describing patent litigation as an "infamously costly and notoriously unpredictable process"), *cert. granted sub nom.* FTC v. Actavis, 133 S. Ct. 787 (Dec. 7, 2012) (No. 12-416); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) (stating that "[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation"); Kelly Casey Mullally, *Legal (Un)certainty, Legal Process, and Patent Law*, 43 Loy. L.A. L. Rev. 1109, 1125 (2010); Opderbeck, *supra* note 3, at 1323–24; *infra* notes 77–78 and accompanying text.

come.[72] Under patent law, when the patent holder sues a party for infringement, both parties hold risk in the subsequent litigation.[73] Whereas the alleged infringer risks its investment in manufacturing the product, the patent holder risks its future profits from the patented product.[74] If the patent holder prevails during trial, the alleged infringer owes damages.[75] Therefore, settlements often involve the alleged infringer's payment to the patent holder in exchange for a license to manufacture the product prior to the patent's expiration.[76] In Paragraph IV disputes, however, the allegedly infringing generic drug company has neither investment in prior development nor potential damages—barring litigation costs—at stake, so this skewed risk allocation gives a generic drug company little reason to settle.[77] Therefore, in disputes where both parties believe they have a substantial chance of success, it is more difficult to persuade the generic drug company to settle without payment.[78] Thus, reverse payments may provide certainty and expedite generic drug market entry in instances where the settlement amounts represent litigation costs or the innovator company's nuisance value.[79]

In settlements such as Schering's, in which substantial probability of patent validity exists, reverse payment settlements may benefit consumers by providing the generic challenger with a market entry date

---

[72] *See* Richard McMillan, Jr. et al., Essay, *Solving the Procedural Quagmire for Testing Reverse Payment Settlements*, 11 MINN. J. L. SCI. & TECH. 801, 815–16 (2010); Opderbeck, *supra*, note 3, at 1325–28.

[73] *See* 35 U.S.C. § 154 (2006 & Supp. V 2011); Kaplow, *supra*, note 3, at 1824.

[74] *See* 35 U.S.C. § 154; Kaplow, *supra* note 3, at 1824. Generally, given the patent's conferral of exclusionary rights, the patent holder profits from its status as the only supplier of the patent product. *See* 35 U.S.C. § 154; Kaplow, *supra*, note 3, at 1824.

[75] 35 U.S.C. § 284–285, 289 (permitting patent holders to seek compensatory damages for infringement, not less than a reasonable royalty for the infringer's use of the invention).

[76] *See* 35 U.S.C. §§ 154, 271 (allowing patent owners the ability to contract within the terms of their patent).

[77] *See* 21 U.S.C. §355(j). Under the Hatch-Waxman Act, when the innovator sues the generic drug company for patent infringement after its Paragraph IV submission, the generic drug company need not have expended any effort in development, clinical testing, or manufacture of the drug. *See* 35 U.S.C. § 355(j).

[78] *See* McMillan et al., *supra* note 72, at 806.

[79] *See* Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283, 304–05 (2012); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN L. REV. 1719, 1740 (2003); McMillan et al., *supra* note 72, at 806. *But see generally* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009) (arguing that reverse payment settlements should be "presumptively illegal").

earlier than the patent's expiration.[80] If the court affirms the contested patent's validity and concludes that the generic drug company did infringe, then the drug innovator may enforce its exclusionary rights, likely through an injunction preventing a generic version's market entry until the end of the patent term.[81] The parties' pretrial settlement of a negotiated generic drug entry date allows some compromise for an earlier generic drug entry date.[82] Thus, the settlement provides consumers with access to lower-cost generic versions prior to the end of the patent term.[83] In Schering's case, if the court had upheld its patent's validity, the generic drug companies would not have been able to market generic K-Dur until the patent's expiration in 2006.[84] Instead, the parties' settlements provided consumer access to generic K-Dur several years earlier through licenses to Upsher and ESI to begin using Schering's patent in 2001 and 2004, respectively.[85]

The Third Circuit's presumption that reverse payments are anticompetitive may discourage generic drug companies from bringing Paragraph IV challenges and deter any publicly beneficial agreements.[86] Rather than resolution through settlement, these types of patent infringement cases will likely be litigated fully through time-consuming trials.[87] Already, there is significant judicial strain from patent litigation due to the technical complexity of examining the patent.[88] Therefore, the Third Circuit's introduction of a standard diverging from the other circuits' standard deters these companies from settlement and creates additional judicial strain if these Paragraph IV patent infringement trials are litigated fully.[89]

In December 2012, the U.S. Supreme Court granted certiorari to an Eleventh Circuit case, *FTC v. Actavis*, which applied the "scope of

---

[80] *See* Opderbeck, *supra* note 3, at 1325–28; McMillan et al., *supra* note 72, at 815–16. The parties' vigorous pretrial efforts suggest that Schering reasonably believed in its patent's validity. *See K-Dur II*, 686 F.3d at 205–06.

[81] *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 202 (2d Cir. 2005); *Schering-Plough*, 402 F.3d at 1074.

[82] *See In re Tamoxifen*, 466 F.3d at 202; *Schering-Plough*, 402 F.3d at 1074; Opderbeck, *supra* note 3, at 1323–24.

[83] *See supra* notes 80–82 and accompanying text.

[84] *See K-Dur II*, 686 F.3d at 205–06.

[85] *See id.*

[86] *See* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1309 (11th Cir. 2003) (suggesting that a per se finding of antitrust liability would chill these settlements); Mullally, *supra* note 71, at 1128–29; *infra* notes 87–89 and accompanying text.

[87] *See Valley Drug*, 344 F.3d at 1309; Mullally, *supra* note 71, at 1128–29.

[88] *See Valley Drug*, 344 F.3d at 1309; Mullally, *supra* note 71, at 1128–29.

[89] *See supra* notes 86–88 and accompanying text.

the patent" test for antitrust scrutiny of a reverse payment settlement.[90] This review presents an opportunity for the Supreme Court to refine the "quick look rule of reason" standard to allow reverse payment settlements that benefit consumers.[91] The Court should take this opportunity to clarify what constitutes an appropriate rebuttal to the presumption that reverse payment settlements violate antitrust law, such as by including in its antitrust analysis the parties' demonstration that their settlement relied upon reasonable belief in a substantial possibility of success in the original patent litigation.[92] Adopting this revised "quick look rule of reason" standard would more comprehensively serve the Hatch-Waxman Act's twofold objective of incentivizing innovation of novel therapeutics while simultaneously expediting public access to generic versions.[93]

Conclusion

In *K-Dur II*, the Third Circuit diverged from other circuit courts in its method of analyzing whether reverse payment settlements violate antitrust law. By applying the "quick look rule of reason" analysis in an effort to further the Hatch-Waxman Act's legislative intent, the Third Circuit rejected the Second, Eleventh, and Federal Circuits' "scope of the patent" test. In so doing, it concluded that all reverse payment settlements are prima facie evidence of unreasonable restraints of trade. Although well-intentioned, the Third Circuit's application of a deviating standard created confusion regarding the level of scrutiny that will be applied to reverse payment settlements, especially because it rejects the analysis of the Eleventh Circuit on the same set of reverse payment settlements.

The Supreme Court's review of this issue in *FTC v. Actavis* presents an opportunity for the Court to set forth a standard that more appropriately balances innovation incentives and public access to ge-

---

[90] 677 F.3d at 1312 (holding in accord with precedent that, absent sham litigation or fraud, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the patent's exclusionary scope).

[91] Petition for Writ of Certiorari, *Watson Pharm.*, 677 F.3d 1298 (No. 12-416), 2012 WL 4750283, at *1 (presenting the question as "[w]hether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held)").

[92] *See* McMillan et al., *supra* note 72, at 815–16; Opderbeck, *supra* note 3, at 1325–28.

[93] *See* H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48, 2670; McMillan et al., *supra* note 72, at 815–16; Mullally, *supra* note 71, at 1125; Opderbeck, *supra* note 3, at 1325–28.

neric drugs. In the meantime, the Third Circuit's decision could have a significant detrimental impact on the pharmaceutical industry because most companies are headquartered within this court's jurisdiction of New Jersey, Delaware, and Pennsylvania.

Janice Ye

Preferred Citation: Janice Ye, Comment, *Merck-y Standards: The Third Circuit's Diverging Analysis of Reverse Payment Settlements in In re* K-Dur Antitrust Litigation, 54 B.C. L. Rev. E. Supp. 29 (2013), http://lawdigitalcommons.bc.edu/bclr/vol54/iss6/4/.