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In re K-Dur Antitrust Litigation: Reopening the Door for Pharmaceutical Competition

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***In re K-Dur* Antitrust Litigation:
Reopening the Door for Pharmaceutical Competition**

Ahalya Sriskandarajah



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By Ahalya Sriskandarajah*

One of the most controversial legal questions in the pharmaceutical industry today concerns settlements of patent infringement suits between branded and generic drug companies. These settlements, which are by-products of the Hatch-Waxman Act, involve payments from the branded manufacturer to the generic drug company in exchange for the generic company staying off the market for a period of time. For nearly a decade, courts considering this issue applied a scope of the patent test to determine the validity of these settlements. Over time, increasing deference was given to a presumption of patent validity, and almost all challenged settlements were deemed valid. In June 2012, the Third Circuit applied a quick look rule of reason test and found the settlement in question invalid. The Third Circuit's departure from the prevailing approach taken by its sister circuits marked a shift towards stricter scrutiny and created a circuit split. After almost a decade of effort by the Federal Trade Commission to get this issue before the Supreme Court, certiorari was granted to a patent settlement case out of the Eleventh Circuit, Actavis. It was the Third Circuit's decision in favor of the FTC's position that clinched the effort this time. Following Actavis, reverse-payment settlements are not categorically immune from the antitrust laws even when within the scope of the patent. Lower courts must now weigh the settlement's possible pro-competitive benefits against its potential anticompetitive effects. As a result, the doors have been reopened for pharmaceutical competition.

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¶1 One of the most controversial legal questions in the pharmaceutical industry today concerns settlements of patent infringement suits between branded and generic drug companies.¹ These settlements, which are byproducts of the Hatch-Waxman Act, involve payments from the branded manufacturer to the generic drug company in exchange for the generic company staying off the market for a period of time.² In effect, the Act creates a financial incentive for branded manufacturers of drugs to settle their patent infringement claims by paying generic manufacturers to refrain from selling their product. These settlements are often called reverse-payment settlements because the plaintiff in the patent infringement suit, the branded company, pays the defendant, the generic company. They are also sometimes referred to as pay-for-delay settlements, although this is an arguably loaded name.³

¶2 The D.C. Circuit and Sixth Circuit were the first to address reverse-payment settlements, but the opinions were inconclusive.⁴ In *Andrx Pharmaceuticals*, the D.C. Circuit dismissed the case on the pleadings.⁵ In *In re Cardizem CD Antitrust Litigation*, the Sixth Circuit's precise holding is unclear because the agreement at issue involved products not covered by the challenged patent.⁶

¶3 The Second, Eleventh, and Federal Circuits decided this issue next and established a judicial policy favoring reverse-payment settlements among federal courts of appeals. These circuits made it clear in decisions issued between 2003 and 2008 that reverse-payment settlements are not prohibited by the antitrust laws as long as the settlement falls within the "scope of the patent."⁷ They agreed that patents confer the right to exclude

¹ See Wendy H. Schacht & John R. Thomas, Cong. Research Serv., IB10105, THE HATCH-WAXMAN ACT: PROPOSED LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENTS 4 (2004), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/IB10105.pdf>.

² See Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 417 (1999).

³ Kurt R. Karst, *Hot Ticket Item—Patent Settlement Agreement Challenges*, FDA LAW BLOG (Aug. 29, 2012), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/08/hot-ticket-item-patent-settlement-agreement-challenges-.html.

⁴ See *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

⁵ J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, *Pharmaceutical Patent Settlements and the Supreme Court*, Remarks at CBI's 2nd Annual Life Sciences Compliance, Legal, and Regulatory Congress 1, 2–3 (Sep. 21, 2012), available at <http://www.ftc.gov/speeches/rosch/120921cbipharmaspeech.pdf>.

⁶ *Id.*

⁷ See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 (11th Cir. 2003).

others from “profiting from the patented invention” and stopping competitors from marketing the products to which the patents apply is an exercise of that right.⁸ Therefore, reverse-payment settlements are not subject to antitrust scrutiny so long as the agreed-upon delay in marketing the allegedly infringing generic does not extend beyond the patent-protection period.⁹ The approach used by these Courts assumes the underlying patent held by the branded company is “not only valid but infringed.”¹⁰ Applying the scope of the patent test, numerous settlements of this type have been found valid under antitrust laws in these circuits.¹¹

¶4 The Third Circuit’s July 16, 2012 decision in *In re K-Dur Antitrust Litigation* is a dramatic departure from the standard set by its sister circuits for resolving the validity of reverse-payment agreements arising under the Hatch-Waxman Act.¹² The Third Circuit, in a unanimous panel decision, squarely rejected the scope of the patent test used by the Second, Eleventh, and Federal Circuits and instead adopted a quick look rule of reason approach.¹³ The Third Circuit took issue with the scope of the patent test’s almost irrefutable presumption of patent validity.¹⁴ As a move toward stricter scrutiny, the quick look rule looks to the “economic realities of the reverse payment settlement.”¹⁵ The rule requires courts to:

treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry [of generic competitors] or (2) offers some pro-competitive benefit.¹⁶

¶5 This Note begins in Part I with an overview of the Hatch-Waxman Act, its impact on the drug development process, and how the Act has spawned reverse-payment settlements between branded and generic pharmaceutical companies. Part II recounts the treatment of reverse-payment settlements in court and focuses on the decisions which gave rise to the scope of the patent test. In particular, the section will examine the evolution of the scope of the patent test and its increasing deference to the presumption of patent validity over time. Part III discusses the Third Circuit’s holding in *In re K-Dur Antitrust Litigation* and how it represents a major step away from deference and towards stricter scrutiny. The benefits and drawbacks of the quick look rule of reason test will be considered in light of the scope of the patent test. This section will discuss how the quick look test better serves the underpinnings of the Hatch-Waxman Act and patent law.

⁸ See *In re Ciprofloxacin*, 544 F.3d at 1333.

⁹ Jeffrey May, *Third Circuit Rejects Scope-of-Patent Test in Antitrust Challenge to K-Dur Patent Settlement*, WOLTERS KLUWER LAW & BUS. (July 16, 2012), <http://antitrustconnect.com/2012/07/16/third-circuit-rejects-scope-of-patent-test-in-antitrust-challenge-to-k-dur-patent-settlement/>.

¹⁰ Rosch, *supra* note 5, at 6.

¹¹ See, e.g., *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012); *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010).

¹² *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

¹³ *Id.*

¹⁴ *Id.* at 214–15.

¹⁵ *Id.* at 218.

¹⁶ *Id.*

Finally, this Note concludes in Part V with a review of what has occurred since *In re K-Dur*. This section looks at the Supreme Court's 2013 decision in *Actavis*,¹⁷ another reverse-payment settlement case, and argues that the Third Circuit's decision paved the way for the Supreme Court's rejection of the scope of the patent test.

I. AN OVERVIEW OF THE HATCH-WAXMAN ACT

¶6 The Drug Price Competition and Patent Term Restoration Act of 1984 is the federal law that established the modern system of generic drugs.¹⁸ The informal name of the Act, Hatch-Waxman, comes from the Act's two major sponsors, Representative Harry Waxman of California and Senator Orrin Hatch of Utah.¹⁹ The Act was legislatively negotiated to strike a balance between two potentially competing policy interests: "(1) inducing pioneering research and development of new drugs, and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."²⁰

¶7 The Act has played a significant role in the U.S. healthcare system in many respects, the most notable of which is the undeniable impact it has had on the emergence of a robust generic drug industry.²¹ It has been successful in making low-cost generic drugs rapidly available to consumers after patent expiration,²² and based on major strides in pharmaceutical research and development, it evidently has not deterred innovation. Despite the Act's undeniable role in the emergence of the generic drug industry, many also argue that certain provisions of the Act have been exploited to benefit generic or branded pharmaceutical manufacturers and that this has occurred at the expense of both innovation and the "timely introduction of lower cost drugs" to market.²³ These critiques arise from the ways in which drug companies, both generic and branded, behave as a result of the Act and how courts treat this behavior.

A. Main Provisions of the Bill

¶8 Prior to the implementation of the Hatch-Waxman Act, the pharmaceutical market lacked generic competition, and no set process for FDA approval of generic drugs existed. A company seeking approval of a generic version of an existing drug was required to file a New Drug Application (NDA) and independently prove that the drug was safe and effective, even if the pioneer drug had been on the market for years.²⁴

Although there was an option to file a "paper NDA"—where published data regarding the safety and efficacy of the drug could be used as proof—only fifteen generic

¹⁷ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

¹⁸ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2006)).

¹⁹ John M. Coster, *The Waxman-Hatch Generic Drug Law 23 Years Later*, U.S. PHARMACIST (June 19, 2007), http://www.uspharmacist.com/content/c/10305/?t=men%27s_health.

²⁰ *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

²¹ See Coster, *supra* note 19.

²² SCHACHT & THOMAS, *supra* note 1, at 1.

²³ *Id.*

²⁴ See Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, NEIFELD IP LAW P.C. 1, 7, <http://www.neifeld.com/pubs/reviewoffdalawrelatedtopharm.pdf>.

drugs used this method between 1962 and 1984.²⁵ The necessary published data was not readily available for most approved drugs, and it was still possible that the FDA would require further proof, such as expensive clinical trials.²⁶ Potential generics had little incentive to enter the market with such an uncertain and expensive approval process. In addition, would-be generic manufacturers were deterred by the looming risk of patent infringement suits and the associated costs. Manufacturers of generic drugs do not stand to profit as much as branded manufacturers and were therefore not willing to incur such high market entry costs.

¶9 In 1984, the Hatch-Waxman Act established a novel approval process for generic drugs that streamlined the introduction of generics to market. A generic manufacturer may now file an Abbreviated New Drug Application (ANDA).²⁷ The ANDA requires the generic manufacturer to include limited tests that demonstrate the bioequivalence of a proposed generic product to an FDA-approved branded product.²⁸ And instead of conducting independent safety and efficacy studies, the Act permits filing an ANDA that relies on the safety and efficacy data acquired during a branded company's clinical trials conducted prior to the approval of the pioneering drug.²⁹ Generics need not repeat these studies. In addition to these changes, the Act prohibits the FDA from asking for any additional proof regarding safety and efficacy.³⁰ These provisions have been crucial in facilitating the availability of generics on the market at the time of the pioneering drug's patent expiration.

¶10 The Act also confers periods of exclusivity to branded drugs in order to compensate for the improvements made to the approval process of generics. Once a new molecular entity or pioneer drug is approved by the FDA, a generic version of that drug cannot be approved for a period of five years.³¹ Another exclusivity provision involves a period of three years after the date of FDA approval of either a new use of a previously approved molecular entity or a new dosage form using that entity that was based on clinical tests.³² During these three years, the FDA is prohibited from approving an ANDA that relies upon such trials.³³

¶11 These exclusivity periods effectively grant a period of insulation from any possible generic competition to the innovators of pioneer drugs. Exclusivity periods, which run concurrently with any patent protection that may or may not expire during these periods, are designed to “recognize the long, costly, and risky process involved in gaining FDA

²⁵ See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999) (“After 1962, there was congressional testimony that there were 150 drugs that were off-patent, but for which there were no generics because generic companies simply would not spend the time and money doing the clinical trials to get to market, and that there were only fifteen ‘paper NDAs,’ for post-1962 generics.”).

²⁶ See Engelberg, *supra* note 2, at 397.

²⁷ 21 U.S.C. § 355(j)(2)(A) (2006).

²⁸ *Id.* § 355(j)(2)(A)(iv).

²⁹ See *id.* § 355(j)(1)–(2); Karki, *supra* note 24, at 10.

³⁰ See 21 U.S.C. § 355(j)(2)(A).

³¹ *Id.* § 355(c)(3)(E)(ii).

³² See *id.* § 355(c)(3)(E)(iii).

³³ *Id.*

approval for an innovative product” and are necessary to “maintain investment incentives.”³⁴

B. Paragraph IV Certifications in Practice

¶12 When a generic manufacturer files an ANDA, it is also required to file a certification that, “in the opinion of the applicant and to the best of his knowledge,” the proposed generic drug does not infringe any patent listed with the FDA as covering the patented drug.³⁵ A generic manufacturer can satisfy this requirement by certifying that one of the following conditions is satisfied with respect to the branded drug: (I) no patent for the drug was filed with the FDA, (II) the patent on the pioneering drug has expired, (III) the ANDA drug will not be marketed until the patent on the existing pioneer drug expires, or (IV) the patent covering the pioneer drug is invalid or would not be infringed by the ANDA generic drug.³⁶ The last of these is commonly known as a Paragraph IV certification and is the provision that gives rise to Hatch-Waxman litigation between generic and branded pharmaceutical companies and the resultant reverse-payment settlements.

¶13 By statute, a Paragraph IV certification constitutes a technical act of patent infringement.³⁷ When a generic manufacturer files an ANDA that is issued with a Paragraph IV certification, the branded company is promptly notified. The branded company has 45 days from notification to file a patent infringement action against the generic company based on the filing of the Paragraph IV certification alone.³⁸ After the suit has been filed, the FDA cannot approve the application until the generic company successfully defends the suit or until 30 months have passed, whichever comes first.³⁹

¶14 If a generic company is the first to file its ANDA with a Paragraph IV certification and continues on to prevail in the subsequent patent infringement lawsuit, that generic is granted a period of market exclusivity that lasts for 180 days.⁴⁰ A 2002 study conducted by the FTC concluded that generic manufacturers that issued Paragraph IV certifications prevailed in 73% of the patent litigation ultimately resolved by a court between 1992 and 2002.⁴¹ Given this relatively impressive success rate and the 180-day exclusivity period, generic manufacturers have good reason to make Paragraph IV certifications. During the 180-day period, the generic manufacturer can price its product slightly below the branded version, take market share, and maintain its price point before any other generics can enter the market and bring down the price significantly. The potential for profits can be especially great for manufactures that market generic forms of so-called “blockbuster drugs.”

³⁴ Letter from Henry G. Grabowski, Professor of Econ. and Dir. of the Program in Pharm. and Health Econ. at Duke University, to Fed. Trade Comm’n Office of the Sec’y 1, 4 (Dec. 22, 2008), *available at* <http://ftc.gov/os/comments/healthcarecompissues/537778-00040.pdf>.

³⁵ *See* 21 U.S.C. § 355(j)(2)(A)(vii).

³⁶ *Id.*

³⁷ 35 U.S.C. § 271(e)(2)(A) (2006).

³⁸ 21 U.S.C. § 355(c)(3)(C).

³⁹ *Id.* § 355(j)(5)(B)(iii).

⁴⁰ *Id.* § 355(j)(5)(B)(iv).

⁴¹ *See* FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4, 16 (2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

¶15 Generic manufacturers are further incentivized to file Paragraph IV certifications because this provision of the Act redistributes risk in favor of generics.⁴² The infringement suit that follows a Paragraph IV certification poses little risk to the generic because it has not yet caused monetary injury to the branded company.⁴³ The generic has filed an ANDA but has not yet marketed its product.⁴⁴ Not only does the generic have a good chance of winning the suit, but in the event that it loses the remedy granted to the branded company is almost guaranteed to be low enough to warrant making the Paragraph IV certification anyway.

¶16 In contrast, the branded company faces substantial risk because it stands to potentially lose its current monopoly if its patent is deemed invalid.⁴⁵ As a result of this shift in risk distribution, branded manufacturers have a financial incentive to settle the patent infringement claims that it makes as a result of Paragraph IV certifications.⁴⁶ These settlement agreements, called reverse-payment settlements, involve payments from the branded company to the generic company in exchange for the generic company's promise to abandon its challenge and delay entering the market. The legality of these agreements under the antitrust laws has come under scrutiny several times over the last decade.

II. THE EVOLUTION OF THE SCOPE OF THE PATENT TEST

¶17 Until recently, the Second, Sixth, Eleventh, and Federal Circuits have been the only circuits to decide the issue of reverse-payment settlements, and all used some variation of the scope of the patent test. Although the D.C. Circuit was the first to be confronted with a reverse-payment settlement case, that case was dismissed on the pleadings⁴⁷ and therefore added little to the evolution of the scope of the patent test. Next, the Sixth Circuit showed some skepticism regarding the validity of patent settlements and struck down the reverse-payment agreement at issue because its reach was beyond the scope of the patent.⁴⁸ However, the actual outcome was unclear because the agreement at issue involved products not covered by the challenged patent.⁴⁹ The other three circuits to use the scope of the patent test applied increasing deference and treated reverse-payment agreements more leniently. Eventually, extreme deference reduced the scope of the patent test to a mere formality with no real analysis of the parties' conduct under the antitrust laws. Essentially all reverse-payment agreements would pass muster under the latest iterations of the scope of the patent test.

A. *The Sixth Circuit*

¶18 *In re Cardizem CD Antitrust Litigation*, in the Sixth Circuit, involved a drug used “for the treatment of angina and hypertension and for the prevention of heart attacks and

⁴² See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 207 (2d Cir. 2006).

⁴³ See *id.* at 206.

⁴⁴ *Id.* at 206–07.

⁴⁵ *Id.* at 207.

⁴⁶ See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003).

⁴⁷ Rosch, *supra* note 5, at 1, 2.

⁴⁸ See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907–08 (6th Cir. 2003).

⁴⁹ Rosch, *supra* note 5, at 3.

strokes.”⁵⁰ One month after the U.S. Patent and Trademark Office (USPTO) issued a patent for the prescription drug Cardizem CD to the branded company Carderm, which then licensed it to Hoescht Marion Roussel, Andrx Pharmaceuticals filed a Paragraph IV certification.⁵¹ Soon after, Carderm and Hoescht sued Andrx for patent infringement, triggering the thirty-month stay “during which the FDA could not approve Andrx’s ANDA.”⁵²

¶19 After several months of ongoing patent infringement litigation, the FDA announced that it would approve Andrx’s ANDA when the thirty-month stay expired.⁵³ This prompted the litigants to enter into an interim settlement, only nine days after the FDA’s announcement, where Andrx agreed not to market any generic version of the drug, including those not at issue in the litigation, until it obtained a final determination that the patent was not infringed.⁵⁴ This meant that Andrx would stay off the market even after FDA approval of its generic version of the drug. In doing so, Andrx would never use its 180-day period of exclusivity under § 355(j)(5)(B)(iv) of the Hatch-Waxman Act and also would prevent other Paragraph IV filers of the same drug from receiving FDA approval.⁵⁵ On the other end of the agreement, Hoescht agreed to pay Andrx \$40 million per year, which would increase to \$100 million per year if the court determined that the patent was not infringed.⁵⁶

¶20 When the FDA issued its final approval of Andrx’s ANDA, Hoechst began to pay Andrx to stay off the market.⁵⁷ Two months later, Andrx reformulated its product and obtained FDA approval on that version as well.⁵⁸ Following this approval, Hoechst and Andrx terminated the interim agreement and settled the infringement suit with Hoescht paying Andrx \$50.7 million, for a total of about \$90 million.⁵⁹

¶21 Of concern to the Sixth Circuit was the notion that the agreement between Hoechst and Andrx prevented the marketing of all generic versions of the drug and that “it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent’s effectiveness in inhibiting competitors.”⁶⁰ The court found that the settlement guaranteed that Hoechst’s only potential competitor, because of the 180-day exclusivity period, would “refrain from marketing its generic version . . . even after it had obtained FDA approval.”⁶¹

¶22 The court concluded the settlement was “a horizontal agreement to eliminate competition” and “a classic example of *per se* illegal restraint of trade” because it temporarily eliminated all of Hoechst’s competition.⁶² This extended the branded

⁵⁰ *In re Cardizem CD*, 332 F.3d at 901.

⁵¹ *Id.* at 902.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *See id.*

⁵⁵ *Id.* at 907.

⁵⁶ *Id.* at 902–03.

⁵⁷ *Id.* at 903.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 908.

⁶¹ *Id.* at 907.

⁶² *Id.* at 908.

company's monopoly beyond what the patent granted. By striking down the agreement, the Sixth Circuit's decision in *Cardizem* punished conduct that was outside the scope of the patent.

B. The Eleventh Circuit

¶23 Subsequent courts took a different view of the scope test, focusing instead on a patent-holder's right to exclude competitors from the market simply by virtue of having a patent issued to it by the USPTO. The first to do so was the Eleventh Circuit in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*⁶³ Abbott, the branded manufacturer, paid two generic manufacturers to refrain from selling or distributing any pharmaceutical product containing the drug at issue until certain conditions were triggered.⁶⁴

¶24 Like other reverse-payment agreements, these settlement agreements came under antitrust scrutiny because agreements between competitors to allocate the market are considered "so obviously anticompetitive . . . that such agreements can be deemed to violate the Sherman Act without much more than an examination of the agreement itself and the relationship of the parties to the agreement."⁶⁵ The district court held that the agreements between Abbott and the generic drug manufacturers were *per se* illegal under section 1 of the Sherman Act.⁶⁶ The court interpreted them as market allocations between horizontal competitors.⁶⁷

¶25 The Eleventh Circuit disagreed and held that the agreements should not be characterized as market allocation agreements where due consideration is given to Abbott's right to exclude.⁶⁸ The court found that a full analysis of the reverse-payment agreement required "consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the Agreements exceed that scope, and the anticompetitive effects thereof."⁶⁹ In other words, the court held that reverse-payment agreements must be analyzed to determine whether they exceed the patentee's right to exclude others from making, using, or selling the patented subject matter. If the agreement falls within the scope of the exclusionary right granted by patent law, antitrust law is not implicated.

C. The Second Circuit

¶26 Courts then moved from punishing conduct outside the scope of the patent to immunizing almost any activity within the scope of the patent. This marked a further shift toward deference. In *In re Tamoxifen Citrate Antitrust Litigation*,⁷⁰ the Second Circuit upheld a settlement agreement regarding a breast cancer treatment drug.⁷¹ Again, the

⁶³ 344 F.3d 1294 (11th Cir. 2003).

⁶⁴ *Id.* at 1300.

⁶⁵ *Id.* at 1303.

⁶⁶ *Id.* at 1304.

⁶⁷ *Id.*

⁶⁸ *Id.* at 1306.

⁶⁹ *Id.* at 1312.

⁷⁰ 466 F.3d 187 (2d Cir. 2006).

⁷¹ *See id.* at 216, 220.

branded manufacturer and patent holder paid the generic manufacturer to refrain from selling the generic version of the drug.⁷² More specifically, the generic agreed to withdraw its challenge on the patent and also agreed, by switching its Paragraph IV certification to a Paragraph III certification, not to enter the market until the branded company's patent expired.⁷³

¶27 In its analysis, the Second Circuit began by clearly asserting that reverse-payment agreements did not constitute *per se* violations.⁷⁴ It concluded that as long as “the patent litigation is neither a sham nor otherwise baseless” or beyond the patent’s scope, the patentee can enter into a settlement “to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”⁷⁵ The court shifted the focus away from what a patent holder could not do, what powers are not conferred by a patent, and what is considered to be beyond the scope of a patent. Instead, the court concluded that because branded manufacturers have patent rights, they have the lawful authority to prevent “all generic versions of [a drug]” and that a competing version “would . . . necessarily infringe the patent.”⁷⁶ This approach assumes that the underlying patent is in fact valid and deserving of monopolistic power and overlooks the importance of having the validity of patents litigated.

D. The Federal Circuit

¶28 In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,⁷⁷ the Federal Circuit continued the move toward leniency and increasing deference. Much like the Second Circuit, the court focused its analysis on the patent system’s right to exclude and the presumption that patents are valid.

¶29 In 1987, the USPTO issued a patent covering the active ingredient in Cipro, a drug prescribed to treat bacterial illnesses.⁷⁸ In 1991, Barr Labs filed an ANDA for a generic version of Cipro and included a Paragraph IV certification, claiming that the patent was invalid.⁷⁹ As in the previous cases, the branded company sued the generic manufacturer for patent infringement.⁸⁰ This time, just before the trial was set to begin, the parties settled.⁸¹ In the settlement, Barr Labs agreed to change its Paragraph IV certification to a Paragraph III certification in exchange for a payment of \$49.1 million.⁸²

¶30 The Federal Circuit found no error in the district court’s decision to grant the branded company’s motion for summary judgment.⁸³ It held that the agreement at issue only “exclude[d] the defendants from profiting from the patented invention,” which is

⁷² *Id.* at 194.

⁷³ *Id.* at 193, 214–15, 218.

⁷⁴ *Id.* at 206.

⁷⁵ *Id.* at 208–09, 213.

⁷⁶ *Id.* at 214.

⁷⁷ 544 F.3d 1323 (Fed. Cir. 2008).

⁷⁸ *Id.* at 1327–28.

⁷⁹ *Id.* at 1328.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* at 1328–29.

⁸³ *Id.* at 1340–41.

“well within” the branded company’s right as the patentee.⁸⁴ It also expressly deferred to a presumption of patent validity when it rejected the argument that a patent’s exclusionary power is limited by the possibility that it is invalid.⁸⁵

¶31 The Federal Circuit went one step further than the Second Circuit⁸⁶ concluding that the court “need not consider the validity of the patent” as long as there is no evidence of fraud before the USPTO or sham litigation.⁸⁷

E. Summary of Case Law Leading up to *In re K-Dur*

¶32 While initial versions of the scope test focused on antitrust liability and on determining what conduct fell outside the scope of a patent’s exclusionary power,⁸⁸ the focus gradually shifted toward presuming that anything that falls within the scope of a patent is valid.⁸⁹ Under the more permissive scope rule, a patentee is essentially bestowed with the right to exclude others from practicing its patent regardless of the effects this might have on market competition and any possibility that the underlying patent is actually invalid.⁹⁰

¶33 Together, the case law leading up to *In re K-Dur* represents the rule that reverse-payment agreements are not prohibited by antitrust laws except in the rare instances where (1) the agreement restrains trade beyond the exclusionary scope of the relevant patent, (2) the underlying patent infringement is a sham, or (3) the patent was obtained by fraud.⁹¹ This rule raises the issue of whether patent infringement suits that arise from Paragraph IV certifications have been reduced to nothing more than a necessary stepping stone in the process of doing business in the pharmaceutical industry. In fact, “no court applying the scope of the patent test has ever permitted a reverse-payment antitrust case to go to trial.”⁹²

III. MOVING AWAY FROM THE SCOPE TEST: *IN RE K-DUR*

¶34 In a dramatic departure from the scope of the patent test, the Third Circuit in *In re K-Dur Antitrust Litigation*⁹³ expressly rejected the scope test and adopted the “quick look rule of reason test.”⁹⁴

⁸⁴ *Id.* at 1333.

⁸⁵ *Id.* at 1334.

⁸⁶ The Second Circuit found that reverse-payment agreements that fall within the scope of the patent were valid so long as the patent litigation is not a sham or otherwise baseless. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208–09, 213 (2d Cir. 2006); *see also supra* notes 74–76 and accompanying text.

⁸⁷ *In re Ciprofloxacin*, 544 F.3d at 1336.

⁸⁸ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003); *see also* *Andrx Pharm., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 804, 811 (D.C. Cir. 2001).

⁸⁹ *See In re Tamoxifen*, 466 F.3d at 213; *In re Ciprofloxacin*, 544 F.3d at 1336.

⁹⁰ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d Cir. 2012).

⁹¹ *Id.*

⁹² *Id.*

⁹³ 686 F.3d 197 (3d Cir. 2012).

⁹⁴ *Id.* at 218.

A. Background

¶35 K-Dur is a sustained-release potassium chloride supplement used to treat potassium deficiencies.⁹⁵ The branded company, Schering, “did not hold a patent for the potassium chloride salt itself, as that compound is commonly known and not patentable.”⁹⁶ Rather, “Schering held a formulation patent on the controlled release coating it applied to the potassium chloride crystals.”⁹⁷ Two separate settlements made with generic manufacturers gave rise to the antitrust litigation.⁹⁸

¶36 Upsher, a generic manufacturer, filed the first ANDA, including a Paragraph IV certification, seeking approval to produce a generic version of K-Dur and was subsequently sued by Schering for patent infringement.⁹⁹ The litigation settled with an agreement which “provided that, while Upsher did not concede the validity, infringement, or enforceability of the . . . patent, it would refrain from marketing its generic” version or any similar product until an agreed upon date.¹⁰⁰ Upsher also granted Schering licenses to make and sell several pharmaceutical products Upsher had developed. In return, Schering agreed to pay Upsher \$60 million over three years.¹⁰¹

¶37 Generic manufacturer ESI filed an ANDA with a Paragraph IV certification only months after Upsher filed its ANDA.¹⁰² The settlement agreement between Schering and ESI “called for Schering to grant ESI a royalty-free license” under the patent beginning on an agreed upon date and for Schering to pay ESI \$5 million up front in addition to an amount between \$625,000 and \$10 million depending on when ESI’s ANDA was approved.¹⁰³ ESI also “represented that it was not developing and had no plans to develop any other potassium chloride product.”¹⁰⁴

¶38 Both the FTC and various private parties filed antitrust suits attacking the two settlements.¹⁰⁵ The Eleventh Circuit heard and decided the FTC challenge using the scope test.¹⁰⁶ The private suits were consolidated in the District of New Jersey and gave rise to the Third Circuit’s review of reverse-payment settlements in this case.¹⁰⁷ The Third Circuit concluded, contrary to the Eleventh Circuit’s holding in the FTC challenge of the same reverse-payment settlements, that an antitrust quick look rule of reason test should apply rather than the scope of the patent test.¹⁰⁸

⁹⁵ *Id.* at 203.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.* at 205–06.

⁹⁹ *Id.* at 205.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.* at 206.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 206–07.

¹⁰⁶ *Id.* at 207, 211–12.

¹⁰⁷ *Id.* at 207.

¹⁰⁸ *Id.* at 218.

B. *The Quick Look Rule of Reason Test*

¶39 The court instructed the District Court to apply a quick look rule of reason analysis to the remanded case.¹⁰⁹ This test, unlike the scope test, looks to the economic realities of the reverse-payment settlement at issue. In particular, the finder of fact “must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”¹¹⁰ In coming to the conclusion that reverse-payments are prima facie evidence of an unreasonable restraint on trade, the court was persuaded by an argument previously put forth by the D.C. Circuit. In *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*¹¹¹, the D.C. Circuit suggested that it only made logical sense that a “payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement.”¹¹²

IV. THE SCOPE TEST’S SHORTCOMINGS

A. *The Scope Test Tends to Protect Weak and Invalid Patents*

¶40 The Third Circuit criticized the scope of the patent test’s practically irrefutable presumption of patent validity because it “assumes away the question being litigated in the underlying patent suit.”¹¹³ In contrast, the Second, Eleventh, and Federal Circuits have agreed that, “in the absence of evidence of fraud before the USPTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”¹¹⁴ In other words, the scope test relies on the presumption that the patent holder would have prevailed on validity issues.¹¹⁵

¶41 This presumption of patent validity is especially concerning because the holders of weak or narrow patents, which are less likely to prevail in court when their validity comes under judicial scrutiny, are the most likely to enter into reverse-payment agreements in the first instance because they have the greatest incentive to do so. Nearly seventy-five percent of generic manufacturers prevail in Paragraph IV-related patent infringement suits that do get decided in court.¹¹⁶ This statistic alone provides some insight into the prevalence of weak patents and the threat patent holders face when their patents come under reevaluation.

¶42 If a branded manufacturer loses the underlying patent infringement case arising from a Paragraph IV certification, it will certainly no longer control the market.

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ 256 F.3d 799 (D.C. Cir. 2001).

¹¹² 256 F.3d at 809.

¹¹³ *In re K-Dur*, 686 F.3d at 214.

¹¹⁴ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).

¹¹⁵ *In re K-Dur*, 686 F.3d at 214.

¹¹⁶ FED. TRADE COMM’N, *supra* note 41, at viii.

Therefore, the holder of a weak or narrow patent has a strong incentive to settle its suits outside of court in order to avoid the possibility of losing its patent and thus control of the market. By allowing reverse-payment settlements to essentially bypass antitrust scrutiny, the scope test effectively allows the holder of a weak patent to “buy its way out of both competition with the challenging competitor and possible invalidation of the patent.”¹¹⁷ The settlement agreements at issue in some of the representative cases discussed in this note reveal just how motivated branded companies with weak patents are to settle their challenges.

¶43 For example, the patent for the controlled-release coating on K-Dur was initially rejected by the USPTO and was then slightly modified by Schering to circumvent the prior art.¹¹⁸ Both companies that filed ANDAs for generic versions of K-Dur had strong arguments for how each generic did not infringe on the pioneer drug. Upsher’s defense “was based on differences between the chemical composition of the controlled release coating in its generic product and that of the invention claimed” in the patented controlled-release coating.¹¹⁹ ESI defended on the ground that its generic version did not employ a coating material with two different ingredients as claimed in the patent.¹²⁰ Due to the narrowness of Schering’s patent, it was very likely that the generic products did not infringe the patent and would have been allowed to enter the market if the case had not settled outside of court. Likewise, the patent at issue in *Valley Drug* was declared invalid in a separate case that took place after the reverse-payment agreement.¹²¹ Once again, the holder of a weak, or in this case an invalid, patent readily agreed to pay the supposedly infringing generic to eliminate the threat to its questionable patent.

¶44 The mere fact that a patent holder would be willing to pay an alleged infringer to settle a case and avoid the potential revocation of its patent should signal a red flag indicating the weakness of the patent. A holder of a strong patent should not be threatened by a Paragraph IV certification, and the cost of continuing litigation is presumably lower, especially after remedies are awarded, than the millions of dollars branded manufactures pay to generic companies in reverse-payment agreements.

B. The Scope Test is Contrary to the Policies Underlying the Hatch-Waxman Act

¶45 Earlier courts that used the scope test did so partially to satisfy the policy goal of encouraging settlement, especially if it meant preserving incentives for innovation. The Second Circuit, for example, stated that rules “severely restricting” settlements could hamper the patent system’s goals by increasing uncertainty and delaying innovation.¹²² But the Third Circuit correctly recognized that the Hatch-Waxman Act itself reflects Congress’s position on the balance between competition and innovation in the pharmaceutical industry.¹²³

¹¹⁷ 686 F.3d at 215.

¹¹⁸ *Id.* at 205.

¹¹⁹ *Id.*

¹²⁰ *Id.* at 206.

¹²¹ *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306–07 (11th Cir. 2003).

¹²² *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006).

¹²³ *In re K-Dur*, 686 F.3d at 217.

¶46 The policy of encouraging settlements is important, but it should be considered in light of countervailing public policy objectives. With respect to the pharmaceutical industry, Congress knowingly dealt with competing policy interests and deliberately decided that the equilibrium should shift toward favoring competition and increasing the availability of low-cost generic drugs.¹²⁴ These preferences are memorialized in the Hatch-Waxman Act. Allowing reverse-payment settlements to escape antitrust scrutiny, as the scope test does, defeats the goals of the Act because reverse-payment settlements eliminate the competition that the Act seeks to increase.¹²⁵

¶47 It is also important to note that the Third Circuit’s quick look rule does not prevent parties from reaching settlements “based on a negotiated entry date for marketing of the generic drug.”¹²⁶ Only reverse-payments are subject to antitrust scrutiny under the Third Circuit’s quick look rule.¹²⁷ This means that the quick look rule does not limit the vast majority of pharmaceutical settlements¹²⁸ and thus continues to uphold the general objective of encouraging settlements where no countervailing policy objectives take precedent.

V. REOPENING THE DOOR FOR PHARMACEUTICAL COMPETITION

¶48 Although the FTC has been questioning reverse-payment settlements for almost a decade now,¹²⁹ the Third Circuit’s decision in *In re K-Dur* marks the first appellate court decision to cast a shadow of uncertainty on the legality of reverse-payment settlements. While the Sixth Circuit was the first to strike down a reverse-payment settlement in *In re Cardizem*, as discussed previously, the facts in that case were sufficiently different from those disputed in the Second, Third, Eleventh, and Federal Circuits because the agreement included products outside the challenged patent.¹³⁰ In summary, the Eleventh, Second, and Federal Circuits all held reverse-payment agreements to be legal provided that they are within the scope of the underlying patent. The Third Circuit, however, was the first to decide in favor of the FTC’s position, holding that these agreements are presumptively anti-competitive.

¹²⁴ *See id.*

¹²⁵ *See id.*

¹²⁶ *Id.* at 217–18.

¹²⁷ *Id.* at 218.

¹²⁸ *See* 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 2 (2011), *available at* <http://www.ftc.gov/os/2011/05/1105mmagreements.pdf> (showing that nearly seventy-five percent of the Hatch-Waxman Act infringement suits that settled in fiscal year 2010 did so without reverse-payments).

¹²⁹ Kevin E. Noonan, *Supreme Court to Review Reverse Payment Settlement Agreements*, PATENT DOCS (Dec. 9, 2012), <http://www.patentdocs.org/2012/12/supreme-court-to-review-reverse-payment-settlement-agreements.html>.

¹³⁰ *See generally In re K-Dur*, 686 F.3d 197; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 207 (2d Cir. 2006); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 (11th Cir. 2003).

A. *Petitions for Certiorari*

¶49 Certiorari petitions were filed asking the U.S. Supreme Court to review both *In re K-Dur* and another challenge to a reverse-payment agreement in the Eleventh Circuit, *Federal Trade Commission v. Watson Pharmaceuticals, Inc.*,¹³¹ which applied the scope test and found the agreement to be legal.¹³² The petition in *Watson Pharmaceuticals* was filed by the FTC, which, instead of simply filing a petition that asked to be bound by the court's decision in *In re K-Dur*, filed a full certiorari petition.¹³³ The FTC argued that *Watson Pharmaceuticals* was the superior vehicle for the Supreme Court to weigh in on reverse-payment settlements because *In re K-Dur* was private litigation while the *Watson Pharmaceuticals* case was “brought by a federal agency charged by Congress with challenging unfair methods of competition.”¹³⁴ The question presented in the FTC's certiorari petition was as follows:

[w]hether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the [Eleventh Circuit] held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).¹³⁵

¶50 The FTC had good reason to want to control how the case was presented to the Court. As the government agency “responsible for reviewing agreements settling litigation under the Hatch-Waxman Amendments” the FTC has a vested interest in ensuring that reverse-payment settlements receive proper legal treatment.¹³⁶ This interest was further bolstered by the growing economic impact of these settlements. A 2010 analysis by the FTC found that reverse-payment settlements cost consumers \$3.5 billion annually.¹³⁷ If companies are deterred from settling, a significant portion of this \$3.5 billion could be recovered by consumers: the constituency Congress intended the Hatch-Waxman Act to protect. “The FTC estimates that about one year after market entry an average generic pharmaceutical product takes over ninety percent of the patent holder's unit sales and sells for fifteen percent of the price of the name brand product” and that consumers are the greatest beneficiaries of generic entry.¹³⁸

B. *Actavis—The Supreme Court Weighs In*

¶51 The Supreme Court granted certiorari on December 7, 2012 in *Watson Pharmaceuticals*, later renamed *Actavis*.¹³⁹ This marked “the culmination of almost a decade of effort by the Federal Trade Commission to get [this issue] before the Court;

¹³¹ 677 F.3d 1298 (11th Cir. 2012), *rev'd sub nom.*, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

¹³² See Noonan, *supra* note 129.

¹³³ *Id.*

¹³⁴ Petition for a Writ of Certiorari at 29, *Actavis*, 133 S. Ct. 2223 (No. 12-416).

¹³⁵ *Id.* at I.

¹³⁶ *Id.* at 29.

¹³⁷ Fed. Trade Comm'n, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

¹³⁸ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012) (citing *id.* at 8).

¹³⁹ See *FTC v. Watson Pharm., Inc.*, 133 S. Ct. 787 (2012).

what clinched the effort this time was the decision in the *K-Dur* case by the Third Circuit in favor of the FTC's position."¹⁴⁰ The case was argued on March 25, 2013, and on June 17, 2013, the U.S. Supreme Court issued its long-awaited ruling on reverse-payment settlements of patent litigation.¹⁴¹

¶52 The Eleventh Circuit had dismissed the FTC's complaint in *Watson Pharmaceuticals*.¹⁴² The Supreme Court, however, disagreed with the Eleventh Circuit's use of the scope of the patent test and held that "the Eleventh Circuit should have allowed the FTC's lawsuit to proceed."¹⁴³ Although the scope of the patent test was rejected, the Third Circuit's quick look rule of reason test was not entirely favored either.¹⁴⁴ The Court rejected the FTC's arguments for finding reverse-payment settlements presumptively unlawful and instead instructed lower courts to use a "rule-of-reason" approach.¹⁴⁵ The Court took issue with the quick look rule because such a rule is appropriate only where a person having even a basic understanding of economics could come to the conclusion that the agreement in question would be anti-competitive.¹⁴⁶ Reverse-payment settlements, according to the Court, do not "meet this criterion" because the effects of these settlement agreements depend on several factors.¹⁴⁷ The rule of reason test is not intended to require empirical proof of the "virtues or vices of the patent system" or a presentation of "every possible supporting fact or . . . every possible pro-defense theory," but the Supreme Court left it up to lower courts to structure the specifics of reverse-payment antitrust litigation using the rule of reason approach.¹⁴⁸

¶53 Following *Actavis*, reverse-payment settlements are not categorically immune from the antitrust laws even when within the scope of the patent. This outcome is an important win for the FTC. Lower courts must now weigh the settlement's possible pro-competitive benefits against its potential anticompetitive effects. Pharmaceutical manufacturers, both branded and generic, should consider the balance of pro- and anticompetitive effects when deciding whether to enter into a settlement. This consideration alone may reduce the number of anti-competitive settlement agreements. Although the Supreme Court did not grant certiorari in *In re K-Dur*, it was the circuit split that the Third Circuit created that provoked the Supreme Court to review and decide this long-standing legal issue.¹⁴⁹ As a result, the doors have been reopened for pharmaceutical competition.

¹⁴⁰ Noonan, *supra* note 129.

¹⁴¹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

¹⁴² *Id.* at 2227.

¹⁴³ *Id.*

¹⁴⁴ *See id.* at 2237.

¹⁴⁵ *Id.* at 2238.

¹⁴⁶ *See id.* at 2237.

¹⁴⁷ *See id.*

¹⁴⁸ *Id.* at 2237–38.

¹⁴⁹ *See id.* at 2230.

