UNC SCHOOL OF LAW

NORTH CAROLINA JOURNAL OF LAW & TECHNOLOGY

Volume 14
Issue 1 *Fall 2012*

Article 9

10-1-2012

In Re K-Dur Antitrust Litigation: Pharmaceutical Reverse Payment Settlements Go beyond the Scope of the Patent

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NORTH CAROLINA JOURNAL OF LAW & TECHNOLOGY
VOLUME 14, ISSUE 1: FALL 2012

IN RE K-DUR ANTITRUST LITIGATION: PHARMACEUTICAL REVERSE PAYMENT SETTLEMENTS GO BEYOND THE "SCOPE OF THE PATENT"

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Reverse payment settlements occur in patent infringement suits by innovative drug manufacturers against potential generic manufacturers under the Hatch-Waxman Act, where the innovator pays the generic and the latter agrees to delay market entry. Three circuit courts have endorsed such settlements under the "scope of the patent" ("SOP") test. In In re K-Dur Antitrust Litigation, *the Third Circuit rejected the SOP test, holding that reverse payment settlements are presumptively illegal. Reverse payment settlements typically involve monopoly sharing and warrant antitrust scrutiny.* K-Dur*'s presumptive illegality approach, as compared to the extremely deferential SOP test, the over-inclusive* per se *approach, or the prohibitively complex full "rule of reason" analysis, is the best practicable judicial approach. Congress and the federal agencies should implement policies to enhance public interest in both a fair competitive market and innovative drug development.*

I. INTRODUCTION

Developing an innovative drug is a risky investment.[1] Creating a "new chemical entity" takes ten to fifteen years and costs more than $1 billion.[2] Additionally, the Food and Drug Administration

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[1] U.S. CONG., OFFICE OF TECH. ASSESSMENT, OTA-H-522, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS, at iii (1993), *available at* http://www.fas.org/ota/reports/9336.pdf.

[2] Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J.

("FDA") approves only five of 5,000 drugs that begin preclinical testing.[3] A patent on an innovative drug has an important role in encouraging innovative drug development [4] and incentivizing studies of new indications or applications of already patented drugs.[5]

After a patent has expired, or has been challenged and invalidated, the patented product passes into the public domain.[6] Upon FDA approval, a generic version of the same drug may be produced and marketed by anyone.[7] While the FDA requires that a generic drug have the same quality and efficacy as its innovative counterpart,[8] some practical and substantive differences can exist between generic and innovative drugs. First, a huge price difference exists—the cost of a generic drug is about eighty to eighty-five percent lower than its innovative counterpart on average.[9] Secondly, inactive ingredients may differ between a generic drug and its innovative counterpart.[10] Thirdly, a generic

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417, 418 (2011) (quoting FOOD AND DRUG LAW: CASES AND MATERIALS 577 (3d ed. 2007)); *see also* CONG. BUDGET OFFICE, PUB. NO 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 2, 19–22 (2006) (discussing that, in 2000, developing an innovative drug of a new molecular entity took about twelve years and cost more than $800 million, including expenditures on failed projects and the value of forgone alternative investments).

[3] Kelly, *supra* note 2, at 418.

[4] *See Pharmaceutical Patents: The Value of Pharmaceutical Patents & Strong Intellectual Property Protection*, INNOVATION.ORG 5, http://www.innovation.org/documents/File/Pharmaceutical_Patents.pdf (last visited Dec. 27, 2012) ("[P]atents are a fundamental incentive to innovative activities in pharmaceuticals and biotechnology." (internal citation omitted)).

[5] *See generally* Henry Grabowski et al., *Does Generic Entry Always Increase Consumer Welfare?*, 67 FOOD & DRUG L.J. 373 (2012) (discussing consumers' interest in innovative drug development, including clinical studies of already patented drugs for new use indications).

[6] *See* 35 U.S.C. § 102 (2006).

[7] *See id.*

[8] U.S. FOOD & DRUG ADMIN., FACTS ABOUT GENERIC DRUGS, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (last visited on Nov. 16, 2012).

[9] *Id.*

[10] *Id.* ("Generic drugs do not need to contain the same inactive ingredients as the brand name product."). An inactive ingredient unique to a generic drug (or,

drug and its innovative counterpart may look different—courts have traditionally recognized an innovator's "trade dress" right that the appearance of an innovative drug not be mimicked by others.[11]

As much as consumers benefit when innovative drugs become available, they also benefit when low-cost generic drugs become available. The FDA estimates that the use of FDA-approved generic drugs saved consumers $158 billion in 2010, an average of $3 billion per week.[12] While cost is just one of several considerations when choosing between innovative and generic drugs,[13] the availability of options is advantageous for consumers.

Congress intended to promote consumer benefits from generic market entry as well as innovative drug development when it

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conversely, an innovative drug) may cause side effects, including allergic reactions. DEPRESSION AND BIPOLAR SUPPORT ALLIANCE, GENERIC AND BRAND NAME DRUGS: UNDERSTANDING THE BASICS 4 (2007), *available at* www.dbsalliance.org/pdfs/GenericRx.pdf.

[11] Jeremy A. Greene et al., *Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health*, 365 NEW ENG. J. MED. 83, 83–84 (2011). The article discusses further that trade dress rights were historically recognized to prevent the sale of counterfeit products. *Id.* In the modern context of innovative and generic drugs, where the FDA approves only those generic drugs that have efficacy equivalent to innovative counterparts, the article recommends a policy to encourage similar appearances between innovative and generic drugs to minimize consumers' confusion. *Id.* at 87–88.

[12] *See* U.S. FOOD & DRUG ADMIN., *supra* note 8 (citing GENERIC PHARMACEUTICAL ASS'N, SAVINGS: AN ECONOMIC ANALYSIS OF GENERIC DRUG USAGE IN THE U.S. (2011), *available at* http://patentdocs.typepad.com/files/gpha-ims-study-web-sep20-11.pdf). *But see* Grabowski, *supra* note 5, at 375–82 (discussing that generic market entry may disadvantage consumers). Generic market entry disincentivizes innovator drug companies from promoting their innovative drugs with free sample distribution. *Id.* at 375–80. An innovative drug with free samples may cost consumers less than a generic drug. *Id.* Further, generic market entry may disincentivize an innovator drug company to conduct costly clinical studies for new indications of the drug at issue because the innovator drug company will no longer be able to gain enough profit from the sales of the innovative drug to fund such clinical studies. *Id.* at 380–82.

[13] *See* DEPRESSION AND BIPOLAR SUPPORT ALLIANCE, *supra* note 10, at 6–7 (discussing other factors such as "medical histories, insurance, and personal preferences").

passed the Hatch-Waxman Act[14] in 1984.[15] The Act was initially successful in encouraging challenges for innovative drug patents and, therefore, in facilitating generic market entry: Consumers saved almost ten billion dollars from the introduction of generic competition with Prozac (an antidepressant), Zantac (an antacid), Taxol (an anti-cancer drug), and Plantinol (an anti-cancer drug) in the 1990's alone.[16] At the same time, however, the Hatch-Waxman framework caused pharmaceutical companies to "game" this complex statute to their benefit.[17]

One of the major gaming activities was a "reverse payment settlement" by an innovative drug company to its generic challenger in patent challenge cases brought under the Hatch-Waxman framework.[18] The settlement payment, usually millions of dollars, [19] flows from the plaintiff (patent holder) to the

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[14] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); 21 U.S.C. § 355 (1984) (amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399) (codified as amended at 21 U.S.C. § 355 (2006)).

[15] Kelly, *supra* note 2, at 421 (discussing the dual motivations of Congress to encourage generic market entry and to encourage innovation and development of new drugs); *see* H.R. REP. NO. 98-857, pt. 1, at 15–17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648–50.

[16] Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39 (2009) (citing *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before the S. Comm. on Commerce, Science, & Transp.*, 107th Cong. 61 (2002) (statement of Kathleen F. Jaeger, President and CEO, Generic Pharm. Ass'n), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-107shrg90155/pdf/CHRG-107shrg90155.pdf).

[17] Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 687, 709 (2009) (explaining that the very regulatory structure that exists to promote competition can ironically create gaming opportunities for competitors bent on achieving anticompetitive goals, and that such "regulatory gaming" is particularly common in pharmaceutical industries).

[18] Carrier, *supra* note 16, at 51.

[19] *See e.g.*, *In re* K-Dur Antitrust Litig., 686 F.3d 197, 205 (3d Cir. 2012) (involving a reverse payment of $60 million over three years); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006) (involving a reverse payment of $21 million); Andrx Pharmaceuticals, Inc. v. Biovail Corp., 256

defendant (alleged patent infringer) "in reverse" of a regular settlement, in return for delaying market entry of generic drugs.[20] A reverse payment settlement is distinct from a typical settlement in that the settling parties share aligned incentives to create a monopoly and share the monopoly deals at the expense of consumers.[21]

Despite the anticompetitive nature of reverse payment settlements, three circuit courts have held that such payments do not violate antitrust law.[22] These courts have used the "scope of the patent" ("SOP") test, which essentially shields any reverse payment settlement made within the scope of the patent from antitrust scrutiny.[23] By contrast, in the recent groundbreaking

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F.3d 799, 804 (D.C. Cir. 2001) (involving four quarterly reverse payments totaling $40 million).

[20] Erica N. Andersen, Note, Schering *the Market: Analyzing the Debate over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and* In re Tamoxifen Citrate Litigation, 93 IOWA L. REV. 1015, 1024 (2008). A "pay-for-delay" settlement is a more descriptive naming of a reverse payment settlement. Herbert J. Hovenkamp, *Antitrust and Patent Law Analysis of Pharmaceutical Reverse Payment Settlements* 1 (Jan. 15, 2011) (unpublished working paper) (on file with the University of Iowa College of Law), *available at* http://dx.doi.org/10.2139/ssrn.1741162.

[21] Carrier, *supra* note 16, at 39–40 (articulating the aligned incentive for monopoly, where the innovative company gains profits from delayed generic entry and the generic company receives more money than it would gain by entering the market).

[22] *See* Fed. Trade Comm'n v. Watson Pharms., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1341 (Fed. Cir. 2008); *Tamoxifen*, 466 F.3d at 216.

[23] *See Watson*, 677 F.3d at 1312 ("Our *Valley Drug*, *Schering-Plough*, and *Andrx* decisions establish the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." (footnote omitted)); *Ciprofloxacin*, 544 F.3d at 1336 ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."); *Tamoxifen*, 466 F.3d at 213 ("Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent."); *see infra* Part III.A.

decision of *In re K-Dur Antitrust Litigation*,[24] the Third Circuit rejected the widely-accepted SOP test and held that payment in exchange for delayed market entry of generic drugs is presumptively an unreasonable restraint of trade in violation of antitrust law.[25]

Reverse payment settlements are often monopoly agreements that warrant antitrust scrutiny.[26] In addition, a reverse payment agreement does not seem to be essential for a mutually beneficial settlement. [27] *K-Dur*'s presumptive illegality approach, as compared to the extremely deferential SOP test, the over-inclusive *per se* approach,[28] or the prohibitively complex full "rule of reason" analysis,[29] is the best and fairest practicable judicial approach.

This Recent Development argues that *K-Dur*'s presumptive illegality approach is the better judicial approach to reverse payment settlements than the classical SOP test or other antitrust standards. This Recent Development also discusses anticipated social and economic impacts of the *K-Dur* decision, and advocates for the role of Congress and the federal agencies, such as the FDA and the Federal Trade Commission ("FTC"), in relevant policymaking. Part II reviews the Hatch-Waxman framework and a basic structure for antitrust scrutiny. Part III outlines the courts'

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[24] 686 F.3d 197 (3d Cir. 2012).

[25] *Id.* at 218.

[26] The economic effect of delayed generic market entry can be enormous. For the twenty-one settlements with reverse payments that occurred between 1993 and 2008, "a one-year delay in generic entry represents, under conservative assumptions, a transfer from consumers to manufacturers producers of at about $14 billion." C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 650 (2009).

[27] *See* Ian Hastings, *Dynamic Innovative Inefficiency in Pharmaceutical Patent Settlements*, 13 N.C. J.L. & TECH. 31, 44 (2011) (discussing that a settlement is traditionally far safer than trials for parties to a patent challenge suit, which is often lengthy, expensive, and unpredictable); Carrier, *supra* note 16, at 74–75 (observing that reverse payments decreased when the FTC enforced scrutiny and increased when circuit courts upheld reverse payment settlements); *infra* notes 149–56 and accompanying text.

[28] *See infra* Part IV.B.1.

[29] *See infra* Part IV.B.2.

approach to addressing reverse payment settlements prior to and in the *K-Dur* decision. Part IV discusses the strengths of the *K-Dur* approach over the SOP test or other antitrust inquiries. Finally, Part V analyzes potential social and economic consequences of *K-Dur*, and advocates that Congress, the FDA, and the FTC are in the best position to ensure a fair pharmaceutical market while encouraging innovative drug development through policymaking.

II. THE HATCH-WAXMAN ACT AND THE STRUCTURE OF ANTITRUST SCRUTINY

Pharmaceutical reverse payment settlements uniquely arose under the Hatch-Waxman framework,[30] invoking the historic tension between patent and antitrust law.[31] To analyze debates over reverse payment settlements, it is critical to understand the Hatch-Waxman Act and the structure of antitrust scrutiny.

A. *The Hatch-Waxman Act of 1984*

To market an innovative drug, an innovator drug company must file a New Drug Application ("NDA") with the FDA.[32] The NDA must address the following: detailed safety and efficacy studies; the components of the drug; the method used in the manufacture, process, and packaging of the drug; and patents issued on the drug.[33] Before the Hatch-Waxman Act, marketing of a generic drug also required an NDA based on safety and efficacy studies conducted independently from those of its bioequivalent innovative drug.[34] To avoid being sued for a patent infringement, a generic company had to wait until the term of the innovative drug patent expired before it started conducting studies on a generic version.[35]

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[30] *See* CHILTON DAVIS VARNER & ANDREW T. BAYMAN, REGULATION OF PHARMACEUTICAL MFRS. § 4.02 8 (ALM Media Properties, LLC, 2012).

[31] *See* Steven W. Day, Note, *Leaving Room for Innovation: Rejecting the FTC's Stance Against Reverse Payments in* Schering-Plough v. FTC, 57 CASE W. RES. L. REV. 223, 223 n.2 (2006).

[32] *See* 21 U.S.C. § 355(a) (2006).

[33] *Id.* § 355(b)(1).

[34] Andersen, *supra* note 20, at 1019.

[35] *Id.*

Congress passed the Hatch-Waxman Act in 1984 to "make available more low cost generic drugs."[36] The Act allows a manufacturer of a new generic drug to file an Abbreviated New Drug Application ("ANDA") with the FDA.[37] In an ANDA, a generic manufacturer must prove that the new drug is a bioequivalent of an innovative drug on the market, but is exempt from independent safety and efficacy studies as required for an NDA.[38] When a generic manufacturer files an ANDA, it is required to certify that, to the best of the applicant's knowledge, the proposed generic drug does not infringe any valid patent listed with the FDA.[39] The generic manufacturer can satisfy this requirement by certifying one of the four criteria with respect to the patent for the listed drug:

> (I) that such patent information has not been filed,
> (II) that such patent has expired,
> (III) of 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 new drug for which the application is submitted.[40]

Filing by a generic manufacturer of an ANDA with the paragraph IV certification constitutes a technical act of patent infringement.[41] Therefore, an innovator drug company (i.e., patent holder) may initiate an infringement suit based on the filing of the paragraph IV certification alone within forty-five days after the filing.[42] If no suit is brought during this period, the FDA may immediately approve the ANDA application.[43] If a suit is timely filed, an automatic stay is granted, preventing the FDA from approving the

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[36] H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

[37] 21 U.S.C. § 355(j)(1) (2006).

[38] *See id.* § 355(2)(A).

[39] *Id.* § 355(j)(2)(A)(vii).

[40] *Id.* Further, if there is more than one patent covering a drug, all of them have to be invalidated for the ANDA filer to be successful in a paragraph IV filing. *See id.*

[41] 35 U.S.C. § 271(e)(2)(A) (2006). Even though the generic has not yet begun marketing its version of the drug, it has intent to market and infringe the patent. Andersen, *supra* note 20, at 1020 & n.26.

[42] 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

[43] *Id.*

generic drug: (1) for thirty months; or (2) until the court finds that the challenged patent is either invalid or not infringed, whichever is earlier.[44]

Multiple companies may file an ANDA for the same drug.[45] A 180-day market exclusivity period, however, is awarded only to the first filer of an ANDA with a paragraph IV certification.[46] During the exclusivity period, the FDA will not approve any subsequent ANDA applications for the drug, therefore, the first-filer will be the only generic manufacturer that competes with the innovative drug in the market.[47]

B. *Amendment of the Hatch-Waxman Act in the Medicare Modernization Act of 2003*

Some pharmaceutical companies took advantage of the Hatch-Waxman provisions for their anticompetitive benefits. In 2003, Congress passed the Medicare Modernization Act ("MMA")[48] to amend the Hatch-Waxman Act and address such "regulatory gaming." The MMA included the following three amendment provisions.[49]

1. *Only One Stay per ANDA*

If a suit is timely filed in response to an ANDA with a paragraph IV certification, an automatic stay of the ANDA approval is granted, as discussed in Part II.A.[50] The original Act did not limit the number of consecutive stays an innovator drug company could invoke.[51] After a generic manufacturer had filed an ANDA and an automatic stay had been triggered, the innovator drug company could list additional patents on the drug in the

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[44] *Id.*

[45] *See id.* § 355(j)(5)(B)(iv).

[46] *Id.*

[47] *Id.*

[48] Medicare 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 (2006)).

[49] *See* Dogan & Lemley, *supra* note 17, at 687 (defining "regulatory gaming" as anticompetitive activities of competitors gaming with loopholes of the very regulatory structure aiming to promote competition).

[50] Andersen, *supra* note 20, at 1020–21.

[51] *Id.*

Orange Book[52] and trigger additional automatic stays.[53] These provisions led to abuse of the system by innovator drug companies, who would file frivolous patents to stall generic entry.[54]

In the MMA of 2003, Congress limited an innovator to one stay per ANDA, and that stay only takes effect when an innovator drug company alleges infringement of a patent already listed in the Orange Book at the time of the ANDA filing.[55]

2. *A "Use It or Lose It" Provision for the 180-Day Market Exclusivity Period*

In the original Act, a 180-day market exclusivity period was triggered either (1) when the first ANDA filer began marketing its generic drug, or (2) when the court ruled for the ANDA filer in the patent infringement suit, whichever is earlier.[56] The FDA interpreted that the provision (2) is triggered only by a successful ruling for the first-filer, but not a successful ruling by subsequent ANDA filers.[57] If the first-filer and the innovator settled the infringement suit and the first-filer did not bring its generic product to market, neither trigger would start the first-filer's 180-day exclusivity period. Accordingly, a subsequent filer of an ANDA is prohibited from marketing its generic drug until after the first-filer's exclusivity period has ended. Therefore, the settling first-filer and innovator could effectively "bottleneck" the market by preventing any other generic from selling the drug.[58]

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[52] The Orange Book search is available electronically. *See* FED. DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm (last visited Nov. 17, 2012).

[53] Andersen, *supra* note 20, at 1020–21.

[54] *Id.* at 1021.

[55] *See id.* (citing the Medicare Modernization Act at 2448–54). In 2003, the FDA also limited the types of patents that a pioneer could list in the Orange Book because certain classes of patents were being filed frivolously by innovators. *Id.* at 1021 n.32.

[56] 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

[57] Andersen, *supra* note 20, at 1022 n.38.

[58] "Bottlenecking" (slowing or stopping competition in a market) in the Hatch-Waxman context refers to the practice of preventing all subsequent generic entry by manipulating the 180-day exclusivity period. *Id.* at 1022 &

In the MMA of 2003, Congress dropped the court-decision trigger of provision (2) and implemented a "use it or lose it"[59] regime.[60] The 180-day market exclusivity period is now triggered solely by the first-filer's entry into the market; however, the first-filer who does not market within a certain period will lose market exclusivity.[61] The first-filer must now market within seventy-five days after the final approval of the ANDA or within thirty months after filing the ANDA, whichever comes first.[62] This amendment would alleviate some of the bottlenecking problems.[63]

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n.39. "Bottlenecking" was at issue in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), and *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). *See infra* note 86 and accompanying text. In 1998, the D.C. Circuit held that provision (2) can be triggered by a successful infringement suit by subsequent filers, not only the first-filer. *See* Andersen, *supra* note 20, at 1022 (discussing *Mova Pharm Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998)). Therefore, another generic manufacturer could challenge the patent and trigger the first-filer's market exclusivity period to run. *Id.* This holding partially alleviated the bottlenecking. *Id.*

[59] *See* Carrier, *supra* note 16, at 48.

[60] 21 U.S.C. § 355 (2006); *see* Carrier, *supra* note 16, at 47–48.

[61] *See* 21 U.S.C. § 355.

[62] *Id.* The MMA further provides that as long as the first-filer "lawfully maintained" its paragraph IV certification, such as by litigating the infringement suit to the end, it may maintain the exclusivity period. *Id.*

[63] *See* Carrier, *supra* note 16, at 49. A close reading of the "use it or lose it" statutory amendment, however, reveals that it may not necessarily trigger forfeiture of a market exclusivity period when the ANDA first filer does not "use it." *See id.* at 48. The forfeiture provisions provide that the first-filer will lose exclusivity if it:

> [F]ails to market the drug by the later of—
> (aa) the earlier of the date that is—
> (AA) 75 days after the date on which the approval of the application of the first applicant is made effective . . . ; or
> (BB) 30 months after the date of submission of the application of the first applicant; or
> (bb) . . . the date that is 75 days after the date as of which . . . at least 1 of the following has occurred:
> (AA) In an infringement action . . . a court enters a final decision . . . that the patent is invalid or not infringed.
> (BB) In an infringement action . . . a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

3. *Antitrust Review by the Federal Trade Commission and the Department of Justice*

Soon after Congress passed the Hatch-Waxman Act, innovator and generic pharmaceutical companies started to settle the Hatch-Waxman patent infringement suits by reverse payment settlements.[64] With a reverse payment settlement, an innovator drug company may exclude competition and enjoy exclusive marketing of the innovative drug, while a generic drug manufacturer enjoys more financial gain than it would have had by marketing its generic drug in the agreed market-delay period.[65] Concerned about the possible anticompetitive effects of reverse payment settlements, Congress amended the Hatch-Waxman Act in the MAA of 2003 to require that pharmaceutical companies file patent litigation settlement agreements with the FTC and the Department of Justice for antitrust review.[66]

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21 U.S.C. § 355(j)(5)(D)(i)(I). The "use it or lose it" provision, codified in (aa), will trigger forfeiture of the exclusivity period only when they occur *later* than the (bb) triggers. Therefore, the parties can bottleneck the market when the (bb) triggers do not occur, that is, until an ANDA-filer *wins* in court. If no ANDA filer wins against the innovator in court, either through a judicial decision or a settlement, the (bb) triggers do not take place, and the forfeiture will not be triggered. *See Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution: Hearing Before the S. Comm. on the Judiciary*, 110th Cong., at 9 (2007) (statement of Jon Leibowitz, Comm'r, Fed. Trade Comm'n), *available at* http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlementssenate.pdf ("[A]lthough a first-filer can forfeit its exclusivity under certain conditions, ordinarily it will be entitled to 180 days of exclusivity."); Carrier, *supra* note 16, at 48–49; Hastings, *supra* note 27, at 41–43; Andersen, *supra* note 20, at 1024.

[64] *See* Carrier, *supra* note 16, at 48–49.

[65] *Id.*

[66] Medicare 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 (2006)). If the FTC or Attorney General subsequently files an antitrust complaint and a court finds for the antitrust plaintiff, the defendant first ANDA filer may lose its 180-day market exclusivity period. *Id.*

C. *Structure of Antitrust Scrutiny*

Courts scrutinize commercial practices under the Sherman Act[67] to determine whether the questioned practice imposes an unreasonable restraint on trade.[68] The following three antitrust standards are commonly used.

1. *The "Rule of Reason" Analysis*

The general approach is the "rule of reason" analysis.[69] This antitrust inquiry consists of three parts.[70] First, the antitrust plaintiff must show that the challenged conduct has produced anticompetitive effects within the market.[71] Second, if the plaintiff meets the initial burden, the burden shifts to the defendant to show that the questioned conduct offers a pro-competitive objective.[72] Finally, the plaintiff may rebut the defendant's justification by showing that the restraint was not reasonably necessary to achieve the pro-competitive objective.[73] The rule of reason analysis requires a weighing of all the relevant circumstances of a case, including market power, the structure of the market, specific information about the relevant business, and the history, nature, and effect of the restraint.[74] A thorough investigation of the industry under review and a balancing of the restraint's positive and negative effects on competition are required.[75]

2. *The* Per Se *Rule*

Courts have recognized that "[s]ome types of restraints . . . have such predictable and pernicious anticompetitive effect, and such limited potential for pro-competitive benefit, that they [should

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[67] 15 U.S.C. § 1 (2006).

[68] *See* State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

[69] *Id.*

[70] *Id.*

[71] U. S. v. Brown Univ., 5 F.3d 658, 668 (3d Cir. 1993).

[72] *Id.* at 669.

[73] *Id.*

[74] *Id.*

[75] THOMAS V. VAKERICS, ANTITRUST BASICS § 1.03, at 1–3 (ALM Media Properties, LLC, 2012).

be] deemed unlawful *per se*."[76] Unlawful practices under the *per se* rule include horizontal price fixing, output limitations, market allocation, and group boycotts.[77] "[T]o condemn a restraint as *per se* illegal, the courts must have had sufficient experience with the particular type of restraint to be able to predict . . . the rule of reason would also condemn the same restraint."[78]

3. *The " 'Quick Look' Rule of Reason Analysis"*[79]

The " 'quick look' rule of reason analysis"[80] is an intermediate standard of antitrust analysis in between the full "rule of reason" inquiry and the *per se* approach. A "quick look rule of reason" inquiry is applied where the plaintiff has shown that the defendant has engaged in practices similar to those subject to per se treatment.[81] Having so shown, a plaintiff is not required to make a full showing of anticompetitive effects within the market. Rather, the defendant has the burden of demonstrating pro-competitive justifications.[82]

III. JUDICIAL APPROACHES TO REVERSE PAYMENT SETTLEMENTS

The FTC has consistently struck down reverse payment settlements as an unreasonable restraint of trade, and therefore a violation of antitrust law.[83] Some pharmaceutical companies have appealed the FTC decisions to the district courts.[84] Apart from the

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[76] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 209 (3d Cir. 2012) (quoting State Oil Co. v. Khan, 522 U.S. 3, 10 (1997)).

[77] *See K-Dur*, 686 F.3d at 209 (citing Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984); N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958)).

[78] VAKERICS, *supra* note 75, at 6.

[79] *Id.* at 4.

[80] *Id.*

[81] United States v. Brown Univ., 5 F.3d 658, 669 (3d Cir. 1993).

[82] *Id.*

[83] *See e.g.*, *In re* Schering-Plough Corp., 136 F.T.C. 956, 1052, 1056–57 (2003).

[84] When the FTC brings antitrust suit against an entity, it is first adjudicated by an administrative law judge, followed by the FTC's final decision. *See* 15

FTC, direct and indirect purchasers of drugs also brought antitrust suit against pharmaceutical companies.[85] Approaches of courts to reverse payment settlements are discussed in this Part.

A. *Judicial Approaches to Reverse Payment Settlements Prior to* K-Dur

Circuit courts are divided on the issue of whether reverse payment settlements are an unreasonable restraint of trade. First two circuit court decisions sided with the FTC. In 2001, the Federal Circuit held that "bottlenecking" [86] was prima facie evidence of an illegal agreement not to compete.[87] In 2003, the Sixth Circuit held that an agreement to not only delay market entry of the drug under patent challenge, but also other drugs, was a horizontal agreement to eliminate competition and a *per se* illegal restraint of trade.[88]

U.S.C. § 45 (2006). The case can subsequently be appealed to a district court, then to a circuit court. *See id.*

[85] These cases are brought directly to a district court. *See, e.g.*, *In re* K-Dur Antitrust Litig., 686 F.3d 197, 207 (3d Cir. 2012) (Forty-four wholesalers and retailers joined as antitrust plaintiffs.); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 896 (6th Cir. 2003) (The suit was brought by indirect and direct purchasers.).

[86] See *supra* note 58 for a discussion of bottlenecking. The *Andrx* decision was adopted in the *K-Dur* decision, although *K-Dur*, unlike *Andrx*, did not involve bottlenecking:

> In holding that a reverse payment is prima facie evidence of an unreasonable restraint of trade, we follow the approach suggested by the DC Circuit in *Andrx* and embrace that court's common sense conclusion that "[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement . . . ."

K-Dur at 218 (quoting Andrx Pharms., Inc. v. Biovail Corp. Int'l., 256 F.3d 799, 809 (D.C. Cir. 2001)). See *infra* Part III.B for a discussion of the *K-Dur* decision.

[87] *Andrx*, 256 F.3d at 803.

[88] *In re* Cardizem CD Antitrust Litig., 332 F.3d at 911; *see* Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 2 (2012) (discussing that the *Cardizem* court applied the SOP test and found that the agreement to delay market entry of drugs uncovered by the patent was outside of the scope of the patent).

By contrast, recent decisions have upheld reverse payment settlements.[89] The Second, Eleventh, and Federal Circuits applied the SOP test.[90] The SOP test asks "whether the agreements restrict competition beyond the exclusionary zone of the patent."[91] A patent grants rights to exclusively produce and market the patented product.[92] Therefore, the SOP test finds no violation of antitrust law "as long as competition is restrained only within the scope of the patent,"[93] unless the patent is procured by fraud or the patent enforcement suit is objectively baseless.[94] The SOP test, presuming a patent to be valid even if its validity is being challenged, typically provides that an anticompetitive settlement agreement for a Hatch-Waxman patent challenge suit is within the scope of the patent.[95] The policies underlying the SOP test include: (1) reasonable implementation of the protections afforded by

[89] Fed. Trade Comm'n v. Watson Pharms, Inc. 677 F.3d 1298, 1315 (11th Cir. 2012); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1341 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 216 (2d Cir. 2006).

[90] *See supra* text accompanying note 23.

[91] *Ciprofloxacin*, 544 F.3d at 1336.

[92] *Tamoxifen*, 466 F.3d at 213–16.

[93] *Id.* at 213 (citation omitted).

[94] *See Watson*, 677 F.3d at 1312 (holding that the SOP test applies "absent sham litigation or fraud in obtaining a patent"); *Tamoxifen*, 466 F.3d at 213 (holding that the SOP test applies "[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless"); *see also* California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508, 511, 515–16 (1972) (holding that a litigant seeking to protect a patent in court will be liable under antitrust law only when the litigation is a mere sham used to cover up anticompetitive agreement).

[95] *See Tamoxifen*, 466 F.3d at 190, 213–16 (upholding a reverse payment settlement under the SOP test, presuming that the patent was valid, even though the District Court held in the underlying patent challenge suit that the patent was invalid); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1306–09 (11th Cir. 2003) (upholding a reverse payment settlement under the SOP test, even though the patent at issue was subsequently declared invalid in another case, because the innovator manufacturer "might have prevailed" in the underlying patent suit).

patent law; and (2) a judicial policy favoring settlement to litigation.[96]

B. *Facts, Holding, and Reasoning in* K-Dur

In *K-Dur*, the drug at issue was K-Dur 20, a sustained-release potassium chloride supplement manufactured and marketed by the Schering-Plough Corporation.[97] Schering held a formulation patent on the controlled release coating.[98] The patent was set to expire on September 5, 2006.[99]

In August 1995, Upsher-Smith Laboratories, a pharmaceutical company, filed the first ANDA with a paragraph IV certification seeking FDA approval to produce a generic version of K-Dur 20.[100] In December 1995, another company, ESI Lederle, filed an ANDA with a paragraph IV certification similarly seeking to manufacture a generic version of K-Dur 20.[101] Schering timely filed a patent infringement suit in response to each company's paragraph IV certification.[102] Subsequently, Schering settled with Upsher and ESI, respectively.[103] In the Schering-Upsher deal entered into in June 1997, Schering paid Upsher $60 million.[104] Upsher, in return, agreed to refrain from marketing its generic version of K-Dur 20 until September 1, 2001 (for approximately four years), at which point Upsher would receive a royalty-free, non-exclusive license under the Schering patent.[105] In the Shering-ESI deal entered into

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[96] *See Valley Drug*, 344 F.3d at 1306–09, 1312.

[97] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 203 (3d Cir. 2012). After the facts at issue in this case, Merck & Co. acquired Schering and is the named defendant in this case. *Id.* at 203. In keeping with the practice of the parties and amici, however, the court will refer to Schering. *Id.*

[98] *Id.* at 203. Schering did not hold a patent for K-Dur 20's active ingredient (potassium chloride), which is a commonly known unpatentable compound. *Id.*

[99] *Id.*

[100] *Id.* at 205.

[101] *Id.* at 206.

[102] *Id.* at 205–06.

[103] *Id.*

[104] *Id.* at 205.

[105] *Id.* at 205–06. Additionally, Upsher granted Schering licenses to make and sell several pharmaceutical products of Upsher, which were mutually abandoned after the settlement. *Id.*

in the fall of 1996, Schering paid ESI $5 million up front and agreed to pay a varying sum depending on when ESI's ANDA would be approved by the FDA, eventually paying an additional sum of $10 million.[106] ESI agreed to refrain from marketing its generic version of K-Dur 20 until January 1, 2004 (for approximately seven years), at which point ESI would receive a royalty-free license under the Schering patent.[107]

In 2001, the FTC brought an action against Schering, Upsher, and ESI alleging violations of section 5 of the FTC Act.[108] Specifically, the FTC alleged that the settlement payments from Schering to Upsher and ESI constituted reverse payments intended to improperly delay generic market entry and preserve a monopoly.[109] The administrative law judge ruled in favor of Schering, Upsher, and ESI.[110] In 2003, the FTC reversed, holding that "the quid pro quo for the payment was an agreement by the generic [companies] to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[111] In 2005, the Eleventh Circuit reversed the FTC under the SOP test.[112] Subsequently, antitrust suits by various private parties attacking the settlements were consolidated in the District of New Jersey,

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[106] *Id.* at 206. The agreement was arranged so that the sooner the FDA would approve ESI's ANDA, the more Schering would pay ESI in return for ESI's withholding market entry of its generic K-Dur 20 until an agreed time. *Id.* The FDA approved ESI's generic K-Dur 20 product in May 1997, two and one-half years after the settlement. *Id.* Schering paid ESI an additional $10 million, while ESI withheld market entry of a generic version of K-Dur 20 for an additional four and one-half years (until January 1, 2004) as required under the agreement. *Id.*

[107] *Id.*

[108] 15 U.S.C. § 45 (2006); *K-Dur*, 686 F.3d at 206–07.

[109] *In re* Schering-Plough Corp., 136 F.T.C. 956, 1092–93 (2003).

[110] *Id.* at 1236, 1243, 1262–63.

[111] *Id.* at 988.

[112] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1069–72 (11th Cir. 2005) (holding that Schering's payment to Upsher was only for the licenses and that Schering's payment to ESI was a reverse payment legitimately within the scope of the patent).

which upheld the settlements.[113] The case was appealed from the District of New Jersey to the Third Circuit.[114]

The Third Circuit reversed the district court on the ground that "a reverse payment is prima facie evidence of an unreasonable restraint on trade."[115] The Third Circuit rejected the SOP test and, on remand, directed the district court to apply the "quick look rule of reason" antitrust analysis [116] based on the anticompetitive realities of reverse payment settlements rather than the labels applied by the settling parties.[117] The court stated that prima facie evidence of an unreasonable restraint on trade could be rebutted "by showing that the [reverse] payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."[118] The merits of the underlying patent suit need not be considered.[119]

The Third Circuit presented four reasons for its rejection of the SOP test.[120] First, the court disputed the "almost unrebuttable presumption of patent validity" of the SOP test.[121] A patent "simply represents a legal conclusion reached by the Patent Office,"[122] and an irrefutable presumption of patent validity is unfounded.[123] In fact, statistics demonstrate that challengers

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[113] *K-Dur*, 686 F.3d, 207–08. Eventually forty-four wholesalers and retailers joined as plaintiffs. *Id.* at 208.

[114] *Id.* at 208.

[115] *Id.* at 218.

[116] See *supra* Part II.C for a discussion of the "quick look rule of reason" analysis.

[117] *K-Dur*, 686 F.3d at 218.

[118] *Id.* For the second possible defense, the patent holder may rebut the prima facie case by demonstrating that the reverse payment offers a competitive benefit that could not have been achieved without reverse payment, for example, to save a generic manufacturer from bankruptcy so that it can market a generic drug to eventually facilitate competition. *Id.*

[119] *Id.*

[120] *Id.* at 214–18.

[121] *Id.* at 214–15.

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

[123] *Id.* at 215. In patent validity challenge cases, a patent is "presumed valid," and the challenger bears the burden of defeating a presumption of validity. 35 U.S.C. § 282 (2006). On the other hand, in patent infringement cases, the patent holder bears the burden of showing infringement. *See id.* § 295 (2006) (establishing burden shifting from infringement plaintiff to defendant in certain

prevail at overwhelming rates in patent challenge suits—according to data from the FTC, generic challengers prevailed in seventy-three percent of the Hatch-Waxman paragraph IV patent challenge cases.[124]

Second, the court rejected an assumption that subsequent patent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger.[125] The court pointed out that subsequent generic challengers are not as motivated as the initial generic challenger, who stands alone to benefit from the 180-day market exclusivity period.[126] In addition, the patent holder also may pay off a whole series of generic challengers to delay market entry.[127]

Third, the court noted the Supreme Court's recognition that valid patents are a limited exception to a general rule of the free exploitation of ideas, and that public interest supports judicial testing and elimination of weak patents.[128] The Supreme Court has held that it is of broad public interest to free "our competitive

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situations as to process patents); Julie E. Zink, *Shifting the Burden: Proving Infringement and Damages in Patent Cases Involving Inconsistent Manufacturing Techniques*, 2 HASTINGS SCI. AND TECH. L.J. 81, 82–84 (explaining common law and statutory presumption of patent non-infringement and subsequent burden shifting in certain situations). The presumption of patent validity or non-infringement is merely a procedural device and is not a substantive right of parties. *See* Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L. J. 83, 85–86 & n.11 (2009); *infra* Part IV.A.

[124] *K-Dur*, 686 F.3d at 215 n.11; *see* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 16 (2002), *available at* http://www.ftc.gov/os/2002/07/genericrugstudy.pdf. According to data from the pharmaceutical industry, generic challengers prevailed in slightly less than half of the Hatch-Waxman patent litigation in 2000–09. Further, when cases that are settled and dropped are taken into consideration in the same data set, generic challenger prevailed in seventy-six percent of their challenges. RBC CAPITAL MKTS., PHARMACEUTICALS: ANALYZING LITIGATION SUCCESS RATES 4 (2010), *available at* http://www.amlawdaily.typepad.com/pharmareport.pdf.

[125] *K-Dur*, 686 F.3d at 215.

[126] *Id.*

[127] *Id.* In fact, Schering bought out both Upsher (the initial generic challenger) and ESI (a subsequent generic challenger). *Id.* at 205–06.

[128] *Id.* at 215–16.

economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents"[129] and "the right to challenge [a patent] is not only a private right to the individual, but it is founded on public policy which is promoted by his making the defense, and contravened by his refusal to make it."[130] Therefore, the court argued, the Supreme Court would not tolerate reverse payment settlements that "permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid."[131]

Lastly, the court noted that the SOP test "nominally protects intellectual property, not on the strength of a patent holder's legal rights, but on the strength of its wallet."[132] The nature of the SOP test is against the Congressional intent underlying the Hatch-Waxman Act. By passing the Act, Congress aimed to encourage generic challenges against innovator pharmaceutical companies and to increase the availability of low-cost generic drugs for consumers.[133]

For all of these reasons, the court rejected the SOP test. Further, the court held that reverse payment settlements are presumptively illegal.[134] Although the court raised thorough reasons for rejecting the SOP test, the court opinion is not explicit as to why the court replaced the SOP test with the "quick look rule of reason" analysis and presumed the reverse payment settlements illegal. The advantage of the *K-Dur*'s "quick look rule of reason" approach is analyzed in Part IV.B.

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[129] *Id.* at 216 (quoting Edward Katzinger Co. v. Chi. Metalic Mfg. Co., 329 U.S. 394, 400 (1947)).

[130] *Id.* (quoting *Kartzinger*, 329 U.S. at 401).

[131] *Id.* at 215–16 (citing Cardinal Chem. Co. v. Morton Int'l, Inc, 508 U.S. 83, 100–01 (1993); Bonito Boats, Inc. v. Thundercraft Boats, Inc., 489 U.S. 141, 146 (1989); United States v. Mansonite Corp., 316 U.S. 265, 277 (1942)).

[132] *Id.* at 217; *see* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1614 (2006).

[133] *K-Dur*, 686 F.3d at 217.

[134] *Id.* at 218.

IV. WHY THE *K-DUR* DECISION IS THE BEST PRACTICABLE JUDICIAL APPROACH

Three circuit courts have applied the SOP test to reverse payment settlements.[135] The Third Circuit rejected the SOP test in *K-Dur*, thereby creating a stark split among circuits.[136] This Part analyzes why the *K-Dur* approach to reverse payment settlements is superior to, and more practicable than, the SOP test or other potential alternative approaches.

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

A central issue to the circuit split is weighing how much a patent ought to protect an innovator drug company from competition—a classical issue of balancing the encouragement of innovation with promotion of competition.[137]

Applying the SOP test to reverse payment settlements is questionable for legal and economic reasons. First, the SOP test incorrectly presumes that every patent is valid.[138] Even though a patent is procedurally "presumed valid" in suits over patent validity, [139] an overwhelming number of patents have been invalidated in Hatch-Waxman patent challenge suits.[140] If the patent is not valid, no scope that protects the patent holders should exist.[141]

Moreover, based on this presumptive validity approach, suits over patent infringement would fall outside of the scope of the

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[135] *See supra* note 89 and accompanying text.

[136] *K-Dur*, 686 F.3d at 218.

[137] *See* Day, *supra* note 31, at 223 n.2, 258–59 (discussing a longstanding inherent conflict of patent and antitrust laws, where patent law allows innovators to control output and prices, while antitrust law prohibits activities to control output and prices).

[138] *See K-Dur*, 686 F.3d at 214; Carrier, *supra* note 16, at 62–63.

[139] 35 U.S.C. § 282 (2006). This presumption that a challenged patent is valid is a procedural device and is not a substantive right of a patent holder. *See* Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983); *supra* note 123 and accompanying text.

[140] *See supra* note 124 and accompanying text.

[141] Andersen, *supra* note 20, at 1054.

patent.[142] For example, in *K-Dur*, Upsher and ESI alleged, in their paragraph IV certification, that they did not infringe Schering's patent.[143] In a patent validity case, the patent is presumed valid and the challenger bears the burden of demonstrating invalidity; by contrast, in a patent infringement case, the patent is presumed not infringed and the patent holder bears the burden of demonstrating infringement.[144] The SOP test maintains that an agreement to delay market entry of a generic version of a patented product falls within the scope of the presumptively valid patent.[145] Applying the same logic, a settlement to delay market entry of a product which presumptively has no infringement problem will fall outside of the scope of the patent, contrary to the Eleventh Circuit decision in *Schering*.[146]

Second, the SOP test's tremendous deference to patent holders is problematic in economic terms. Legal and economic scholars have warned of anticompetitive characteristics of reverse payment settlements,[147] a factor that the SOP test does not consider. The FTC estimates that the savings to purchasers of drugs that would result from eliminating reverse payment settlements would be at

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[142] Carrier, *supra* note 88, at 7.

[143] *K-Dur*, 686 F.3d. at 205–06; *see* Carrier, *supra* note 88, at 7 (discussing that Upsher and ESI's noninfringement claims were plausible because Schering's patent did not cover the active ingredient of K-Dur 20, but covered the coating material); *see also supra* note 98 and accompanying text (discussing Schering's K-Dur 20 patent).

[144] *See supra* note 123 and accompanying text.

[145] *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212–13 (2d Cir. 2005).

[146] Schering-Plough Corp. v. Fed. Trade Comm'n, 344 F.3d 1294, 1072 (11th Cir. 2003) (holding the settlement terms between Schering and ESI "to be within the patent's exclusionary power, and reflect a reasonable implementation of the protections afforded by patent law" (internal quotation omitted)).

[147] *See* Carrier, *supra* note 123, at 90 ("Of all the types of business activity, agreements by which competitors divide markets lead to the most extreme anticompetitive effects because they restrict all competition between the parties on all grounds."); Hemphill, *supra* note 132, at 1593–94 (analyzing aligned incentives of the innovator and generic drug companies in reverse payment settlements).

least 3.5 billion dollars annually.[148] Moreover, a reverse payment does not seem to be an essential deal for settling parties to make. Data demonstrate that nearly seventy-five percent of Hatch-Waxman Act infringement suits that settled in 2010 did so without reverse payments.[149] The data illustrates that both an innovator drug company and a generic challenger have incentives to settle a Hatch-Waxman patent infringement suit even without reverse payment—to avoid the risk of unpredictable outcome of litigation and to reach at mutually agreeable result faster and cheaper.[150]

Other data demonstrate that reverse payment settlements decreased when challenged and increased when upheld by the courts.[151] Between 1992 and 1999, eight of the fourteen final settlements between innovative and generic companies involved reverse payments.[152] In 2000, the FTC announced enforcement of antitrust scrutiny on reverse payment settlements.[153] Between 2000 and 2004, none of the twenty reported agreements involved a reverse payment.[154] Following decisions by the Second and Eleventh Circuits upholding reverse payment settlements,[155] such deals re-appeared and increased. Three out of eleven, fourteen out of twenty-eight, and fourteen out of thirty-three Hatch-Waxman

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[148] FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[149] FED. TRADE COMM'N, 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 2010, at 2 (2011), *available at* http://www.ftc.gov/os/2011/05/1105mmagreements.pdf.

[150] Hastings, *supra* note 27, at 53–54.

[151] Carrier, *supra* note 16, at 74–75.

[152] *Id.*

[153] *Id.* at 75 (citing Abbott Laboratories, and Geneva Pharmaceuticals, Inc.; Analysis to Aid Public Comment, 65 Fed. Reg. 17,502, 17,506 (Fed. Trade Comm'n Apr. 3, 2000) (notice).

[154] Carrier, *supra* note 16, at 75.

[155] *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 197, 216 (2d Cir. 2006); Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1072 (11th Cir. 2005).

settlements that took place in 2005, 2006, and 2007, respectively, included reverse payment.[156]

In sum, the SOP test allows a patent holder to "buy its way out of" both fair competition and possible patent invalidation,[157] and permits a generic challenger to share the monopoly rents.[158] The Third Circuit correctly held that the SOP test provides an unjust advantage to innovator and generic drug companies.[159] Rejection of the SOP test in the *K-Dur* decision[160] is a significant victory for the public interest in the creation of a fair and competitive pharmaceutical market.

B. *Moving Beyond the "Scope of the Patent" Test:* K-Dur's *"Quick Look Rule of Reason" Analysis*

The *K-Dur* court replaced the SOP test with a "quick look rule of reason" analysis.[161] The court's decision to apply this analysis highlights the court's view that reverse payment settlements are by nature similar to transactions that are held to be *per se* unlawful, such as horizontal price fixing.[162] Given the potential pernicious anticompetitive effect of reverse payment settlements,[163] this view is reasonable. Comparing the *K-Dur*'s "quick look rule of reason" approach with other possible antitrust analysis, as discussed in this

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[156] *See* Carrier, *supra* note 16, at 75.

[157] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 215 (3d Cir. 2012).

[158] *See id.* at 216; Carrier, *supra* note 16, at 39 (discussing parties' aligned incentives for reverse payment settlements).

[159] *See K-Dur*, 686 F.3d at 214–18. *But see* Day, *supra* note 31, at 257–61 (advocating that reverse payment settlements should be permitted as innovators' rights within the scope of the patent to encourage pharmaceutical innovation and promote a long-term consumer welfare).

[160] *Id.* at 214.

[161] *See id.* at 218; *supra* Part II.C (discussing a "quick look rule of reason" analysis). Under a "quick look rule of reason" analysis, *K-Dur* held that reverse payment settlements established a presumption of unreasonable restraint on trade, whereas a full "rule of reason" analysis would have conducted a detailed fact-specific analysis. *K-Dur*, 686 F.3d at 218. Similarly, *K-Dur* placed the burden on antitrust defendants to rebut the presumption of unreasonableness, whereas a full "rule of reason" analysis would have first placed a burden on the antitrust plaintiff to establish unreasonableness. *See id.*

[162] *See supra* Part II.C (discussing the *per se* rule of antitrust analysis).

[163] *See supra* note 147 and accompanying text.

Part, reveals why the *K-Dur* approach is the best practicable judicial approach.

1. *The* Per Se *Rule*

Holding that reverse payment settlements are *per se* illegal would over-punish the settling parties for two reasons. First, courts may not have had sufficient experience with reverse payment settlements to "decisively predict that the 'rule of reason' analysis also would condemn" them.[164] In such cases, courts should not apply the *per se* rule.[165] Second, reverse payment settlements may not always be a *per se* unreasonable restraint on trade. The reverse payment may possibly be for something other than a delay in market entry, such as for legitimate side deals.[166] Alternatively, even when payment was indeed for delay in market entry, it might have been done for legitimate anticompetitive justifications.[167] The *K-Dur* court pointed out that in a situation where a modest cash payment enables a cash-starved generic manufacturer to avoid bankruptcy and to begin marketing a generic drug, a reverse payment may have an overall effect of increasing competition in the market.[168] In addition, there will be a situation where a small innovator drug company intends to conduct clinical studies to address a new therapeutic use of its patented drug for a long-term competitive benefit, but cannot afford the studies if a generic version of the drug enters the market and its revenue decreases. In such a situation, a review by a court may be warranted as to whether the reverse payment settlement had a justifiable pro-competitive justification for a long-term perspective.[169]

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[164] VAKERICS, *supra* note 75, at 7–8.

[165] *Id.*

[166] For example, payment from an innovator to an alleged infringer may represent a licensing fee granting the former the right to produce and market the latter's product. Schering and Upsher included this licensing agreement in their settlement terms to justify payment from Schering to Upsher. *See K-Dur*, 686 F.3d at 205–06.

[167] *See id.* at 218.

[168] *Id.*

[169] *See* Grabowski, *supra* note 5, at 380–82.

By contrast to the rigid *per se* rule, the *K-Dur* approach allows antitrust defendants to present evidence to rebut the presumption of illegality of reverse payment settlements.[170]

2. *The Full "Rule of Reason" Approach*

The full "rule of reason" approach in a complex reverse payment settlement case is prohibitively challenging. This approach considers all relevant circumstances of a case, including the merits of the underlying patent litigation, amount of the settlement value, and the estimated profit and loss born by the companies had the generic drug entered into the market without delay.[171]

First, the full "rule of reason" analysis would consider merits of underlying patent suits.[172] In one suggested approach, a court may presume a reverse payment settlement to be illegal when a generic challenger is likely to win the patent challenge suit, and, on the other hand, uphold a reverse payment settlement when a patent holder is likely to win the patent challenge suit.[173] This approach, however, is infeasible because it is impossible to predict the outcome of patent litigation, which is technical and complex by nature.[174] Moreover, the Federal Circuit has sole jurisdiction, and

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[170] The Sixth Circuit held that the reverse payment settlement was *per se* illegal in *In re Cardizem CD Antitrust Litig.* 332 F.3d 896, 908 (6th Cir. 2003). This case involved an atypical reverse payment settlement. *Id.* The settlement had a bottlenecking effect on the drug in the patent suit, and involved an agreement to delay the market entry of drugs other than the drug in the patent suit. *Id* at 904. Therefore, the court held that the settlement was a horizontal agreement not to compete and *per se* illegal. *Id.* at 908; *see* Carrier, *supra* note 88, at 2.

[171] *See supra* Part II.C (discussing the full "rule of reason" antitrust analysis).

[172] *Id.*

[173] *See* Henry N. Butler et al., *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 107–08 (2010) (discussing Professor Daniel Crane's model that considers the merits of the patent infringement suit in the antitrust analysis of reverse payment settlements).

[174] *See* Carrier, *supra* note 16, at 73; Hastings, *supra* note 27, at 44.

therefore expertise, over patent suits.[175] Encouraging other circuit courts to second-guess the merits of the underlying patent suits and to base their antitrust reasoning on such assumptions may cause inconsistent and unjust decisions, and create jurisdictional problems.

Another reason why considering the merits of underlying patent suits is inappropriate is because whether a reverse payment settlement is illegal under antitrust law should not depend on the strength of a patent. In a patent suit, there is no such thing as a guaranteed victory: Even the holder of a strong patent has a good chance to lose, and therefore, an incentive to settle.[176] If an innovator and generic company choose to settle with a reverse payment to accomplish their aligned incentive to share the monopoly,[177] they should be held to have violated the antitrust law, regardless of the strength of the innovator's patent.

Second, the "full rule of reason" analysis would consider the amount of the settlement value as a proxy for the legality of the settlement.[178] Under this approach, if the settlement value is greater than the amount the generic manufacturer would gain by entering the market, the settlement will be presumptively illegal.[179] If the settlement is less than the generic manufacturer's anticipated gain by market entry, but more than its potential legal fees, the burden will be on the antitrust plaintiff to prove patent invalidity.[180] If the settlement is for less than the generic manufacturer's potential legal fees, the settlement will be presumed valid.[181] This approach would be impracticable because it is often difficult to accurately estimate a generic manufacturer's anticipated market

[175] *Court Jurisdiction*, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, http://www.cafc.uscourts.gov/the-court/court-jurisdiction.html (last visited Nov. 27, 2012).

[176] Hastings, *supra* note 27, at 44.

[177] *Id.* at 53–54 (comparing a patent suit to a coin toss and showing how the values of even strong patent suits may be diminished).

[178] *See supra* Part II.C (discussing the full "rule of reason" antitrust analysis).

[179] Andersen, *supra* note 20, at 1053–56.

[180] *Id.*

[181] *Id.*

gains.[182] Except for cases where generic companies clearly received more than they ever could have gained by entering the market,[183] or where they clearly received less than their potential legal fees, many cases would fall near the borderline. Establishing bright lines to classify them into the three categories would be challenging.

In summary, the fact-specific inquiry of full "rule of reason" analysis, specifically in the context of complex reverse payment settlements, is unlikely to be accurate and, when not accurate, would result in inconsistent and unjust court decisions.[184]

3. K-Dur's *"Quick Look Rule of Reason" Analysis*

By contrast to full "rule of reason" analysis, *K-Dur*'s presumptive illegality approach bypasses a prohibitively complicated inquiry into every relevant circumstance of the case.[185] It is straightforward and consistent, and saves courts from assessing the merits or settlement value of underlying patent suits.[186]

K-Dur's presumption of illegality is warranted because of the extremely anticompetitive nature of a reverse payment settlement in general.[187] At the same time, the *K-Dur* approach has the potential to over-punish antitrust defendants engaging in reverse payment settlements. Theoretically, the holder of a valid patent is entitled to market exclusivity, including reverse payment settlements. Therefore, one could argue that the holder of a strong patent may be over-punished by the *K-Dur* approach because he is likely entitled to a monopoly deal. This argument is rebutted on two grounds. First, the legality of reverse payment settlements

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[182] *See id.* at 1054–63.

[183] *See* Carrier, *supra* note 16, at 73.

[184] *But see* Butler, *supra* note 173, at 114–25 (advocating for the full "rule of reason" analysis of reverse payment settlements because such contextual analysis will best balance type I errors—overinclusive prosecution of procompetitive or neutral business conduct—and type II errors—underinclusive prosecution of anticompetitive business activities).

[185] *See supra* Part II.C (discussing the full "rule of reason" and "quick look rule of reason" antitrust analyses).

[186] Hastings, *supra* note 27, at 63.

[187] Carrier, *supra* note 123, at 90.

should not be based on the strength of the patent.[188] In a patent suit, a strong patent does not necessarily turn out to be a valid patent.[189] Second, in the *K-Dur* approach, the antitrust defendants are given an opportunity to rebut the presumption of illegality.[190] This rebuttal opportunity is critical for courts to avoid erroneously punishing antitrust defendants who did not engage in illegal anticompetitive activities.

Another potential limitation of the *K-Dur* approach is that it may not effectively accomplish the goal of reducing pharmaceutical costs and promoting consumer welfare. Such a goal and a reflection on public policy are beyond the *K-Dur* decision, however. The holding is that pharmaceutical reverse payments presumptively violate antitrust law—no more, no less. The social and economic implications of the *K-Dur* decision are discussed in Part V.

For all stated reasons in this Part, the *K-Dur* method is the best practicable judicial approach to reverse payment settlements.

V. ECONOMIC AND SOCIAL CONSEQUENCES OF THE *K-DUR* DECISION

The *K-Dur* decision is in accord with Congressional intent underlying the Hatch-Waxman Act to promote public welfare by encouraging prompt market entry of generic drugs and fair competition.[191] Judicial intervention, as in *K-Dur*, can be a powerful tool to address social problems. At the same time, the effects of judicial intervention are complex and often unpredictable.[192] This Part discusses possible social and economic consequences of the *K-Dur* decision and the role of Congress and

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[188] *See supra* Part IV.B.2.

[189] *See* Hastings, *supra* note 27, at 44.

[190] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).

[191] *See* H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647; Carrier, *supra* note 123, at 84 (discussing that reverse payment settlements are atypical settlements "that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme").

[192] Hemphill, *supra* note 26, at 671 & n.171.

the federal agencies in making antitrust and patent policies to address such consequences.

A. *The Decision May Discourage Settlements of Hatch-Waxman Patent Suits and Increase Litigation in Courts*

To be sure, *K-Dur* does not intend to discourage settlements of Hatch-Waxman patent challenge cases.[193] Moreover, the FTC is unlikely to prosecute any settlements that fall under the $2 million safe harbor.[194] Nevertheless, when companies are prohibited from settling with large reverse payment deals, they may choose to litigate patent challenge suits to the end, rather than to settle without a reverse payment. This result would be against the general judicial policy favoring settlements.[195]

At first, a decrease in settlements and an increase in litigation would seem to go against public interest because of the extra time and cost required for litigation. Economic modeling, however, has shown that settlements that include a cash payment from the innovator to the challenger provide consumers with less economic benefit than seeing the litigation to completion.[196] Specifically, economic scholars believe that, in terms of cost borne by consumers, the cost of reverse payment settlements is greater than

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[193] *K-Dur* specifically aims to eliminate accompanying reverse payment deals. *K-Dur*, 686 F.3d at 216. A patent holder is still encouraged to settle the patent challenge, allowing a generic challenger to enter the market at any point earlier than the patent expiration date. *See id.*

[194] Fed. Trade Comm'n v. Bristol-Myers Squibb Co., 135 F.T.C. 444, 496 (2003); Kenneth L. Glazer et al., *Third Circuit Sides with FTC Position on So-Called Pay-for-Delay Settlements, Virtually Guaranteeing Supreme Court Review on the Issue*, K&L GATES (July 25, 2012), http://www.klgates.com/third-circuit-sides-with-ftc-position-on-so-called-pay-for-delay-settlements-virtually-guaranteeing-supreme-court-review-on-the-issue-07-25-2012/.

[195] *K-Dur*, 686 F.3d at 216.

[196] Hemphill, *supra* note 132, at 1572 n.81 (citing Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, 4 INNOVATION POL'Y & ECON. 145, 159–73 (2004); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 407–08 (2003)). A mathematical model demonstrates that consumers economically benefit more from litigation than reverse payment settlements. *See* Hemphill, *supra* note 132, at 1591–93.

that of full litigation expenses.[197] The scholars point out that a settlement undermines subsequent generic challengers' incentive to challenge a patent, thereby harming consumers.[198] Therefore, an increase in litigation would actually be beneficial to consumers in this context.

B. *The Decision May Discourage Potential Generic Manufacturers To Bring Patent Challenge Litigation*

When settlements with lucrative reverse payment deals are prohibited, some potential generic manufacturers might be discouraged from bringing patent challenge suits and marketing generic drugs.[199] This outcome would counter the Congressional intent underlying the Hatch-Waxman Act, which was to encourage potential generic manufacturers to bring patent challenges and to produce generic versions of drugs.[200] At the same time, however, a ban on reverse payments may incentivize generic manufacturers to be selective in bringing patent challenges.[201] The system where a generic manufacturer could capture profit by entering into a reverse payment settlement incentivizes generic manufacturers to challenge valuable patents, not weak patents, to obtain good reverse payment deals.[202] If the *K-Dur* decision alleviates the burden on innovative drug companies to defend many frivolous patent challenges by encouraging generic challengers to become more selective in bringing suits against weak patents, this would benefit consumers by reducing the cost of pharmaceutical litigation, which would eventually lower pharmaceutical market prices.

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[197] Hemphill, *supra* note 132, at 1572 & n.81.

[198] *Id.*

[199] *Id.* at 1575 (suggesting that a ban on reverse payment settlements would reduce challengers' settlement options and incentive to challenge patents, thereby reducing competition).

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

[201] *See* Hastings, *supra* note 27, at 34.

[202] *Id.*

C. K-Dur *May Not Effectively Eliminate Reverse Payment Settlements*

It remains unclear whether the *K-Dur* decision will effectively eliminate reverse payment settlements. First, until the Supreme Court potentially clarifies the issue, the stark circuit split may result in forum shopping by litigating parties.[203] Pharmaceutical companies are typically multi-state corporations that are subject to personal jurisdiction in multiple states and federal districts.

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[203] Given the stark circuit split created by *K-Dur* decision, the issue may be ripe for review by the United States Supreme Court. The Solicitor General, at the request of the FTC, has petitioned the Supreme Court for a writ of certiorari in another pharmaceutical reverse payment settlement case, *Fed. Trade Comm'n v. Watson Pharm.*, 677 F.3d 1298 (11th Cir. 2012), on October 4, 2012. Petition for Writ of Certiorari for Plaintiff-Appellant, Fed. Trade Comm'n v. Watson Pharm., Inc., No. 12-416 (U.S. Oct. 4, 2012), 2012 WL 4750283. As for *K-Dur*, both Merck (the named defendant which acquired Schering after the fact at issue, *see supra* note 97) and Upsher separately petitioned the Supreme Court for a writ of certiorari in August 2012. Petition for Writ of Certiorari for Defendant-Appellant, Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., No. 12-265 (U.S. Aug. 30, 2012); Petition for Writ of Certiorari, Merck & Co. v. La. Wholesale Drug Co., No. 12-245 (U.S. Aug. 24, 2012). In addition, BayerAG, the New York Intellectual Law Association, and the Pharmaceutical Research and Manufacturers of America ("PhRMA") filed amicus briefs respectively. Amici Bayer AG & Bayer Corp.'s Brief in Support of Petitioners, Merck & Co. v. La. Wholesale Drug Co., No. 12-245 (U.S. Sept. 24, 2012); Amici Bayer AG & Bayer Corp.'s Brief in Support of Petitioners, Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., No. 12-265 (U.S. Sept. 24 2012); Brief of Amicus Curiae N.Y. Intellectual Property Law Ass'n as Amicus Curiae in Support of Petitioners, Merck & Co. v. La. Wholesale Drug Co., No. 12-245 (U.S. Sept. 24, 2012); Brief of Amicus Curiae N.Y. Intellectual Property Law Ass'n as Amicus Curiae in Support of Petitioners, Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., No. 12-265, (U.S. Sept. 24, 2012); Brief for Pharm. Research and Mfrs. of Am. (PhRMA) as Amicus Curiae In Support of Petitioner, Merck & Co. v. La. Wholesale Drug Co., No. 12-245 (U.S. Sept. 24, 2012). The petition for a writ of certiorari for *Watson* was granted on December 7, 2012. *Docket for No. 12-416*, SUPREME COURT OF THE UNITED STATES, http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-416.htm (last visited Dec. 16, 2012). The petition for a writ of certiorari for *K-Dur* is pending at the Supreme Court as of December 16, 2012. *Docket for No. 12-456*, SUPREME COURT OF THE UNITED STATES, http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-245.htm (last visited Dec. 16, 2012).

Second, even after the official ban of reverse payment settlements by the *K-Dur* decision, pharmaceutical companies may continue to make anticompetitive deals by hiding reverse payments in a series of complex transactions. For example, in *K-Dur*, Schering paid to Upsher for an apparent licensing agreement to make and sell Upsher's products.[204] The FTC and antitrust plaintiffs alleged that this payment was a disguised reverse payment because the delayed market entry of Upsher's generic version of K-Dur 20 was a part of consideration for Schering's payment.[205] In addition, the licensing agreement was abandoned after the settlement, supporting the notion of disguise.[206] Another example of side deals involves Solvay.[207] Solvay settled patent litigation on its innovative drug, AndroGel, with generic manufacturers.[208] As a side deal to the settlement, Solvay paid one generic manufacturer for backup manufacturing, even though the latter did not manufacture the drug; Solvay paid another generic manufacturer for co-promotion that far exceeded the market rate.[209] As companies attempt to disguise reverse payments, unwinding complex transactions and tracking down evidence of reverse payment settlements would become a more burdensome and challenging task for the FTC and the courts.[210]

D. *The* K-Dur *Decision May Be Applied to a Wider Context Beyond Pharmaceutical Reverse Payment Settlements*

"Antitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to

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[204] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 205–06 (3d Cir. 2012).
[205] *Id.*
[206] *Id.*
[207] Carrier, *supra* note 123, at 94.
[208] *Id.*
[209] *Id.*
[210] Kenneth Glazer & Jenée Desmond-Harris, *Reverse Payments: Hard Case Even Under Good Law*, ANTITRUST SOURCE, Spring 2010, AT 14, 18–19 (2010), *available at* http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/glazer_desmond_harris_Anti_Spring2010_4.authcheckdam.pdf.

which it applies."[211] In the *K-Dur* decision, the court cautioned that "our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry."[212] Just as the court was concerned, this approach of presuming that any cash flow from the patent holder to the challenger in a settlement of a patent suit is unreasonable and illegal may possibly be "borrowed" and applied in a wider context beyond Hatch-Waxman patent challenge suits—for example, patent litigation in cell phone industries. Limitless application of the *K-Dur* decision without attention to specific nature of the industry would undermine the significance of patents and innovation.[213]

E. *Antitrust and Patent Rulemaking By Congress and the Federal Agencies*

Congress and federal agencies, such as the FTC and the FDA, are in the best position in directing policies following the *K-Dur*. A court is limited in its capacity to establish policies based on aggregate data.[214] By contrast, Congress and federal agencies are capable of developing an optimal rule by independently collecting the relevant information.[215] Congress has, in fact, recently considered new legislation to regulate reverse payment settlements. For example, a proposed Senate bill of 2009 ("Senate Bill 369")[216] would treat agreements by which generic manufacturers "receive[d] anything of value" in exchange for "agreeing not to research, develop, manufacture, market, or sale" as presumptively anticompetitive.[217] Settling parties may rebut the presumption by

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[211] Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411–12 (2004) (quoting Concord v. Boston Edison Co., 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.) (internal quotation marks omitted)).

[212] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 216 (3d Cir. 2012).

[213] *See* Day, *supra* note 31, at 257–61 (advocating that patent law promotes long-term consumer welfare by incentivizing innovation).

[214] *See* Hemphill, *supra* note 26, at 671 (discussing the nature of a court as a fact-finder of each case).

[215] *Id.*

[216] Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009).

[217] Substitute Amendment to S. 369, 111th Cong. § 28(a)(2)(A) (2009).

demonstrating the agreement's procompetitive effects.[218] This bill proposes an approach to reverse payment settlements similar to the *K-Dur*.[219]

Another Senate bill of 2009 ("Senate Bill 1315")[220] seeks to maintain a strong incentive for generic drug manufacturers to enter the market by expanding eligibility of the 180-day market exclusivity period.[221] Specifically, the bill would award the market exclusivity period not only to the first ANDA filer with a paragraph IV certification (as the current legislation does) but also to (1) the first challenger to win a court decision in the patent challenge suit; and (2) an ANDA filer that was not sued for infringement, provided that no other generic manufacturer has begun marketing the drug.[222] This amendment would incentivize generic manufacturers to challenge a patent, win in court, and actually market the drug, even after the first-filer has settled with the patent holder.[223]

An alternative option would be to allow reverse payment settlements without antitrust scrutiny, but upon finding of a reverse payment settlement, to transfer exclusivity from the settling generic manufacturer to the next ANDA filer.[224] This option and Senate Bill 1315 would both allow reverse payment settlements to occur, but would reduce their potential to be anticompetitive by maintaining strong incentives for other generic manufacturers to enter the market.[225]

Regulatory and judicial "gaming" by pharmaceutical companies would continue. Congress and the FTC are in the best

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[218] *Id.* § 28(a)(2)(B).

[219] On the other hand, the House version of legislation would prohibit such agreements across the board. H.R. 3962, 111th Cong. § 2573 (2009). This is similar to the *per se* approach and may be overinclusive. *See* Carrier, *supra* note 123, at 95; *supra* Part IV.B.1.

[220] Drug Price Competition Act, S. 1315, 111th Cong. (2009).

[221] *Id.*

[222] *Id.* § 2(a)(1)(B)(III)(bb).

[223] *See* Butler et al., *supra* note 173, at 122–23; Carrier, *supra* note 123, at 100–03.

[224] *See* Butler et al., *supra* note 173, at 124.

[225] *Id.* at 122–24; Carrier, *supra* note 123, at 100–03.

position to oversee reverse payment settlements post *K-Dur* and to take on the challenging task of implementing policies that would best balance innovation and competition for consumers' benefit.

VI. CONCLUSION

The *K-Dur* decision replaced the unlimited protection of reverse payment settlements under the SOP test with a "quick look rule of reason" antitrust scrutiny and presumed that reverse payment settlements are illegal.[226] The SOP test is problematic because (1) its presumption of patent validity is not always warranted and (2) its deference to patent holders permit economically alarming monopoly shared between innovative and generic pharmaceutical companies through reverse payment settlements. Settling long, expensive, and unpredictable patent challenge cases offers advantages to both parties even without reverse payments. Reverse payment agreements typically seem to be optional deals at the cost of consumers, and warrant antitrust scrutiny.

Holding reverse payment settlements *per se* illegal, however, would be overinclusive. On the other hand, the full "rule of reason" analysis is theoretically ideal in minimizing overinclusive and underinclusive errors, by weighing all relevant facts, including the merits of the underlying patent challenge case, settlement value, market power, financial ability of settling parties, and side deals. This approach, however, would be practically challenging. It would be complex, costly, and time-consuming, and would result in inaccurate and inconsistent decisions. Additionally, unpredictability and nontransparency of the outcome of the "full rule of reason" analysis will leave the industry and consumers in confusion. By contrast, *K-Dur*'s presumption of illegality approach is straightforward and saves the court from analysis of prohibitively complex facts, while allowing antitrust defendants to demonstrate pro-competitive benefits of the agreement and rebut the presumption of unreasonable restraint on trade. Therefore, the

[226] *In re* K-Dur Antitrust Litig. 686 F.3d 197, 218 (3d Cir. 2012).

K-Dur decision offers the best practicable judicial approach to reverse payment settlements.

The pharmaceutical industry's regulatory and judicial gaming will continue. The *K-Dur* decision, however, is a positive step toward facilitating consumer's access to affordable generic drugs under antitrust law, while continuing to protect pharmaceutical companies' incentive to develop innovative drugs under patent law. Public interest in a fair competitive market and innovative drug development must be balanced and furthered by Congress and the federal agencies, such as the FDA and the FTC, through the pharmaceutical antitrust and patent policy-making.

NORTH CAROLINA JOURNAL OF LAW & TECHNOLOGY

VOLUME 14, ISSUE 2
SPRING 2013

SPECIAL SYMPOSIUM ISSUE

U.S. v. Jones: Defining a Search in the 21st Century

January 25, 2013

Published by:

North Carolina Journal of Law & Technology

University of North Carolina School of Law
Chapel Hill, North Carolina

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North Carolina Journal of Law & Technology
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Articles are available online at ncjolt.org and through Lexis-Nexis, Westlaw, and Hein Online subscription services. Back issues and complete sets of the *North Carolina Journal of Law & Technology* may be ordered directly from William S. Hein & Co., 1285 Main Street, Buffalo, New York 14209-1987. Orders may also be placed by calling Hein at (800)-828-7571, via fax at (716)-883-8100, or e-mail to order@wshein.com.

PUBLICATION INFORMATION

The text and citations of the *North Carolina Journal of Law & Technology* conform to *The Bluebook: A Uniform System of Citation* (19th ed. 2010). Materials cited "on file with the *North Carolina Journal of Law & Technology*" will be retained for a maximum of five years from date of publication. The journal is printed by Joe Christensen, Inc. in Lincoln, Nebraska. Publication number ISSN: 1542-5177.

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This publication is funded in part by Student Fees that were appropriated and disbursed by the Student Government at the University of North Carolina at Chapel Hill and the Student Bar Association of the University of North Carolina School of Law.

NORTH CAROLINA JOURNAL OF LAW & TECHNOLOGY
VOLUME 14, 2012–2013

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