Stuck in Neutral: The Future of Reverse Payments Agreements in Hatch-Waxman Litigation

Alex E. Korona[†]

[†] J.D. Candidate, 2011, Seton Hall University School of Law; B.S., 2006, University of Pittsburgh. I would like to thank my fellow *Circuit Review* members for their hard work and diligent efforts in reviewing my comment. Additionally, I would like to thank my advisor, Professor David Opderbeck, for introducing me to this topic and providing his expertise and guidance. Finally, I owe a great deal of gratitude to my family and friends for their support and words of encouragement throughout my time in law school.

I. INTRODUCTION

Reverse payment agreements,[1] in which a brand-name drug manufacturer makes a payment to a generic drug manufacturer to settle a patent dispute, have saved consumers billions of dollars by allowing generic manufacturers to enter the market before the brand-name's patent has expired.[2] A current debate in the pharmaceutical industry is the legality of reverse payment agreements in Hatch-Waxman litigation.[3] The crux of this dispute is whether reverse payment agreements amount to antitrust violations, effectively limiting trade.[4] Many parties, including politicians and legal scholars, have attempted to tackle this issue but have yet to reach a consensus that balances both patent law and antitrust law concerns.[5] In addition to the political and scholarly debate, the issue has also created a split in the federal courts.[6]

This Comment advocates for the continued legality of reverse payment agreements and explores the regulatory background that has encouraged them.[7] Recent court decisions favor the continued legality of reverse payment settlements.[8] Moreover, these settlement agreements should be permitted as they effectuate the purpose of the Hatch Waxman Act, increasing market access for generic pharmaceutical manufacturers.[9] By refusing to allow such settlements, the purpose of the HWA is frustrated through creating an environment that discourages settlement and thus prevents access to generic manufacturers for a longer period of

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[1] Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494 (2007). The "reverse" designation refers to the fact that the patent holder is paying the alleged infringer, rather than vice versa. *Id.*

[2] Sheila Kadura, Note, *Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements Between Branded-and Generic-Pharmaceutical Companies?*, 86 TEX. L. REV. 647, 651–52 (2008). When a generic form of a drug enters the market it is able to offer a lower price because of lower development costs, while at the same time creating competition in the market. *Id.*

[3] Erica N. Andersen, Note, Schering *the Market: Analyzing the Debate over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and In re Tamoxifen Citrate Litigation,* 93 IOWA L. REV. 1015, 1018 (2008).

[4] *See infra* Part IV.

[5] Andersen, *supra* note 3, at 1027–28. Patent law and antitrust law, for practical purposes, are opposed to each other. *Id.* While patent law grants a right of exclusion, antitrust law promotes competition and equal access. *Id.*

[6] *See infra* Part IV.

[7] *See infra* Part II.

[8] Joblove v. Barr Labs., Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187 (2d Cir. 2006); Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294 (11th Cir. 2003); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.), 544 F.3d 1323 (Fed. Cir. 2008).

[9] *See infra* Part V.

time. Finally, a blanket declaration that all reverse payments are per se illegal is not a sound rule because it cuts against our judicial system's fundamental policy in favor of settlement.[10]

II. THE HATCH-WAXMAN ACT

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (HWA or "the Act").[11] The purpose of the HWA was to accelerate the approval process for low-cost generic versions of established drugs.[12] Specifically, the HWA added subsection (j) to 21 U.S.C. § 355, which described the process for an Abbreviated New Drug Application (ANDA).[13] This amendment allows generic drug manufacturers to obtain approval for a bioequivalent[14] form of a drug that has already been approved for safety and effectiveness.[15] As a result, generic manufacturers can bring a new drug to market at a much lower cost because the regulatory and testing process is far less comprehensive.[16]

When filing an ANDA, a generic manufacturer must file one of four types of certification regarding the already existing drug to which the generic manufacturer claims bioequivalence.[17] A paragraph IV certification, which certifies that the brand-name's patent is invalid or

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[10] *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 202 (2d Cir. 2006) (noting the courts analysis would proceed under a longstanding preference for the settlement of litigation).

[11] Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, 22 U.S.C. § 355(j) (2006), 98 Pub. L. No.98–417, 98 Stat. 1585 (codified as scattered sections of titles 21 and 35 of the United States Code); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 191.

[12] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 191.

[13] *Id.*; 21 U.S.C. § 355(j) (2006).

[14] 21 C.F.R. § 320.1(e) (2010) ("*Bioequivalence* means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.").

[15] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 191; David W. Opderbeck, *Rational Competition Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1307 (2010).

[16] Opderbeck, *supra* note 15, at 1307.

[17] 21 U.S.C. § 355(j)(2)(A)(vii) (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 191 (citing 21 U.S.C. § 355(j)(2)(A)(vii) (2006)) ("An ANDA filer must certify, with respect to each patent that claims the listed drug for the bioequivalent of which the ANDA filer is seeking approval, either that no patent was filed for the listed drug (a 'paragraph I' certification), that the patent has expired (a 'paragraph II' certification), that the patent will expire on a specified date and the ANDA filer will not market the drug until that date (a 'paragraph III' certification), or that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new drug (a 'paragraph IV' certification).")

would not be infringed by the generic's product, brings up a unique set of issues and is the type of certification involved in Hatch-Waxman litigation.[18] When a paragraph IV ANDA is filed, the filer must notify the affected patent owner of the certification, which enables that patent owner to bring suit against the ANDA filer for patent infringement within forty-five days.[19] In fact, the filing of a paragraph IV certification is a per se act of patent infringement.[20] If the patent owner does not bring a lawsuit, the Food and Drug Administration (FDA) is free to approve the ANDA immediately.[21] But if the patent owner chooses to bring a lawsuit, the FDA will stay the ANDA approval for thirty months or until the court returns a decision regarding the validity of the patent or its infringement.[22] This type of certification often leads a pioneering drug manufacturer, which holds the patent for the drug in question, to enter into a settlement agreement and make a reverse payment to the generic manufacturer.[23] This reverse payment is made to not only end the litigation, but also to establish the time when the generic manufacturer can enter the market.[24]

The HWA provides important incentives to generic drug manufacturers for choosing paragraph IV certification.[25] First, the HWA allows challenges to already existing patents without the risk of incurring infringement damage costs as long as the generic drug has not been marketed.[26] Second, the first ANDA filer of a paragraph IV certification will usually be entitled to an exclusivity period during which the FDA cannot approve any other ANDA filer until 180 days after: (1) the first day the first filer commercially markets the drug; or (2) a court determines that the patent in question is invalid or has not been infringed.[27] These tremendously important incentives are the driving reasons for the rise of settlement agreements and reverse payments

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[18] 21 U.S.C. § 355(j)(2)(A)(vii) (2006); Opderbeck, *supra* note 15, at 1307.

[19] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 191 (citing 21 U.S.C. § 355(j)(2)(B) (2006)).

[20] 35 U.S.C.S. § 271(e)(2)(A) (LexisNexis 2010) ("It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(j) . . . ."); Martin S. Masar III, Article, *Effects of the Federal Circuit Judges on Hatch-Waxman Litigation*, 19 DEPAUL J. ART TECH. & INTELL. PROP. L. 315, 322 (2009).

[21] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 191 (citing 21 U.S.C. § 355(j)(2)(B)).

[22] *Id.*

[23] Opderbeck, *supra* note 15, at 1307–08.

[24] *Id*. at 1308.

[25] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 192; Opderbeck, *supra* note 15, at 1307.

[26] Opderbeck, *supra* note 15, at 1308.

[27] 21 U.S.C. § 355(j)(5)(4)(B)(iv)(I)–(II) (2006).

between pioneering and generic drug manufacturers because the "[p]aragraph IV process changes the ordinary risk calculus for patent litigation," as "[t]he patent owner risks losing its patent, but the alleged infringer does not risk a damage award.".[28]

III. SETTLEMENT AGREEMENTS AND REVERSE PAYMENTS

Due to the incentives provided for generic drug manufacturers under the HWA, which encourage the filing of an ANDA under paragraph IV, brand-name drug companies are compelled to protect their exclusive patent rights.[29] Brand-name drug companies have done this by negotiating compromises with their generic competitors through settlement agreements and reverse payments.[30] These settlements are further encouraged by the fact that generic manufacturers have much to gain and little to lose by challenging the patent, while the exact opposite is true for brand-name manufacturers.[31]

A reverse payment "has been used as shorthand to characterize a variety of diverse patent settlement agreements that involve a transfer of consideration from the patent owner to the alleged infringer."[32] The reverse designation refers to the fact that the payments flow from the patent holder to the alleged infringer, in contrast to settlements in typical patent litigation cases where payments flows from the alleged patent infringer to the patent holder.[33] A reverse payment settlement will generally require the generic drug company to refrain from producing a generic form of a drug in return for monetary payment.[34] While the

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[28] Opderbeck, *supra* note 15, at 1307.

[29] Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 460 (2008).

[30] *Id*.

[31] *Id*. at 459–60. The brand-name manufacturer, as the holder of the New Drug Application (NDA), has limited remedies when successful in HWA litigation. *Id*. at 459. If the court holds the brand's patent to be invalid or that the generic's use is not infringing, the FDA approves the ANDA and the generic begins to market its version of the drug, which reduces the brand's market share. *Id*. at 459–60. Even if the court holds the patent to be valid, the NDA holder is still likely to lose profits, because of lower prices and the loss of consumer loyalty. *Id*. at 460. Although the brand could force the generic out, the brand often will not do this for fear of ruining its public image, as consumers rely on the lower priced generic. *Id*. The circumstances are very different for the generic. *Id.* The generic stands to gain a tremendous profit by winning in litigation, but if it loses, those losses will be relatively small because it has practically no research and development costs to recoup. *Id.* These low research costs enable the generic to afford the millions of dollars required to litigate. *Id.* Therefore, the HWA sets up an environment where generics stand to gain greatly and lose little by litigating. *Id.*

[32] Holman, *supra* note 1, at 494.

[33] Holman, *supra* note 1, at 494.

[34] Opderbeck, *supra* note 15, at 1307–08.

specifics of an agreement will vary on a case-by-case basis, these settlements often address the length of the generic marketing restriction, the market exclusivity period, and other licensing issues.[35] The most radical form of settlement is one that terminates litigation and forces the generic manufacturer to wait until the patent expires to enter the market.[36] In most cases, however, the patent holder and the generic company agree to some sort of reduction to the remaining patent term.[37] Term splitting most often results in the generic drug entering the market earlier than the point in which the patent would have originally expired, but later than would have been possible had the generic company won the litigation by proving the patent invalid.[38]

IV. PROBLEMS ARISING FROM REVERSE PAYMENT SETTLEMENTS

Reverse payments have been the subject of antitrust suits in multiple federal circuit courts and have resulted in a circuit split regarding the legality of the payments.[39] These cases involve actions brought by the Federal Trade Commission (FTC) and private antitrust actions brought by interested third parties.[40] The FTC has begun to equate reverse payments with market allocation agreements,[41] which traditionally have been per se antitrust violations in cases not involving patents.[42] The private antitrust actions often closely follow FTC actions.[43]

Currently, there are four different opinions in the federal circuit courts regarding the legality of reverse payment settlements.[44] The Second Circuit has reasoned that reverse payments are legal based on judicial policy that favors settlement.[45] The Sixth Circuit has held that

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[35] *Id*.
[36] Holman, *supra* note 1, at 494.
[37] *Id*. at 495; Opderbeck, *supra* note 15, at 1308.
[38] Holman, *supra* note 1, at 495.
[39] Opderbeck, *supra* note 15, at 1308.
[40] *Id*.
[41] United States v. Topco Assoc., 405 U.S. 596, 608 (1972). A market allocation agreement is an agreement between competitors at the same level of the market made to minimize competition. *Id.*
[42] Holman, *supra* note 1, at 531–32.
[43] Opderbeck, *supra* note 15, at 1308.
[44] Joblove v. Barr Labs., Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187 (2d Cir. 2006); La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896 (6th Cir. 2003); Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294 (11th Cir. 2003); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.), 544 F.3d 1323 (Fed. Cir. 2008).
[45] *See* In *re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187.

reverse payments are per se unlawful.[46] The Eleventh Circuit has developed an approach that tests the exclusionary powers of a patent.[47] Finally, the Federal Circuit has determined that reverse payments are presumed legal because they are within the scope of the protection powers provided by a patent.[48]

A. The Second Circuit

In *In re Tamoxifen Citrate Litigation*, the Second Circuit held that reverse payments should remain legal because the agreement did not give rise to an antitrust violation.[49] The case provided an opportunity for the court to look at "issues at the intersection of intellectual property law and antitrust law."[50] Additionally, the court noted that although "the particular factual circumstances of this case are unlikely to recur, the issues presented have been much litigated and appear to retain their vitality."[51]

Imperial Chemical Industries, PLC ("ICI") developed Tamoxifen, a breast cancer drug, and passed ownership of the resulting patent to Zeneca, Inc. and its subsidiaries (collectively referred to as "Zeneca").[52] In December 1985, four months after ICI was awarded the Tamoxifen patent, Barr Labs, Inc. ("Barr") filed an ANDA requesting FDA approval to market a generic form of Tamoxifen.[53] In September 1987, Barr amended its ANDA to include paragraph IV certification.[54] ICI filed an infringement suit against Barr, which triggered the thirty-month stay of approval.[55]

In April 1992, the district court declared ICI's Tamoxifen patent invalid and ICI appealed.[56] While the appeal was pending, Zeneca (the successor to ICI's patent) entered into a settlement agreement with Barr in 1993.[57] The settlement agreement between Zeneca and Barr stated that Barr would receive $21 million and a non-exclusive license to sell Zeneca-manufactured Tamoxifen under Barr's label.[58] Additionally, Barr agreed to change its paragraph IV certification to a paragraph III

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[46] *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896.
[47] *See Valley Drug Co*., 344 F.3d 1294; *Schering-Plough Corp.*, 402 F.3d 1056.
[48] *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323.
[49] *See In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d at 190.
[50] *Id*.
[51] *Id*.
[52] *Id*. at 193.
[53] *Id*.
[54] *Id*.
[55] *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d at 193.
[56] *Id.*
[57] *Id*.
[58] *Id.*

certification[59] and therefore not market its own generic version until 2002, when the patent expired.[60] Eventually, the circuit court terminated the litigation in response to Zeneca's and Barr's joint motion to dismiss the appeal and vacate the judgment.[61]

Following the execution of the agreement between Zeneca and Barr, consumers and consumer groups across the United States filed approximately thirty lawsuits that challenged the legality of the settlement agreement.[62] The lawsuits were consolidated into a class action that alleged the settlement agreement effectively prevented other generic manufacturers from entering the market, directly inflating the price of Tamoxifen.[63] In dismissing the lawsuit, the district court reasoned that while an agreement "between a monopolist and a potential competitor ordinarily violate[s] the Sherman Act,[64] [it is] not necessarily unlawful when the monopolist is a patent holder," as long as the agreement is in good faith and does not try to go beyond the scope of the patent monopoly.[65]

The Second Circuit affirmed the lower court's decision,[66] expressing a preference for settlement.[67] The court held that reverse payments are not per se violations of the Sherman Act because it is not illegal for a patent holder to pay for the right to exclude[68] when that right is already granted by a patent.[69] The Second Circuit also noted that reverse payments are to be expected in a drug patent context due to the incentives provided by the HWA.[70]

Addressing the plaintiff's allegation that the mere size of reverse payments make them unlawful, the Second Circuit reasoned that the value of the reverse payment is of little concern as "long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is

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[59] 21 U.S.C. § 355(j)(2)(A)(vii)(III)–(IV) (2006). A paragraph III filing certifies that the ANDA applicant will not market the drug until the patent expires, where as a paragraph IV filing certifies that the patent is invalid or will not be infringed when the generic manufacturer enters the market. *Id.*

[60] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 193–94.

[61] *Id*. at 194.

[62] *Id* at 196.

[63] *Id*. at 196–97.

[64] The Sherman Act, or Sherman Antitrust Act is a federal statute that governs monopolistic practices and illegal restraints of trade. 15 U.S.C. §§ 1–7 (2006).

[65] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 197.

[66] *Id*. at 466 F.3d at 206.

[67] *Id.* at 202–03

[68] The right to exclude is the patent holder's statutory right to prevent others from making or using that same invention. 35 U.S.C. § 154 (2006).

[69] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 206.

[70] *Id*.

presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."[71] The plaintiffs argued that the reverse payment was greater than what Barr could ever have made in revenue by entering the market with its own generic product.[72] The court stated that while large payments may protect weak patents, there is no reason to deem a patent invalid based on the size of the payment or on the patent holder's fear of losing the patent.[73] Further, the court stated that a rule restricting payment size would fail to give proper consideration to the patent holder's incentive to settle the lawsuit as an insurance method against the possibility of losing a patent.[74] Finally, the court noted that if a patent is truly too weak, the holder of that patent will be unable to continue making settlement payments as multiple generic manufacturers bring successive lawsuits.[75]

B. The Sixth Circuit

Directly contrasting the Second Circuit, the Sixth Circuit held reverse payments are illegal because they are unlawful restraints of trade.[76] In *In re Cardizem CD Antitrust Litigation.*, the settlement agreement was between Hoechst Marion Roussel, Inc. ("HMR") and the generic manufacturer Andrx Pharmaceuticals, Inc. ("Andrx"), who was attempting to produce a generic version of HMR's Cardizem CD, a heart and blood pressure medication.[77] Andrx filed a paragraph IV certification in relation to HMR's patent in late 1995.[78] Subsequently, HMR filed a patent infringement suit against Andrx, which instituted the thirty-month stay on approval of Andrx's paragraph IV certification.[79] In September 1997, the FDA tentatively approved[80] Andrx's paragraph IV

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[71] *Id*. at 208–09.
[72] *Id*. at 208.
[73] *Id*. at 210.
[74] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 210.
[75] *Id*. at 211–12. ("There is, of course, the possibility that the patent holder will continue to buy out potential competition . . . . We doubt, however, that this scenario is realistic.").
[76] La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 900 (6th Cir. 2003).
[77] *Id* at 899, 901.
[78] *Id*. at 902.
[79] *Id*.
[80] 21 U.S.C. § 355(j)(5)(B)(iii) (2006). A generic manufacturer's ANDA is granted tentative approval when a brand-name manufacturer has filed an infringement action against the generic manufacturer. *Id.* In such a case, the FDA has approved the substance of generic manufacturer's ANDA, but withholds final approval until the end of a thirty-month stay or the infringement action reaches a conclusion, whichever is the earlier. *Id.*

certification.[81] As a result of this development, HMR entered into a settlement agreement with Andrx in September of 1997.[82] The agreement contained numerous provisions, including one requiring HMR to pay $40 million per year to Andrx along with the potential of an additional $100 million per year given a second set of conditions.[83] Specifically, the agreement provided that Andrx would not produce its generic version of Cardizem CD until (1) there was a final determination that the Cardizem CD patent was invalid; (2) HMR and Andrx executed a license agreement; or (3) HMR entered a license agreement with a third party.[84] Andrx also agreed to dismiss its counterclaims against HMR, "to diligently prosecute its ANDA, and to not 'relinquish or otherwise compromise any right accruing thereunder or pertaining thereto,' including its 180-day period of exclusivity."[85] In turn, HMR promised that the previously mentioned $40 million per year payments to be made to Andrx would begin when Andrx's ANDA received final approval.[86] HMR also promised to pay Andrx $100 million per year, less any interim payments, when: (1) the patent was determined not infringed; (2) HMR dismissed the infringement action; or (3) there was a final ruling that did not decide the patent issues of validity or infringement and HMR did not refile its infringement action.[87] Finally, HMR agreed not to seek preliminary injunctive relief in its continuing infringement litigation with Andrx.[88] This agreement ended with final payments by HMR to Andrx totaling $89.83 million.[89]

Plaintiffs challenging the agreement between HMR and Andrx commenced an action in August 1998 in the Eastern District of Michigan.[90] The plaintiffs' claim was that but for the settlement agreement, Andrx would have been able to bring its product to market at a lower price than HMR and that the agreement prevented other potential generic manufacturers from gaining market entry.[91] According to the

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[81] *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 902. The tentative approval would have become final in July 1998 following the thirty-month stay required by the provisions of a paragraph IV certification or if HMR would have been unsuccessful in its infringement action against Andrx, which ever would have been sooner. *Id*.

[82] *Id*.

[83] *Id*. at 902–03.

[84] *Id*. at 902.

[85] *Id*.

[86] *Id*.

[87] *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 903.

[88] *Id*.

[89] *Id*. at 903.

[90] *Id*.

[91] *Id*. at 904.

plaintiffs, the settlement agreement amounted to an antitrust violation under the Sherman Act.[92]

The Sixth Circuit concluded that the agreement was "at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of per se illegal restraint of trade."[93] The court reasoned that the settlement agreement could not be viewed simply as an effort to impose patent rights or as a temporary settlement to the infringement litigation.[94] The court concluded "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."[95] This was fundamental to the court's holding that reverse payment agreements are per se illegal.[96] The court further reasoned that by classifying reverse payments agreements as per se antitrust violations, courts would be able to presume such agreements were anticompetitive without a need to expend judicial resources to pinpoint the exact anticompetitive effects.[97]

C. The Eleventh Circuit

The Eleventh Circuit addressed the issue of reverse payments in two separate cases, *Valley Drug Co. v. Geneva Pharm., Inc.* [98] and *Schering-Plough Corp. v. FTC*.[99] In both cases, the Eleventh Circuit held that reverse payments are legal,[100] effectively siding with the Second Circuit. Essentially, the Eleventh Circuit determined that reverse payment agreements are not per se unlawful because they do not exceed the rights naturally granted by a patent.[101]

Valley Drug Co. made its way to the circuit court after the district court granted the plaintiffs' motion for partial summary judgment.[102] The lawsuit was filed in relation to two separate settlement agreements; one between Abbott Laboratories ("Abbott") and Geneva Pharmaceuticals ("Geneva") and another between Abbott and Zenith

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92 *Id*.
93 *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 908.
94 *Id*.
95 *Id*.
96 *Id*.
97 *Id*. at 909.
98 344 F.3d 1294 (11th Cir. 2003).
99 402 F.3d 1056 (11th Cir. 2005).
100 *Schering-Plough Corp.*, 402 F.3d at 1058; *Valley Drug Co*., 344 F.3d at 1295.
101 *Schering-Plough Corp.*, 402 F.3d at 1076; *Valley Drug Co*., 344 F.3d at 1306.
102 *Valley Drug Co*., 344 F.3d at 1295.

Goldline Pharmaceuticals ("Zenith").[103] Abbot, the patent holder for the drug Hytrin, entered into separate settlement agreements with the generic manufacturers Zenith and Geneva.[104]

Between 1993 and 1996, Geneva submitted multiple ANDA paragraph IV certifications related to various Hytrin patents held by Abbott.[105] With one exception, Abbott filed patent infringement suits against Geneva for all of the paragraph IV certifications.[106] Geneva admitted to infringement but contested the validity of the patents.[107]

Zenith filed its ANDA paragraph IV certification in June 1994.[108] Abbott subsequently filed additional patents, which forced Zenith to amend its ANDA to bring it in line with the newly filed Abbott patents.[109] Rather than amending its ANDA, however, Zenith filed suit against Abbott to: (1) force Abbot to delist the newly filed patents so that Zenith could avoid amending its ANDA; and (2) secure a declaration that it did not infringe Abbott's patents.[110] Abbott counterclaimed for infringement.[111]

In March of 1998, Abbott and Zenith entered into a settlement agreement that dismissed Zenith's claims and Abbott's counterclaims.[112] The agreement also required Abbott to pay Zenith $3 million up front, $3 million after three months, and an additional $6 million per quarter until March 1, 2000, as long as Zenith complied with certain clauses and contingencies of the agreement.[113] Specifically, Zenith admitted the validity of the Abbott patents and agreed not to sell any form of the patented drug until another party did so or the patent expired.[114] Zenith also agreed not to transfer its ANDA application to a third party or assist any other party in the development of a generic version of Abbott's drug.[115]

One day after the execution of the agreement with Zenith, Abbott and Geneva entered into a separate settlement agreement.[116] The

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[103] *Id*. at 1296.
[104] *Id*.
[105] *Id.* at 1298–99.
[106] *Id*. Abbott made efforts to amend one of its complaints when it was notified that it did not file an infringement suit regarding one of the paragraph IV certifications. *Id.*
[107] *Id*. at 1299.
[108] *Valley Drug Co*., 344 F.3d at 1299.
[109] *Id*.
[110] *Id*.
[111] *Id*.
[112] *Id*. at 1300.
[113] *Id*.
[114] *Valley Drug Co*., 344 F.3d at 1300.
[115] *Id*.
[116] *Id*.

agreement limited Geneva from selling or distributing any version of the patented drug until that patent was determined to be invalid, the patent expired, or another party began to sell a generic form of the drug.[117] Geneva also promised not to transfer its 180-day exclusivity period and to oppose any subsequent ANDA filer.[118] In return, Abbott agreed to pay Geneva $4.5 million per month until another generic manufacturer brought its product to market or until Abbott succeeded on its infringement claim.[119]

Following an action filed by the FTC, a class action suit commenced that alleged the agreements between Abbott and each of the generic manufacturers were per se illegal under the Sherman Act.[120] On appeal, the Eleventh Circuit held that the payments from the patent holder to the alleged infringer did not automatically amount to a violation of antitrust laws.[121] The thrust of the Eleventh Circuit's argument focused on the exclusionary powers of the patent.[122] The court reasoned that while normally, a firm making monthly payments in exchange for a competitor's acquiescence would violate antitrust laws, Abbott's patent lawfully entitled it to exclude others.[123] The court noted, however, that any agreement that extends the scope of the patent might raise antitrust concerns.[124] The Eleventh Circuit also stated that even if a patent was subsequently declared invalid, exposing the patent holder to antitrust liability over any settlement agreement could undermine the innovation and the incentive to file patents.[125]

The Eleventh Circuit addressed the issue of reverse payment settlement agreements again in *Schering-Plough Corp. v. FTC*.[126] Similar to *Valley Drug Co.,* the issue in *Schering-Plough Corp.* arose from two settlement agreements: one between Schering-Plough Corp. ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher") and a second between Schering and ESI Lederele, Inc. ("ESI").[127] In late 1995, Upsher filed an ANDA with paragraph IV certification for its generic version of a Schering drug and Schering responded by filing a patent

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[117] *Id*.
[118] *Id*.
[119] *Id*.
[120] *Valley Drug Co*., 344 F.3d at 1301.
[121] *Id*. at 1310–11.
[122] *Id*. at 1304–06.
[123] *Id*. at 1304.
[124] *Id*. at 1312.
[125] *Id*. at 1304, 1308 (noting that patents encourage investment and innovation, along with public disclosure of inventions).
[126] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005).
[127] *Id*. at 1058, 1060.

infringement suit.[128] Before the trial began in 1997, Schering and Upsher executed a settlement agreement.[129] The agreement stated that Upsher would delay market entry while Schering received licenses from Upsher and agreed to make an initial payment of $60 million dollars in addition to various milestone payments.[130]

Also in 1995, ESI filed an ANDA with paragraph IV certification.[131] Once again, Schering filed a patent infringement suit.[132] After engaging in court-supervised mediation for fifteen months, a settlement offer developed. Schering offered to divide the remaining patent life with ESI.[133] In addition, Schering also agreed to pay $5 million towards ESI's legal fees and up to an additional $10 million if ESI received FDA approval by a certain date.[134]

On March 30, 2001, the FTC filed an administrative complaint against Schering, Upsher, and ESI's parent, American Home Products Corporation ("AHP"), alleging that the agreements were a restraint on trade, violating both the Federal Trade Commission Act and the Sherman Act.[135] The FTC argued that when a generic company receives anything of value to refrain or restrict its activities, an unlawful restraint on trade results.[136]

The Eleventh Circuit rejected the findings of the FTC and again turned to the exclusionary powers that are inherent to a patent.[137] The court furthered this notion, stating, "a patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work."[138] With respect to patent and antitrust related issues, the court determined that one must examine: "(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

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[128] *Id*. at 1058–59.

[129] *Id*. at 1060.

[130] *Id*. at 1059. This agreement was unique because Schering refused to simply make payments for Upsher to stay out of the market. *Id.* This being the case, Upsher in addition to staying out of the market, also offered various licenses for another drug to Schering in order to receive the settlement payments. *Id.*

[131] *Id*. at 1060.

[132] *Schering-Plough Corp.,* 402 F.3d at 1060.

[133] *Id*.

[134] *Id*. at 1060–61. There was also an additional side agreement for various unrelated licenses that Schering purchase from ESI. *Id.*

[135] *Id* at 1061.

[136] *Id.* at 1062. The FTC did carve out a narrow exception stating that compromises related to entry date and payments under $2 million dollars for litigation costs were allowable as long as the FTC was informed of such a settlement. *Id.*

[137] *Id*. at 1066–67.

[138] *Schering-Plough Corp.,* 402 F.3d at 1067.

effects."[139] In applying this test to the facts, the Eleventh Circuit found that the agreements did not exceed the exclusionary provisions of Schering's patent.[140] Furthermore, the court reasoned that to prohibit reverse payments would "reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."[141]

D. The Federal Circuit

The Federal Circuit addressed the issue of reverse payments in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, holding that reverse payments should remain legal because they do not extend the exclusionary zone of the patent.[142] In October 1991, Barr[143] filed an ANDA with paragraph IV certification for a generic version of the Cipro drug patented by Bayer A.G. and Bayer Corp. (collectively "Bayer").[144] Bayer followed Barr's ANDA with a patent infringement suit in January 1992.[145] But before trial commenced, Bayer entered into an agreement with Barr and its affiliated companies.[146] In this agreement, Bayer agreed to pay Barr $49.1 million to change its ANDA to a paragraph III filing, which essentially required Barr to admit the validity of Bayer's patent and wait until the patent expired to enter the market.[147] Barr also pledged to refrain from manufacturing a generic version of Cipro in the United States.[148] In return, Bayer would provide Barr with Cipro to sell under the Barr label or pay Barr a reverse payment once quarterly until December 31, 2003.[149] Total payments from Bayer to Barr amounted to $398.1 million.[150]

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[139] *Id.* at 1066.
[140] *Id*. at 1076.
[141] *Id*. at 1075 (quoting Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003)).
[142] Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.), 544 F.3d 1323 (Fed. Cir. 2008).
[143] Barr is the same familiar generic manufacturer that was involved in *In re* Tamoxifen Citrate Litig.; *See supra* Part V.A.
[144] *Ark. Carpenters*, 544 F.3d at 1328.
[145] *Id.*
[146] *Id*.
[147] *Id*. at 1328–29.
[148] *Id.* at 1329. ("Beginning at least six months before the *'444 patent* expired, Bayer agreed to allow Barr to sell a competing ciprofloxacin product. Bayer and Barr then entered into a consent judgment, whereby Barr affirmed the validity and enforceability of the *'444 patent* and admitted infringement.").
[149] *Id*. at 1329.
[150] *Ark. Carpenters*, 544 F.3d at 1329 n.5.

In 2000 and 2001, the settlement agreement between Bayer and Barr was challenged by a series of antitrust actions.[151] In this case, the district court granted summary judgment in favor of the defendants, a decision that was affirmed by the Federal Circuit.[152] The Federal Circuit, similar to the Eleventh Circuit,[153] centered its argument on the exclusionary power of a patent.[154] The Federal Circuit held that "the essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee."[155] What's more, the court noted that the law has a long-standing policy that favors settlement and that policy applies to patent litigation.[156] The court distinguished the facts of this case from the decision in the Sixth Circuit[157] stating that the agreement in question there required the generic manufacturer not to give-up its exclusivity period and "provided that the generic manufacturer would not market non-infringing versions of the generic drug. Thus, the agreement clearly had anticompetitive effects outside the exclusion zone of the patent."[158] The court concluded that its analysis was entirely consistent with rulings in the Second and Eleventh Circuits and with Supreme Court precedent.[159]

V. THE FUTURE OF REVERSE PAYMENT AGREEMENTS

A ban on reverse payment settlements is not an appropriate solution to the circuit split regarding the legality of such settlements for two primary reasons. First, reverse payment settlements harmonize with the overarching judicial policy in favor of settlement. Second, reverse payments actually enhance competition and innovation while furthering the purpose of the HWA. Therefore, because the Supreme Court has not granted certiorari to settle the split on the issue, other options must be

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[151] *Id*.

[152] *Id*. at 1341.

[153] Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

[154] *Ark. Carpenters*, 544 F.3d at 1333.

[155] *Id*.

[156] *Id*.

[157] *See* La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896 (6th Cir. 2003).

[158] Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.), 544 F.3d 1323, 1335 (Fed. Cir. 2008).

[159] *Id*. at 1336 ("We conclude that in cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent . . . [t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.") (citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 175-77 (1965) (recognizing that patents are an exception to the general rule against monopolies.)).

explored to determine what the best solution is for reverse payment settlements to remain presumptively legal. The best option is for Congress to take action and provide new legislation that would clarify the HWA and create an environment that limits reverse payments by shifting some of the incentives currently contained in the Act. These legislative changes would allow for closer regulation of reverse payments while preserving the important policy considerations of settlement and innovation.

A. Supreme Court Intervention and Judicial Solutions

While the contradiction in the circuit courts over the legality of reverse payments is an issue ripe for Supreme Court intervention, the Court has yet to grant certiorari.[160] The Supreme Court could provide the lower courts valuable guidance that would enable more uniform decisions. Furthermore, because such a robust circuit split exists regarding these reverse payments,[161] the opposing views of the Sixth Circuit (advocating a per se illegality stance) and the remaining circuits[162] (advocating for presumptive legality stance based on the exclusionary powers of a patent and the general policy in favor of settlement) will provide the Supreme Court with a plethora of case law on which to base its decision.

Alternatively, some legal scholars have posited that a true circuit split does not exist.[163] The argument is that the Sixth Circuit's decision did not rule reverse payments to be illegal per se, but rather focused on the illegality of agreements that affect the 180-day exclusionary period for first filers and extended protection to products that did not infringe the patent at issue.[164] According to some scholars, the Eleventh Circuit merely characterized the reverse payments as a troubling aspect of settlement agreements.[165] The Sixth and Eleventh Circuits' commentary reinforce the position that Supreme Court intervention is warranted.

Finally, because the continued legality of reverse payment settlements is perhaps best validated by established judicial principles that favor settlement, the Supreme Court should step in to further its significant interest. Our courts have a "longstanding adherence to the principle that '[they] are bound to encourage' the settlement of

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[160] Opderbeck, *supra* note 15, at 1316.
[161] *See supra* Part IV.B.
[162] *See supra* Parts IV.A, C, and D.
[163] *See generally* Holman, *supra* note 1, at 572–78 (discussing the decisions of the circuit courts).
[164] Holman, *supra* note 1, at 573.
[165] *Id*.

litigation."[166] Additionally, the general policy in favor of settlement "extends to the settlement of patent infringement suits"[167] because "the nature of [it] is often inordinately complex and time consuming."[168] This policy is critical to reverse payment settlements because the act of filing a paragraph IV certification is considered by statute an act of patent infringement, settlement of which would be impossible without a reverse payment.[169] Also, restricting settlement options creates an environment where the cost of patent enforcement is effectively increased, thereby "impair[ing] the incentives for disclosure and innovation."[170] Finally, "[n]othing in the legislative history supports a conclusion that Hatch-Waxman lawsuits cannot be settled."[171]

It follows that a rule that makes reverse payment settlement agreements per se illegal would limit the options available to the litigants.[172] The district court reasoned:

> If brand-name manufacturers are unable to control or limit their risk by settling Hatch-Waxman litigation, they, like generic manufacturers, may be less inclined to invest the research and development ("R&D") costs associated with bringing new drugs to the market. The pharmaceutical industry depends greatly on R&D and the economic returns to intellectual property created when a successful new drug is brought to market. A rule prohibiting settlements of Hatch-Waxman patent litigation can have grave consequences for R&D and, in turn, severe consequences for consumers.[173]

If the return-on-investment that brand-name drug companies receive from creating intellectual property decreases, then brand-name companies will not be able to adequately recover their research and development costs and new drug innovation will decrease.[174] This would

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[166] Joblove v. Barr Labs., Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 202 (2d Cir. 2006) (quoting Gambale v. Deutsche Bank AG, 377 F.3d 133, 143 (2d Cir. 2004)).

[167] Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003).

[168] Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976).

[169] 35 U.S.C.S. § 271(e)(2)(A) (LexisNexis 2010).

[170] Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1308 (11th Cir. 2003).

[171] *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003).

[172] *Id*.

[173] *Id*.

[174] *Id.* (quoting Hausman Decl. 61); Henry Grabowski, *Patents, Innovation, and Access to New Pharmaceuticals*, 5 J. INT'L. ECON. L. 849, 850–53 (2002).

result in fewer new drugs, the availability of which traditionally leads to a healthier United States population and growth for the economy.[175]

B. Legislative Options

Currently, there are bills pending in the United States Senate and the House of Representatives that would make reverse payments illegal.[176] The Senate bill would prohibit an ANDA filer from receiving anything of value for agreeing to delay the development and deployment of a generic drug.[177] Still, some legal scholars have posited that the strict limitations imposed by the Senate bill and a similar one in the House would be inappropriate in the context of a patent system and unduly hinder the rights of patent holders.[178]

Rather than an absolute ban on reverse payments, Professor Christopher Holman has suggested that Congress introduce legislation requiring fee shifting in Hatch-Waxman litigation.[179] Specifically, the hypothetical legislation would introduce a type of two-way fee shifting, sometimes called the "British-rule," where the loser of the litigation pays the legal fees for both sides.[180] By enacting this type of legislation, government could generally discourage litigation in the first place and therefore reduce the need for reverse payments.[181] By forcing the loser of the litigation to pay for all of the litigation costs, each of the parties must take extra care in considering the merits of their case.[182] This type of legislation would influence both sides of an ANDA paragraph IV dispute. [183]

On one side, the potential of having to pay the legal fees for both sides would presumably deter generic manufacturers from bringing unjustifiable paragraph IV certifications with the hopes of scoring a quick settlement from the brand-name manufacturer.[184] Under such

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[175] *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d at 256 (citing Hausman Decl. 61).

[176] *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); *see* Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009); Opderbeck, *supra* note 15, at 1318–19.

[177] S. 369, 111th Cong. § 3 (2009).

[178] Holman, *supra* note 1, at 582; Kadura, *supra* note 2, at 657.

[179] *See generally* John R. McNair, Note, *If Hatch Wins, Make Waxman Pay: One-Way Fee Shifting as a Substitute Incentive to Resolve Abuse of the Hatch-Waxman Act*, 2007 U. ILL. J.L. TECH. & POL'Y 119, 134–140 (2007) (discussing the shifting of litigation fees).

[180] *Id*. at 134–35.

[181] *Id*. at 135.

[182] *Id*.

[183] *Id*.

[184] *Id*. at 134–38.

circumstances, if the generic manufacturer filed a weak paragraph IV certification, the brand-name manufacturer would be able to recover its legal fees for defending a patent it strongly believed was valid, when it might have otherwise settled to avoid the costs of litigation.[185] This would add a financial risk for generic manufacturers that does not currently exist under the HWA.[186]

On the other hand, this scheme would force brand-name manufacturers to concede when one of its patent is weak or invalid.[187] This is because the brand-name manufacturer would not want to risk paying for all the litigation costs for both parties when it is likely that the brand-name manufacturer would lose the patent as a result of the paragraph IV litigation.[188] Here, the brand-name manufacturer would be less likely to force the generic manufacturer into expensive litigation that might otherwise require the generic manufacturer to concede due to the fact that the generic manufacturer typically has far less financial resources.[189] The brand-name manufacturer would no longer be able to use its financial clout to force the generic manufacturer into a settlement in a case where the brand-name manufacturer's patent was weak.[190] This would serve the purpose of the HWA by overturning invalid and weak patents.[191]

By preventing (1) the generic manufacturer filing a baseless paragraph IV to obtain fast settlement payments and (2) the brand-name manufacturers from forcing generic manufacturers into litigation over what the brand-name manufacturer believes to be a weak or invalid patent, the need for reverse payments can be reduced to a far more limited set of circumstances. No longer would either litigant incur the costs to dispute a weak argument asserted by the other party. Rather, the parties could reserve reverse payment settlement agreements for those circumstances where each side has a legitimate belief in the validity of its argument, specifically, when the brand-name manufacturer believes its patent is strong and the generic manufacturer believes the contrary. Only then would the brand-name and generic manufacturers enter a settlement agreement to avoid the uncertainty of patent litigation.[192] The most likely result of settlements under this set of circumstances would allow for the generic manufacturer to get an earlier entry date and the brand-

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185 *See* McNair, *supra* note 179, at 134–38.
186 *Id*. at 135–36.
187 *Id*. at 135.
188 *Id*. at 135.
189 *Id*. at 135–36.
190 *Id*.
191 McNair, *supra* note 179, at 120–21.
192 *See infra* Part V.D.

name to have additional time to recoup its development costs without either party losing the litigation and those respective benefits.[193]

C. Enacting Stricter Regulation and Its Impact

A ban on reverse payment settlement agreements, as proposed by bills currently in Congress,[194] would not be appropriate primarily because of its chilling effect on the patent holder's exclusionary rights.[195] This is a view outlined in both the Eleventh and Federal Circuits' decisions regarding reverse payments.[196] Enforcement agencies have also weighed in, stating that settlement agreements are not anticompetitive simply because the agreement contains a reverse payment provision.[197] Specifically, the FTC has reasoned that because of the inherent complexity of patent litigation, any settlement agreement must be given a meaningful evaluation, rather than be presumed illegal on its face because of a reverse payment provision.[198] Finally, legal scholars have also supported a more lenient approach than an absolute ban on reverse payments.[199] The consensus among all of these groups indicates that the bill currently in Congress does not properly account for the rights of a valid patent holder.[200]

Experts have argued that reverse payment settlement agreements can actually enhance competition and enable earlier entry of generic drug products.[201] For example, reverse payments provided the only avenue for the generic manufacturers in both the Second and Federal Circuit cases to enter the market prior to the expiration of the brand-name manufacturers' patents, as later cases involving those same brand-name manufacturers and other generic companies verified the validity of the brand-name manufacturers' patents.[202] Therefore, the generic

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[193] *Id*. The generic would get an earlier entry date than waiting for the patent to expire and the brand-name would get longer market exclusivity than it would if the patent was found invalid. *Id.*

[194] *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); *see* Protecting Consumer Access to Generic Drugs Act, H.R. 1706, 111th Cong. (2009).

[195] Kadura, *supra* note 2, at 657.

[196] Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294 (11th Cir. 2003); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.), 544 F.3d 1323 (Fed. Cir. 2008); *See supra* Parts V.C. and D.

[197] Kadura, *supra* note 2, at 658.

[198] *Id.*

[199] *Id*. at 657.

[200] *Id*. at 658.

[201] *Id*. at 660.

[202] Joblove v. Barr Labs., Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187 (2d Cir. 2006); Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin

manufacturers in those two cases would have been blocked from bringing their product to market by the valid patent if not for the settlement agreements that granted them earlier access.[203]

Additionally, reverse payments can also foster a procompetitive atmosphere in two circumstances.[204] The first is where the parties to the litigation fail to assess their likelihood of a successful outcome.[205] The second is where the generic manufacturer would be willing to negotiate an entry date, but is financially unable to maintain operations until that date without a payment from the brand-name manufacturer.[206] The first situation is procompetitive because reverse payments allow opposing sides to use payments to balance the risks associated with proceeding with the unpredictability of a trial decision.[207] The second situation encourages competition, as the generic manufacturer gets the dual benefit of payment, which keeps the generic manufacturer financially viable, and early entry, which stimulates competition in the market.[208] In sum, a ban on reverse payment settlements, while eliminating the anticompetitive drawbacks, would also eliminate the procompetitive incentives that allow early entry for generics in situations where that would not otherwise be possible.[209]

The ban on reverse payments and on stricter regulations regarding these payments would also have a significantly adverse effect on the ability of parties to settle. Any legislation that does so would cut against the general principle that favors settlement over litigation.[210] This would present a particularly difficult problem in pharmaceutical litigation, where settlement is already unusually hard to achieve.[211] Pharmaceutical patent litigation, however, has two distinct qualities that make patent holders desire settlement.[212] First, the patent holder has a tremendous amount to lose if it does not succeed on its infringement claim.[213] Second, patent litigation is inherently unpredictable, such that even the most confident patent holder could be unsure as to whether a court might

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Hydrochloride Antitrust Litig.), 544 F.3d 1323 (Fed. Cir. 2008); *See supra* Parts V.A and D; Kadura, *supra* note 2, at 660.

[203] *See supra* Parts V.A and D; Kadura, *supra* note 2, at 660.

[204] Kadura, *supra* note 2, at 660–61.

[205] *Id.*

[206] *Id*. at 661.

[207] *Id*.

[208] *Id*.

[209] *Id.*

[210] Kadura, *supra* note 2, at 661–62.

[211] *Id* at 661.

[212] *Id* at 662.

[213] *Id*.

find the patent in question invalid.[214] Therefore, allowing reverse payments makes settlement possible.[215] By making a reverse payment, the patent holder is able to keep the generic company off the market and thus make a profit in an exclusive market.[216] Without the ability to make the reverse payment as a hedge against losing at trial, the patent holder has no incentive to settle and will await the court's final determination on the validity of the patent because the generic manufacturer is not going to accept an agreement that limits market entry without some sort of compensation.[217] Therefore, with no way to limit the generic manufacturer's entry to the market via a settlement agreement, the patent holder has nothing additional to lose by going to trial.

Stricter regulations such as those noted above could have a considerable impact on the ability of parties to settle disputes in the context of Hatch-Waxman litigation. While current proposals in Congress aim to eliminate reverse payment agreements,[218] perhaps a more moderate alternative exists. One possible solution is for government to impose a statutory system that regulates reverse payment agreements rather than banning them outright. By outlining specific criteria that agreements must follow, the government could carefully control what is going on in a reverse payment agreement and ensure that the agreement does not cross the lines of antitrust law. This would not only preserve the ability of the parties to settle, but would allow for more regulatory oversight of the agreement. The oversight process could include regulation of a number of areas from payment values, which might be set based on a generic's anticipated profit, to actual market entry date.

In particular, the focus of any legislation that regulates reverse payments should be on the economic terms of the agreement. Specifically, the regulations should limit the maximum amount of a reverse payment. The limit for the maximum payment could be based upon the projected profit that the generic manufacturer would make by entering the market with its own version of the brand-name manufacturer's drug. That maximum amount, however, should be reduced by an amount that would reflect the cost the generic manufacturer would incur by litigating a paragraph IV certification to conclusion through trial with a final verdict as to the validity of the

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214 *Id*.
215 *Id*. at 662.
216 Kadura, *supra* note 2, at 661–62.
217 *Id*. at 662–63.
218 *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); *see* Protecting Consumer Access to Generic Drugs Act, H.R. 1706, 111th Cong. (2009).

brand-name manufacturer's patent. This reduction is necessary to appropriately balance the rewards and risks between the brand-name manufacturer and the generic manufacturer.

Under this proposed scheme, the generic manufacturer stands to gain the same amount of money that it would have by successfully litigating its paragraph IV certification and entering the market, but without the risk of losing that litigation. The generic manufacturer would have the incentive to settle and take the payment described because it would not be able to gain anything additional by litigating, other than proving the patent to be invalid or not infringed. The reduction in the maximum payment by the amount of the generic manufacturer's litigation costs is necessary to avoid the situation where a generic manufacturer files a paragraph IV certification with no intent to actually litigate it, only hoping to get a fast settlement from the brand-name manufacturer. This situation represents a bonus to the generic as the brand-name manufacturer settles quickly to avoid the uncertainties of litigation and the generic manufacturer has risked nothing. Meanwhile, because the terms of any reverse payment agreement would require the generic manufacturer to attest to the validity of the brand-name manufacturer's patent, the generic manufacturer should only want to litigate in a situation where it was confident that it would win the paragraph IV litigation. This is because winning the paragraph IV litigation would allow the generic manufacturer to enter the market immediately and is the only benefit that the generic manufacturer could obtain going through litigation.

On the other side, the brand-name manufacturer gains the advantage of keeping its exclusive use of the market without incurring costs to litigate and risk a loss in paragraph IV litigation. This retention of an exclusive market is critical because it gives the brand-name manufacturer more time to recoup its investment in the drug development process.[219] Moreover, when the brand-name manufacturer is allowed to settle through a reverse payment it avoids the costs of litigation that can also hurt the brand-name manufacturer's profits. The more efficiently a brand-name manufacturer recovers its investment in a drug and begins earning a profit from it, the sooner the brand-name manufacturer can reinvest those profits in future drug development and innovation.[220]

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[219] Kadura, *supra* note 2, at 650.

[220] Christopher Lea Lockwood, Comment, Biotechnology Industry Organization v. District of Columbia*: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 ALB. L.J. SCI. & TECH. 143, 167 (2009).

Additionally, this scheme would be assisted by requiring the reverse payment agreement to include an early market entry provision that would allow the generic manufacturer to enter the market at some point earlier than the end of the brand-name manufacturer's patent term. This early market entry should be regulated using a set of guidelines that would attempt to provide benefits to both the parties. In particular, the brand-name manufacturer and the generic manufacturer should split the remaining term of the brand-name manufacturer's patent. For half of that period, the brand-name manufacturer would continue to enjoy its complete and total market exclusivity. Then, in the second half of the remaining patent term, the generic manufacturer would be allowed to enter the market. Significantly, however, the brand-name manufacturer and the generic manufacturer would be forced to enter into a licensing agreement for this remaining term of the patent. This is because the brand-name manufacturer still has its patent rights, as the patent is presumptively valid. Therefore, the generic manufacturer must pay the brand-name manufacturer for the right to use that technology.

The benefits of the above licensing scheme would be two-fold. First, the brand-name manufacturer would be able to recover more of its investment through licensing fees. Second, the generic would be allowed to enter the market earlier than would have otherwise been possible due to the patent right of the brand-name manufacturer. The earlier entry of the generic would be a benefit to consumers because the generic manufacturer would be able to offer lower prices for its version of the patented drug.[221] Then upon the expiration of the patent, the generic could enter the market without paying licensing fees and the price of the generic version of the drug would presumably drop again, which is a further benefit to consumers.

D. Reverse Payments Serve the Purposes of the Hatch-Waxman Act

"The Hatch-Waxman Act was enacted in 1984 with the dual purposes of reimbursing pharmaceutical patent holders for time lost on the effective life of the patent due to the approval process of the FDA while also encouraging generic drug manufacturers to enter the market, including providing incentives to challenge invalid patents or develop non-infringing drugs."[222] Prior to the HWA, only thirty-five percent of brand-name drugs generated generic competitors.[223] This is no longer the case today, as virtually all patented drugs spawn a generic

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[221] *See* Kadura, *supra* note 2, at 652.
[222] McNair, *supra* note 179, at 120–21.
[223] *Id*. at 121.

competitor.[224] Reverse payment settlements have generally contributed to this trend. For example, generic forms of Prozac and Paxil entered the market three years early and saved consumers an estimated $2.5 billion and $2 billion, respectively.[225] A generic form of Prilosec came to market fifteen years before its patents expired, saving consumers an estimated $360 million per year.[226]

Reverse payments also serve the HWA's purpose of providing a brand-name manufacturer patent term extension so that the brand-name manufacturer can recoup more of its development costs.[227] In the case of a reverse payment, the circumstances are more like a "quasi-patent term" extension because a settlement agreement extends the brand-name company's patent rights in instances where the generic would have been successful in its paragraph IV filing.[228] On the other hand, a settlement agreement forces the brand-name manufacturer to give up its patent rights earlier than would be required when the brand successfully defends against a generic company's paragraph IV filing.[229] Extended market exclusivity is critical because it allows the brand-name to recoup more of its investment.[230] When a brand-name is able to recoup more of its investment, it is able to reinvest more in future development.[231] Without recovering investment, brand-name manufacturers would not be able to produce today's ground-breaking new drugs."[232] It follows that without these brand-name drugs there would be nothing for the generic manufacturers to replicate and learn from, but more importantly "there would be little hope of finding new treatments and cures," because

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[224] *Id*. ("[G]eneric drugs comprised more than 47% of prescriptions filled in July 2002 whereas generic drugs comprised only 19% of prescriptions filled in 1984 when the Hatch-Waxman Act was enacted.").

[225] Kadura, *supra* note 2, at 652.

[226] *Id*.

[227] Integra Lifesciences I, LTD v. Merck KGaA, 331 F.3d 860, 865 (Fed. Cir. 2003) ("The 1984 Act had two purposes. In the first place, the 1984 Act sought to restore patent term to pharmaceutical inventions to compensate for the often-lengthy period of pre-market testing pending regulatory approval to sell a new drug. These regulatory delays can deprive a patentee of many years of its patent's term.").

[228] Holman, *supra* note 1, at 495. This is not a true patent term extension because the patent term is actually being reduced; however, the term is being extended beyond the term that would be expected given a successful filing of a paragraph IV certification. *Id*.

[229] *Id.*

[230] Kadura, *supra* note 2, at 650.

[231] Lockwood, *supra* note 220, at 167.

[232] Charlie Mead, *Drug Companies Aggressively Protecting Patents*, MEDILL REPORTS, Feb. 9, 2010, http://news.medill.northwestern.edu/chicago/news.aspx?id=156010.

innovation would become prohibitively expensive for brand-name manufacturers[233]

VI. CONCLUSION

Reverse payment agreements should continue as legal and exploitable methods of resolving litigation under the HWA because they serve the Act's purpose of allowing generic drug manufacturers to have a more efficient route in gaining approval for their product so that they may bring it to the market. The Act establishes a statutory structure that encourages reverse payment settlement agreements. These agreements have been the topic of scholarly, regulatory, and even circuit court debate because these payments raise possible antitrust violations. One view, expressed by the Sixth Circuit and certain experts, reasons that such payments should be per se illegal, as they do in fact violate antitrust laws. Nonetheless, to make a blanket decree that these reverse payments are per se illegal is not sound policy and could result in more negative consequences. Furthermore, creating a per se illegality standard for reverse payment agreements clashes with patent law's exclusionary principals. Therefore, the decisions rendered in the Second and Federal Circuits represent a more sound policy that reverse payments should be presumed legal. As long as these reverse payments do not extend the scope of the patent, they are not creating a restraint of trade that would not already exist via the monopoly granted by a patent. Taking away the ability to enter into a reverse payment settlement eliminates one of the major advantages and reasons to settle patent disputes without litigation. This effect goes against the longstanding policy of favoring settlement over litigation and is perhaps the best reason for allowing reverse payment settlements to continue. Finally, reverse payments have become an important by-product of the HWA. In many cases reverse payments further the Act's purpose of granting generic drug manufacturers earlier access to the market, thereby providing consumers with more affordable generic drugs.

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[233] *Id*.