REASONABLE REVERSAL
THE APPLICATION OF THE RULE OF REASON IN THE K-DUR ANTITRUST LITIGATION

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INTRODUCTION

In its July 2012 opinion, the Third Circuit employed a truncated rule of reason analysis to determine that Schering-Plough’s reverse settlement with Upsher-Smith Laboratories (“Upsher”) was an unreasonable restraint on trade. While this decision further splits the circuits regarding the legality of these settlements, its reliance on a truncated rule of reason analysis is a new approach. Until this decision, circuit courts viewed these settlements as per se illegal, or permissible when within the scope of the underlying patent, depending on the jurisdiction hearing the case. With this most recent decision on reverse settlements, the pendulum has swung back toward consumers, at least in the Third Circuit.

THE HATCH–WAXMAN ACT & REVERSE SETTLEMENTS

Reverse settlements are an inadvertent outgrowth of a consumer-focused legislative effort. In 1986, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch–Waxman Act (“Act”), with the intent of promoting generic competition with patented drugs.¹ Prior to the Act, patent laws dissuaded generic-producing firms from developing or marketing a generic version of a patented drug by exposing them to a potential infringement suit and substantial damages.² The Act, among other

² See Gregory Dolin, Reverse Settlements as Patent Invalidity Signals, HARV. 24 J.L. & TECH. 281, 287–89 (2011) (explaining that prior to the Hatch–Waxman Act, using a patented drug as a template as a starting point from which
provisions, created an Abbreviated New Drug Application ("ANDA") process that allowed generics to gain accelerated regulatory approval by demonstrating that the generic drug was the bioequivalent to the patented drug. While patent-holding firms could file an infringement suit following a generic firm’s ANDA filing, the generic firm would only incur litigation costs and having no exposure to infringement damages should a court determine that the generic product infringed on the existing patent.\(^3\) Additionally, the Act permitted firms to begin developing generic alternatives prior to the patent’s expiration without facing the threat of an infringement suit, allowing them to immediately compete in the market following the patent’s expiration.\(^4\) Congress believed that this new regulatory mechanism would result in a decrease in drug costs and an increase in drug competition.\(^5\)

The legislation also created the irresistible incentive for so-called “reverse settlements.” Under a reverse settlement, a generic firm that filed an ANDA and intended to challenge an existing patent could accept consideration, generally cash payments, to refrain from bringing its generic product to the market for a period of time. The term “reverse settlement” refers to the fact that a patent-holding firm initially files the infringement suit, but then pays the generic firm to settle its own claim. Under this framework, the patent-holder, who actually brought the infringement suit against the generic, settles its own claim by paying the generic-producing firm. The Federal Trade Commission ("FTC") has labeled these settlements “pay-for-delay” cases

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a firm would develop a generic drug constituted infringement when the patent was still in effect, even if the firm developing the generic did not market its drug until after the patent’s expiration).

\(^3\) Id. at 293–94.

\(^4\) Id. at 287–89.

because the patent-holder pays the generic to refrain for a time from entering the market. This practice has proven highly contentious, leading direct and indirect purchasers and federal agencies like the FTC to bring suits against both the patent-holder and the generic firm for entering into these agreements.

**Previous Appellate Jurisprudence**

The Sixth Circuit’s decision of *In re Cardizem* in 2003 took a hard line against reverse settlements, explaining that such arrangements were *per se* illegal.\(^7\) Agreements such as reverse settlements, the court determined, were nothing more than horizontal agreements designed to allocate market share. The Sixth Circuit differentiated these agreements from the monopoly provided by patents, stating that the acquisition of a temporary monopoly by means of a patent was wholly different from paying a competitor to remain outside the market.\(^8\) However, subsequent decisions from other circuits disagreed with this analysis.

Following the *Cardizem* decision, the Eleventh, Second, and Federal Circuits all subsequently decided that where patent-holders settled infringement claims within the protections of the patent, no antitrust violation occurred.\(^9\) For example, the Eleventh Circuit has heard three cases specifically addressing the issue of reverse settlements.\(^10\) In its most recent case, *FTC v. Watson Pharmaceuticals, Inc.*, the Eleventh Circuit clarified that its scope of the patent test did not consider the strength of the underlying patent, but only whether the settlement

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\(^7\) In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (2003).

\(^8\) Id.

\(^9\) See, e.g., *FTC v. Watson Pharmas., Inc.*, 677 F.3d 1298 (11th Cir.2012); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharmas., Inc.*, 344 F.3d 1294 (11th Cir.2003).

\(^10\) *Watson Pharmas.*, 677 F.3d 1298; *Schering-Plough*, 402 F.3d 1056; *Valley Drug*, 344 F.3d 1294.
exceeded the patent’s scope. The Second Circuit used the same test in its 2006 decision of *In re Tamoxifen Citrate Antitrust Litigation*. In fact, in its opinion, the Second Circuit interpreted the Act as promoting reverse settlements because they provided extra incentive for generic firms. Similarly, the Federal Circuit applied the scope of the patent test in its 2008 decision of *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.

**K-Dur Decision**

The Third Circuit offered a new perspective on reverse settlements in July 2012 with its decision of *In re K-Dur Antitrust Litigation*. The case centers around two patents for a drug produced by Schering-Plough (subsequently acquired by Merck) called K-Dur 20 (“K-Dur”), a prescription drug that treats high blood pressure. In August 1995, Upsher filed an ANDA, and in June 1997, it entered into a reverse settlement agreement, following Schering-Plough’s initiation of litigation proceedings. As a part of the agreement, Upsher agreed to refrain from marketing its generic version of K-Dur for four years and gave Schering-Plough licensing rights to produce some drugs developed by Upsher; in exchange, Upsher received $60 million.

Following this agreement, consumer advocates attacked the settlement, claiming the arrangement was anticompetitive. The FTC filed suit, alleging that the settlement was anticompetitive because it was an unreasonable restraint on trade. In June 2002, the Administrative Law Judge found that the agreement did not even constitute a reverse settlement, reasoning that the $60 million paid by Schering-Plough was for the licenses it received, not to

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11 *Watson Pharms.*, 677 F.3d at 1311–13 n. 8, 1313–14.
12 *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006).
13 *Id.* at 206 (explaining that prior to Hatch-Waxman, patent-holders could waive the potential infringement damages they were due in the case of a determination that the generic infringed; under the Act, the generics could at least obtain some consideration for their efforts).
14 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).
16 *Id.* at 205–06.
17 *Id.* at 205.
18 *Id.* at 206–07.
delay Upsher’s product entry.\textsuperscript{19} The FTC unanimously reversed this decision, concluding that the payment was for Upsher’s delayed market entry and constituted an unreasonable restraint on trade.\textsuperscript{20} Schering-Plough appealed this decision to the Eleventh Circuit, which used the scope of the patent test to reverse the FTC’s decision.\textsuperscript{21}

The Third Circuit’s decisions arose out of the facts previously described, however direct and indirect purchasers brought their own claim in this action.\textsuperscript{22} A Special Master certified the class of wholesalers and retailers in December 2008, and in February of the following year issued a report to the district court recommending that the court grant Schering-Plough’s motion for summary judgment, utilizing a scope of the patent analysis.\textsuperscript{23} The district court followed the recommendation of the Special Master, and the plaintiffs appealed to the Third Circuit.

Though the Third Circuit noted the prevalence of the scope of the patent test in other Circuits,\textsuperscript{24} and even recognized its use in district courts within the Third Circuit, the circuit court opted to apply a different analysis—a quick look rule of reason.\textsuperscript{25} In its opinion, the Third Circuit first dissected the underlying assumptions of the scope of the patent test, namely its assumption of the patent’s validity.\textsuperscript{26} Attacking this assumption as overstated, the court cited a number of studies indicating that generic challenges to patents frequently prevail.\textsuperscript{27} The Third

\textsuperscript{19} Id. at 207.
\textsuperscript{20} In re Schering-Plough Corp., Final Order, 136 F.T.C. 956, 1052 (2003).
\textsuperscript{21} Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005)
\textsuperscript{22} In re K-Dur Antitrust Litig., 686 F.3d 197, 207–08 (3d Cir. 2012).
\textsuperscript{23} Id. at 208.
\textsuperscript{24} Id. at 211–14 (providing an overview of the Eleventh, Second, and Federal Circuit decisions applying the scope of the patent analysis).
\textsuperscript{25} See, e.g., King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F.Supp.2d 514, 528–29, 533 (E.D.Pa. 2010) (using the scope of the patent analysis, but denying a motion to dismiss because the plaintiffs alleged that the underlying patent suit was meritless).
\textsuperscript{26} In re K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012).
Circuit also noted that testing and eliminating weak patents is a practice that serves the public interest.

To support this point, the opinion reviewed the Supreme Court’s reasoning in *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co.*, wherein the Court considered whether a patent licensor could be estopped from challenging the validity of a patent under an agreement that had a price-fixing term.\(^{28}\) In *Edward Katzinger*, the Court reasoned that if the patent was invalid, the price-fixing term in the contract would violate antitrust laws, and as a result, the licensor had the ability to challenge the patent.\(^{29}\)

The Third Circuit in *K-Dur* reasoned that a similar rationale applied because if the underlying patent was invalid, the settlement would amount to an agreement to allocate market share.\(^{30}\) Consequently, the patent’s validity could prove crucial when determining whether a settlement violated the antitrust laws.

Recognizing the intent behind the Act was to balance incentives between generic firms seeking market entry and patent-holders seeking protection on their R&D investment, the Third Circuit determined that a truncated rule of reason analysis was appropriate.\(^{31}\) Under this approach, the Third Circuit would view reverse settlements within the context of generic pharmaceutical products as restraints of trade. A defendant could then rebut this presumption by showing either that the payment was for something other than delayed generic entry or that the settlement had some procompetitive effect.\(^{32}\) Accordingly, the Third Circuit reversed and

\(^{28}\) *In re K-Dur Antitrust Litig.*, 686 F.3d at 216 (discussing *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co.*, 329 U.S. 394 (1947)).

\(^{29}\) *Edward Katzinger*, 329 U.S. at 399, 401–02.

\(^{30}\) *In re K-Dur Antitrust Litig.*, 686 F.3d at 216.

\(^{31}\) *Id.* at 217.

\(^{32}\) *Id.* at 218.
remanded the case, allowing Schering-Plough the opportunity to demonstrate that either exception applied.  

**CONCLUSION**

This recent decision has further split the circuits’ analysis of reverse settlements. However, the Third Circuit’s application of a rule of reason analysis represents a middle path between two extremes. The Sixth Circuit’s *per se* analysis would effectively eliminate reverse settlements and push parties toward litigation; as a result, the prospect of an expensive patent litigation could chill generics’ efforts to challenge patents. Conversely, the scope of the patent test removes consumer considerations from the settlement calculus, depriving consumers from the intended benefit of the Hatch–Waxman Act and even forcing them to finance these settlements as they continue paying monopoly prices for brand-name drugs. The Third Circuit’s approach adopts a presumption that favors consumers, but also offers pharmaceutical companies the option of entering into reverse settlements and defending them with procompetitive rationales. In either case, a rule of reason analysis benefits consumers as it promotes a more competitive pharmaceutical market.

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33 *Id.*