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REVERSE PAYMENT SETTLEMENTS: CAN JUDICIARY PROVIDE ADEQUATE SOLUTION?

I. INTRODUCTION

The current system for the provision of pharmaceuticals is highly inefficient.¹ The world spends \$1 trillion on medicines.² In the United States, the total healthcare system spending on pharmaceuticals has reached \$320 billion in 2011.³ Millions of people face suffering or death because they cannot afford the patented drugs sold at 20 to 50 times their cost of production.⁴ Prices of medicines directly affect their accessibility, even in the countries with universal insurance system like the United Kingdom.⁵

The US government created an incentive for the pharmaceutical innovators by awarding them with patent rights which grant an “exclusive rights to use the patented product, enabling high mark-ups through which innovators can profit if demand for the product is large enough even at high prices.”⁶ A patent gives to its owner a legal right to exclude others, for limited time periods, from making, using, or selling the patented product without the patent owner’s permission, and the state sanctions the violators of the patent rights.⁷ The proponents of strong patent protection for pharmaceutical companies note the importance of providing an incentive for

¹ Danielle Celermajer & Thomas Pogge, *A Cure for All Ills of the Pharmaceutical Benefits Scheme*, THE SYDNEY MORNING HERALD (March 7, 2012), <http://www.smh.com.au/opinion/society-and-culture/a-cure-for-all-ills-of-the-pharmaceutical-benefits-scheme-20120306-1ui91.html>.

² Aidan Hollis & Thomas Pogge, *Vision & Origin of the Health Impact Fund*, HEALTH IMPACT FUND (last visited Jan. 19, 2013), <http://healthimpactfund.com/origin>.

³ *The Use of Medicines in the United States: Review of 2011*, IMS INSTITUTE FOR HEALTHCARE INFORMATICS (Apr. 2012), [http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHI Medicines in U.S Report 2011.pdf](http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHI%20Medicines%20in%20US%20Report%202011.pdf).

⁴ Celermajer, *supra* note 1.

⁵ Amitava Banerjee, Aidan Hollis & Thomas Pogge, *The Health Impact Fund: Incentives for Improving Access to Medicines*, 375 THE LANCET 166 (Jan. 9, 2010), [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)61296-4/fulltext?_eventId=login](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)61296-4/fulltext?_eventId=login).

⁶ *Id.*

⁷ 35 U.S.C. § 154(a) (2006).

innovation.⁸ According to this standpoint,⁹ the social good resulting from the development of new medicines outweighs the anti-competitive effects of patents which protect the patentees' prices from competition.¹⁰ The patent owners further justify high prices for their drugs by emphasizing the immense financial burdens of pharmaceutical research and development.¹¹ The cost incurred by the pharmaceutical companies is at least in the hundreds of millions of dollars for each successful product.¹² Hence, the pharmaceutical companies should be entitled to financial returns promoted by a system with strong patent protection.¹³

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act,¹⁴ commonly known as the Hatch-Waxman Act (“the Act”), to encourage the generic drug manufacturers to challenge weak patents of the brand name drug companies, thereby ensuring that lower cost generic versions of the drug are available to public.¹⁵ If such challenges are successful, they result in substantial cost cutting for both the consumers and the health care system by allowing the generic drugs to enter the market long before the expiration of the brand name manufacturers' patents.¹⁶ The pharmaceutical and generic drug companies, however, have found a way to circumvent the provisions of the Act. By settling the patent challenge lawsuits, the companies still benefit from the Hatch-Waxman Act provisions but effectively undermine the Act's goals of lowering the drug prices and making pharmaceuticals more accessible to the

⁸ William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L. REV. 581, 667 (2007).

⁹ See Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J. L. & TECH. 307, 307 (1987) (“Only effective patent protection provides the incentives necessary to enable pharmaceutical companies to commit the required resources.”).

¹⁰ Fisher, *supra* note 8 at 667-68.

¹¹ Banerjee, *supra* note 5.

¹² *Id.*

¹³ Fisher, *supra* note 8 at 668.

¹⁴ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

¹⁵ See 21 U.S.C. § 355 (2006).

¹⁶ Eugene R. Quinn, *FTC Seeks SCOTUS Review in AndroGel “Pay-for-Delay” Case*, IPWATCHDOG (Oct 4, 2012, 6:06 PM), <http://www.ipwatchdog.com/2012/10/04/ftc-seeks-scotus-review-androgel/id=28563>.

public. These settlements, where brand name pharmaceutical companies pay generic drug producers to delay entering the market, are known as “reverse payment settlements,” “reverse settlements,” or pay-for-delay” agreements¹⁷ because a patent holder makes the payment to a patent challenger. Studies by the Federal Trade Commission (“FTC”) have found that reverse settlements result in the annual cost of \$3.5 billion to consumers from the loss of competition caused by the delay of generic drug entry into the market.¹⁸ The issue of whether a reverse payment settlement is the act of unlawful monopoly or merely a settlement favorable to both companies became a subject of a sharp dispute in all three branches of government and created a split among the circuits.¹⁹ Some proposed solutions to the controversy take a patent law posture, others an antitrust approach, and neither the judiciary nor the legislature appears to be willing to embrace a more effective middle-ground approach proposed by scholars.²⁰ This Comment delineates a global solution based on the use of financial regulation and the creation of a new payment system to control the prices of brand name pharmaceutical. This proposal would not only address the damaging results of reverse payment settlements but significantly improve access to pharmaceutical worldwide.

Part II of this Comment provides an overview of the Hatch-Waxman framework. Part III explains the harmful effects of reverse payment settlements on the consumers and reasons why these settlements, unlike other settlements, should not be favored over litigation under the public policy. Part IV addresses in detail the circuit split regarding the appropriate standard to evaluate

¹⁷ See, e.g., David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1305, 1315 (2010); see also 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 (2007) (the agreements are sometimes referred to as “pay for delay, exit, or exclusion payment settlements”).

¹⁸ FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 2* (2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

¹⁹ Hayden W. Gregory, *Sorting Things Out: Patents, Antitrust Law, and Settlement of Hatch-Waxman Act Infringement Suits*, LANDSLIDE, Sept.-Oct. 2012, at 3.

²⁰ *Id.*

the legality of the reverse settlements. Part V describes the proposed legislative solutions, none of which were ultimately adopted by Congress. Part VI addresses various approaches to the pay for delay controversy proposed by renowned scholars and pertinent administrative agencies. Part VII evaluates the most effective judicial solution while taking into account the applicable public policy considerations. Finally, Part VIII explains why even the most effective judicial solution would only resolve a small fraction of the overall problem of drug accessibility and provides an overview of the new fair, cost-effective ways to pay for pharmaceutical innovation outside of the patent system, which could work globally or nationally to address the crucial problem of drug accessibility worldwide and in the United States.

II. THE HATCH-WAXMAN ACT FRAMEWORK IN PHARMACEUTICAL PATENT LITIGATION

The Hatch-Waxman Act encourages generic manufacturers to compete with name brand companies and to attempt to enter the market by filing a paragraph IV certification.²¹ The pharmaceutical company which seeks to begin marketing a new prescription drug must obtain an approval from the Food and Drug Administration (“FDA”).²² This requires the company to submit a New Drug Application (“NDA”) listing extensive information about the drug, including any patents pertaining to the drug’s components and indications.²³ The Hatch-Waxman Act allows a potential generic drug manufacturer to submit an abbreviated application for approval with the FDA, also known as an Abbreviated New Drug Application (“ANDA”).²⁴ In filing an ANDA, the generic manufacturer can rely on the FDA’s prior ruling approving the NDA filed by the brand name company.²⁵ The generic manufacturer who files an ANDA must also recognize

²¹ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

²² 21 U.S.C. § 355(a).

²³ 21 U.S.C. § 355(b)(1).

²⁴ See 21 U.S.C. § 355(j) (the Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399).

²⁵ 21 U.S.C. § 355(j)(2)(A).

any patents covering the brand name drug and certify that, “in the opinion of the applicant and to the best of his knowledge,” the patent is either invalid or it is not infringed by the proposed generic drug (known as “paragraph IV certification”).²⁶ The ANDA applicant must also notify, in writing, every patentee affected by the ANDA that the applicant has filed a paragraph IV certification.²⁷ The patentee will have 45 days after the generic manufacturer submits its paragraph IV certification to file a patent infringement lawsuit.²⁸ Filing of the suit will trigger an automatic stay – the FDA will postpone its approval of the generic drug until either 30 months pass, or a district court determines that the patent is either invalid or not infringed, whichever is earlier.²⁹

The Hatch-Waxman Act provides an incentive to the generic manufacturers in form of the 180-day exclusivity period to encourage generic production and challenge brand name patents.³⁰ Following FDA approval of the ANDA, the first generic manufacturer who files a paragraph IV certification is entitled to a 180-day exclusivity period during which the generic manufacturer has an exclusive right to commercially market its drug.³¹ The exclusivity period begins to run when the first ANDA applicant puts its drug on the market, and the subsequent ANDA applications by other generic drug companies will not be approved by the FDA during this period.³² This allows the successful challengers of brand name drug patents to sell their

²⁶ 21 U.S.C. § 355(j)(2)(A)(vii)(III)-(IV); for a more detailed explanation *see* Angela Foster and Ebony J. Foster, *Reverse Payment Settlements: ‘Legal, Illegal or Unlawful’*, INTELLECTUAL PROPERTY & LIFE SCIENCES, 209 N.J.L.J. 916, at S-4 (Sept. 17, 2012).

²⁷ 21 U.S.C. § 355(j)(2)(B)(iii)(I); *see also* Gregory, *supra* note 19, at 3 (“By statute, a paragraph IV certification is an act of infringement.”).

²⁸ 21 U.S.C. § 355(j)(5)(B)(iii).

²⁹ 21 U.S.C. § 355(j)(5)(B)(iii)(I).

³⁰ Eugene R. Quinn, *Pharma Reverse Patent Payments Are Not An Antitrust Violation*, IPWATCHDOG (Apr. 29, 2010, 4:41 PM), <http://www.ipwatchdog.com/2010/04/29/reverse-payments-not-antitrust-violation/id=10339>.

³¹ 21 U.S.C. § 355(j)(5)(B)(iv).

³² *Id.*

generic versions of the drugs at extremely competitive prices.³³

It is important to note that only the first filer of the ANDA with a paragraph IV certification is entitled to the 180-day period of market exclusivity:³⁴ “even if the first filer never becomes eligible to use its 180-day exclusivity period because it settles, loses, or withdraws the litigation, that potential benefit will not pass to subsequent filers.”³⁵ The first applicant is typically the most determined to challenge the patent of the brand name company.³⁶ Ideally, at the culmination of the 180-day window, all generic drug manufacturers would be able to enter the market quickly after the first filer’s successful challenge of the patent.³⁷ As a result, the consumers would have access to low-cost generic drugs in accordance with the goals of the Hatch-Waxman Act.³⁸ This part of the framework is what allows the companies to easily undermine the objectives of the Act.³⁹ A brand name patentee can simply settle the patent challenge lawsuit by paying off the first ANDA filer.⁴⁰ Any subsequent generic manufacturers can file a paragraph IV certification, but because they are not entitled to the 180-day exclusivity period, they lose the incentive to challenge the patent.⁴¹ As a result, the brand name company who owns even the weakest patent successfully avoids any generic competition until the end of

³³ Quinn, *supra* note 30.

³⁴ 21 U.S.C. § 355(j)(5)(D)(iii).

³⁵ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012), *petition for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245), *available at* <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-245.htm>; *petition for cert. filed*, (Aug. 29, 2012) (No. 12-265), *available at* <http://www.supremecourt.gov/search.aspx?FileName=/docketfiles/12-265.htm> (citing 21 U.S.C. § 355(j)(5)(D)(iii)).

³⁶ See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1583 (2006) (indicating that there is “a sharp difference in incentives . . . between [the] ANDA-IV filer and all other generic firms”).

³⁷ Quinn, *supra* note 30.

³⁸ H.R. Rep. No. 98-857(I), at 14-15, reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

³⁹ David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 331 (2000) (“The competitive concern is that the 180-day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws and the Hatch-Waxman Act by delaying generic entry for a substantial period.”).

⁴⁰ *K-Dur*, 686 F.3d at 204; *see also* Quinn, *supra* note 30.

⁴¹ *Id.*

the patent term.⁴²

Aware of the possibility of antitrust violations resulting from reverse settlements,⁴³ Congress amended the Hatch-Waxman Act in 2003 to require pharmaceutical companies who settled patent challenge lawsuits to file their settlement agreements with the FTC and the Department of Justice (“DOJ”) for antitrust examination.⁴⁴ While the FTC has vigorously opposed reverse payment settlements, the federal circuits have disagreed as to the lawfulness of the reverse payment settlements, creating a split.⁴⁵

III. THE HARMFUL EFFECTS OF THE REVERSE PAYMENT SETTLEMENTS

According to a 2010 study conducted by the FTC, “[p]ay-for-delay agreements are estimated to cost American consumers \$3.5 billion per year – \$35 billion over the next 10 years” due to the unavailability of lower-cost generic drugs.⁴⁶ About a year after the first generic version of a drug enters the market, this generic version, on average, replaces over 90% of the brand name company’s unit sales.⁴⁷ In addition, the price of the generic version is approximately 85% lower than the price of the brand name pharmaceutical prior to the market

⁴² Quinn, *supra* note 30; see also 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,882-83 (Aug. 6, 1999) (codified at 21 C.F.R. pt. 314) (“It can be mutually beneficial for the innovator and the generic company that is awarded 180 days of generic exclusivity to enter into agreements that block generic competition for extended periods. This delayed competition harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments.”).

⁴³ See S. Rep. No. 107-167, at 4 (2002).

⁴⁴ *K-Dur*, 686 F.3d at 204 (citing Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066, 2461-64 (codified as amended at 21 U.S.C. § 355(j))).

⁴⁵ *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 110th Cong. 1 (2009) (prepared statement of Richard A. Feinstein, Director, Bureau of Competition, Federal Trade Commission), available at <http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf>.

⁴⁶ FTC, *Pay for Delay: How Drug Company Pay Offs Cost Consumers Billions 2* (2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> (citing Jon Leibowitz, Chairman, Fed. Trade Comm’n, “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*) at 8 (June 23, 2009), available at <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>)).

⁴⁷ FTC, *supra* note 46.

entry of the generic drug.⁴⁸ Because of the sharp difference between the generic and the brand name drug prices, the entry of the generic drug on the market amounts to a significant benefit to the consumers but results in a loss of revenue to the brand name producers.⁴⁹ To avoid this revenue loss, makers of brand name pharmaceuticals offer to settle the litigation challenging their drug patent.

Generally, public policy favors settlements over expensive and lengthy litigation process. In the Hatch-Waxman context, however, the FTC posits that courts should presume that reverse settlements are unlawful because they violate antitrust laws and unnecessarily increase consumers' health care costs by billions of dollars.⁵⁰ Similarly, the DOJ has opined that reverse settlements should be presumed unlawful, noting that such presumption would be rebuttable with a showing that a settlement "provide[s] a degree of competition reasonably consistent with the parties' contemporaneous evaluations of their prospects of litigation success."⁵¹ Eugene Quinn, the intellectual property scholar, indicates that the Hatch-Waxman Act aimed to balance "two competing policy interests: (1) inducing pioneering research and development of new drugs; and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."⁵² What resulted, however, was "a full employment act for lawyers, and underground funding of generic drug manufacturers who have an incentive to challenge patented drugs."⁵³ The courts are faced with a challenge of formulating framework which would incorporate public policy favoring

⁴⁸ FTC, *supra* note 46.

⁴⁹ *K-Dur*, 686 F.3d at 208; FTC, *supra* note 46.

⁵⁰ FTC, *supra* note 46; Opderbeck, *supra* note 17 at 1317 n.123 (citing Appeal Brief of Counsel Supporting the Complaint, *In re Schering-Plough Corp.*, No. 9297 (Fed. Trade Comm'n Aug. 9, 2002), available at <http://www.ftc.gov/os/2002/08/scheringtrialbrief.pdf>).

⁵¹ Opderbeck, *supra* note 17 at 1318 n.131 (citing Brief for the United States in Response to the Court's Invitation at 10, Ark. *Carpenters Health & Welfare Fund*, No. 05-2851-cv(L), available at <http://www.justice.gov/atr/cases/f247700/247708.pdf>).

⁵² Eugene R. Quinn, *Senate Bill Would Prevent Reverse Pharma Payments*, IPWATCHDOG (Feb. 6, 2009, 4:47 PM), <http://www.ipwatchdog.com/2009/02/06/senate-bill-would-prevent-reverse-pharma-payments/id=1950>.

⁵³ *Id.*

settlements over litigation yet simultaneously address the harmful effects of reverse payment settlements in the Hatch-Waxman Act context.

IV. THE CIRCUIT SPLIT OVER THE APPROACH TO THE PAY FOR DELAY ISSUE

The circuit courts disagree over the legality of reverse payment settlements and the appropriate standard of law to apply. Under the Sherman Act, “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”⁵⁴ The Supreme Court has continuously disallowed only those restraints on trade that are unreasonable.⁵⁵ In analyzing the reverse settlements, the circuit court opinions have shared a focus on the exclusionary power of the patent, but split concerning ways to balance the patentees’ rights against the policy interest in encouraging generic drug competition.⁵⁶ The Supreme Court of the United States has granted the government’s petition for a writ of certiorari on December 7, 2012 to review the highly contested issue of the lawfulness of reverse settlements.⁵⁷ Below is an overview of the three predominant legal theories concerning the validity of reverse settlements: the *per se* approach, the scope of the patent rule, and the rule of reason.

A. One Approach: Reverse Payment Settlements are Per Say Illegal

Some courts have found that because certain agreements are always unreasonable, and their anti-competitive implications clearly outweigh any potential pro-competitive benefits, these types of settlements are unlawful *per se*.⁵⁸ This hard-line approach applies where a “practice

⁵⁴ 15 U.S.C. § 1.

⁵⁵ See *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

⁵⁶ Opderbeck, *supra* note 17 at 1316.

⁵⁷ *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 81 U.S.L.W. 3324 (U.S. Dec. 7, 2012) (No. 12-416), available at http://www.supremecourt.gov/orders/courtorders/120712zr_3f14.pdf.

⁵⁸ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012), *petition for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245), available at <http://www.supremecourt.gov/Search.aspx?FileName=/docket files/12-245.htm>; *petition for cert. filed*, (Aug. 29, 2012) (No. 12-265), available at

facially appears to be one that would always or almost always tend to restrict competition or decrease output.”⁵⁹ For example, courts have held horizontal price fixing, output limitations, market allocation, and group boycotts to be *per se* illegal.⁶⁰

The Sixth Circuit’s decision of *In re Cardizem CD Antitrust Litigation* exemplifies the application of *per se* analysis.⁶¹ In *Cardizem*, the generic manufacturer Andrx agreed not to market its version of the patented blood-pressure drug Cardizem CD of Hoescht Marion Roussel, Inc. (“HMR”) until it obtained a conclusive decision that the generic version did not infringe patent held by HMR.⁶² The purchasers of Cardizem CD brought a lawsuit, alleging that the generic company’s agreement to delay market entry caused them to suffer antitrust harm.⁶³ The court was concerned with the terms of the settlement which prevented the marketing of generic versions of not only the brand name patented drug, but also drugs “not at issue in the pending litigation.”⁶⁴ The Sixth Circuit reasoned that the brand name manufacturer paid “the only potential competitor \$40 million per year to stay out of the market.”⁶⁵ The court distinguished between merely taking advantage of a monopoly “that naturally arises from a patent” and “altogether . . . bolster[ing] the patent’s effectiveness in inhibiting competitors by paying [off the only competitor].”⁶⁶ The court concluded that the settlement was “a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a

<http://www.supremecourt.gov/search.aspx?FileName=/docketfiles/12-265.htm> (citing 21 U.S.C. § 355(j)(5)(D)(iii)) (quoting *State Oil Co.*, 522 U.S. at 10)).

⁵⁹ *K-Dur*, 686 F.3d at 209 (citing *Broad. Music, Inc. v. Columbia Broad Sys., Inc.*, 441 U.S. 1, 19-20 (1979)).

⁶⁰ See *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *N. Pac. Ry. v. United States*, 356 U.S. 1, 5 (1958).

⁶¹ *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).

⁶² *Id.* at 902.

⁶³ *Id.* at 904.

⁶⁴ *Id.* at 908 n.13.

⁶⁵ *Id.* at 908.

⁶⁶ *Id.*

classic example of a *per se* illegal restraint of trade.”⁶⁷

A few years before *Cardizem*, the D.C. Circuit decided a *Andrx Pharms., Inc. v. Biovail Corp. Int'l*.⁶⁸ In *Andrx*, rather than resolving the patent challenge lawsuit by settlement,⁶⁹ the name brand pharmaceutical company offered a payment to the generic manufacturer if it agreed to delay marketing the generic version of the drug, while allowing the patent challenge lawsuit to continue.⁷⁰ The payments were to begin on the date FDA approved the generic version of the drug and end when either the generic producer began selling its version of the drug or the abovementioned patent challenge lawsuit was resolved in favor of the patent holder.⁷¹ After obtaining the FDA approval, the brand name manufacturer began making payments of \$10 million per quarter to the generic manufacturer,⁷² and the generic manufacturer avoided triggering the 180-day exclusivity window by refraining from entering its version of the drug on the market.⁷³ The court held that the agreement at issue violated Sherman Act, explaining that the agreement was “so broad that part of the restraint suppress[ed] competition without creating efficiency.”⁷⁴ Despite these successful challenges of pay-for-delay deals against the patentee’s, other courts approached the issue differently, resulting in a deep split of authority.⁷⁵

B. Another Approach: the Scope of the Patent Analysis

Some courts declined to apply the *per se* rule and allowed reverse payment agreements

⁶⁷ *In re Cardizem*, 332 F.3d at 908. The Court also found the instant agreement resulted in the delay of the entry of other competitors into the market because Andrx had refused to utilize its exclusivity window. *Id.* at 907.

⁶⁸ *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002).

⁶⁹ Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 295 (The settlement at issue was the same settlement described above in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004)).

⁷⁰ *See Andrx*, 256 F.3d at 803.

⁷¹ *Id.*

⁷² *Id.* at 809.

⁷³ *Id.* at 804.

⁷⁴ *Id.* at 815.

⁷⁵ Laura J. Grebe, *Comment: Generic Entry in a Rough Economy--Proposed Legislation May Ease Health Care Costs*, 14 MARQ. INTELL. PROP. L. REV. 167, 179 (2010).

on the grounds that they are valid settlements in patent infringement actions.⁷⁶ Under the “scope of the patent” test implemented by these courts, the reverse settlement will not be invalidated if the exclusion does not exceed the scope of the patent, the patent owner’s infringement lawsuit was not objectively baseless, and the patent was not obtained fraudulently.⁷⁷

The Eleventh Circuit considered the issue of pay for delay deals in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*⁷⁸ In *Valley Drug*, a name brand pharmaceutical company sued a generic producer for infringement of its patent, and the generic producer claimed the patent was invalid.⁷⁹ The parties settled the lawsuit by entering into two agreements, one of which was a final settlement of specific claims, and the other was structured in a similar way to the agreements in *Andrx* and *Cardizem* and became effective while the litigation continued.⁸⁰ The agreements stated that the brand name company would provide large payments to the generic producer to delay the market entry of the generic drug until the brand manufacturer’s patent expires.⁸¹ The district court held that the settlements involved were *per se* illegal and violated Sherman Act.⁸² The Eleventh Circuit reversed, reasoning that the name brand company’s patent gives it the right to exclude competitors.⁸³ According to the test set forth by the Eleventh Circuit, the court must consider “the scope of the exclusionary potential of the patent, the extent to which [the] provisions of the agreements exceed that scope, and the anticompetitive effects

⁷⁶ *Id.*

⁷⁷ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006) (citing *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294,1312 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004)); *see also* Foster, *supra* note 26 at S-5.

⁷⁸ *Valley Drug*, 344 F.3d at 1294.

⁷⁹ *Id.* at 1299.

⁸⁰ *Id.* at 1300.

⁸¹ *Id.* Subsequently, the court determined in another case that the brand name company’s patent was invalid. *Id.* at 1306-7.

⁸² *Id.* at 1301, 1306.

⁸³ *Valley Drug*, 344 F.3d at 1306.

thereof.”⁸⁴ If any part of the settlement agreement reached beyond the protections provided by the brand name company’s patent, the court would apply traditional antitrust scrutiny to those parts of the settlement.⁸⁵

The Eleventh Circuit applied the *Valley Drug* framework in *Schering-Plough Corp. v. FTC*.⁸⁶ Schering-Plough (“Schering”), a large pharmaceutical company, manufactured numerous drugs, including K-Dur 20, a potassium chloride supplement.⁸⁷ Schering-Plough owned a patent on the extended-release coating used in K-Dur 20, which was scheduled to expire in 2006.⁸⁸ Upsher-Smith (“Upsher”), a competing drug company, filed an ANDA for a generic version of K-Dur 20.⁸⁹ In response, Schering sued for an infringement of their coating patent.⁹⁰ Before the trial began, the parties signed a settlement whereby Schering agreed to pay royalty fees as well as 10-15% royalty payments for five of Upsher’s other drugs.⁹¹

Meanwhile, a second competing generic manufacturer, ESI Lederle, Inc. (“ESI”), filed an application with the FDA to market its own generic version of K-Dur 20,⁹² including a paragraph IV certification challenging Schering’s extended release coating.⁹³ Consequently, Schering settled with ESI as well, agreeing to pay ESI up to \$15 million for ESI postponing market entry of its generic K-Dur 20 version.⁹⁴ The FTC challenged both settlements as antitrust law violations, but an administrative law judge (“ALJ”) upheld the agreements.⁹⁵ On appeal, the

⁸⁴ *Id.* at 1311-12.

⁸⁵ *Id.* The court remanded the case to determine whether the agreement was a “reasonable implementation” of the “protection afforded by the patents.” *Id.* at 1312.

⁸⁶ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

⁸⁷ *Id.* at 1058.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.* at 1059.

⁹¹ *Schering-Plough*, 402 F.3d at 1059-60.

⁹² *Id.* at 1060.

⁹³ *Id.* at 1060 n.5.

⁹⁴ *Id.* at 1061.

⁹⁵ *Id.* 1061. Because the FTC is an administrative agency, the hearing took place before the ALJ.

Eleventh Circuit agreed with the ALJ and rejected the *per se* rule.⁹⁶ Instead, the court applied the antitrust test articulated in *Valley Drug*.⁹⁷ The court explained that, taking into account the presumption of patent validity, the scope of Schering's patent allowed the company to exclude patent infringers, but the company could not exclude beyond that.⁹⁸ The court decided that both agreements did not exceed the scope of the patent at issue and the payment from Schering to Upsher was not a reverse settlement but a payment for drug licenses.⁹⁹ In contrast, the agreement with ESI did involve a reverse payment.¹⁰⁰ Nevertheless, the court focused on the judicial policy favoring settlements¹⁰¹ and held that the agreements in question were valid.¹⁰²

The more recent case to adopt this approach is *FTC v. Watson Pharmaceuticals*,¹⁰³ where the Eleventh Circuit clarified that its version of the "scope of the patent" analysis conformed to the analysis adopted by the Second and Federal Circuits.¹⁰⁴ The court upheld a settlement concerning a testosterone drug, indicating that "[a] patent holder and any of its challengers cannot enter into an agreement that excludes more competition than the patent has the potential to exclude."¹⁰⁵ The court explained that the phrase "strengths of the patent" used in *Schering-*

⁹⁶ *Schering-Plough*, 402 F.3d at 1065.

⁹⁷ *Id.* at 1065-1066.

⁹⁸ *Id.* at 1068.

⁹⁹ *Id.* at 1071. The court decided that in the Upsher agreement, the royalty payments were for royalties on the drug licenses for five drugs other than K-Dur 20, and there was no evidence that these payments were excessive. *Id.*

¹⁰⁰ *Id.* at 1072.

¹⁰¹ *Schering-Plough*, 402 F.3d at 1072 (citing *Standard Oil Co. v. U.S.*, 283 U.S. 163 (1931)).

¹⁰² *Id.* at 1076.

¹⁰³ *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 81 U.S.L.W. 3324 (U.S. Dec. 7, 2012) (No. 12-416).

¹⁰⁴ Michael A. Carrier, *Article: Why The "Scope Of The Patent" Test Cannot Solve The Drug Patent Settlement Problem*, 2012 STAN. TECH. L. REV. 1. (2012). The Eleventh Circuit explained that "its prior opinions did not call for an evaluation of the strength of the patent but rather only a determination whether, absent sham litigation or fraud in obtaining the patent, the settlement agreement exceeded the scope of the patent." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012), *petition for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245), *available at* <http://www.supremecourt.gov/Search.aspx?FileName=/docket files/12-245.htm>; *petition for cert. filed*, (Aug. 29, 2012) (No. 12-265), *available at* <http://www.supremecourt.gov/search.aspx?FileName=/docketfiles/12-265.htm> (citing 21 U.S.C. § 355(j)(5)(D)(iii)) (citing *Watson*, 677 F.3d at 1311-13 n.8, 1313-14).

¹⁰⁵ *Watson*, 677 F.3d at 1308.

*Plough Corp. v. FTC*¹⁰⁶ referred to “the potential exclusionary scope of the patent,” meaning “the exclusionary rights appearing on the patent’s face and not the underlying merits of the infringement claim.”¹⁰⁷

The Second Circuit considered the pay for delay issue in *In re Tamoxifen Citrate Antitrust Litigation*.¹⁰⁸ At issue in this case was a patent for Tamoxifen, a widely used breast cancer drug.¹⁰⁹ Imperial Chemical Industries, PLC (“ICI”), the holder of the drug patent, marketed the drug through Zeneca, ICI’s subsidiary, under the brand name Nolvadex(R).¹¹⁰ Barr, another pharmaceutical company, filed an ANDA with a paragraph IV certification, seeking approval of its generic version of Tamoxifen, and ICI responded with filing an infringement suit.¹¹¹ After the district court held that the patent was invalid, the ICI appealed the infringement suit decision, but the parties settled while the case was on appeal.¹¹² Pursuant to their agreement, ICI granted Barr a license to sell an unbranded version of Tamoxifen under Barr’s label and agreed to pay Barr \$21 million as well cover the costs of material supplies for Barr of \$35.9 million over a ten year period.¹¹³ In exchange, Bar agreed to refrain from pursuing its paragraph IV certification and manufacturing its own generic version of Tamoxifen until ICI’s patent expired.¹¹⁴ The settlement ended the lawsuit between the parties instantly,¹¹⁵ unlike some of the cases mentioned above where the brand name company would be making the payments pending the resolution of the infringement action.

¹⁰⁶ *Schering*, 402 F.3d at 1056 (Eleventh Circuit’s version of the scope of the patent test seemed to focus on the patent’s “exclusionary potential” and “likelihood” of obtaining an injunction).

¹⁰⁷ *Watson*, 677 F.3d at 1311 n.8.

¹⁰⁸ *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007).

¹⁰⁹ *Id.* at 190.

¹¹⁰ *Id.* at 193.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Tamoxifen*, 466 F.3d at 194.

¹¹⁴ *Id.* at 193-194 (the parties obtained a vacatur of the district court’s decision invalidating the patent).

¹¹⁵ *Id.* at 215.

Subsequently, Barr’s use of its 180-day exclusivity period prevented other paragraph IV challengers from obtaining approval for their versions of Tamoxifen.¹¹⁶ While these companies again disputed the validity of ICI’s patent in court, consumer organizations filed an action challenging the lawfulness of the ICI-Barr settlement.¹¹⁷ The district court dismissed the antitrust plaintiffs’ claims, reasoning that, even though the horizontal agreements like the one at issue typically violate the Sherman Act, they may still be lawful when the party preventing competition is the patentee.¹¹⁸ The Second Circuit agreed,¹¹⁹ rejecting the idea that reverse settlements are *per se* violations of antitrust law.¹²⁰ The court explained that as long as “the patent litigation is neither a sham nor otherwise baseless” or beyond the scope of the patent, the patentee can enter into an agreement “to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”¹²¹ The court held that “there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.”¹²² The only two exceptions to this “scope of the patent” analysis occur where the patent was obtained by fraud or where the patent enforcement action was objectively baseless.¹²³ The brand name company’s patent in this case would have effectively precluded all generic versions of Tamoxifen as any such generic drug would infringe the patent.¹²⁴ The Second Circuit also admitted that the result of the Hatch-Waxman Act encouraging reverse payments was potentially disturbing, but the judicial preference for

¹¹⁶ *Id.* at 214.

¹¹⁷ *Id.* at 196.

¹¹⁸ *Tamoxifen*, 466 F.3d at 197.

¹¹⁹ *See Quinn*, *supra* note 30 (“The Tamoxifen court ruled that such a settlement agreement does not exceed the scope of the patent where (1) there was no restriction on marketing non-infringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm’s patent; and (3) the agreement did not bar other generic manufacturers from challenging the patent.”).

¹²⁰ *Tamoxifen*, 466 F.3d at 206.

¹²¹ *Id.* at 208-09, 213.

¹²² *Id.* at 213 (internal quotation marks and citations omitted).

¹²³ *Id.*

¹²⁴ *Id.* at 214.

settlement counterbalanced such troubling outcomes.¹²⁵

The Second Circuit distinguished *Cardizem* by pointing out that in addition to a large reverse payment, the settlement in that case involved a condition that the generic producer would not market other non-infringing products which were not at issue in the case.¹²⁶ In contrast, the *Tamoxifen* settlement only concerned the drug covered by the brand name company's patent, and did not "restrain[] the introduction or marketing of unrelated or non-infringing products."¹²⁷

In subsequent reverse settlement litigation the Second Circuit panel of judges noted that the *Tamoxifen* decision lead to a substantial increase in the number of reverse settlements, declared that *Tamoxifen* was wrongly decided, and the panel encouraged the petitioners to apply for rehearing *en banc*.¹²⁸ Rehearing *en banc* was subsequently denied, with one of the judges dissenting.¹²⁹

The Federal Circuit also applied the scope of the patent analysis in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, indicating that "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."¹³⁰ The court upheld an agreement concerning an antibiotic, grounding its reasoning on the patent system's presumption of the patents' validity, which gives the patentee "the right to exclude others from profiting by the patented invention."¹³¹ Accordingly, the court "agree[d] with the Second and Eleventh Circuits . . . that, in the absence of evidence of fraud before the PTO or sham litigation,

¹²⁵ *Tamoxifen*, 466 F.3d at 211 ("We are not unaware of a troubling dynamic that is at work in these cases. The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.").

¹²⁶ *Id.* at 213-14.

¹²⁷ *Id.*

¹²⁸ *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 108-10 (2d Cir. 2010), *cert. denied*, 604 F.3d 98 (2011).

¹²⁹ *See Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779 (2d Cir. 2010).

¹³⁰ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 129 S.Ct. 2828 (2009).

¹³¹ *Id.* at 1333, 1337.

the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”¹³² The court came to a conclusion that “all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent.”¹³³ The scope of patent test in *Ciprofloxacin* and other cases described above focused on the exclusionary power of the patent, but some courts have deviated from this approach and instead leaned toward the antitrust analysis which could more effectively further Congressional goals of increasing competition between the pharmaceutical companies.¹³⁴

C. The “Quick Look” Rule of Reason Approach – the In Re K-Dur Matter

Some courts rejected the scope of patent analysis and instead applied the framework considering the anticompetitive market effects of the settlement to determine whether the settlement posed an unreasonable restraint on commerce.¹³⁵ To determine whether a restraint on trade is unreasonable and therefore a violation of antitrust law, the courts generally apply the “rule of reason”.¹³⁶ “the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.”¹³⁷ This “rule of reason” inquiry consists of three steps: first, the movant must prove that the challenged conduct led to anti-competitive results within the market.¹³⁸ If the movant can meet this burden, “the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective.”¹³⁹ The

¹³² *Id.* at 1336.

¹³³ *Id.*

¹³⁴ See H.R. Rep. No. 98-857, pt. 2, at 14-15 (1984).

¹³⁵ *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993) (citing *Cont’l T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977)).

¹³⁶ *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

¹³⁷ *Id.*

¹³⁸ *Brown Univ.*, 5 F.3d at 668.

¹³⁹ *Id.* at 669.

movant can then rebut the defendant’s pro-competitive argument by proving that the restraint created by the defendant is not reasonably necessary to accomplish the pro-competitive end.¹⁴⁰

The Third Circuit applied the rule of reason framework to a reverse payment settlement in *In re K-Dur Antitrust Litigation* (“K-Dur”).¹⁴¹ *K-Dur* held that reverse settlements should be presumed to constitute unreasonable restraints on trade, unless the parties can show otherwise.¹⁴² Some scholars have characterized the decision as “a home run in favor of antitrust scrutiny.”¹⁴³ According to one source, “[a]n appellate court had not offered such a skeptical treatment of [the reverse settlement] agreements since 2003, when the Sixth Circuit found one to be *per se* illegal.”¹⁴⁴

K-Dur concerned the same settlements which gave rise to *Schering*.¹⁴⁵ The FTC filed a suit against the pharmaceutical companies Schering, Upsher, and ESI, claiming that the two settlements reached between these companies unreasonably restrained trade, violating Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.¹⁴⁶ The FTC argued that the reverse payments from Schering to the two generic brand companies, Upsher and ESI, effectively caused

¹⁴⁰ *Id.*; *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 209 (3d Cir. 2012), *petition for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245), *available at* <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-245.htm>; *petition for cert. filed*, (Aug. 29, 2012) (No. 12-265), *available at* <http://www.supremecourt.gov/search.aspx?FileName=/docketfiles/12-265.htm> (citing 21 U.S.C. § 355(j)(5)(D)(iii)).

¹⁴¹ *K-Dur*, 686 F.3d at 197. On August 24, 2012, and August 29, 2012, two petitions for writ of certiorari by defendants Merck & Co. and Upsher, respectively, were filed appealing the Third Circuit’s decision in *K-Dur*. Petition for Writ of Certiorari, *Merck & Co. v. La. Wholesale Drug Co.* (No. 12-245) (Aug. 24, 2012), *available at* <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-245.htm>; Petition for Writ of Certiorari, *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.* (No. 12-265) (Aug. 29, 2012), *available at* <http://www.supremecourt.gov/search.aspx?FileName=/docketfiles/12-265.htm>.

¹⁴² Foster, *supra* note 26 at S-4.

¹⁴³ Quinn, *supra* note 16.

¹⁴⁴ *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); see Michael Carrier, *Reverse Payment Home Run for Pharma Antitrust Enforcement*, IPWATCHDOG (Jul. 16, 2010, 3:50 PM), <http://www.ipwatchdog.com/2012/07/16/reverse-payment-home-run-for-pharma-antitrust-enforcement/id=26491>.

¹⁴⁵ *K-Dur*, 686 F.3d at 211 (citing *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006) (“*Schering-Plough Corp. v. FTC*, arose out of the same settlement agreement as the instant appeal.”)).

¹⁴⁶ *Id.* at 206-7.

a delay in the market entry of the generic drugs, thereby improperly preserving Schering's monopoly.¹⁴⁷ The ALJ dismissed the FTC's complaint, holding that the agreements did not violate Section 5 of the FTC Act.¹⁴⁸ Applying the rule of reason, the FTC unanimously reversed the ALJ's decision, explaining that there was a "direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry" and that this agreement "unreasonably restrain[ed] commerce."¹⁴⁹ According to the FTC's decision, the entry of the parties into a reverse settlement raises a red flag and can result in a *prima facie* evidence that an agreement violates anti-competition laws.¹⁵⁰ The FTC posited that the reverse payment at issue was unlawful because the defendants could not show either that the settlement payment was for something other than generic drug's delayed entry, or that the payment had pro-competitive effects.¹⁵¹ Consequently, Schering appealed the ruling of the FTC to the Eleventh Circuit, which reversed the ALJ's decision.¹⁵² Other private parties filed lawsuits alleging that the agreements violated antitrust laws, which were consolidated in the District of New Jersey.¹⁵³ The district court adopted the scope of the patent test.¹⁵⁴

On appeal, the Third Circuit disagreed with the district court's reasoning, and instead adopted a "quick look" rule of reason analysis.¹⁵⁵ The court explained that in some instances courts use "an antitrust analysis that falls between the full rule of reason inquiry on the one hand and the rigid *per se* approach on the other," also known as "quick look" or "truncated rule of

¹⁴⁷ *Id.* at 207.

¹⁴⁸ *Id.* (citing *In re Schering-Plough Corp.*, Initial Decision, 136 F.T.C. 956, 1092, 1263 (2002)).

¹⁴⁹ *Id.* (citing *In re Schering-Plough Corp.*, Final Order, 136 F.T.C. 956, 991, 1000-01, 1052 (2003)).

¹⁵⁰ *K-Dur*, 686 F.3d at 207 (citing *Schering*, 136 F.T.C. at 991, 1000-01).

¹⁵¹ *Id.* (citing *Schering*, 136 F.T.C. at 956, 988-89, 1061).

¹⁵² *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

¹⁵³ *K-Dur*, 686 F.3d at 207.

¹⁵⁴ *Id.* at 208.

¹⁵⁵ Foster, *supra* note 26 at S-5.

reason” analysis.¹⁵⁶ The quick look rule of reason test applies where the plaintiff can demonstrate that “the defendant has engaged in practices similar to those subject to *per se* treatment.”¹⁵⁷ The fact finder treats any agreement between a generic patent challenger and the patentee where the patent challenger delays market entry of its generic drug in exchange for the payment as *prima facie* evidence of an unreasonable restraint on commerce.¹⁵⁸ If the plaintiff can meet this burden, he or she is no longer required to demonstrate the anti-competitive results of these practices on the market; instead, the burden shifts to the defendant, who can rebut the presumption of illegality by showing that the reverse agreement has pro-competitive benefits or that the payment was for a purpose other than delaying market entry.¹⁵⁹

The clear split between the circuits, made sharper by the *K-Dur* decision, finally set the stage for the Supreme Court’s resolution of the reverse payment settlement issue. In December of 2012, the Supreme Court granted certiorari in *Watson*.¹⁶⁰ The defendants in *K-Dur* also sought Supreme Court review, but the Court is holding that petition pending its ruling in *Watson*.¹⁶¹ The Court is likely to hear oral argument in *Watson* during the last two weeks of March 2013.¹⁶²

V. PROPOSED LEGISLATIVE SOLUTIONS TO PAY FOR DELAY PROBLEM

In deciding *Watson*, the Supreme Court should take into consideration the legislative history and proposed legislative solutions to reverse settlements. Even the main drafters of the Hatch-Waxman Act, Senator Orrin Hatch and Congressman Waxman, expressed disapproval of

¹⁵⁶ *K-Dur*, 686 F.3d at 209 (citing *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993)).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 218.

¹⁵⁹ *Id.*

¹⁶⁰ *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 81 U.S.L.W. 3324 (U.S. Dec. 7, 2012) (No. 12-416).

¹⁶¹ *U.S. Supreme Court to Rule on “Pay-for-Delay” Antitrust Issue*, MCDERMOTT WILL & EMERY (Dec. 10, 2012), <http://www.mwe.com/US-Supreme-Court-to-Rule-on-Pay-for-Delay-Antitrust-Issue-12-10-2012>.

¹⁶² *Id.*; Lisa H. Wang, *Proposed Bill Seeks to Answer the Pay for Delay Debate*, IP LAW ALERT (Feb. 7, 2013), <http://www.iplawalert.com/tags/payfordelay>.

reverse settlements.¹⁶³ Many scholars as well as the FTC and the DOJ have put forth an array of solutions to the pay for delay controversy.¹⁶⁴ For example, Christopher M. Holman proposed eliminating the 180-day exclusivity period for first Paragraph IV applicants from the Hatch-Waxman Act to avoid many of the reverse payment settlement issues.¹⁶⁵ Another option would be to allow subsequent generic ANDA filers who submit a paragraph IV certification to be eligible for the 180-day exclusivity window.¹⁶⁶ Yet these solutions might prove ineffective because lessening the advantages for generic drug manufacturers to challenge patented drugs could disincentivize them from challenging name brand patents,¹⁶⁷ despite the fact that generic drug manufacturers would still retain other incentives to challenge patents without incurring considerable risk.¹⁶⁸

Though Congress is well aware of the Hatch-Waxman issue concerning pay for delay deals, so far its attempts to address the problem have failed.¹⁶⁹ The past few Congresses included several propositions of the bills to outlaw or limit the use of the reverse payment settlements in the context of Hatch-Waxman patent infringement lawsuits.¹⁷⁰ Some of the earlier Senate bills, such as S. 316 in the 110th Congress (2007-2008), promoted a *per se* illegality approach, seeking to amend the Clayton Act to adopt the presumption of illegality as to reverse settlement.¹⁷¹ This drastic measure was deemed politically unacceptable, and subsequent bills proposed instead to

¹⁶³ Quinn, *supra* note 30.

¹⁶⁴ Opderbeck, *supra* note 1717 at 1320.

¹⁶⁵ Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494-500 (2007).

¹⁶⁶ Quinn, *supra* note 30.

¹⁶⁷ Quinn, *supra* note 52 (“The generic drug companies have every incentive in the world under Hatch-Waxman to challenge the patents held by pharmaceutical companies, but they reap a tremendous reward when they challenge the patents and then ultimately back off due to a settlement of the dispute.”).

¹⁶⁸ Opderbeck, *supra* note 17 at 1326 (*citing* 35 U.S.C. § 271(e)(4) (2006)).

¹⁶⁹ Quinn, *supra* note 16.

¹⁷⁰ Opderbeck, *supra* note 17 at 1318 (*citing* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 2(b) (as reported and amended by S. Comm. on the Judiciary, Oct. 15, 2009); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 11th Cong. § 2(a) (2009)).

¹⁷¹ Gregory, *supra* note 19 at 3.

apply the established antitrust rule of reason framework to evaluate the legality of reverse payments.¹⁷² S. 369, entitled the Preserve Access to Affordable Generics Act,¹⁷³ introduced in 111th Congress, initially advised for the *per se* approach, but its later modification called for the rule of reason approach, treating reverse payments as presumptively anti-competitive and allowing for the presumption to be overcome with a showing that the pro-competitive results of the deal outweighed the anti-competitive outcomes.¹⁷⁴ In addition, the bill contained a list of factors that the court could incorporate into its rule of reason framework.¹⁷⁵ The bill would also allow a safe harbor for agreements in which the ANDA applicant is permitted to enter the market earlier and is reimbursed for “reasonable litigation expenses not to exceed \$ 7,500,000.”¹⁷⁶

The present successor of S. 369, S. 27 in the current 112th Congress adopts the rule of reason approach as well.¹⁷⁷ Like its first two predecessors, S. 27 was favorably reported in 2011, but the likelihood of this bill coming to a vote in the full Congress is low.¹⁷⁸ Based on the Senate’s inability to enact any of these measures, the Senate opponents of reverse payments have

¹⁷² *Id.*

¹⁷³ Wang, *supra* note 162.

¹⁷⁴ Opperbeck, *supra* note 17 at 1319 (citing S. 369 § 3(a). The revised version of the bill explained that reverse settlements “have unduly delayed the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law.” S. 369 § 2(a)(6)(B). If passed, S. 369 would amend the Clayton Act by adding a Section 29. See S. 369, 111th Cong. (2009)).

¹⁷⁵ *Id.* (quoting S. 369 § 3(a)). The factors are:

- (1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;
- (2) the value to consumers of the competition from the ANDA product allowed under the agreement;
- (3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;
- (4) the revenue the ANDA filer would have received by winning the patent litigation;
- (5) the reduction in the NDA holder’s revenues if it had lost the patent litigation;
- (6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and
- (7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

¹⁷⁶ *Id.*

¹⁷⁷ Gregory, *supra* note 19 at 3.

¹⁷⁸ *Id.* S. 316 and S. 369 were also favorably reported, but neither of the two came to a vote in the full senate. *Id.*

put forward proposals endorsing more limited solutions.¹⁷⁹ Specifically, on May 24, 2012, Senator Bingamon proposed an amendment to S. 3187, the FDA Safety and Innovations Act, which would disqualify the generic drug manufacturers who were the first to apply for an approval of their generic version of the drug, but subsequently agreed to delay market entry, from their eligibility for the 180-day exclusivity period.¹⁸⁰ This amendment, however, failed by a vote of 28-67.¹⁸¹

The reason behind Congress' inability thus far to address the problem of reverse payment settlements may be the fact that these agreements are a natural result of the Hatch-Waxman framework.¹⁸² The legislation itself authorizes any “gaming” pertaining to the Hatch-Waxman framework.¹⁸³ The Hatch-Waxman Act creates a scheme of risk distribution where generic manufacturers have all the incentives to file a paragraph IV certification.¹⁸⁴ The potential benefits a brand name company may receive from entering its drug on the market or from receiving a reverse payment from the patentee as a settlement of the patent infringement suit outweigh any losses the generic manufacturers may incur.¹⁸⁵ Conversely, the brand name company may lose its monopoly over the drug and end up liable for costs and attorneys fees – a high stake.¹⁸⁶ In summary, thus far the proposed solutions to pay-for-delay problem have not been successful.

VI. ALTERNATE APPROACHES TO REVERSE PAYMENT SETTLEMENTS

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *See In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 206-07 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007).

¹⁸³ Practising Law Institute, *FTC Fed up with Hatch-Waxman Gaming, Goes on Offense*, PATENT LAW PRACTICE CENTER (Oct. 11, 2012, 6:17PM), <http://patentlawcenter.pli.edu/2012/10/11/ftc-fed-up-with-hatch-waxman-gaming-goes-on-offense>.

¹⁸⁴ *Tamoxifen*, 466 F.3d at 207 (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006)).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*; *see also* Opderbeck, *supra* note 17 at 1325-26 (citing *Schering*, 402 F.3d at 1070).

In addition to the conflicting judicial frameworks adopted by the circuits who considered the reverse settlement issue and the failed attempts by Congress to address the problem, the relevant administrative agencies as well as a number of scholars have proposed ways to address the harmful outcomes of reverse payment settlements.

A. Presumption of Illegality Versus Determining the Strength of the Patent on the Merits

The proposed legal and legislative frameworks to deal with reverse payment settlements are either based on the antitrust law or center around patent law. The FTC recommended that the federal legislation simply disallows all settlements in situations where the generic drug company receives compensation in exchange for not placing its generic product on the market.¹⁸⁷ The Third Circuit agreed with the FTC that the courts should not consider the merits of the underlying patent challenge lawsuit, thereby adopting the test based on antitrust law.¹⁸⁸ Under this test, unless countervailing proof is available, “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.”¹⁸⁹ The DOJ similarly posited that it is “neither necessary nor appropriate” for the court to determine the likelihood of success of the patent challenge claim because such information would have been available to the parties at the time they reached the settlement agreement.”¹⁹⁰ Yet, the DOJ indicated that “[l]iability properly turns on whether, in avoiding the prospect of invalidation that accompanies infringement litigation, the

¹⁸⁷ Opderbeck, *supra* note 17 at 1317 (citing *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 110th Cong. 1 (2009) (prepared statement of Richard A. Feinstein, Director, Bureau of Competition, Federal Trade Commission), available at <http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf>).

¹⁸⁸ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 219 (3d Cir. 2012) (citing *In re Schering Plough Corp.*, Final Order, 136 F.T.C. 956, 988 (2003) (internal citations and brackets omitted)).

¹⁸⁹ *Id.*

¹⁹⁰ Opderbeck, *supra* note 17 at 1318 (citation omitted).

parties have by contract obtained more exclusion than warranted in light of that prospect.”¹⁹¹

The DOJ further explained that if the payment to the potential patent infringer does not exceed the costs of litigation, the payor would rebut the presumption of illegality.¹⁹² According to the DOJ, the settlement agreements that prevent generic entry before the patent expires would not meet this burden.¹⁹³

Scott Hemphill agreed that “a settlement should be accorded a presumption of illegality as an unreasonable restraint of trade if the settlement both restricts the generic firm's ability to market a competing drug and includes compensation from the innovator to the generic firm.”¹⁹⁴ Hemphill acknowledged that such strict antitrust approach could create over-deterrence and invalidate potentially beneficial settlements.¹⁹⁵ Nevertheless, Hemphill indicated that under-deterrence would be more detrimental because allowing reverse settlements will continue decreasing public's access to the pharmaceutical products.¹⁹⁶ Likewise, Michael Carrier favored the antitrust framework and considering reverse settlements presumptively unlawful.¹⁹⁷

Conversely, Daniel Crane advocated that reverse settlements should be resolved under the intellectual property law and that the courts should assess the probability of success of the patent challenge lawsuit on the merits.¹⁹⁸ The courts should make *ex ante* determination of the likelihood that the patent challenger's lawsuit is successful.¹⁹⁹ Based on this determination, the courts would invalidate the settlements in which the probability of the challenger's success was

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1616 (2006).

¹⁹⁵ *Id.*; see C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629, 663-70 (2009).

¹⁹⁶ *Id.*

¹⁹⁷ Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 67-70 (2009).

¹⁹⁸ Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 750 (2002).

¹⁹⁹ *Id.*

high.²⁰⁰ According to Crane, restrictive tests to determine the validity of reverse settlements would be detrimental and create uncertainty.²⁰¹ David W. Opderbeck agreed that any framework which would hold all reverse payments presumptively unlawful would pose a threat of over-deterrence and invalidate potentially beneficial and legitimate reverse settlements.²⁰² Opderbeck also notes, however, that “[p]atent rights are probabilistic, not certain, because validity and infringement are always decided after the alleged infringement through litigation.”²⁰³ Hence, it is impossible to make an *ex ante* determination of the patent scope with certainty.²⁰⁴

B. Using the Settlement Value to Determine the Strength of the Patent

The FTC and DOJ recommendations are in conformance with the Third Circuit’s reasoning in *In re K-Dur*. Herbert Hovenkamp, Mark Janis, and Mark A. Lemley propose a somewhat similar framework to adjudicate pay for delay agreements as that adopted in *K-Dur*.²⁰⁵ These scholars, like the *K-Dur* decision, posit that reverse payments should be presumed unlawful, and the burden to prove the infringement should rest on the plaintiff.²⁰⁶ Under their framework, however, intellectual property litigation concerning patent strength would still be required in highly contested cases,²⁰⁷ and the rule of reason should apply only in certain cases where the antitrust analysis is clear.²⁰⁸ The authors recognize that litigating the validity of the patent is costly,²⁰⁹ thus, only in highly contested cases the plaintiff who filed the infringement suit would be required to demonstrate that “(1) that the *ex ante* likelihood of prevailing in its

²⁰⁰ *Id.*

²⁰¹ *Id.* at 749.

²⁰² Opderbeck, *supra* note 17 at 1323.

²⁰³ *Id.* at 1331-32.

²⁰⁴ *Id.* at 1332.

²⁰⁵ See Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003).

²⁰⁶ *Id.* at 1759.

²⁰⁷ *Id.* at 1729.

²⁰⁸ *Id.* at 1725, 1732-33; see also Opderbeck, *supra* note 17 at 1320-21 for a more detailed explanation of the framework proposed by Hovenkamp, Janis, and Lemley.

²⁰⁹ *Id.* at 1732.

infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.”²¹⁰ Yet, the courts “need not be particularly searching” in their inquiry concerning the patent infringement; they must only focus on determining where “there is a legitimate dispute being settled.”²¹¹

Thomas Cotter opposes the proposal that the courts should analyze the patent challenge disputes on their merits.²¹² Cotter notes that such approach would undermine the benefits the parties seek to achieve by settling.²¹³ Instead, Cotter argues that the potential value of the litigation costs should be compared to the amount of the settlement to determine the validity of the agreement.²¹⁴ Opderbeck opines that both approaches mentioned above are problematic because they “threaten to over-deter potentially beneficial settlements.”²¹⁵ Such over-deterrence would result from both the proposals comparing the settlements amounts with the litigation costs to determine the settlement’s lawfulness and the proposals using the settlement amount to determine the strength of the patent at issue.²¹⁶ Such approaches could result in “false positives” as they fail to recognize that reverse settlements may in fact be beneficial to the consumers in certain cases.²¹⁷ Opderbeck explains that if the settlement amounts are used as the only measure to determine the validity of the patent, the patent will either be upheld and prevent any generic competition during the remainder of the patent term, or the patent will be struck down.²¹⁸ Yet, the terms of most reverse settlements allow market entry of the generic drug at some point before

²¹⁰ Hovenkamp, *supra* note 205 at 1732.

²¹¹ *Id.* at 1760.

²¹² Thomas F. Cotter, Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley, 87 MINN. L. REV. 1789, 1815 (2003).

²¹³ *Id.* at 1795.

²¹⁴ *See generally id.* at 1802-10.

²¹⁵ Opderbeck, *supra* note 17 at 1323.

²¹⁶ *Id.* at 1324-25.

²¹⁷ *Id.* (citing C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629, 669-70 (2009)).

²¹⁸ *Id.*

the patent expiration date.²¹⁹ A reverse payment agreement that leads to a reduced patent term is often more beneficial to the public than the patent challenge litigation and subsequent appeals.²²⁰

The settlement amounts should not be used to determine the strength of the patent because many reverse settlements include license agreements and other side deals.²²¹ In addition, the generic Paragraph IV applicant does not risk much by filing the infringement suit, while the patent owner risks losing a significant revenue-producing asset.²²² The patent owner must also factor in the possibility of additional Paragraph IV applicants challenging its patent when determining the amount of the settlement.²²³ Therefore, settlement value should not be used as an indicator of the strength of the patent.

C. Creating a Scale of Anticompetitive Effects to Evaluate the Reverse Settlement

Each of the approaches discussed above is problematic in one way or another and revolves around the exclusionary power of the patent.²²⁴ Opderbeck proposed evaluating reverse settlements based on an inquiry into the actual anti-competitive effects of these agreements,²²⁵ which would be more efficient and allow more certainty in the settlement bargaining process.²²⁶ A Settlement Competition Index (“SCI”) would “provide[] a rough empirical gauge of the potential anticompetitive effects of the settlement.”²²⁷ The SCI would be based on two criteria: “(1) The difference in product market concentration that would likely result from the agreement and (2) [t]he probability that the patent will be held to be valid and infringed.”²²⁸ In other words,

²¹⁹ *Id.*

²²⁰ Opderbeck, *supra* note 17 at 1324-25.

²²¹ *Id.* at 1325 (citing Hemphill, *supra* note 195 at 663-69).

²²² *Id.* at 1325-26 (citation omitted).

²²³ *Id.* at 1328.

²²⁴ *Id.*

²²⁵ *See generally* Opderbeck, *supra* note 17 at 1323-1329.

²²⁶ *Id.* at 1329.

²²⁷ *Id.*

²²⁸ *Id.*

the first part assesses the power of the patent, and the second part assesses its scope.²²⁹ The lower range of the SCI would be a “safety zone,” and the settlements falling under it would be presumed lawful based on the legitimate exclusionary power of the patent.²³⁰ Settlements falling at the higher range of the SCI would be declared *per se* illegal.²³¹ Settlements falling in the middle would undergo a balancing test under the rule of reason.²³² When the settlement at issue requires such heightened evaluation, the court or regulatory agency would consider a number of factors under the rule of reason to establish whether the agreement was reasonable.²³³ Opderbeck notes that because the agreements falling at the middle range of SCI would involve a degree of uncertainty and expense to evaluate, the companies will be less likely to enter into such settlements.²³⁴

Indeed, the SCI would streamline the court’s task of evaluating the legality of reverse payment settlements and circumvent the problem of over- and under-deterrence. The *ex ante* determination of the patent validity, however, would still be required for the settlements falling in the middle range of the spectrum. Opderbeck proposes that to avoid a “‘trial within a trial’ on patent strength,” courts could engage experts or institute procedures to reasonably estimate patent strength without holding a complete infringement trial.²³⁵ Because a complete, final determination of patent’s validity would not be necessary, and a reasonable assessment would be satisfactory for this proposal, utilization of an index such as SCI would be the most effective framework for the judiciary to answer the question of reverse settlement lawfulness.

²²⁹ *Id.* at 1339.

²³⁰ Opderbeck, *supra* note 17 at 1329.

²³¹ *Id.*

²³² *Id.*

²³³ *Id.* at 1346 (The factors include the amount of the reverse settlement payment; the length of delay in generic entry; the existence and nature of any ancillary licenses; the existence and nature of any licenses related to products unrelated to the patented compound; and any other facts suggesting that the agreement is, or is not, likely to have unreasonable anticompetitive effects.”).

²³⁴ *Id.* at 1347.

²³⁵ Opderbeck, *supra* note 17 at 1337.

VII. THE MOST EFFICIENT JUDICIAL SOLUTION TO THE PAY FOR DELAY PROBLEM

The scope of the patent test adopted by the Eleventh, Second, and Federal Circuits does not provide adequate solution to the pay for delay issue. The Third Circuit in *K-Dur* explained that where the court applies the scope of the patent test, a reverse payment case usually does not go to trial, thus the test fails to subject reverse settlements to any antitrust scrutiny.²³⁶ The courts who adopted the scope of the patent test to adjudicate the validity of pay for delay settlements have failed to recognize “that the ‘scope of the patent’ test applied by the courts assumes the very validity that is at issue in these cases.”²³⁷ Therefore, the courts must look at whether the patent is actually valid and take into account the fact that patents merely represent “a legal conclusion reached by the Patent Office.”²³⁸ In many cases patents turn out to be invalid or not infringed, and according to a study conducted by the FTC, “in Hatch-Waxman challenges made under Paragraph IV, the generic challenger prevailed seventy-three percent of the time.”²³⁹ This explains the incentive that the holder of a weak patent has to settle the patent challenge lawsuit, thereby buying its way out of the competition with the generic company as well as possible patent invalidation.²⁴⁰

Therefore, the scope of the patent test would allow the patent holder of even the weakest patent to prevail, resulting in under-deterrence of the illicit reverse settlement and causing serious detriment to consumers by delaying entry of generic drugs on the market. Applying the *per se* approach to all reverse settlements would cause over-deterrence and invalidate some

²³⁶ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d Cir. 2012).

²³⁷ Carrier, *supra* note 144.

²³⁸ *K-Dur*, 686 F.3d at 215 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

²³⁹ *Id.* (citing FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>; Kimberly A. Moore, *Judges, Juries, and Patent Cases — An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 385 (2000) (noting that between 1983 and 1999 the alleged infringer prevailed in forty-two percent of patent cases that reached trial)).

²⁴⁰ *Id.* (citing *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 211 (2d Cir. 2006) (“The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.”)).

reverse settlements which would potentially benefit the public. Therefore, most of the solutions to the pay for delay problem adopted by the circuit courts or proposed by the distinguished scholars would cause over- or under-deterrence of the reverse settlements. The best judicial solution to this challenging issue is the creation of a scale based on the anticompetitive effects of reverse settlements such as the one proposed by David W. Opderbeck.²⁴¹ Adopting this approach would prevent over- and under-deterrence by allowing the courts or regulatory agencies to uphold the settlements potentially beneficial to the consumers while declaring those with highly anti-competitive effects *per se* unlawful.

Public interest favors exploitation of ideas, and because weak patents may undermine this goal, it is in the best interest of the public that the weak patents are eliminated through the court system.²⁴² Congress enacted the Hatch-Waxman Act with a goal of attaining balance between the interests of the patentees and the necessary incentives to the patent challengers to enable and encourage competition in the pharmaceutical industry.²⁴³ As the Third Circuit elucidated, “[t]he line that Congress drew between these competing objectives strongly supports the application of rule of reason scrutiny of reverse payment settlements in the pharmaceutical industry.”²⁴⁴ This approach is not inconsistent with the scale-based approach described above: the courts would consider the anticompetitive effects of the settlements falling at the middle of the sliding scale

²⁴¹ See generally Opderbeck, *supra* note 17 at 1323-1329.

²⁴² *K-Dur*, 686 F.3d at 215-216 (citing *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 100-01 (1993) (explaining the “importance to the public at large of resolving questions of patent validity” and noting the danger of “grant[ing] monopoly privileges to the holders of invalid patents”); *Bonito Boats, Inc. v. Thundercraft Boats, Inc.*, 489 U.S. 141, 146 (1989) (noting that the patent laws embody “a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy”); *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) (“It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.”)).

²⁴³ *Id.* at 217 (citing 130 Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman underscoring the “fundamental balance of the bill”); H.R. Rep. No. 98-857, pt. 2, at 30 (1984) (emphasizing that the bill achieves “what the Congress has traditionally done in the area of intellectual property law[:] balance the need to stimulate innovation against the goal of furthering the public interest”), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2715.)).

²⁴⁴ *Id.*

more deeply based on their merits. Hence, some form of the sliding scale framework should be adopted by the Supreme Court as the most effective judicial solution to the problem.

VIII. USE OF FINANCIAL REGULATION TO FIGHT THE PROBLEM OF DRUG ACCESSIBILITY, INCLUDING THE HARMFUL RESULTS OF REVERSE PAYMENT SETTLEMENTS

Even if the Supreme Court adopts a form of the sliding scale framework described above, the reverse settlements will still remain a source of lengthy, costly, and complicated litigation, at least for those settlements deserving higher scrutiny. Furthermore, the fundamental interest of the consumers in the availability of accessibly-priced generic drugs will only be addressed partially with the resolution of the current circuit split. The larger-scale problem of the accessibility of drugs to the public will remain largely unresolved.

Despite the justifications to the current patent system delineated at the beginning of this Comment, this system results in wastefulness, in part because the pharmaceutical companies have to cover the costs of filing and litigating patents, often in many countries.²⁴⁵ Moreover, the pharmaceutical companies are profit-oriented and place very low or no emphasis on promoting the optimum use of their products or ensuring that the medicines are utilized by only those who need them.²⁴⁶ Therefore, the current patent system results in excessive drug prices that should instead be subject to competition, in line with the aims of the Hatch-Waxman Act. To alleviate this dire problem, the government should take measures involving financial regulation by implementing specific types of payment systems.

One institutional reform proposed by many scholars, known as the Health Impact Fund (“HIF”), could alleviate the problems of the newly globalised patent monopoly by providing an

²⁴⁵ Banerjee, *supra* note 5.

²⁴⁶ *Id.*

additional source of incentives and rewards to promote development of new pharmaceuticals.²⁴⁷

The HIF would allow more effective use of available medicines, higher profits for drug companies, and the worldwide improvement of the health delivery system.²⁴⁸ This novel way of paying for pharmaceutical improvement would provide pharmaceutical companies with constant financial incentives to develop drugs that have significant effects on global health and to provide these drugs worldwide at the lowest possible cost of manufacture and distribution.²⁴⁹

The HIF would be formed as an international agency underwritten by governments.²⁵⁰

The pharmaceutical companies would have the option to register with the HIF their most effective new products.²⁵¹ Registering will enable these companies to receive a set amount of remuneration for a defined time period, like 10 years.²⁵² Each registrant would receive a share of the fund proportional to the registrant's contribution to the improvement of health due to their registered product.²⁵³ The registrant would thus be encouraged to produce medications addressing the most harmful global health threats.²⁵⁴ To receive its share of funds, the registrant would also be required to sell the product "at no more than the lowest feasible cost of production and distribution, and after the end of the reward period offer free licences [sic] to enable generic manufacture and sales."²⁵⁵ This would allow the populations otherwise unable to afford the pharmaceuticals sold at a patent mark-up to gain access to these pharmaceuticals due to their low sale prices.²⁵⁶ Moreover, the registrant companies would have incentives to ensure that their

²⁴⁷ *Id.*

²⁴⁸ Celermajer, *supra* note 1.

²⁴⁹ Banerjee, *supra* note 5.

²⁵⁰ *Id.*

²⁵¹ Celermajer, *supra* note 1.

²⁵² Banerjee, *supra* note 5.

²⁵³ *Id.*

²⁵⁴ Celermajer, *supra* note 1.

²⁵⁵ Banerjee, *supra* note 5. Additionally, HIF can "reward development of new products, new uses for existing products, and clinical testing of traditional medicines that patents alone cannot stimulate." *Id.*

²⁵⁶ Celermajer, *supra* note 1.

products, in addition to being widely available, are also adequately prescribed and optimally used, because their reward would be based on the global health impact of their product.²⁵⁷

The most significant objection to the proposal of creating the HIF is the difficulty of assessing global health impact of a particular medicine.²⁵⁸ In comparison with the present situation, however, the advantages of the HIF are obvious because its basis for rewards would use much more information than the current reward system takes into account.²⁵⁹ Furthermore, the cost of obtaining the global effects data is outweighed by the cost-effectiveness produced by HIF, saving money to all those who pay for medicines, including all patients, rich and poor, and taxpayers.²⁶⁰

William W. Fisher and Talha Syed agree with the idea of “increasing . . . the extent to which pharmaceutical firms must conduct research on diseases common in developing countries or by requiring the firms to make the fruits of that research available at low prices to the residents of those countries.”²⁶¹ In addition, to address the drug accessibility issue on a national, as opposed to global, level, Fisher and Syed propose amending or modifying laws which govern the production and distribution of pharmaceuticals.²⁶² Specifically, the government should increase control over the prices of pharmaceuticals, establish closer monitoring over what investment choices the pharmaceutical companies make, and dedicate more public funds to drug research and development.²⁶³

The states have an ability to set rates for pharmaceuticals: “Congress gave the states significant flexibility in rate setting in order to encourage them to experiment with different

²⁵⁷ *Id.*

²⁵⁸ Banerjee, *supra* note 5.

²⁵⁹ *Id.*

²⁶⁰ *Id.*

²⁶¹ William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L. REV. 581, 674 (2007).

²⁶² *Id.*

²⁶³ *Id.*

payment and health delivery models that would reduce cost and deliver care more efficiently.”²⁶⁴ Through the Medicaid Act and other legislation, Congress clarified its position that rates must be appropriate to accomplish other program goals, such as providing that the public has equal access to health care that is timely and of good quality.²⁶⁵ In addition, the states must follow certain procedural guidelines to comply with the law, including proposing rates for federal approval and providing the public with adequate notice and chance to comment.²⁶⁶ While the delivery and payment system addressed in the article pertains to rate setting for health care services, the pharmaceuticals can be subjected to a similar approach. Medicare and Medicaid could regulate their expenditures by covering only a percentage of the brand name drug cost that equals or somewhat exceeds the expected cost of this drug’s generic version. Private insurance companies could establish similar cost regulation frameworks.

Centers for Medicaid and Medicare Services (“CMS”) delegated the responsibility to oversee the state rate-setting process to the U.S. Department of Health and Human Services (“HHS”).²⁶⁷ Until very recently, the HHS has not utilized its rulemaking power to offer guidance to the states, health care providers, or the consumers about the rate-setting procedure and factors the states should consider to evaluate the adequacy of such rates.²⁶⁸ Similarly, the CMS has not exercised its enforcement authority to refuse state rate cuts that infringe federal law.²⁶⁹

In accordance with the recommendations of the Institute of Medicine, Stephen M. Shortell and Lawrence P. Casalino suggest creating a national system measuring performance by

²⁶⁴ Brietta R. Clark, *Medicaid Access, Rate Setting and Payment Suits: How the Obama Administration Is Undermining Its Own Health Reform Goals*, 55 *HOW. L.J.* 771, 774 (2012).

²⁶⁵ *Id.* at 774.

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *Id.* at 775.

²⁶⁹ Clark, *supra* note 264.

assessing the quality and cost of health care.²⁷⁰ This measurement system could be used by CMS to develop a payment system based on value of the services rendered.²⁷¹ The Agency for Health Research and Quality (“AHRQ”) could take on the responsibility to monitor the payment system.²⁷² Additionally, Shortell and Casalino advocate that “Medicare make fundamental changes in payment to reward providers based on the value (outcomes achieved / cost) of care delivered.”²⁷³ The CMS should have the authority to allocate the rewards to health providers based on the results they achieved.²⁷⁴ Once again, although the article focuses on health care providers, similar approach can be implemented to regulate the quality and cost of pharmaceutical products.

Although one could regard such government regulation as an unlawful interference with the companies’ freedom,²⁷⁵ the state action already heavily influences the shape of all of its markets, including the market in pharmaceuticals.²⁷⁶ Because of the persistent market failures with respect to the pharmaceutical industry and its failure to maximize social welfare, the governmental interference, participation, and monitoring in allocation of healthcare funds is not only desirable but necessary.²⁷⁷

IX. CONCLUSION

The judiciary, the legislature, and the legal scholars agree that the objective of the Hatch-

²⁷⁰ Stephen M. Shortell & Lawrence P. Casalino, *Accountable Care Systems for Comprehensive Health Care Reform* (Mar. 2007), at 18, available at <http://www.policyarchive.org/handle/10207/bitstreams/21919.pdf>.

²⁷¹ *Id.*

²⁷² *Id.* at 18-19.

²⁷³ *Id.* at 20.

²⁷⁴ *Id.*

²⁷⁵ Fisher, *supra* note 261.

²⁷⁶ *Id.* at 675 (explaining that “all transactions within those markets take place within a legal-institutional framework enforced by government, a framework that shapes considerably the liberty and bargaining power of agents and the resultant distribution of goods.”)

²⁷⁷ *Id.*

Waxman Act was to increase the availability of low cost generic drugs to the public.²⁷⁸ The long-standing dispute regarding the reverse settlements should be resolved by the Supreme Court by adopting the sliding scale approach based on the relative anticompetitive effect of the reverse settlement. This would ensure that the legitimate settlements are upheld while anti-competitive behavior based on invalid patents is eliminated. Nevertheless, the judicial solution to pay-for-delay deals is insufficient to meet the goals of the Hatch-Waxman Act. Establishing the HIF is a fair, cost-efficient way of promoting research and development of important pharmaceuticals and making these pharmaceuticals accessible worldwide. In the United States, to drastically increase the accessibility of pharmaceuticals and thereby improve health, the federal government, the states, and the private insurance companies should consider effectuating financial regulation techniques, such as rate setting for the prices of specific drugs, to reduce the costs of health care and provide long-term benefits to the consumers.

²⁷⁸ H.R. Rep. No. 98-857, pt. 1, at 14, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.