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**Antitrust Law**—Rejecting the “Scope of the Patent” Test in Analysis of Reverse Payments in Pharmaceutical Industry—*In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir.), *petition for cert. filed*, 81 U.S.L.W. 3090 (U.S. Aug. 29, 2012) (No. 12-265); 81 U.S.L.W. 3090 (U.S. Aug. 24, 2012) (No. 12-245)

The Sherman Antitrust Act (Sherman Act) prohibits businesses from contracting, combining, and conspiring to restrain trade or commerce.<sup>1</sup> Reverse-payment-patent-settlement agreements between brand-name and generic pharmaceutical companies—whereby a brand-name-patent holder pays its generic competitor to drop a pending patent suit and refrain from producing its generic drug for a definite period of time—are generally subject to antitrust review under the Sherman Act.<sup>2</sup> In *In re K-Dur Antitrust Litigation*,<sup>3</sup> the Court of Appeals for the Third Circuit considered whether reverse-payment agreements between Schering-Plough Corporation (Schering) and its generic competitors Upsher-Smith Laboratories (Upsher) and ESI Lederle (ESI) amounted to an unreasonable restraint on trade.<sup>4</sup> Parting with other circuits that more recently addressed the issue, the court expressly rejected the common scope-of-the-patent test and held that reverse-payment agreements between a pharmaceutical patent holder and a potential generic competitor constitute a prima facie violation of the Sherman Act’s proscription against unreasonable

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1. See 15 U.S.C. § 1 (2006) (proscribing all contracts, combinations, or conspiracies in restraint of trade). Section 1 of the Sherman Act has not been interpreted literally. See *Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 342-43 (1982) (recognizing Congress did not intend to prohibit every agreement restraining trade). The Court has interpreted § 1 as only prohibiting agreements that are unreasonable restraints on trade. See *Standard Oil Co. v. United States*, 221 U.S. 1, 66 (1911) (announcing rule-of-reason test). Under the rule-of-reason test, the court must “consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable.” *Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918). In limited instances, the Court has departed from the rule-of-reason test and adopted per se rules where the type of restraint is manifestly anticompetitive. See *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (applying per se rule where practice appears to always restrict competition).

2. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111–1118, 117 Stat. 2066, 2461–64 (codified as amended at 21 U.S.C. § 355(j) (2006)) (requiring review of reverse-payment agreements by Federal Trade Commission (FTC) and Department of Justice (DOJ)). These settlements are characterized as “reverse payment agreements” because the brand-name-patent holder, or plaintiff, pays the alleged infringer, or defendant, millions of dollars to end the patent litigation. See Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers*, 26 SANTA CLARA COMPUTER & HIGH TECH. L.J. 141, 147 (2009) (characterizing reverse-payment agreements).

3. 686 F.3d 197 (3d Cir.), *petition for cert. filed*, 81 U.S.L.W. 3090 (U.S. Aug. 29, 2012) (No. 12-265); 81 U.S.L.W. 3090 (U.S. Aug. 24, 2012) (No. 12-245).

4. See *id.* at 202. Merck & Co. acquired Schering while this case was pending; however, in keeping with the practice of the parties the court continued to refer to Schering. See *id.* at 203 n.2. This Comment does the same.

restraints on trade.<sup>5</sup>

On September 5, 1989, Schering was granted a patent ('743 Patent) on the controlled-release potassium-chloride supplement, K-Dur 20 (K-Dur).<sup>6</sup> In late 1995, Upsher and ESI filed individual Abbreviated New Drug Applications (ANDA) with the Food and Drug Administration (FDA) seeking approval to make and sell generic versions of K-Dur.<sup>7</sup> In response to notification of the ANDA filings, Schering initiated separate patent-infringement suits against Upsher and ESI in the United States District Courts for the District of New Jersey and for the Eastern District of Pennsylvania.<sup>8</sup> Prior to adjudicating the merits of either infringement suit, however, Schering negotiated settlements with Upsher and ESI.<sup>9</sup>

In 2001, the Federal Trade Commission (FTC) filed a complaint against Schering, Upsher, and ESI, alleging that the parties' patent-litigation settlements unreasonably restrained trade because the reverse-payment

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5. *See id.* at 218. The scope-of-the-patent test was introduced by the Eleventh Circuit. *See Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) (remanding for consideration of exclusionary scope of patent).

6. 686 F.3d at 205; *see also* U.S. Patent No. 4,863,743 (filed Feb. 19, 1986) (claiming controlled-release dispersible tablet containing ethylcellulose with viscosity greater than forty centipoise).

7. 686 F.3d at 205-06. New drugs must be approved by the FDA before being marketed and sold. *See* 21 U.S.C. § 355(a) (2006). The approval process requires submission of a New Drug Application (NDA) demanding a multitude of information on the drug's safety, efficacy, and method of production, and disclosure of any patents related to its composition or methods of use. *See id.* § 355(b). The patent information submitted in the NDA is published in the FDA Orange Book. *See Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA, <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (last updated Feb. 2013) (listing drug products approved by FDA). A manufacturer of a generic version of a patented drug may file an ANDA, thereby relying on the FDA's prior determinations of safety and efficacy of the patented drug. *See* § 355(j). In connection with the ANDA submission, a generic manufacturer must also file one of four certifications attesting that to its knowledge the generic drug does not infringe on any patent on file with the FDA. *See id.* § 355(j)(2)(A)(vii). Both Upsher and ESI submitted "paragraph IV certifications" with their ANDAs. *See* 686 F.3d at 203-04; *see also* § 355(j)(2)(A)(vii)(IV) (requiring certification "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted"). In particular, Upsher and ESI both certified that their generics would not infringe the '743 Patent. *See* 686 F.3d at 205-06.

8. 686 F.3d at 205-06. When a generic drug manufacturer files a paragraph IV certification it must consult the Orange Book and provide written notice to each patent holder affected by such certification in the ANDA. *See* § 355(j)(2)(B)(iii)(I). Upon notice of a paragraph IV certification, the patent holder has forty-five days to initiate a patent-infringement suit based on this certification alone. *See id.* § 355(j)(5)(B)(iii). A paragraph IV certification constitutes a technical act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A) (2006). If the patent holder initiates an infringement suit within the specified window, the FDA will stay approval of the ANDA until the earlier of thirty months have passed, or the court hearing the infringement suit determines the patent is infringed or invalid. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I).

9. 686 F.3d at 205-06. The Schering-Upsher settlement agreement provided that while Upsher did not concede validity or infringement of Schering's patent, it would refrain from marketing its generic potassium-chloride drug until September 1, 2001. *Id.* at 205. In addition, Upsher granted Schering a license to make and sell certain drugs that Upsher had developed, including Niacor-SR, in consideration for Schering paying Upsher sixty million dollars over three years. *Id.* Subsequent to the agreement, the parties abandoned plans to make Niacor-SR. *Id.* at 206. The Schering-ESI settlement agreement provided ESI with a royalty-free license to make its generic drug beginning on January 1, 2004. *Id.* Schering also paid ESI five million dollars up front and an additional ten million dollars when ESI's ANDA was approved by the FDA in 1999. *Id.*

provisions were intended to improperly preserve Schering's drug-patent monopoly.<sup>10</sup> The FTC Administrative Law Judge originally dismissed the complaint; however, in December 2003, the FTC unanimously reversed, concluding that the reverse payments at issue violated antitrust laws because the parties could not demonstrate their procompetitive effects, or that they were for a purpose other than delaying market entry.<sup>11</sup> After Schering appealed the FTC's ruling, the Eleventh Circuit reversed on grounds that Schering had the right to exclude competitors as the K-Dur patent holder, and that public policy favors settlement of costly litigation.<sup>12</sup>

Wholly independent of the FTC's complaint, a group of wholesalers and retailers that purchased K-Dur directly also filed suit under antitrust law for the alleged illegality of Schering's settlement agreements with Upsher and ESI.<sup>13</sup> These cases were consolidated into the instant class action, *In re K-Dur Antitrust Litigation*.<sup>14</sup> The district court adopted the recommendation of the Special Master and granted summary judgment to Schering, Upsher, and ESI, finding that the settlements were subject to antitrust scrutiny only if they exceeded the scope of Schering's patent or if the underlying claims of patent infringement were objectively baseless.<sup>15</sup> On appeal, the Third Circuit rejected the district court's application of the scope-of-the-patent test and, on remand, directed the district court to instead use a "quick look" rule-of-reason analysis.<sup>16</sup> The Third Circuit further held that the trier of fact must treat any reverse payment to a generic competitor as *prima facie* evidence of an

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10. *Id.* at 206-07. The FTC is empowered to prevent persons, partnerships, or corporations from using unfair methods or deceptive acts or practices in or affecting commerce. See 15 U.S.C. § 45(a)(2) (2006).

11. 686 F.3d at 207. Compare *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1092, 1236, 1243 (2003) (acknowledging explanations for payments to ESI and Upsher other than delayed market entry), *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), with *id.* at 988-89 (recognizing quid pro quo between reverse payment and generic manufacturers' agreement to delay entry).

12. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (setting aside FTC's ruling). The Eleventh Circuit rejected the FTC's conclusion that the sixty million dollars paid to Upsher was independent of the licenses obtained from Schering. See *id.* at 1069-71. The court further acknowledged the reverse payment under the Schering-ESI agreement and found it acceptable in light of judicial policy favoring settlement. See *id.* at 1072.

13. See 686 F.3d at 207-08. Any person injured in his business or property by action forbidden under antitrust laws may bring suit in district court. See 15 U.S.C. § 15.

14. See 686 F.3d at 207-08.

15. See *id.* at 208. The Special Master applied a presumption that Schering's '743 Patent was valid and found Schering could exclude infringing products through the duration of its patent term. *Id.* Schering's exclusionary period under the '743 Patent extended through September 5, 2006; neither the Schering-Upsher nor the Schering-ESI agreement delayed market entry beyond this date. See *In re K-Dur Antitrust Litig.*, No. 01-1652(JAG), 2009 WL 508869, at \*27 (D.N.J. Feb. 6, 2009) (outlining duration of Schering's '743 Patent term), *rev'd*, 686 F.3d 197 (3d Cir. 2012); see also *supra* note 9 (explaining Upsher and ESI reverse-payment agreements only delayed entry until 2001 and 2004, respectively).

16. 686 F.3d at 218. The "quick look" rule-of-reason analysis applies where the defendant allegedly engaged in practices similar to those treated as per se violations. See *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993) (articulating analysis under "quick look" rule-of-reason test). Under the "quick look" test, a defendant has the burden of proving the restraint on trade is justified by procompetitive effects. See *id.*

unreasonable restraint on trade.<sup>17</sup>

When Congress passed the Drug Price Competition and Patent Term Restoration Act—commonly known as the Hatch-Waxman Act (Hatch-Waxman)—its ostensible purpose was to jump-start drug competition and increase availability of low-cost generic drugs to consumers.<sup>18</sup> Hatch-Waxman attempted to balance competing objectives of providing patent protection to stimulate innovation, and creating incentives for competition in the pharmaceutical industry.<sup>19</sup> In its patent jurisprudence, the Supreme Court has also emphasized careful balance between these objectives—specifically the importance of testing and eliminating weak patents.<sup>20</sup>

In the years following enactment of Hatch-Waxman, reverse-payment agreements were used to resolve a number of patent-infringement suits arising under its regulatory framework.<sup>21</sup> In response to concerns about the

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17. 686 F.3d at 218. The court acknowledged this evidence may be rebutted by showing that the purpose of the payment was other than to delay market entry, or that it offered procompetitive benefits. *Id.*

18. *See* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2006)) (establishing ANDA process for generic-drug approval); *see also* S. REP. NO. 107-167, at 4 (2002) (“Under Hatch-Waxman, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices.”).

19. *See* H.R. REP. NO. 98-857, pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714 (explaining bill balances stimulating innovation against goal of furthering public interest). To encourage patent challenges, Hatch-Waxman provides the first successful filer of an ANDA and paragraph IV certification with a 180-day exclusivity period in which no additional ANDAs will be approved, beginning on the date the generic competitor begins commercial marketing. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2006). As a counterbalance, Hatch-Waxman promotes continued development of proprietary drugs by providing patent holders with patent-life extensions to offset delays corresponding to the FDA approval process. *See* 35 U.S.C. § 156 (2006) (outlining requirements to obtain patent-life extensions). In the context of paragraph IV certification patent litigation, the FTC found that generic challengers have prevailed in a majority of cases. *See* FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 16* (2002) [hereinafter *FTC STUDY*], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (concluding generic applicants prevailed in seventy-three percent of litigated challenges).

20. *See* *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993) (illustrating “importance to the public at large of resolving questions of patent validity”); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (“From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.”); *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) (“It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly . . . .”). When a plaintiff challenges the validity of a patent, the plaintiff bears the burden of defeating a presumption of validity; however, the presumption is intended as a procedural device and not a substantive right. *See* *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). When a patent-infringement suit is initiated, the plaintiff (patent holder) bears the burden of proving that the defendant infringed on a valid patent. *See* *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008).

21. *See* S. REP. NO. 107-167, at 4 (recognizing creation of pacts between brand-name and generic drugmakers intended to limit competition); *see also* *FTC STUDY*, *supra* note 19, at 26 (describing settlement agreements involving delay to market); Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 *HARV. J.L. & TECH.* 281, 282 (2011) (noting new settlement agreements concerning patented drugs developed over last decade). Although some commentators argue reverse-payment agreements are a natural byproduct of Hatch-Waxman, there has been just as much criticism of the agreements for promoting an end run around

anticompetitive effects of such agreements, Congress amended Hatch-Waxman, requiring brand-name and generic pharmaceutical companies to file all patent-litigation settlements with the FTC and Department of Justice (DOJ) for antitrust review.<sup>22</sup> The FTC has made reverse-payment settlements a top enforcement priority, estimating these settlements cost consumers billions of dollars annually in prescription-drug savings.<sup>23</sup>

For nearly a decade, the Supreme Court had declined to comment on the legality of reverse-payment agreements, allowing the issue to percolate in the lower courts.<sup>24</sup> Initially, the lower courts reacted to reverse-payment

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litigation. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1614 (2006) (arguing avoidance of litigation under Hatch-Waxman inconsistent with regulatory scheme).

22. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066, 2461-64 (codified as amended at 21 U.S.C. § 355(j) (2006)) (requiring review of reverse-payment agreements by FTC and DOJ). The number of reverse-payment-settlement agreements filed with the FTC continues to increase since this legislative amendment. See Bureau of Competition, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012, FTC, <http://www.ftc.gov/os/2013/01/130117mmareport.pdf> (last visited Feb. 16, 2013) (outlining record number of patent-litigation settlements filed in last fiscal year). Over one-quarter of settlements in fiscal year 2012 involved potential reverse-payment provisions, representing a significant increase from the previous year. See *id.* Resolution of the underlying patent litigation triggered by Hatch-Waxman may be crucial in determining the anticompetitive effects of reverse-payment agreements. See Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 6 (2012) (suggesting validity of patent fundamental to analyzing reverse-payment agreements). If the brand-name drug patent is valid, the reverse-payment agreement may fall within the exclusionary scope of the patent and present no antitrust concern. See *id.* In contrast, if the brand-name drug patent is invalid, then it has no scope and the patent holder is not entitled to eliminate competition from generic competitors through a reverse-payment agreement. See *id.* Antitrust review of reverse-payment agreements is not readily designed to address patent validity issues and has been criticized as the improper vehicle for policing such agreements. See Brief of Amici Curiae Law Professors Gregory Dolin, Kent Bernard, et al. in Support of Respondents at 9-17, *FTC v. Actavis, Inc.*, No. 12-416 (filed Feb. 28, 2013), 2013 WL 840036, at \*9-17 (arguing antitrust law improper tool for assessing patent validity); Dolin, *supra* note 21, at 318-26 (advocating patent-law solution to concerns over reverse-payment agreements). Watson Pharmaceuticals has changed its name to Actavis Inc. since purchasing the drugmaker in October 2012. See *Watson Pharma Changes Name to Actavis Inc.*, BLOOMBERG BUSINESSWEEK, Jan. 24, 2013, <http://www.businessweek.com/ap/2013-01-24/watson-pharma-changes-name-to-actavis-inc-dot>.

23. See Jon Leibowitz, Chairman, FTC, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution) (June 23, 2009), available at <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf> (asserting elimination of reverse payments as high priority); see also FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> (estimating reverse payments cost consumers \$3.5 billion per year). Upon generic market maturation—typically one year after market entry—generic drug prices on average are eighty-five percent lower than brand-name prices. See FTC, *supra*, at 8.

24. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002).

settlements by subjecting them to strict antitrust scrutiny.<sup>25</sup> In later cases, however, the courts tended to apply the scope-of-the-patent test, permitting reverse-payment agreements so long as: market exclusion does not exceed the patent's scope; the patent holder's infringement suit is not objectively baseless; and the patent was not procured by fraud.<sup>26</sup> Members of Congress, who have generally been unhappy with judicial tolerance of reverse-payment agreements, have proposed a number of bills attempting to address the issue.<sup>27</sup> On December 7, 2012, however, the Supreme Court finally agreed to review a recent reverse-payment agreement case in *FTC v. Watson Pharmaceuticals, Inc.*,<sup>28</sup> presumably to resolve the intercircuit conflict over the competitive effects of these agreements.<sup>29</sup>

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25. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (holding reverse payment classic horizontal per se illegal restraint); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 811 (D.C. Cir. 2001) (holding reverse payment preserves monopolistic conditions).

26. See *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1311-13 (11th Cir.) (clarifying reverse-payment analysis does not require evaluating strength of patent, only its scope), *cert. granted*, 133 S. Ct. 787 (2012); *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 110 (2d Cir. 2010) (following precedent in applying scope-of-patent test); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007) (declaring no cognizable antitrust injury if competition restrained within scope of patent); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065-66 (11th Cir. 2005) (acknowledging patent holders' right to exclude competitors and judicial policies favoring settlement); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) (holding patent gives brand-name manufacturer ability to exclude competitors); see also *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 528-29 (E.D. Pa. 2010) (following Eleventh Circuit in applying scope-of-patent test), *abrogated by In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012). In his dissent in *Tamoxifen*, Judge Pooler argued the scope-of-the-patent test "is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 224 (2d Cir. 2006) (Pooler, J., dissenting), *cert. denied*, 551 U.S. 1144 (2007). In *Arkansas Carpenters*, a subsequent Second Circuit reverse-payment case, the judicial panel admitted they thought *Tamoxifen* was decided incorrectly. See *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 108-10 (2d Cir. 2010). Regardless of which antitrust analysis is applied by the courts, most agree that avoiding the merits of underlying patent litigation is acceptable. See J. Thomas Rosch, Comm'r, FTC, Remarks at CBI's 2nd Annual Life Sciences Compliance, Legal, and Regulatory Congress: Pharmaceutical Patent Settlements and the Supreme Court \*4 (Sept. 21, 2012) (transcript available at 2012 WL 4363166) (addressing one similarity in analysis across circuits).

27. See Preserve Access to Affordable Generics Act, S. 214, 113th Cong. § 3 (2013) (providing rebuttable presumption of illegality for reverse payments where generic agrees to delay market entry); Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. § 2(a) (2012) (prohibiting reverse-payment agreements); see also Timothy A. Weil, Note, *Devising a Legislative Solution to the Reverse Payment Dilemma: How Congress Can Balance Competition, Innovation, and the Public Policy Favoring the Settlement of Disputes Without Litigation*, 55 ST. LOUIS U. L.J. 741, 758 (2011) (arguing rebuttable presumption of illegality in legislative bill reconciles need for competition and promoting settlements). But see Dolin, *supra* note 21, at 307-08 (discussing debatable congressional findings supporting legislative efforts); Sandoval, *supra* note 2, at 179 (criticizing lack of reasoning for only regulating settlements concerning patent infringement in pending legislation).

28. 677 F.3d 1298 (11th Cir.), *cert. granted*, 133 S. Ct. 787 (2012).

29. See *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1304-05 (11th Cir.), *cert. granted*, 133 S. Ct. 787 (2012). In *Watson*, brand-name patent holder Solvay Pharmaceuticals and generic manufacturers Watson

In *In re K-Dur Antitrust Litigation*, the Third Circuit considered whether the reverse-payment agreements between Schering, Upsher, and ESI constituted unreasonable restraints on trade.<sup>30</sup> While recognizing the limited monopolies afforded by patent law, the Third Circuit concluded that the scope-of-the-patent test afforded an “almost un rebuttable presumption of patent validity” and, as a practical matter, failed to subject the reverse-payment agreements to any antitrust analysis.<sup>31</sup> The court reasoned that the presumption of patent validity undercut the very issue of the underlying patent litigation and was misguided by the line of Supreme Court precedent on general patent competition.<sup>32</sup> The Third Circuit also reasoned that applying the scope-of-the-patent test in legal challenges to brand-name patents was contrary to the congressional goals of Hatch-Waxman.<sup>33</sup> The court further relied on the balanced goals of Hatch-Waxman in rationalizing the adoption of the “quick look” rule-of-reason analysis on remand.<sup>34</sup>

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Pharmaceuticals and Paddock Laboratories entered into reverse-payment agreements concerning the development of generic versions of a topical testosterone-gel medication. *See id.* (describing circumstances of reverse-payment agreements between parties). The FTC challenged the agreements, alleging that “Solvay was *not likely to prevail*” in its infringement suit against the generic competitors, and that the brand-name patent was “unlikely to prevent generic entry.” *Id.* at 1305-06 (internal quotation marks omitted). The Eleventh Circuit rejected the FTC’s argument and held the agency’s allegation insufficient to state a claim. *See id.* at 1312 (declining to follow rule urged by FTC to adopt). In its petition for certiorari and corresponding brief, the FTC asked the Supreme Court to decide “[w]hether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful.” Brief for the Petitioner at I, *FTC v. Watson Pharm., Inc.*, No. 12-416 (filed Jan. 22, 2013), 2013 WL 267027, at I. The Supreme Court heard oral argument in this case on March 25, 2013 and is anticipated to deliver an opinion near the end of the current term. *See generally* Transcript of Oral Argument, *FTC v. Actavis, Inc.*, No. 12-416 (filed Mar. 25, 2013), *available at* 2013 WL 1193216.

30. *See* 686 F.3d at 202.

31. *See id.* at 214 (identifying no policy supporting presumption of patent validity when analyzing reverse-payment agreements). The court noted that the presumption of validity is merely a procedural device in challenges to patent validity and not a substantive right according to Federal Circuit precedent. *See id.*; *see also supra* note 20 (describing burdens involved in patent validity and infringement litigation). The court recognized—as the defendants conceded—that no reverse-payment suit has progressed to trial when courts applied the scope-of-the-patent test. *See* 686 F.3d at 214.

32. *See* 686 F.3d at 214 (concluding presumption misguided in litigation involving infringement rather than patent validity). The court outlined the long history of Supreme Court cases promoting the testing and elimination of weak patents. *See id.* at 215-16; *see also supra* note 20 and accompanying text (outlining Court’s position on patent competition).

33. *See* 686 F.3d at 214 (reasoning goals of Hatch-Waxman undermined when patent holder pays generic competitor not to compete). Hatch-Waxman intended to increase availability of low-cost generic drugs. *See id.* at 217. The court identified an FTC study from 2002, outlining the high percentage of generic manufacturers that succeeded in their paragraph IV challenges. *See id.* at 215; FTC STUDY, *supra* note 19, at 16 (finding generic manufacturers prevail in seventy-three percent of patent challenges). In reviewing this FTC study and the concession made by the majority in *Tamoxifen*, the court explained, “reverse payments enable the holder of a patent that the holder knows is weak to buy its way out of both competition with the challenging competitor and possible invalidation of the patent.” 686 F.3d at 215 (citing *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 211 (2d Cir. 2006) (“The 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.”)).

34. *See* 686 F.3d at 217.

In reaching its conclusion, the Third Circuit acknowledged its holding ran counter to prevailing judicial policies promoting settlement.<sup>35</sup> Nonetheless, the court determined that the countervailing public-policy objectives outlined in Hatch-Waxman—that patent challenges are necessary to protect consumers from unfettered brand-name-drug-monopoly rents—justified its deviation.<sup>36</sup> The court was also unpersuaded by the Second Circuit’s suggestion that subsequent generic challenges would be able to eliminate weak patents preserved through reverse payments; instead, the court embraced the Federal Circuit’s conclusion that payment flowing from the brand-name patent holder to a generic manufacturer strongly suggests anticompetitive intent.<sup>37</sup>

In analyzing anticompetitive effects of reverse-payment agreements, the Third Circuit properly rejected the scope-of-the-patent test.<sup>38</sup> Both Upsher’s and ESI’s paragraph IV certifications claimed that their respective generic products did not infringe Schering’s ‘743 Patent.<sup>39</sup> Under traditional patent-infringement analysis, the burden lies with the plaintiff to prove that the patent was valid and was otherwise infringed.<sup>40</sup> Presumption of patent validity under the scope-of-the-patent test not only circumvents the plaintiff’s burden of proving infringement, but also improperly affords him the power to exclude generic competitors without adjudicating the merits of the infringement issue—the essence of the underlying litigation.<sup>41</sup> Similarly, the scope-of-the-

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[I]n passing the Hatch-Waxman Act, Congress drew a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical industry. The line that Congress drew between these competing objectives strongly supports the application of rule of reason scrutiny of reverse payment settlements in the pharmaceutical industry.

*Id.* (citations omitted).

35. See *id.* at 217 (explaining Third Circuit decisions generally support settlement).

36. See *id.* (emphasizing statements in legislative record promoting generic patent challenges); see also *supra* note 18 (quoting statement from Senate report regarding goals of Hatch-Waxman).

37. See 686 F.3d at 215 (noting initial generic challenger has most motivation due to 180-day exclusivity period); *id.* at 218 (embracing approach by *Andrx* court by inferring anticompetitive intent of parties in reverse payments). Additionally, the court agreed with the principle the FTC set forth in *In re Schering-Plough Corp.*, which stated that “[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.” See *In re Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003) (citations omitted); see also 686 F.3d at 218 (disregarding merits of underlying patent litigation).

38. See 686 F.3d at 214 (criticizing application of scope-of-patent test where underlying suit involves patent infringement); see also Carrier, *supra* note 22, at 7 (arguing scope-of-patent test inappropriate for analyzing noninfringement claims). In patent-infringement litigation, the patent must be valid and infringed for the patent holder to prevail; acknowledging mere existence of the patent under scope-of-the-patent analysis does not resolve infringement. See Carrier, *supra* note 22, at 7 (arguing inapplicability of scope-of-patent test to infringement suits).

39. See 686 F.3d at 205-06 (stating Upsher and ESI paragraph IV certifications claimed noninfringement of ‘743 Patent).

40. See *supra* note 20 (summarizing burdens of proof in patent validity and infringement suits).

41. See Carrier, *supra* note 22, at 7 (cautioning presumption of patent validity only procedural device); Dolin, *supra* note 21, at 322-24 (recommending reverse-payment analysis addresses brand-name patent

patent test cannot account for the nuanced implications of whether the generic competitor or patent holder would prevail in patent litigation.<sup>42</sup>

By adopting the “quick look” rule-of-reason analysis, the Third Circuit essentially retreated to the application of a per se rule and held that reverse-payment agreements are presumptively anticompetitive.<sup>43</sup> In doing so, the court clearly departed from, and contradicted, other circuits’ reasoning and holdings as they relate to the exact same type of reverse-payment agreements.<sup>44</sup> On the other hand, the presumption of anticompetitive effect serves to discourage brand-name patent holders and generic competitors from entering into reverse-payment agreements, and promotes consumer access to generic drugs through litigated challenges, as Hatch-Waxman originally contemplated.<sup>45</sup> Notwithstanding the resulting intercircuit conflict, the Third Circuit’s holding is similar to the scope-of-the-patent test in one respect—both avoid considering the merits of the underlying patent suit.<sup>46</sup> It is precisely this similarity that leads to the unsatisfactory resolution by the judiciary on the competitive effects of reverse-payment agreements using antitrust principles.<sup>47</sup> In order to fully appreciate the competitive effects of these agreements, a court must look beyond the mere existence of a reverse-payment agreement.<sup>48</sup>

The question before the Supreme Court in *FTC v. Watson Pharmaceuticals, Inc.* posits a choice between applying the scope-of-the-patent test and the

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validity); Sandoval, *supra* note 2, at 163-64 (suggesting plaintiff’s burden to prove infringement undermined by scope-of-patent-test); *see also supra* note 33 (quoting Second and Third Circuits’ conclusions that reverse payments may benefit weak patents).

42. *See supra* note 22 and accompanying text (illustrating potential competitive effects of reverse-payment agreements dependent on patent validity determinations); *see also* Dolin, *supra* note 21, at 284 (explaining test cannot account for consumer benefit in certain cases where patent holder prevails).

43. *See* 686 F.3d at 218 (directing lower court to apply “quick look” test); *see also* Rosch, *supra* note 26, at \*4 (noting similarity of Third Circuit test to per se unlawful standard).

44. *See* 686 F.3d at 218 (refusing to follow other circuits in applying scope-of-patent test); *see also supra* note 26 (highlighting recent circuit case adopting scope-of-patent test). *Compare* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005) (holding no antitrust violation for reverse payments to generic competitors), *with* 686 F.3d at 218 (holding reverse payment treated as prima facie evidence of unreasonable restraint on trade).

45. *See* Hemphill, *supra* note 21, at 1614 (stating Hatch-Waxman deliberately promotes litigated challenges). “Since litigation is the instrument by which the [Hatch-Waxman] regulatory arrangement accomplishes its ends, it is difficult to argue that an end-run on the instrument is consistent with the scheme.” *Id.*

46. *See* 686 F.3d at 218 (agreeing consideration of merits of underlying patent suit unnecessary); *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1313-15 (11th Cir.) (concluding retrospective inquiry into merits of patent suit not practical), *cert. granted*, 133 S. Ct. 787 (2012); *see also* Rosch, *supra* note 26, at \*4 (noting one similarity in analysis across circuit courts).

47. *See* Carrier, *supra* note 22, at 6 (asserting patent-validity determination central to analyzing pharmaceutical settlements); Dolin, *supra* note 21, at 318 (arguing competitive effects of settlement turn on likely conclusion of underlying patent litigation).

48. *See* Brief of Amici Curiae Law Professors Gregory Dolin, Kent Bernard, et al. in Support of Respondents, *supra* note 22, at 3-4 (arguing competitive effects of patent validity impossible to assess by existence of reverse-payment agreement alone); *supra* note 22 (resolving underlying patent dispute crucial in analysis of reverse-payment agreements).

“quick look” rule-of-reason analysis adopted by the Third Circuit.<sup>49</sup> The Court explored alternative methods during recent oral argument in the case, including the full-blown rule-of-reason approach and a five-factor analysis fashioned by Justice Breyer.<sup>50</sup> Both alternatives remain grounded in antitrust jurisprudence, are disfavored by the parties, and garner criticism from fellow Justices.<sup>51</sup> In the days leading up to the anticipated opinion in *FTC v. Watson Pharmaceuticals, Inc.*, the Court should strongly consider whether antitrust laws provide the most suitable vehicle for policing reverse-payment agreements.<sup>52</sup>

In *In re K-Dur Antitrust Litigation*, the Third Circuit examined whether reverse-payment-settlement agreements between a brand-name drug manufacturer and its generic competitors violated the Sherman Act by amounting to unreasonable restraints on trade. By weighing the competing objectives under Hatch-Waxman and observing the relevant patent-competition precedent, the Third Circuit properly rejected the scope-of-the-patent test for reviewing reverse-payment agreements. The Third Circuit’s holding, however, perpetuates an intercircuit conflict concerning the anticompetitive effects of these agreements and continues to ignore the merits of the underlying patent suit. Although the Supreme Court is positioned to rule on the legality of reverse-payment agreements in *FTC v. Watson Pharmaceuticals, Inc.* later this year, the Court should reevaluate whether antitrust laws are the appropriate tool for addressing concerns regarding the anticompetitive effects of reverse-payment agreements between brand-name patent holders and their generic competitors.

*Abbey P. Coffin*

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49. See Brief for the Petitioner, *supra* note 29, at 1 (stating question presented before Court).

50. See Transcript of Oral Argument, *supra* note 29, at 13-18, 21-22 (discussing alternative rule-of-reason and factor-based approaches).

51. See *supra* note 1 (describing antitrust rule-of-reason doctrine); see also Transcript of Oral Argument, *supra* note 29, at 22, 38 (rejecting rule-of-reason and factor-based analysis suggestions).

52. See Transcript of Oral Argument, *supra* note 29, at 10-11 (suggesting Court should not rectify congressional mistake under Hatch-Waxman); Brief of Amici Curiae Law Professors Gregory Dolin, Kent Bernard, et al. in Support of Respondents, *supra* note 22, at 9-17 (opining antitrust laws ineffective tool for policing reverse-payment agreements); Carrier, *supra* note 22, at 8 (arguing scope-of-the-patent test cannot resolve whether settlements violate antitrust laws); Dolin, *supra* note 21, at 318-26 (advocating patent-law solution to concerns over reverse-payment agreements); see also *supra* note 27 and accompanying text (describing proposed legislative solutions to concerns regarding reverse-payment agreements).