SUPREME COURT "QUICKLY" ENDS CIRCUIT SPLIT OVER REVERSE PAYMENTS WITHOUT THE ADOPTION OF A "QUICK" ANALYSIS: WHY THE RULE OF REASON IS INFERIOR TO THE "QUICK LOOK" RULE OF REASON

Adrianna Exler[1]

I. INTRODUCTION

The laws of innovation and intellectual property have been well established and prominently secured in the United States since the enactment of the U.S. Constitution. Article I, Section 8 of the U.S. Constitution states: "Congress shall have Power . . . To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[2] The patent rights granted to an inventor, upon successful acceptance by the Patent and Trademark Office (PTO), are directly correlated to upholding the Constitutional principle of promoting innovation of the arts and sciences.

The current existing laws of the Patent Act of 1952 comprise Title 35 of the United States Code, which grant patent holders the right to exclude others from making, using, offering for sale, or selling the invention.[3] The right to exclude is an intricate

[1] Managing Notes Editor, Rutgers Journal of Law & Public Policy; J.D. Candidate May 2014, Rutgers University School of Law – Camden.

[2] U.S. CONST. art. I, § 8, cl. 8.

[3] 35 U.S.C.A. § 154(a)(1) (2012).

aspect of the Patent Act in protecting the inventions of the patent holder. "The constitutional reward of a patent, together with the constitutional requirements of utility, novelty, and non-obviousness, represent a delicate balance struck between the need to encourage innovation and the avoidance of exclusive rights that stifle competition without any concomitant advantage to society."[4] This *quid pro quo* balance of innovation and competition is the essence of what our founding fathers envisioned in the adoption of Article I, Section 8 of the U.S. Constitution.[5]

The intricacies of patent protection are especially critical to the pharmaceutical drug industry. Judge Posner of the Seventh Circuit Court of Appeals provides three reasons that emphasize the crucial need for the patent protection of drug companies.[6] First, "[n]ew drugs cost millions of dollars to develop."[7] Second, drug companies do not accrue money over the life of the patent for their invention because it takes years of testing to bring a new product to the market.[8] Third, those who copy the drug after it has been disclosed are able to reap the benefits at a significant lesser cost than those who spent a large portion of money and time in developing the original drug.[9] It is evident that pharmaceutical drug companies are part of an industry that is affected by the patent laws and loopholes that may follow from lack of adequate patent protection.

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[4] Gene Quinn, *The Constitutional Underpinnings of Patent Law*, IPWATCHDOG (May 11, 2011, 11:50 AM), http://www.ipwatchdog.com/2011/05/11/the-constitutional-underpinnings-of-patent-law/id=16865/; *see* Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 146 (1989) ("The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'").

[5] Quinn, *supra* note 4.

[6] Alison Frankel, *3rd Circuit Shocker: Pay-for-Delay Drug Settlements are Illegal*, REUTERS (July 17, 2012, 4:28 PM), http://blogs.reuters.com/alison-frankel/2012/07/17/3rd-circuit-shocker-pay-for-delay-drug-settlements-are-illegal/.

[7] *Id.*

[8] *Id.*

[9] *Id.*

"[D]isputes arise when a drug manufacturer develops a generic equivalent to a brand drug" and tries to gain entry into the market for that drug.[10] The Hatch-Waxman Act facilitates the settlement of such disputes in which there is payment from the brand name drug manufacturer to the generic manufacturer.[11] These payments are known as reverse payments, which flow from patentees to the challengers and "may even exceed what the generic could have earned by entering the market."[12] Essentially, the reverse payment settlement establishes that the brand name manufacturer will pay the generic manufacturer to not enter its drug into the market and to ultimately not compete.

Reverse payments, or pay-for-delay settlements, have become increasingly popular with pharmaceutical companies over recent years and have become increasingly controversial among the courts that adhere to the issues arising from such settlements. In recent years, the courts have "blessed" reverse payments, explaining that they increase innovation and reduce costs.[13] However, the courts have not come to an agreement on how to adequately answer the question of whether, and to what extent, reverse payments are lawful, and therefore, a split among the United States Circuit Courts of Appeals has become apparent. [14] As a result, the United States Supreme Court granted certiorari to review the underlying antitrust violations of reverse payments and to settle the issue of the legality of such

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[10] Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 255, 256 (2009).

[11] *Id.* at 257. The Hatch-Waxman Act encourages generic manufactures to challenge the patents of brand name manufactures and "puts in place the legal regime for resolving these disputes." *Id.* at 256.

[12] MICHAEL A. CARRIER, INNOVATION FOR THE 21ST CENTURY HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST 346 (2009).

[13] *Id.* at 97.

[14] Kendyl Hanks et al., *"Pay-for-Delay" Settlements: Antitrust Violation or Proper Exercise of Pharmaceutical Patent Rights?*, AMERICAN BAR ASSOCIATION: BUS. LAW TODAY (Jan. 27, 2011), http://apps.americanbar.org/buslaw/blt/content/2011/01/article-hanks.shtml.

payments once and for all in its recent decision of *FTC v. Actavis, Inc.*[15]

This note focuses on the Third Circuit decision of *In re K-Dur Antitrust Litigation*, which was vacated and remanded to the Third Circuit in light of the Supreme Court's recent holding in *FTC v. Actavis, Inc.*[16] The Third Circuit took the path less traveled by the circuit courts in deciding the legality of reverse payment settlements and held that the scope of the patent test "improperly restricts the application of the antitrust law . . . "[17] In place of the scope of the patent test, the court adopted a rule of reason antitrust analysis based test called the quick look rule of reason that concentrates on "the economic realities of the reverse payment settlement rather than the labels applied by the settling parties."[18] Essentially, the Third Circuit created a circuit split on the issue of reverse payments, and thus, increased the likelihood that the Supreme Court would eventually take up the issue.[19]

This note argues that the Supreme Court's implementation of a full rule of reason analysis in determining the legality of reverse payments between a brand name pharmaceutical manufacturer and a generic pharmaceutical manufacturer is not a favorable analysis in light of the Third Circuit's implementation of a quick look rule of reason analysis. A quick look analysis is not only supported by the underlying principles of the Hatch-Waxman Act, but it is also aligned with Supreme Court precedent of patent litigation as well as the utilitarian theory of patent law. While the analysis portion itself adheres to whether or not the settlement constitutes an antitrust violation, a quick look rule of reason analysis also aligns with pertinent principles of well-established patent law. In analyzing the issue of reverse payments, violations of both antitrust law and patent

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[15] FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

[16] *See* Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013);* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013).

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

[18] *Id.* at 218.

[19] Frankel, *supra* note 6.

law must be considered; a quick look rule of reason analysis does just that.

Part II of this note reviews the history of the Circuit Split among the courts on the legality of reverse payment settlements. It explores the landmark cases of the different circuits and a timeline of what the courts have most recently held in deciding this matter. Part II concludes by discussing the Supreme Court's recent ruling on the issue and its implementation of a full rule of reason analysis for reverse payments.

Part III explores the reasons why the application of the Third Circuit's quick look rule addresses both antitrust scrutiny as well as patent law. Support is offered from Supreme Court precedent cases, the underlying principles of the Hatch-Waxman Act, and the utilitarian theory of patent law. It then goes on to discuss how the numerous flaws that are present within the scope of the patent test make such a test less favorable for determining the legality of reverse payments.

Part IV considers the potential problems of the Supreme Court's suggested implementation of a full rule of reason analysis for cases in the pharmaceutical market. It then compares the quick look rule of reason analysis to the full rule of reason analysis to indicate the shortcomings associated with the latter in antitrust scrutiny analysis.

This note concludes by emphasizing why the Third Circuit's adoption of a quick look rule of reason should not have been vacated by the Supreme Court, but rather upheld and encouraged for future courts in addressing this issue. The courts should not stray away from the strong foundation of the utilitarian theory of patent law and the purposes the theory seeks in promoting innovation, especially in the pharmaceutical industry. In following through with the decisional process on the legality of reverse payment settlements, the courts must remain cognizant of the importance of protecting consumers and deterring monopolies within the pharmaceutical markets.[20] The quick look rule of reason satisfies all these objectives and more; thus, it is the more favorable approach in adhering to the controversial issue of reverse payment settlements.

[20] *In re K-Dur*, 686 F.3d at 217.

II. CIRCUIT SPLIT ON THE LEGALITY OF REVERSE PAYMENT SETTLEMENTS

With the enactment of the Hatch-Waxman Act of 1984, generic drug manufacturers and brand name manufacturers were encouraged to settle patent litigation through agreements set forth in the framework of the Act. More recently, these agreements have involved large payments from brand patentees to generic challengers referred to as reverse payments, which differ from licensing payments that flow from challengers to patentees.[21] The Federal Trade Commission (FTC) does not look fondly upon reverse payment settlements and considers such settlements to be *per se* violations of the Sherman Antitrust Act.[22] "[O]ne of the worst things about pay-for-delay settlements, in the eyes of the FTC, is that they have the blessing of the federal judiciary."[23]

The earlier rulings by federal circuit courts held that reverse payment settlements constituted illegal restraint of trade. The more recent federal circuit court decisions have held that these settlements are "natural by-products" of the Hatch-Waxman Act[24] and do not violate antitrust laws.[25] The circuit split among the federal circuit courts on the legality of reverse payment settlements recently came to an end when the Supreme Court rejected both the scope of the patent test and the quick-look rule of reason analysis for determining the legality of such agreements, and rather held that reverse payment settlements should be evaluated for antitrust violations under a rule of reason approach.

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[21] Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39 (2009).

[22] Hanks et al., *supra* note 14.

[23] Frankel, *supra* note 6.

[24] Carrier, *supra* note 21, at 40.

[25] Frankel, *supra* note 6; *see In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206 (2d Cir. 2006) (concluding that reverse payments are not *per se* violations of the Sherman Act and such allegations do not suffice to assert an antitrust violation).

A. STRICT ANTITRUST SCRUTINY

The first two courts – the D.C. Circuit and the Sixth Circuit – to rule on the question of reverse payments concluded that such payments should be subject to strict antitrust scrutiny and held that reverse payments are prima facie evidence of an illegal restraint of trade.[26]

1. D.C. Circuit

In *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, Andrx filed an Abbreviated New Drug Application (ANDA) with the FDA seeking approval to manufacture and sell the generic form of Cardizem CD, which is a brand name prescription drug manufactured by Hoechst Marion Roussel, Inc. (HMRI).[27] In response, HMRI entered into an agreement with Andrx in which HMRI would pay Andrx forty million dollars a year to not market or sell its generic form of Cardizem CD.[28] The purpose the agreement was to delay Andrx from triggering its 180-day exclusivity period, which in turn prevented the FDA from granting approval to any subsequently filed applications from manufacturers.[29] The D.C. Circuit concluded that such an agreement was composed of anticompetitive provisions, one of which directed Andrx to "continue to pursue its ANDA so as to forestall other applicants from receiving final FDA approval," and such provisions "could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions".[30]

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[26] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 210 (3d Cir. 2012).

[27] Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 803 (D.C. Cir. 2001).

[28] *Id.*

[29] *Id.* at 804.

[30] *Id.* at 811 (discussing the difference between restraints on trade that are *per se* unlawful and ancillary restraints that are not *per se* unlawful because they facilitate productive activity).

2. Sixth Circuit

The Sixth Circuit decision of *In re Cardizem CD Antitrust Litigation* arises from the same reverse payment agreement that was considered and decided by the D.C. Circuit. As a result of this settlement, several other pharmaceutical companies brought forth claims to challenge that such a settlement was "a violation of the antitrust laws and argued that, but for the agreement . . . the generic version would have come on the market earlier . . . "[31] The Sixth Circuit emphasized the point made by the D.C. Circuit that the agreement not only delayed the entry of Andrx into the market, but also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity.[32] Moreover, the court held in finality that such an agreement was an agreement to eliminate competition in the market for Cardizem CD throughout the entire country, which is a classic example of a *per se* illegal restraint of trade.[33]

Until the recent ruling of the Third Circuit, no other appellate court or district followed the D.C Circuit or the Sixth Circuit conclusion that reverse payment settlements constitute a *per se* illegal restraint of trade.[34]

B. SCOPE OF THE PATENT TEST

The more recent decisions of the circuit courts on the legality of reverse payment settlements have held a contrary view from that of the earlier circuit courts on this issue. These courts adopted the scope of the patent test, which holds that such settlements are permissible as long as they do not extend beyond the exclusionary scope of the patent at issue.[35]

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[31] Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 294–95 (2011).

[32] *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 907 (6th Cir. 2003).

[33] *Id.* at 908.

[34] Hanks et al., *supra* note 14.

[35] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 209 (3d Cir. 2012).

1. Eleventh Circuit

The landmark case, decided by the Eleventh Circuit, on the issue of reverse payment settlements was *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* Abbott Laboratories manufactured Hytrin, a drug used to treat hypertension and enlarged prostate.[36] Two generic pharmaceutical competitors, Geneva Pharmaceuticals and Zenith Goldine Pharmaceuticals, filed ANDAs challenging Abbott's patents on Hytrin.[37] Abbott responded by filing infringement suits against both generic competitors.[38] To settle the claims, Abbott entered into reverse payment agreements with both Geneva and Zenith that directed the two generic competitors to ultimately delay the release of their generic form of Hytrin by not selling or distributing the drug until Abbott's patent expired or someone else introduced a generic form of Hytrin.[39]

The district court issued an order holding that the agreements were *per se* illegal under Section 1 of the Sherman Act.[40] The Eleventh Circuit reversed, holding that the exclusion of infringement competition is the essence of the patent grant.[41] Furthermore, the court reasoned that to the extent effects of the agreement are "within the scope of the exclusionary potential of the patent," those effects should not be subject to *per se* antitrust condemnation.[42]

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[36] Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1298 (11th Cir. 2003). The patent has since expired, and Abbott was issued other patents for the various crystalline forms of the compound used in Hytrin. *Id.*

[37] *Id.* at 1298–99.

[38] *Id.* at 1299.

[39] *Id.* at 1300.

[40] *Valley Drug Co.*. at 1301.

[41] *Id.* at 1306.

[42] *Id.* 1311. Provisions of the agreement found to go beyond the exclusionary scope of the patent "may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate [Section] 1 of the Sherman Act." *Id.* at 1312 (quoting *Standard Oil Co., Ind. v. United States*, 283 U.S. 163, 175 (1931)).

The Eleventh Circuit subsequently confirmed its holding set forth in *Valley Drug Co.* in the decision of *Schering-Plough Corp. v. Federal Trade Commission*. Schering manufactures and markets K-Dur 20, which is used to treat high blood pressure or congestive heart disease. [43] Similar to the facts of *Valley Drug Co.*, two generic competitors of Schering, Upsher-Smith Laboratories and ESI Lederle, Inc., sought FDA approval to market a generic form of K-Dur 20.[44] Schering entered into settlements with both of the generic competitors, which set forth specific dates on which Upsher and ESI would be able to enter the market with their generic form of K-Dur 20.[45]

The FTC filed a complaint against Schering alleging that the agreements were illegal restraints of trade in violation of both the Federal Trade Commission Act and the Sherman Act.[46] "[T]he Commission concluded that the *quid pro quo* for the payment was an agreement to defer the entry dates, and that such delay would injure competition and consumers."[47] The Eleventh Circuit reversed, reemphasizing that neither the rule of reason nor the *per se* analysis is appropriate in the context of deciding the legality of reverse payment settlements.[48] Instead, the court adopted the standard as set forth in *Valley Drug Co.* and concluded that the proper analysis of antitrust liability encompasses the examination of: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[49]

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[43] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005).

[44] *Id.* at 1058, 1060.

[45] *Id.* at 1059-60. The settlement between Schering and ESI allowed ESI to enter into the market on January 1, 2004, almost three years before the Schering patent's September 2006 expiration date. *Id.* at 1060.

[46] *Id.* at 1061.

[47] *Id.* at 1062.

[48] *Schering-Plough Corp.,* 402 F.3d at 1065.

[49] *Id.* at 1066 (citing Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003)).

2. Second Circuit

The Second Circuit was the next court to review the legality of reverse payment settlements in the case of *In re Tamoxifen Citrate Antitrust Litigation*. Zeneca, Inc. manufactured the drug Tamoxifen, which was known as the most prescribed cancer drug in the world.[50] Barr Laboratories, a generic manufacturer, sought to market a generic version of Tamoxifen by filing an ANDA with the FDA.[51] Zeneca sued Barr for patent infringement, but Zeneca did not prevail on its claim as the district court held the patent to be invalid for withholding crucial information on the safety and effectiveness test results.[52] While the appeal was pending, Zeneca and Barr executed a settlement agreement in which Barr agreed not to market its own version of Tamoxifen until Zeneca's patent expired.[53] Moreover, Barr promised to reenter the market with a Paragraph IV certification if a later lawsuit declared the patent invalid which could delay the entry of other generic challengers.[54]

In response to the settlement agreement, consumers filed some thirty lawsuits challenging the legality of the agreement.[55] The plaintiffs alleged that the settlement agreement unlawfully facilitated Zeneca's continuing monopolization of the market and provided for the sharing of unlawful monopoly profits between Zeneca and Barr.[56] The main concern of the plaintiffs was the "excessiveness" of the value that Barr received from the settlement agreement in comparison to the value Barr could

[50] *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 193 (2d Cir. 2006).

[51] *Id.*

[52] *Id.*

[53] *Id.* at 193–94.

[54] *Id.* at 194. The 180-day exclusivity period would once again come into play for Barr as a "first filer" and prevent other generic manufacturers from challenging the patent through an ANDA. *Id.*

[55] *In re Tamoxifen*, 466 F.3d at 196.

[56] *Id.* at 196–97.

have realized by entering the market with its own competitive generic product.[57]

The Second Circuit began its discussion by noting that reverse payments are not *per se* violations of the Sherman Act.[58] The court reasoned that as long as the patent litigation is neither a sham nor baseless, the patent holder may enter into an agreement to protect that which it is presumably entitled.[59] In conclusion, the court agreed with the Eleventh Circuit holding in *Valley Drug* that a settlement agreement between a brand-name pharmaceutical manufacturer and a generic pharmaceutical manufacturer cannot be the sole basis for a violation of antitrust law, unless the effects of the agreement exceed the scope of the patent's protection.[60]

3. Federal Circuit

The Federal Circuit, which has exclusive jurisdiction over the patent laws, addressed the issue of the legality of reverse settlement agreements in the case *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.[61] This case involved the settlement between Bayer Corp., the manufacturer and patent holder of ciprofloxacin hydrochloride (Cipro), and Barr Laboratories, the generic manufacture as dealt with in the *Tamoxifen* case.[62] Barr filed an ANDA, including a Paragraph IV certification, and asserted that Bayer's patent was invalid and

[57] *Id.* at 208.

[58] *Id.* at 206. The court does not "think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation." *Id.* at 206 (citing *Valley Drug Co.*, 344 F.3d at 1309 (2003)).

[59] *Id.* at 208–09.

[60] *In re Tamoxifen*, 466 F.3d at 212 (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005)).

[61] Dolin, *supra* note 31, at 299.

[62] *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1327 (Fed. Cir. 2008).

unenforceable.[63] Bayer responded by suing Barr for patent infringement in the district court.[64]

Before the trial took place, Bayer entered into a settlement agreement with Barr in which Barr agreed to not enter its generic version of Cipro to the market until Bayer's patent expired. [65] Barr agreed to change its Paragraph IV certification to a Paragraph III certification.[66] In return, Bayer agreed to make a settlement payment of $49.1 million.[67] Consumers of Cipro then filed antitrust actions in federal court challenging the settlement agreement and alleging that such an agreement constituted an illegal market allocation in violation of the prohibitions on restraint of trade contained in the Sherman Act.[68]

The Federal Circuit did not find these allegations persuasive and found that the essence of the agreement – to exclude others from profiting from the patented drug – was within Bayer's rights as the patentee.[69] The court used an analysis adopted by the Second and Eleventh Circuits stating that "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."[70] Therefore, the court concluded that in the absence of fraud or sham litigation, "the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement…"[71]

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[63] *Id.* at 1328.

[64] *Id.*

[65] *Id.* at 1328–29. This was one of four settlement agreements that Bayer entered into; all based on lawsuits that challenged the validity of the patent for ciprofloxacin hydrochloride. *Id.* at 1328.

[66] *Id.*

[67] *In re Ciprofloxacin*, 544 F.3d at 1329.

[68] *Id.*

[69] *Id.* at 1333.

[70] *Id.* at 1336.

[71] *Id.*

C. THIRD CIRCUIT REVIVAL OF STRICT ANTITRUST SCRUTINY

On July 16, 2012, the FTC was able to claim victory over the accomplishment of a decade-long goal: "getting a Federal Circuit Court of Appeal (the [Third] Circuit) to support its position that so-called 'reverse-payments' between innovator pharmaceutical companies and generic drugmakers . . . are anticompetitive and barred by Federal antitrust law . . . ."[72]

The Third Circuit case, *K-Dur*, involves Schering-Plough's patent on K-Dur, a potassium chloride supplement used to treat potassium deficiencies and side effects from the treatment of high blood pressure.[73] Upsher, a generic pharmaceutical company, filed the first ANDA in seeking approval to manufacture a generic version of K-Dur.[74] In response, Schering sued Upsher for patent infringement.[75] The parties executed efforts to settle the infringement claim and entered into an agreement in which Upsher would refrain from marketing its generic form and in return, Schering promised to pay sixty million dollars over the course of three years.[76] Additionally, Upsher granted licenses to Schering to make and sell several products that Upsher had already developed.[77]

As if one reverse settlement agreement wasn't enough, Schering additionally entered into an agreement with ESI, a second generic pharmaceutical company seeking FDA approval to make and sell a generic version of K-Dur.[78] The settlement

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[72] Kevin E. Noonan, *Merck Asks Supreme Court to Review Third Circuit K-Dur Decision*, JD SUPRA (Aug. 29, 2012), http://www.jdsupra.com/legalnews/merck-asks-supreme-court-to-review-third-36477/.

[73] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 203 (3d Cir. 2012).

[74] *Id.* at 205.

[75] *Id.* The defense used by Upsher against Schering's patent infringement suit was based on differing chemical compositions of the controlled release coating of the generic product and that of the patented invention. *Id.*

[76] *Id.*

[77] *Id.*

[78] *In re K-Dur*, 686 F.3d at 206.

agreement called for Schering to pay ESI five million dollars up front and up to an additional maximum of ten million dollars if the FDA approved ESI's ANDA.[79] The FDA approved ESI's ANDA and Schering paid the additional ten million dollars in exchange for ESI's agreement not to develop any other potassium chloride products.[80] As a result of the Schering-Upsher agreement and the Schering-ESI agreement, the FTC filed a claim alleging that both agreements unreasonably restrained trade in violation of the Federal Trade Commission Act.[81]

In reviewing the legality of the reverse settlement agreements at issue, the Third Circuit rejected the precedent held by its sister circuits and found such agreements to be presumptively illegal.[82] Instead of adopting the scope of the patent test, the Third Circuit implemented a quick look rule of reason. This test is an "analysis based on the economic realities of the reverse payment settlement."[83] The court concluded that reverse payment settlements, in which a generic patent challenger agrees to delay entry into the market, must be treated as prima facie evidence of an illegal restraint on trade.[84] The court also articulated that this presumption is rebuttable by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.[85] The conclusion that reverse settlements are prima facie evidence of an unreasonable restraint of trade is fully supported by the approach adopted by the D.C. Circuit in *Andrx*, in which the

[79] *Id.*

[80] *Id.*

[81] *Id.* at 206–07.

[82] Noonan, *supra* note 72; *see In re K-Dur*, 686 F.3d at 214 ("After consideration of the arguments of counsel, the conflicting decisions in the other circuits . . . and our own reading, we cannot agree with those courts that apply the scope of the patent test.").

[83] *In re K-Dur*, 686 F.3d at 218.

[84] *Id.*

[85] *Id.*

court held that such a payment strongly suggests an anticompetitive intent of the parties to the agreement.[86]

The FTC's views and conclusions about the effects of reverse payments also played a significant role in the Third Circuit's holding that such settlements are an illegal restraint on trade. The FTC strongly opposes reverse payments and believes the effects to be anticompetitive.[87] In reviewing the legality of both the Schering-Upsher and Schering-ESI settlements, as set forth in *K-Dur*, the FTC found that both were in violation of antitrust law and a restraint on commerce.[88] The FTC ultimately applied a quick look rule of reason analysis that was later adopted by the Third Circuit in its *K-Dur* opinion, and concluded that "the possible existence of a reverse payment raises a red flag and can give rise to a prima facie case that an agreement is anticompetitive."[89]

The Third Circuit's revival of applying strict antitrust scrutiny has been described as a "blockbuster."[90] Not only is this decision in direct correlation with the views of the FTC, but it is also in direct opposition with the holding of three other U.S. Court of Appeals' decisions on the issue; thus, creating a strong

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[86] *Id.* (quoting Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809 (D.C. Cir. 2001)).

[87] Eric J. Stock & Hogan Lovells, *U.S. Appeals Court Holds "Reverse Payment" Patent Settlements Unlawful, Setting Up Strong Case for U.S. Supreme Court Review*, WOLTERS KLUWER (Aug. 6, 2012), http://kluwercompetitionlawblog.com/2012/08/06/u-s-appeals-court-holds-reverse-payment-patent-settlements-unlawful-setting-up-strong-case-for-u-s-supreme-court-review/.

[88] *In re K-Dur*, 686 F.3d at 207; *see* Schering-Plough Corp., 136 F.T.C. 956, 1052 (2003) (reversing the ALJ's ruling, finding that there was a "direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry" and that such a settlement was an unreasonable restraint on commerce).

[89] *In re K-Dur*, 686 F.3d at 207; *see Schering-Plough Corp.*, 136 F.T.C. at 988 ("Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.").

[90] Frankel, *supra* note 6.

desire to have the U.S. Supreme Court review the legality of reverse payments in the pharmaceutical patent industry.[91]

D. SUPREME COURT PUTS AN END TO THE CIRCUIT SPLIT

The Supreme Court of the United States issued its decision on the legality of reverse payment settlements between a brand name pharmaceutical manufacturer and a generic pharmaceutical manufacturer on June 17, 2013, thereby ending the circuit split created by the Third Circuit just a year earlier. In *FTC v. Actavis*, the Court reversed the Eleventh Circuit's decision affirming the dismissal of a FTC challenge to a reverse payment settlement between Solvay Pharmaceuticals and Actavis.[92] The Eleventh Circuit held that a reverse payment settlement is immune from antitrust attack as long as its anticompetitive effects fall within the scope of the patent.[93] However, the Supreme Court disagreed and held that reverse payment settlements, such as the one in this case, "can sometimes violate the antitrust laws."[94] Accordingly, the Court ruled that the Eleventh Circuit should have allowed the FTC challenge to proceed.[95]

In this Supreme Court case, Solvacy Pharmaceuticals obtained a patent for its drug AndroGel.[96] Actavis and Paddock each then filed an ANDA for generic drugs modeled after AndroGel and certified under Paragraph IV that Solvacy's patent was invalid.[97] After the FDA approved of Actavis' and Paddock's generic product, each company entered into a reverse payment settlement with Solvacy, agreeing not to enter its product into

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[91] Stock, *supra* note 87.

[92] FTC v. Actavis, Inc., 133 S. Ct. 22237 (2013).

[93] *Id.* (citing FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012)).

[94] *Actavis*, 133 S. Ct. at 2227.

[95] *Id.*

[96] *Id.* at 2229.

[97] *Id.*

the market for several years.[98] Subsequently, the FTC filed suit alleging that Actavis and Paddock violated the Federal Trade Commission Act by unlawfully agreeing to abandon their patent challenges, to refrain from launching their low-cost generic drugs, and to share in Solvacy's monopoly profits.[99] The District Court dismissed the complaint, and the Eleventh Circuit affirmed relying on the scope of the patent test.[100]

In delivering the opinion for the Court, Justice Breyer[101] accepted the notion that the anticompetitive effects of an agreement fall within the scope of the patent, but agreed that this characterization alone does not immunize an agreement from antitrust scrutiny because the patent "may or may not be valid, and may or may not be infringed."[102] Justice Breyer cautioned that the unusual structure of reverse payment agreements could have significant adverse effects on competition, as a result of the brand name pharmaceutical manufacturer paying a sizable sum to the generic pharmaceutical manufacturer to stay out of the market despite the lack of potential liability.[103] Thus, "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."[104]

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[98] *Id.*

[99] *Id.* at 2229–30.

[100] *Actavis*, 133 S. Ct. at 2230. The Eleventh Circuit recognized that public policy favors, and that courts could not require parties to continue litigation as a means of avoiding antitrust liability. *Id.* (citing Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1313–14 (11th Cir. 2003)).

[101] *Id.* at 2226. Justices Kennedy, Ginsburg, Sotomayor, and Kagan joined Justice Breyer. Justice Alito recused himself and took no part in the consideration or decision of this case. *Id.*

[102] *Id.* at 2230–31.

[103] Harvard Law Review Ass'n, *F. Hatch-Waxman Act – Reverse-Payment Settlements* – FTC v. Actavis, Inc., 127 HARV. L. REV. 358, 361–62 (2013) (citing *Actavis*, 133 S. Ct. at 2231).

[104] *Actavis*, 133 S. Ct. at 2231. The Supreme Court has previously recognized that patent and antitrust policies are both relevant in determining the scope of the patent and the antitrust immunity conferred by the patent. *Id.*

While the Court recognizes the general public policy favoring the settlement of disputes, it does not conclude that the patent-related factor should be the determining factor in this case.[105] Rather, Justice Breyer sets forth five reasons why this policy should not govern the result and why the FTC should have been given the opportunity to prove its antitrust claim.[106] First, the payment amounts to a purchase of "patent-like protection"[107] for the patentee of the exclusive right to sell its product despite the potential invalidity of the patent, thus leading to adverse competitive effects on the market.[108] Second, the anticompetitive consequence of the settlement will sometimes prove to be unjustified under certain circumstances.[109] Third, where there exists the threat of unjustified anticompetitive harm in relation to a reverse payment, the patentee will likely have the power to bring about that harm in practice.[110] Fourth, an antitrust action is more feasible than litigating the patent's validity, and it is not normally necessary to litigate a patent's validity in order to answer the antitrust question.[111] Fifth, the risk of antitrust litigation over an unjustified reverse payment does not prevent the parties from settling the case through other arrangements, such as allowing the generic manufacture to enter the patentee's market prior to the patent's expiration.[112]

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[105] *Id.* at 2234.

[106] *Id.*

[107] Harvard Law Review Ass'n, *supra* note 103, at 362.

[108] *Actavis*, 133 S. Ct. at 2234.

[109] *Id.* at 2235–36. The presence of unjustified anticompetitive consequences may suggest that the parties intended the settlement as a mechanism for sharing monopolistic profits. Harvard Law Review Ass'n, *supra* note 103, at 362.

[110] *Actavis*, 133 S. Ct. at 2236.

[111] *Id.* "An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival . . . [and] suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market . . . ." *Id.*

[112] *Id.* at 2237; Harvard Law Review Ass'n, *supra* note 103, at 362.

The Court then went on to hold that the implementation of the quick-look rule of reason over the rule of reason approach is appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."[113] The Court does not believe that reverse payment settlements meet this criterion, as the existence and degree of anticompetitive consequences is dependent upon multiple factors and varies among the industries.[114] As a result of these complexities, the Court concluded that the FTC must adopt a rule of reason analysis in proving its case.[115] However, the Court leaves to the lower courts the structuring of rule of reason antitrust litigation.[116]

The majority opinion has only created more uncertainty to this decade-long issue that has been haunting the circuit courts.[117] This decision will significantly impact present and future antitrust litigation over reverse payment settlements, and do little more than further complicate the already controversial stance existing amongst the courts.

III. FAVORABLE APPLICATION OF A QUICK LOOK RULE OF REASON IN ANALYZING ANTITRUST VIOLATIONS

The Third Circuit's decision in *K-Dur* was certainly a shock amongst the federal judiciary in which federal circuit courts

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[113] *Actavis*, 133 S. Ct. at 2237 (quoting Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999)).

[114] *Id.*

[115] *Id.*

[116] *Id.* at 2238.

[117] Kevin D. McDonald et al., *Antitrust Alert: Supreme Court Holds Reverse Payment Settlements Potentially Anticompetitive – Further Guidance Awaits*, JONES DAY (June 2013), http://www.jonesday.com/Antitrust-Alert--Supreme-Court-Holds-Reverse-Payment-Settlements-Potentially-Anticompetitive--Further-Guidance-Awaits-06-29-2013/?RSS=true ("Litigation over patent settlements will now be more complex and less certain, because *Actavis* raises many more questions than it answers.").

have made rulings for nearly a decade holding that reverse payment settlements are not anticompetitive, under the scope of the patent test, as long as they do not block the generic manufacturer from entering the market once the brand-named manufacturer's patent rights expire.[118] In rejecting the scope of the patent test as set forth by the Second Circuit in the opinion of *Tamoxifen*, the Third Circuit concluded that the scope of the patent test does not subject such payments to the necessary strict antitrust scrutiny. Thus, the Third Circuit created a circuit split regarding the appropriate standard to be applied in assessing antitrust violations of such settlements on the basis of precedent and principles.[119]

A quick look rule of reason is said to not only be in alignment with the Hatch-Waxman Act – as will be discussed later – but also is supported from Supreme Court precedent on issues of patent litigation and competition, as is indicated below. This section also discusses the flaws that are inherent in using the scope of the patent test in determining the legality of reverse payment settlements in light of antitrust principles. Finally, this section concludes by exploring the rule of reason analysis adopted by the Supreme Court and why such an approach is inferior to the Third Circuit's quick look rule of reason analysis in examining reverse payment settlements.

A. SUPPORT FROM SUPREME COURT PRECEDENT ON PATENT LITIGATION AND COMPETITION

In the opinion of *K-Dur*, the Third Circuit "question[s] the assumption underlying the view of the Second Circuit and other courts that subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger."[120] The court shows support for this analysis with a long line of Supreme Court cases and the public policy interest in adhering to judicial testing and eliminate invalid patents.[121] The Supreme Court has

[118] Frankel, *supra* note 6.

[119] *See* Noonan, *supra* note 72.

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

[121] *Id.*

stated, "It is the public interest which is dominant in the patent system 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."[122]

While the Supreme Court has yet to rule on the issue of the legality of reverse payments, the Court has adhered to the issues surrounding patent validity and antitrust violations, all of which are logically correlated to the settlements between a brand name patent holder and a generic competitor. The Supreme Court continuously denotes the importance of antitrust scrutiny and the need for such analysis to reflect the environmental setting of the regulated industry to which it applies.[123] The pharmaceutical industry is a highly regulated industry that must seek the free flow of a competitive economy for all participants in such a market. The conveyance of reverse payments permits the sharing of monopoly profits between competitors without any assurance that the underlying patent is valid.[124]

Through its extensive analysis into the patent system, the Supreme Court has come to recognize that valid patents are the exception to the rule of the "free exploitation of ideas."[125] A patent "affords no immunity for a monopoly not fairly or plainly within the grant;" therefore, patents are to be strictly construed.[126] Additionally, the Supreme Court recognizes the importance

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[122] *Id.* at 216 (quoting Edward Katzinger Co. v. Chi. Metallic Mfg. Co., 329 U.S. 394, 401 (1947) (internal citations and quotation marks omitted)).

[123] Verizon Commc'ns., Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411-12 (2004).

[124] *In re K-Dur*, 686 F.3d at 216; *see also* United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1136 (D.C. Cir. 1981) (suggesting that certain patent arrangements might cause anticompetitive effects by "giv[ing] potential competitors incentives to remain in cartels rather than turning to another product, inventing around the patent, or challenging its validity").

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

[126] *Id.* at 216 (citing United States v. Masonite Corp., 316 U.S. 265, 277 (1942)); *see also* Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.").

of maintaining a "careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy."[127] This *quid pro quo* balance of innovation and competition is the essence of what our founding fathers envisioned in the adoption of Article I, Section 8 of the U.S. Constitution.[128] Congress has participated in maintaining and upholding these values instilled in the Constitution through the passage of the Hatch-Waxman Act, which seeks to balance the need for patent protection and the need for incentives for competition in the pharmaceutical industry.[129]

Therefore, it is evident that the Third Circuit's adoption of the quick look rule of reason is more in sync with the precedent set forth by the Supreme Court than are the principles of the scope of the patent test implemented by the earlier rulings of the circuit courts. The quick look rule of reason has a basis in the economic realities and effects that reverse payments have on the competitive economy and the free flow of trade within the market.[130] The Third Circuit's reasoning also recognizes the importance of the values permeated in the Constitution to promote innovation along with competition; values that fall to the wayside through an analysis under the scope of the patent test.

B. FLAWS WITHIN THE IMPLEMENTATION OF THE SCOPE OF THE PATENT TEST

The Third Circuit set out the reasons why the scope of the patent test is not the appropriate standard for courts to apply when determining the legality of reverse payments entered into between the patent holder pharmaceutical company and the generic challenger. The first issue the court has with the test is

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[127] *In re K-Dur*, 686 F.3d at 216 (citing Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 146 (1989)).

[128] Quinn, *supra* note 4.

[129] *In re K-Dur*, 686 F.3d at 217.

[130] *Id.* at 218.

the "almost unrebuttable presumption of patent validity," which "assumes away the question that is being litigated in the underlying patent suit . . . ."[131] The presumption of the patent validity would in turn enforce a presumption that the patent holder would have prevailed.[132] This presumption is only a procedural evidentiary presumption, not to be relied on by patentees as substantive evidence.[133]

Courts have upheld settlement agreements on the basis of Section 282 of the Patent Act, which states that patents shall be presumed valid.[134] "Many patents issued by the PTO are later found to be invalid or not infringed."[135] The presumption of patent validity should be "entitled to the least amount of deference in situations in which the parties enter agreements that prevent validity from even being challenged."[136] As stated above, this presumption is contrary to the Supreme Court's recognition that the interest of public policy favors judicial testing and elimination of weak patents.[137] Patent litigation and validity challenges play an important role in ensuring that the public does not suffer adverse effects of weak and invalid patents.[138] The presumption of patent validity in reverse settlement agreements is contrary to the interest of public policy upheld by Supreme Court precedent and all together precludes the crucial issue from being tested for antitrust liability purposes.[139]

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[131] *Id.* at 214; *see* Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983) ("The presumption, like all legal presumptions, is a procedural device, not substantive law.").

[132] *In re K-Dur*, 686 F.3d at 214.

[133] CARRIER, *supra* note 12, at 367.

[134] *Id.* at 366; *see* 35 U.S.C.A. § 282 (West).

[135] *In re K-Dur*, 686 F.3d at 215.

[136] CARRIER, *supra* note 12, at 367.

[137] Stock, *supra* note 87.

[138] CARRIER, *supra* note 12, at 367. Professor Carrier notes that the presumption of patent validity should be interpreted as weak under circumstances that do not allow for the testing of the patent at issue. *Id.*

[139] *Id.*

The second issue with the scope of the patent test closely follows the issue on the presumption of validity of the patent that is contested between the brand name pharmaceutical company and generic challengers.[140] The Second, Eleventh, and Federal Circuits all conveyed this policy matter in ruling that a reverse settlement agreement did not restrain competition in the market if it was within the scope of the patent itself.[141] These courts have presumed that the patent in question is valid, and that the settlements prevent entry from an infringing product that is not legally entitled to be on the market.[142] However, in terms of antitrust violation, the fact that an agreement reaching beyond the scope of the patent violates the antitrust laws does not necessarily mean that an agreement falling within the "facial" scope of the patent is valid.[143]

The crucial question in determining whether or not the agreement falls within the scope of the patent claims is still dependent on whether or not the patent is valid. Professor Michael Carrier emphasizes that the mere existence of a patent does not mean that the patent is valid;[144] as mentioned by the Third Circuit in *K-Dur*, the PTO issues many patents that are later determined to be invalid or not infringed.[145] If the underlying patent is deemed to be valid, then agreements permitting entry before the end of the patent term are within the exclusionary scope of the patent.[146] However, where a patent is

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[140] Carrier, *supra* note 21, at 65. ("Courts have tended to uphold reverse payments as a type of activity falling within the scope of the patent.").

[141] Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 2012 STAN. TECH. L. REV. 1, 5 (2012) [hereinafter Carrier, *Why the "Scope of Patent"*]. The courts that followed the scope of the patent test reasoned that a reverse settlement payment could not harm competition as long as "(1) the exclusion of the generic does not exceed the patent's scope; (2) the patent holder's infringement case was not objectively baseless; and (3) the patent was not procured by fraud on the patent office." Stock, *supra* note 87.

[142] Stock, *supra* note 87.

[143] Carrier, *Why the "Scope of Patent"*, *supra* note 141, at 5.

[144] *Id.* at 5.

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

[146] CARRIER, *supra* note 12, at 369.

deemed to be not valid, then there is no scope at all and the agreements should be subject to antitrust scrutiny.[147]

Professor Carrier also found the issue of infringement to be a problem with the scope of the patent test. Just as the mere existence of a patent cannot prove the patent to be valid, the mere existence of a patent cannot dispose of the issue of infringement.[148] Unlike a challenge against the validity of a patent where the challenger bears the burden of showing invalidity, in a case of patent infringement, it is the patent holder who bears the burden of showing infringement.[149] When the resulting payments greatly exceed the cost of litigation, the plaintiff must have doubts as to the validity of its patent or the infringer.[150] It is consumers, rather than the parties entering into a settlement agreement, who forego the gains that could have been attained had the patent litigation been completed in its entirety.[151]

The final reason the Third Circuit rejects the scope of the patent test as the appropriate test for analyzing the legality of reverse payments is that the theory underlying the test is contrary to the policies of the Hatch-Waxman Act. Under the provisions of the Hatch-Waxman Act, generic manufacturers are encouraged to challenge weak or invalid patents on brand name

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[147] *Id.* Professor Carrier reemphasizes the idea that the presumption of validity is a procedural device, not sufficient enough to prove substantial validity of the patent. "In assuming the very validity it seeks to prove, therefore, scope is not an appropriate inquiry." *Id.*

[148] Carrier, *Why the "Scope of Patent"*, *supra* note 141, at 7. The scope of the patent test cannot properly address the question of whether or not the generic challenger's drug infringes the patent of the brand name patent holder.

[149] *In re K-Dur*, 686 F.3d at 214 (citing Egyptian Goddess, Inc. v. Swisa, *Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008)).

[150] Scott A. Backus, *Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has Schering-Plough Created the Blueprint for Defensible Antitrust Violations?*, 60 OKLA. L. REV. 375, 405 (2007) ("The result is to deny the public the benefits of competition that it could otherwise obtain.") (quoting Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25 (2004)).

[151] Backus, *supra* note 150, at 405.

drugs so consumers can enjoy lower drug prices.[152] This purpose is undermined by the application of the scope of the patent test because the test allows the patent holder to pay the potential genetic competitor not to compete,[153] which essentially disposes of free competition and efficiency among drug manufactures in the market.

The policies of the Hatch-Waxman Act promote efficiency within the drug markets, which is consistent with the goals of antitrust laws.[154] Moreover, the policies of the Hatch-Waxman Act are consistent with the goals of patent law—to promote innovation by conferring a legal monopoly.[155] However, patent law has built-in safeguards to limit the monopoly profits a patent holder may benefit from during the life of the patent.[156] "[I]f there is any tension between the Hatch-Waxman Act and patent law, the more specific aims of the Hatch-Waxman Act should prevail."[157]

The Hatch-Waxman Act creates patent settlements involving reverse payments that fall between the two extremes of settlements where delayed generic entry is not supported by patent protection and is in violation of the antitrust laws, and settlements that are clearly within the patent protection and do not constitute a violation of antitrust laws.[158] Due to the variations of results from such settlements, there has been much discussion and disagreement among judicial, administrative,

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[152] *In re K-Dur*, 686 F.3d at 217 (citing S. Rep. No. 107-167, at 4 (2002)); *see* 21 U.S.C.A. § 355(j)(5)(B)(iv) (West) (providing successful challengers with a 180-day marketing exclusivity period).

[153] *In re K-Dur*, 686 F.3d at 217.

[154] Davis, *supra* note 10, at 270 ("To the extent that the law can be interpreted so that generic challenges to brand patents are encouraged when they would promote efficiency, the Hatch-Waxman Act and background antitrust principles can serve a common purpose."). *Id.*

[155] *Id.*

[156] *Id.* A legal monopoly is only available to "putative patent holder[s]" for their inventions that meet the criteria necessary for issuance of a valid patent. *Id.*

[157] *Id.*

[158] Backus, *supra* note 150, at 387.

and academic commentators on the proper application of antitrust principles. A quick look approach—as implemented by the Third Circuit—is the paramount approach for settlements that are clearly anticompetitive from a quick look, but also may contain pro-competitive justifications.[159] "[I]n passing the Hatch-Waxman Act, Congress drew a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical industry."[160] Application of the rule of reason analysis for reverse payment settlement properly analyzes these conflicting objectives while maintaining a focus on antitrust violations.[161]

Determining the appropriate analysis of evaluating reverse payments has become a very pressing issue.[162] From a financial aspect, studies and analyses show that consumers have overpaid by an estimate of sixteen billion dollars as a result of reverse payments.[163] Congress places an emphasis on the public interest to eliminate weak and invalid patents, along with promoting the free flow of competition in the drug industry, in order to increase the availability of low cost generic drugs.[164] Additionally, Congress's public policy objectives—as is apparent

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[159] *Id.* at 388.

[160] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 217 (3d Cir. 2012).

[161] *Id.*

[162] Davis, *supra* note 10, at 266. A leading scholar on the topic of reverse payments, C. Scott Hemphill, portrays this issue as "the most important unresolved issue in U.S. antitrust policy . . . ." *Id.* (citing C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 631 (2009)).

[163] Hemphill, *supra* note 162, at 661; *see also* Jon Leibowitz, Chairman, FTC, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution) 8 (June 23, 2009), *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf. The FTC concludes from its studies that "[e]ven with conservative assumptions and limitations, eliminating these pay-for-delay settlements would still save consumers $35 billion over ten years . . . ."

[164] *In re K-Dur*, 686 F.3d at 217. This goal of the Third Circuit is mirrored by the framework and policies embedded in the Hatch-Waxman Act.

through the passage of the Hatch-Waxman Act—indicate that challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.[165] The underlying theories and principles of the scope of the patent test simply cannot amount to the public interest that is at stake in light of antitrust issues and restraint on competition in the pharmaceutical drug industry.

C. RULE OF REASON ANALYSIS FALLS INFERIOR TO QUICK LOOK APPROACH

In 1890, Congress passed the Sherman Antitrust Act to alleviate restraint of trade conflicts arising from business agreements and to further the legislative objectives of consumer welfare and fair competition.[166] Power was delegated to the courts to flesh out gaps in the Sherman Act.[167] The courts began by distinguishing between those agreements that had no other purpose than to harm consumers from those agreements that were harmless licensing agreements with legitimate purposes.[168] The courts traditionally addressed anticompetitive situations of Sherman Act violations through either a *per se* rule analysis or a rule of reason analysis.[169] The shift to a quick look rule of reason analysis arose in response to the "reflexive application" of the *per se* analysis by courts in situations where the conduct at issue "arguably had a valid competitive purpose."[170] Justice Burger

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[165] *Id.*

[166] CARRIER, *supra* note 12, at 61.

[167] *Id.*

[168] *Id.* at 62.

[169] Catherine Verschelden, *Is the Quick-Look Antitrust Analysis in* PolyGram Holding *Inherently Suspect?*, 32 IOWA J. CORP. L. 447, 448 (2007); *see* CARRIER, *supra* note 12, at 56–57. Agreements that are "so likely to lead to competitive harm and so unlikely to offer benefits" are struck down under a *per se* analysis. *Id.* at 56. The rule of reason is a more comprehensive analysis that "balance[s] an agreement's anticompetitive and procompetitive effects" before determining the fate of the restraint. *Id.* at 57.

[170] Max R. Shulman, *The Quick Look Rule of Reason: Retreat from Binary Antitrust Analysis*, 2 SEDONA CONF. J. 89, 90 (2001).

validated this notion that courts were abusing the use of a *per se* antitrust analysis in his dissent in *United States v. Topco Associates*:

> Nor do I believe that a new per se rule should be established in disposing of this case, for the judicial convenience and ready predictability that are made possible by per se rules are not such overriding considerations in antitrust law as to justify their promulgation without careful prior consideration of the relevant economic realities in the light of the basic policy and goals of the Sherman Act.[171]

In the notorious Supreme Court case of *Standard Oil Co. v. United States.*, the Court concluded that, in determining whether conduct amounts to a restraint on trade in violation of Section 1 of the Sherman Antitrust Act, the rule of reason is the applicable test. [172] The rule of reason test requires a detailed analysis of plaintiff's allegations in combination with countless justifications on behalf of the defendant.[173] This standard stood in contrast to the rule of *per se* illegality, which affords the defendant no defense or opportunity for justification.[174] The rule of reason requires that there be a showing of market power and anticompetitive effects within the relevant market that outweigh any justified procompetitive effects of the questioned action.[175] However, because the rule of reason analysis allows

[171] United States v. Topco Assocs., 405 U.S. 596, 614–15 (1972). The majority of the Court held that the restraint was a horizontal agreement and therefore a *per se* violation of Section 1 of the Sherman Act; regardless of the fact that there were procompetitive economic realities underlying the purpose of the agreement. *Id.* at 606, 608.

[172] Harvard Law Review Ass'n, As, *Quick Look Rule of Reason*, 124 HARV. L. REV. 400, 400–01 (2010); *see* Standard Oil Co. v. United States., 221 U.S. 1, 66 (1911) ("[I]n every case where it is claimed that an act or acts are in violation of the [antitrust] statue the rule of reason, in the light of the principles of law and the public policy which the act embodies, must be applied.").

[173] Harvard Law Review Ass'n, *supra* note 172, at 400-01.

[174] Harvard Law Review Ass'n, *supra* note 172, at 407.

[175] Shulman, *supra* note 170, at 89.

for an endless amount of defenses and explanations, in connection with a low standard of legality, most conduct not categorized as *per se* illegal is unimpeded by the rule of reason and deemed legal.[176] Therefore, this would lead one to conclude that if conduct is *per se* illegal on its face, then such conduct is legal regardless of the quality of proofs introduced in the rule of reason analysis.

The complex and unruly application of the rule of reason requires a three-step process. First, the plaintiff must demonstrate that the conduct in question had adverse effects on the market as a whole in the relevant market.[177] Second, the burden shifts to the defendant to show that conduct has justified procompetitive effects.[178] Finally, the burden shifts back to the plaintiff to show that there exists a less restrictive alternative means to achieve the procompetitive effects.[179]

The quick look rule of reason analysis establishes middle ground between a *per se* rule analysis and a full extensive rule of reason analysis.[180] Courts generally apply a quick look rule of reason analysis to market restraints that appear to be anticompetitive, but are unfamiliar to traditional antitrust analysis.[181] The Supreme Court in *California Dental Association v. FTC* reasoned that a quick look analysis is appropriate when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."[182]

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[176] *Id.* at 95.

[177] Anne-Marie C. Yvon, *Settlements Between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments*, 75 FORDHAM L. REV. 1883, 1887 (2006); *see also* K.M.B. Warehouse Distribs. Inc. v. Walker Mfg. Co., 61 F.3d 123, 127 (2d Cir. 1995).

[178] Yvon, *supra* note 177, at 1887–88.

[179] *Id.* at 1888.

[180] Shulman, *supra* note 170, at 89.

[181] *Id.*

[182] Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999).

Unlike a *per se* rule that declares all anticompetitive conduct on its face to be an illegal restraint of trade without any analysis into the possible procompetitive effects of the restraint, the quick look test "shifts the burden of proof onto the defendant to prove that the conduct created plausible [procompetitive] efficiencies."[183] Where such procompetitive justifications are plausible, the plaintiff must show that the conduct harmed consumers in order for the anticompetitive justifications to outweigh the procompetitive justifications.[184] To the extent the case at hand would have otherwise received *per se* treatment because of the facially anticompetitive conduct, the quick look analysis refines the *per se* approach by requiring a look at the argued justifications.[185] To the extent the antitrust issues of the case would have been analyzed under the full blown rule of reason analysis, the quick look analysis lessens the burden on the plaintiff to show a competitive harm through the nature of the restraint and shifts the burden to the defendant to show procompetitive justifications.[186]

The quick look rule of reason analysis successfully achieves this balance of proffered justifications by decreasing the amount of detail that is usually observed in a full rule of reason analysis and implements the opportunity for defendants to justify the conduct at issue.[187] Additionally, the quick look analysis is more efficient for courts to apply in determining issues of antitrust violations because such analysis does not expend judicial resources beyond its means as the rule of reason approach does.[188] Rather, "courts must carefully analyze the facts at issue

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[183] Harvard Law Review Ass'n, *supra* note 172, at 407; *see also* Verschelden, *supra* note 169, at 452. ("In situations where actors take anticompetitive steps and proffer no plausible justification or only very weak justifications for their conduct, use of a quick-look analysis is advantageous.").

[184] Verschelden, *supra* note 169, at 452.

[185] *Id.*

[186] *Id.* at 451

[187] *Id.* at 452. The quick look analysis relieves the plaintiff from the burden of having to show market power or actual anticompetitive effects from the conduct at issue. *Id.*

[188] *Id.* at 452–53.

to give certain facts that require 'more than cursory treatment' their due."[189]

Courts have become more akin to applying a quick look rule of reason analysis as a "track switching" device in order to dissect the supposed anticompetitive market restraint at issue before determining which antitrust analysis treatment to implement—*per se* analysis or rule or reason analysis.[190] The Supreme Court has become less reluctant to apply a quick look rule analysis in light of the fallacies a strictly *per se* or rule of reason analysis can impose on a naked restraint.[191] The trend of applying a quick look analysis promotes the underlying values of efficiency, detail, and practicality—"analyzing naked and nearly naked restraints in more detail . . . without launching a full rule of reason analysis."[192] Despite a variety of mixed results from the application of a quick look analysis, the Supreme Court has introduced such analysis in its opinion of cases in the fields of sports, professional associations, and academia.[193]

For example, in *NCAA v. Board of Regents of University of Oklahoma*, the Supreme Court refused to apply a *per se* rule to the NCAA agreement to limit the number of televised college football games and to fix the payments that colleges receive from the televised networks because restraints of competition of this type are necessary in the industry if the product is to be available to the public.[194] The Court held that the nature of NCAA's regulations is seen as a procompetitive mechanism to enhance the competition among the institutions; thus, "a fair

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[189] Verschelden, *supra* note 169, at 453 (citing Cal. Dental Ass'n v. FTC, 526 U.S. 756, 773 (1999)).

[190] Shulman, *supra* note 170, at 89-90. The court will first take into account the factors of the "challenged conduct, the market in which it operates, the possible anticompetitive effects and the proffered procompetitive justifications" before condemning the proper analysis for possible violations. *Id.* at 90.

[191] Verschelden, *supra* note 169, at 456.

[192] *Id.*

[193] Shulman, *supra* note 170, at 91; *see, e.g.*, FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 458–59 (1986); Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 692 (1978).

[194] NCAA v. Bd. of Regents of Univ. of Okla., 468 U.S. 85, 100–01 (1984).

evaluation of their competitive character requires consideration of the NCAA's justifications for the restraints."[195] However, after review of the proffered justifications, the Court concluded that the procompetitive effects of the NCAA plan did not outweigh the anticompetitive effects and the restraint constituted a violation against the Sherman Act.[196]

The Supreme Court has previously acknowledged the benefits of using a quick look rule of reason analysis over that of the *per se* approach on the one end of the spectrum and the full-blown rule of reason approach on the other end of the spectrum. Yet, the Supreme Court did not find the quick look analysis to be the appropriate analysis in determining the antitrust issue of reverse payments. The rule of reason approach is far too complex and unruly to use in cases involving the pharmaceutical industry.[197] First, it is unclear which relevant market should be the focus of the analysis – that of the brand name drug, the generic product, or that of other drugs used for the same medical condition.[198] Furthermore, the lengthy, detailed, fact-based analysis could cause significant delays in the entry of generic products and have adverse effects on the "highly time-sensitive pharmaceutical industry."[199]

The quick look rule of reason is a happy medium between the forces of two evils. This is the best suited approach for addressing issues regarding reverse payment settlements, and proves to uphold the policies of the Hatch-Waxman Act and the principles set forth by the Supreme Court in finding a solution in

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[195] *Id.* at 103; *see* Shulman, *supra* note 170, at 92.

[196] Shulman, *supra* note 170, at 92; *see Bd. of Regents*, 468 U.S. at 120 (holding "that by curtailing output and blunting the ability of member institutions to respond to consumer preference, the NCAA has restricted rather than enhanced the place of intercollegiate athletics in the Nation's life.").

[197] *See* Yuki Onoe, *"Pay-For-Delay" Settlements in Pharmaceutical Litigation: Drawing a Fine Line Between Patent Zone and Antitrust Zone*, 9 J. MARSHALL REV. INTELL. PROP. L. 528, 543–44 (2009).

[198] *Id.* at 543.

[199] *Id.* at 544 ("If the parties trying to settle before the patent expiration have to wait until the FTC conducts a thorough analysis, the settlement may be significantly delayed, and the pro-consumer effect may be negated").

the most efficient way to benefit the consumers of the pharmaceutical industry.

IV. ALIGNMENT OF THE HATCH-WAXMAN ACT AND UTILITARIAN THEORY OF PATENT LAW

Congress enacted the Hatch-Waxman Act in 1984 with the intent to increase generic competition and foster innovation in the pharmaceutical drug industry.[200] In seeking to increase generic competition, Congress ultimately encouraged generic drug manufacturers to challenge the patents of brand-name pharmaceutical manufacturers.[201] When disputes arise between the generic challenger and the brand name patent holder, the Hatch-Waxman Act puts in place the legal regime for resolving such disputes.[202] The Hatch-Waxman Act was Congress's response to "the problems of insufficient generic entry and inadequate innovation through a carefully calibrated balance among patent term extension, nonpatent exclusivity, and generic competition."[203]

This section portrays the alignment of the objectives of the Hatch-Waxman Act and the underlying principles of the utilitarian theory that are prevalent in not only patent law, but in all of intellectual property law. The overall theme of a balance between stimulating innovation and furthering the public interest through increased competition is evident under both regimes. In reviewing issues on the legality of reverse payment settlements, an analysis under the quick look rule of reason adheres to this balancing theme and such an analysis is in alignment with the principle objectives of the Hatch-Waxman Act and the utilitarian theory.

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[200] CARRIER, *supra* note 12, at 347 (citing 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.A § 355 (West))).

[201] *See supra* accompanying text note 11.

[202] Davis, *supra* note 10, at 256.

[203] CARRIER, *supra* note 12, at 351.

A. THE HATCH-WAXMAN ACT: POLICIES, PROVISIONS, AND AMENDMENTS

Congress passed the "landmark legislation" of the Hatch-Waxman Act as a mechanism designed to balance the competing interests between innovative pharmaceutical companies and generic drug manufacturers.[204] In balancing these competing interests, the Act focused primarily on encouraging the innovative pharmaceutical companies to continue their efforts in the investment of new drug development, while also encouraging increased generic drug competition in the pharmaceutical market.[205] The Act definitively provides the views of Congress on innovation and competition in the pharmaceutical drug market, and provides guidance to the courts in dealing with complex issues of patent and antitrust law.[206]

Title I of the Act sought to create "a streamlined generic drug application process . . . and rewards the first company to successfully seek approval for a generic version of a given drug with a valuable 180-day exclusivity period."[207] The Act implements a faster and less expensive application process for generic manufacturers to satisfy the safety and effectiveness trials required for FDA approval.[208] Before the Hatch-Waxman Act was enacted, generic manufacturers would have to independently prove the safety and effectiveness of the offered products even though the generic drugs have the same active ingredients, dosage, administration, performance, and safety as

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[204] Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011).

[205] *Id.*

[206] CARRIER, *supra* note 12, at 346.

[207] Melanie Brown, *Reverse Payment Settlements in the European Commission's Pharmaceutical Sector Inquiry Report: A Missed Opportunity to Benefit from U.S. Experience*, 33 COLUM. J.L. & ARTS 377, 380 (2010).

[208] *Id.*; *see* CARRIER, *supra* note 12, at 348. Prior to Hatch-Waxman, the FDA approval process for generic manufactures could not start during the patent term because such required trials constituted an infringement on the drug patent. CARRIER, *supra* note 12, at 348.

patented brand drugs.[209] The Act permitted generic manufacturers to submit an ANDA rather than a New Drug Application (NDA), as is necessary for companies that seek FDA approval to enter a new drug into the market. Under the ANDA, the generic manufacturer need only submit data regarding bioavailability and bioequivalence to indicate that its generic drug is just as safe and effective as the patented brand drug.[210] Additionally, an ANDA applicant is required to file one of the four following certifications for each Orange Book patent listing relating to the listed drug: (I) the patent information has not been filed with the FDA and does not appear in the Orange Book; (II) the patent has expired; (III) it will not seek approval until the expiration of the patent; or (IV) the patent is invalid or will not be infringed by the generic drug.[211]

Title II to the Act states that a Paragraph IV certification constitutes an act of infringement in itself, even though the act of filing occurs before the generic drug is approved or entered on the market.[212] As was added under the 2003 Amendments to the Act, an ANDA applicant must provide notice to the patent holders within twenty days of filing such a certification.[213] The notice to the patent holder must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."[214] After receiving such notice, if the patent holder files an infringement action against the ANDA applicant within 45 days, then the patent

[209] CARRIER, *supra* note 12, at 348–49.

[210] Kelly, *supra* note 204, at 420.

[211] *Id.* at 423; *see* 21 U.S.C.A. § 355(j)(2)(A)(vii); *see also* CARRIER, *supra* note 12, at 352 ("[T]he first two certifications, the FDA can approve the ANDA immediately . . . the third, approval is granted when the patent expires . . . [i]t is the fourth certification that has resulted in settlement agreements raising antitrust concern.").

[212] Brown, *supra* note 207, at 381; *see also* Backus, *supra* note 150, at 383 ("The [P]aragraph IV ANDA . . . is an artificial patent infringement suit created by the Hatch-Waxman Act since no actual infringement has taken place in submitting the ANDA.").

[213] 21 U.S.C.A. § 355(j)(2)(B)(ii–iii); *see* CARRIER, *supra* note 12, at 352.

[214] 21 U.S.C.A. § 355(j)(2)(B)(iv)(II).

holder receives an automatic 30-month stay of FDA approval over the ANDA.[215] However, if the patent expires or if the patent is ruled not infringed or invalid, then the FDA may approve the ANDA once all regulatory requirements are fulfilled.[216] The 30-month stay operates similarly to a preliminary injunction, effectively preventing the ANDA applicant from marketing its generic product during the indicated period.[217] The purpose of the 30-month stay is to allow for adequate time to consider the patent suit fully before the generic ANDA is approved.[218]

Furthermore, the Act provides that the first ANDA applicant to file a Paragraph IV certification with the FDA in regards to a brand name patent will be granted a 180-days of marketing exclusivity.[219] The FDA will not approve of any subsequent ANDAs for the same brand name patent drug until the 180-days of exclusivity for the first ANDA have expired.[220] The Act conveys that this 180-day market exclusivity period commences with the first commercial marketing of the generic version of the drug or a court finding that that patent is invalid or not infringed.[221] The generic manufacturer who is granted the 180-day exclusivity period is able to secure a significant portion of the generic market before any other generic manufacturers can seek to gain entry.[222] This provision of the Hatch-Waxman Act, along with the enactment of the ANDA, provides incentives to generic manufacturers to challenge potentially invalid brand name drug patents.

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[215] 21 U.S.C.A. § 355(j)(5)(B)(iii); *see* Kelly, *supra* note 204, at 424. The court has the discretion to increase or decrease the 30-month stay period if it is determined that either of the parties failed to expedite the proceedings. Kelly, *supra* note 204, at 424.

[216] Kelly, *supra* note 204, at 424.

[217] CARRIER, *supra* note 12, at 352.

[218] Brown, *supra* note 207, at 381. The 30-month default period may be extended or shortened depending on the issues involved in the litigation. *Id.*

[219] Kelly, *supra* note 204, at 424.

[220] *Id.* at 424–25.

[221] 21 U.S.C.A. § 355(j)(5)(B)(iv); *see* Backus, *supra* note 150, at 384.

[222] Backus, *supra* note 150, at 384.

The Hatch-Waxman Act also encouraged research-based pharmaceutical companies to continue their efforts in the "research and development of new drugs to cure or ameliorate medical problems – also a very important goal to American consumers."[223] Pioneer pharmaceutical companies had been discouraged from continuing their innovation efforts because of the lengthy FDA approval process, which required the companies to show not only that the patented drug was safe for its intended use, but also that it was effective.[224] These FDA requirements took pioneer companies additional years of testing and clinical trials to satisfy, and would occur only after the issuance of the patent; thus eroding the effective life of the drug patent term.[225] In response to this threat on innovation, the Act provided a patent term extension for companies that suffer from delayed marketing of its patented drug because of the additional regulatory review required by the FDA.[226] The extension takes into account half the time spent on clinical trials of the drug and the time spent waiting for FDA approval based on the results of the trials.[227]

In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act, and implemented amendments to the Hatch-Waxman Act based on cases of abuse of its provisions.[228] Implementing limitations on the automatic 30-month stay provision was a central focus of the new

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[223] Kelly, *supra* note 204, at 418.

[224] CARRIER, *supra* note 12, at 349.

[225] *Id.* The effective life of the patent is the period between FDA approval and the patent expiration.

[226] Kelly, *supra* note 204, at 418. The concern over the pharmaceutical market erosion is due in part to the average ten to fifteen years it takes to develop new drugs. *Id.*

[227] CARRIER, *supra* note 12, at 350. The extension can provide up to five years with a total of fourteen years of protection with the remaining patent term. CARRIER, *supra* note 12, at 350.

[228] CARRIER, *supra* note 12, at 353 (referencing Medicare Prescription Drug, Improvement, and Modernization Act of 2003, PUB. L. NO. 108-173, § 1112, § 1113, 117 Stat. 2066).

revisions.[229] The automatic 30-month stay was limited to patents of the brand name company that were submitted to the FDA before a generic challenger submitted the ANDA on the patented drug.[230] The Act also placed limits on the 180-day marketing exclusivity by revoking the exclusivity of the first filer if the filer failed to market the drug 75 days after FDA approval, or 75 days after a court finding of invalidity or non-infringement, whichever should occur later.[231] Moreover, the enactment of the Medicare Act required the pioneer company and generic challenger to file settlement agreements over issues of the 180-day exclusivity period or the marketing and sale of a drug with the FTC and Department of Justice within ten days of the agreement.[232]

Thus, the provisions of the Hatch-Waxman Act encompass the goals Congress set out to achieve in enacting this legislation. The Act provided "mechanism[s] to accelerate generic drug entry into the pharmaceutical market"[233] through the creation of the ANDA and increased competition by creating a 180-day marketing exclusivity period for the first generic manufacturer to file an ANDA. Moreover, the Act increased incentives for innovation among pioneer pharmaceutical companies through patent term extensions and an automatic 30-month stay for brand firms that instituted an infringement action against an ANDA filer with a Paragraph IV certification.[234] The enactment of the Medicare Act and the 2003 revision to the Hatch-Waxman Act sought to ameliorate any antitrust and anticompetitive issues that arose from the original provisions of the Act among the brand name firms and generic challengers.

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[229] *Id.*

[230] *Id.* This revision addressed the problem of brand firms listing a patent in the Orange Book after the generic submission of the ANDA, in order to sue for infringement and gain an additional 30-month stay. *Id.*

[231] *Id.* at 354; *see* 21 U.S.C.A. § 355(j)(5)(D)(i)(I).

[232] CARRIER, *supra* note 12, at 354–55.

[233] Kelly, *supra* note 204, at 425.

[234] *Id.* If an infringement action is commenced, then the FDA may not approve of an ANDA applicant until seven and a half years following the FDA approval of the patent holder's drug. *Id.*

While the provisions of the Hatch-Waxman Act have been subject to harsh criticism for creating an environment that encourages reverse payments and anticompetitive settlements[235], nevertheless, the Act continues to maintain a strong foundation in balancing the competing interests of innovation and competition within the pharmaceutical market.

B. THE ROLE OF UTILITARIAN THEORY IN PATENT LAW

The theory of utilitarianism is the dominant purpose in American patent law.[236] The underlying goal of the theory is to promote the benefit of societal welfare by rewarding inventors "to invent . . . and to reveal information to the public about these inventions that stimulates further innovation."[237] The reward of patent protection over the inventors' exclusive rights in their valuable technological or scientific inventions encourages these inventors to invest their time in producing socially valuable works, thus, serving the purpose of the utilitarian theory to maximize social welfare.[238] Ultimately, the utilitarian theory establishes a cost-benefit analysis by weighing the benefits to society through the creation of valuable invention, against the cost to society from the patent laws implemented to protect the inventor's exclusive rights to the invention.[239]

The underlying objectives of utilitarianism are consistent with the language embedded in the U.S. Constitution: "Congress shall have Power . . . To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and

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[235] CARRIER, *supra* note 12, at 369; *see In re* Tamoxifen Citrate Antitrust Litig., 466 F. 3d 187, 206 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005).

[236] Jeanne C. Fromer, *Expressive Incentives in Intellectual Property*, 98 VA. L. REV. 1745, 1750–51 (2012).

[237] *Id.* at 1751.

[238] *Id.* at 1752. If the protection rights afforded to inventors are too extensive, it could adversely affect society by preventing competition in the protected works and preventing subsequent creators from enhancing the previous innovation into new works. *Id.*

[239] *Id.*

Discoveries."[240] Congress has acted upon this grant of power by enacting statutes creating patent rights to maintain a satisfactory balance between the rights granted to the inventors and the benefits conferred upon the public through their inventions.[241] Moreover, the Supreme Court is cognizant of the constitutional foundation of the utilitarian theory in patent law and has recognized the importance of promoting the society welfare.[242]

The rationale behind the utilitarian theory of intellectual property law is focused on the idea that without regulated incentives for inventors and creators, "the rate of produce of socially beneficial new works will not be performing at an optimal level."[243] "Ideally, exclusive rights should only be granted if their social costs . . . are outweighed by the benefits that accrue from encouraging innovation, such that the patent grant results in a net increase in social welfare."[244] It is this increase in the benefits to the overall societal welfare that is of central importance to the theory of utilitarianism in providing protection of intellectual property.[245]

Intellectual property is characterized as a public good that is both nonexclusive and nonrival[246] "Nonexclusivity" means that

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[240] CARRIER, *supra* note 12, at 45; *see* U.S. CONST. art. I, § 8, cl. 8.

[241] Viva R. Moffat, *Mutant Copyrights and Backdoor Patents: The Problem of Overlapping Intellectual Property Protection*, 19 BERKELEY TECH L.J. 1473, 1476–77 (2004).

[242] Anna B. Laakmann, *An Explicit Policy Lever for Patent Scope*, 19 MICH. TELECOMM. TECH. L. REV. 43, 47-48 (2012); *see* Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) ("The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts.") (citing Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974)).

[243] Moffat, *supra* note 241, at 1479. "If an inventor spends two years developing an improvement . . . only to have it copied and distributed immediately upon its first sale, she likely will not be inclined to invest her resources in further improvements . . . ." *Id.*

[244] Laakmann, *supra* note 242, at 48.

[245] Moffat, *supra* note 241, at 1481.

[246] CARRIER, *supra* note 12, at 46.

the owner of the idea cannot exclude others from possession of that same idea.[247] "Nonrivalrous" means that one person's use of the idea does not inhibit the amount of the idea left for others to use.[248] This unique characteristic of intellectual property increases the likelihood of free riders.[249] Free riders are opportunists who could copy or imitate the innovation of an inventor without undergoing the lengthy and expensive research and development processes that the original inventor was subjected to.[250] This unfavorable behavior would deter inventors from investing their time and money in crafting new works of innovation.[251] As a result, Congress enacted statutes of patent law to protect the exclusive rights of the inventors.

It is evident that Congress sought to protect two competing interests through the enactment of patent law statutes. On the one hand, there is a need to encourage inventors to continue to develop new and innovative goods for the welfare of society.[252] On the other hand, there is a need to protect the exclusive rights granted to the inventor through the issuance of a patent.[253] The patent rights granted to an inventor by Congress through the issuance of a patent are part of the patent bargain: "[I]nventors whose works qualify for patent protection receive a limited monopoly . . . and society, the public, gets something in return."[254] Granting inventors absolute rights unlimited in scope and duration was not what Congress had in mind when

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[247] *Id.* Tangible property is exclusive—the owner may prevent another from possessing that which is his.

[248] *Id.* Tangible property is rivalrous—once one possesses the object there is nothing left for others to take.

[249] *Id.*

[250] *Id.* "[F]ree riders only need to cover the much lower marginal costs of producing each item." *Id.*

[251] CARRIER, *supra* note 12, at 46.

[252] Moffat, *supra* note 241, at 1477.

[253] *Id.* The grant of patent rights is seen as a compromise to avoiding disfavored monopolies in the market. *Id.*

[254] *Id.* at 1483.

enacting patent laws to protect the rights of inventors.[255] Instead, the Supreme Court recognized the *quid pro quo* nature of the patent system where inventors would be granted limited rights for a limited duration and at the expiration of those granted rights, the patent would be disclosed into the public domain.[256]

The dominant theory of utilitarianism, as is apparent in patent law and all of intellectual property law, " . . . rest[s] on the premise that the benefit to society of creators crafting valuable works offsets the costs to society of the incentives the law offers to creators."[257] The principles underlying the utilitarian theory are in respect similar to those principles of the Hatch-Waxman Act. Both utilitarianism and the Act have an ultimate purpose to secure a balance between competing interests within patent law. Should this balance go awry in either situation, the consequences can be detrimental to the benefits that both desire to confer upon the general welfare of society. Thus, in determining the validity of reverse payments, courts should not stray away from the policies of the Hatch-Waxman Act, nor from the core competency principles of the utilitarian theory that are embedded in the foundation of all of patent law.

C. QUICK LOOK RULE OF REASON ALIGNMENT WITH THE POLICIES OF THE HATCH-WAXMAN ACT AND THE UTILITARIAN THEORY OF PATENT LAW

In *K-Dur*, the Third Circuit was similarly cognizant of the fact that certain restraints in the extensively regulated pharmaceutical industry are essential to maintaining the Congressional balance of intellectual property protection and

[255] *Id.* at 1480. "The grant of a monopoly over intellectual property may also produce noneconomic costs: limited access to new ideas, thoughts, and creations; restricted public discourse; and concentration of wealth." Moffat, *supra* note 241, at 1480.

[256] *Id.* at 1483–84; *see* Fromer, *supra* note 236, at 1752 ("[P]atent laws ensure both that the works they protect fall into the public domain in due course and that third parties are free to use protected works for certain socially valuable purposes.").

[257] Fromer, *supra* note 236, at 1752.

enhanced competition.[258] While there is an overall general judicial preference in favor of reverse settlement payments, the decision of the Third Circuit urges that such settlements should not displace the public policy objectives of the Hatch-Waxman Act: " . . . that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers."[259] The court clearly notes that in adopting the quick look rule of reason analysis, only those settlements involving reverse payments between the brand name pharmaceutical manufacturer and generic challenger are subject to antitrust scrutiny.[260] This quick look analysis does not limit or impair the parties' ability to reach settlements based on a date for marketing of the generic drug and entry,[261] which would essentially be a settlement that enhances competition within the pharmaceutical industry.

Moreover, the Third Circuit's quick look analysis, as applied to the facts in *K-Dur*, allows for a shift in the burden from the generic challenger to the patent holder in weighing the anticompetitive effects of the payment against the procompetitive effects of the payment, if any are apparent.[262] Where reverse payments based on delayed market entry by the generic challenger are at issue, such payments are treated as *prima facie* evidence of an unreasonable restraint on trade, which the patent holder has the opportunity to rebut through a showing that (1) the payment was for some other purpose than delayed entry, or (2) the payment offers procompetitive benefits for the consumer.[263]

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[258] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 217 (3d Cir. 2012).

[259] *Id.* at 217.

[260] *Id.* at 218.

[261] *Id.* at 217–18.

[262] *Id.* at 218.

[263] *Id.* The Third Circuit follows the D.C. Circuit approach in *Andrx* in holding that a reverse payment constitutes as prima facie evidence of an unreasonable restraint on trade. *Id.*; *see* Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809 (D.C. Cir. 2001) (concluding that the idea of a reverse payment "may suggest strongly the anticompetitive intent of the parties").

The implementation of a quick look rule of reason analysis delves into the factual competitive justifications of the restraint in question before determining the ultimate antitrust treatment appropriate to employ.[264] This empirical analysis is consistent with the principal objectives of the Hatch-Waxman Act to increase competition in the pharmaceutical market and to prohibit unjustified monopoly agreements.[265] Not only does the court benefit from a less in-depth and less time-consuming factual analysis as required by the rule of reason analysis, but the party against whom antitrust scrutiny is raised has the benefit of proffering justifications for the restraint that would otherwise be disallowed under the *per se* rule. Furthermore, the Hatch-Waxman Act increases the availability of low-cost generic drugs in the pharmaceutical market through the creation of the ANDA and the 180-day exclusivity period in order to encourage generic manufacturers to challenge the holders of weak or invalid patents. The application of the rule of reason as held by the Supreme Court is not aligned with this purpose of the Hatch-Waxman Act because the lengthy and unruly analysis process can deter the entry of generic products into the market and cause a negative impact on the consumers that are dependent on the generic pharmaceutical market.[266] Thus, it is discernable that the quick look analysis and the Act both seek to achieve the same purpose in antitrust law – to promote the free flow of trade and competition while being mindful of judicial efficiency and practicality.

In addition, the quick look rule of reason analysis aligns with the dominant theory of utilitarianism underlying patent law. Just as the quick look analysis weighs the anticompetitive effects of a restraint against the procompetitive effects in order to ascertain the overall benefits conferred upon the consumer, the utilitarian theory validates the issuance of a patent only where the social costs of granting exclusive rights to the inventor are outweighed by the benefit to social welfare.[267] Both approaches

[264] Verschelden, *supra* note 169, at 452.

[265] Kelly, *supra* note 204, at 417.

[266] Onoe, *supra* note 197, at 544.

[267] Laakmann, *supra* note 242, at 48.

depict a means to an end – the balancing of potential effects from either a market restraint on trade or the issuance of a patent is carried out for the sole purpose of achieving enhanced societal welfare.

This consistent alignment of the principles, policies, and objectives embedded in the Hatch-Waxman Act, utilitarian theory, and quick look rule of reason analysis casts a positive light on the Third Circuit "blockbuster"[268] decision in *K-Dur*. Although the Supreme Court rejected a quick look rule of reason analysis in determining the antitrust validity of reverse settlement payments, this approach is judicially sound in that it takes into account the market effects from such restraint rather than focusing its decision solely the scope of the patent. This discrepancy distinguishes the Third Circuit decision as a paramount ruling diligently correlated to the constitutional delegation of power to Congress to promote innovation and foster the enrichment of consumer welfare through patent laws.

V. CONCLUSION

The Supreme Court should not have overturned the Third Circuit's adoption of the quick look rule of reason analysis. While this decision departed from the decade-long foundation established by its sister circuits on such an issue, the Third Circuit's analysis and conclusion did not depart from the Congressional principles, values, and objectives embedded in patent law.

The Supreme Court's precedent on issues of competition in the patent realm favors the interest of public policy to scrutinize the validity of patents in order to regulate the free flow of trade and competition within specified industries. The scope of the patent test falls short of this judicial objective because the focus of this analysis is on the presumed rights of the patent holder and not on the nature and effect of the reverse payment on the competitive economy. The nature of the settlement payment is in fact a restraint on the market where a generic challenger agrees to delay entry into the pharmaceutical market, even if litigation would have revealed the patent of the brand name pharmaceutical company were invalid or not infringed.

[268] Frankel, *supra* note 6.

The purpose of the quick look rule of reason analysis is consistent with the Supreme Court objectives to promote public policy interests in competition along with the Congressional principles as set forth in the Hatch-Waxman Act. The quick look rule embraces antitrust policies of prohibiting market restraints while encouraging procompetitive agreements. This analytical process of weighing competing market interests mirrors the intricate framework of the dominant theory in all of intellectual property law – utilitarianism.

Whether it is a balance between competition and innovation, anticompetitive effects and procompetitive effects, or social costs and social benefits, the paramount purpose of any antitrust analysis is to seek out those agreements or restraints that enhance the enrichment of societal welfare. The quick look rule of reason analysis of reverse settlement payments between the brand name pharmaceutical manufacturer and generic pharmaceutical manufacturer does just that – the rule opens the doors to agreements that confer benefits upon consumers, but willingly closes the doors to those agreements that have no other purpose than to harm competition and the market economy.