

REVERSE PAYMENTS IN THE PHARMACEUTICAL INDUSTRY: FINDING THE RIGHT PRESCRIPTION

KENT W. ROYALTY*
SUZANNE OLIVA**
WILLIAM A. FIX***

I. INTRODUCTION

Escalating prescription drug prices and the resulting impact on consumers have placed the costs associated with pharmaceutical medicines into the forefront of public consciousness. Political candidates, lobbyists, media personalities, and industry experts have offered various reasons for the high prices of pharmaceutical prescriptions and have suggested a wide array of possible solutions to lessen those costs. One of the most significant efforts to control rising pharmaceutical prices occurred when Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984¹ (also called the Hatch-Waxman Act). The Hatch-Waxman Act was designed to reduce prescription drug prices by encouraging and facilitating the development of generic drugs.² The Act accomplishes these goals by reducing the obstacles of generic entry into the pharmaceutical marketplace and by providing rewards for generic companies that challenge existing brand patents.³

* J.D., LL.M., C.F.P., Emil C.E. Jurica Professor of Accounting, St. Mary's University, San Antonio, Texas.

** J.D., C.P.A., Visiting Assistant Professor of Accounting, St. Mary's University, San Antonio, Texas.

*** J.D. (in progress), Research Fellow, Center for Terrorism Law, St. Mary's University, San Antonio, Texas.

¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282).

² Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L. J. 585 (2003). "This Abbreviated New Drug Application (ANDA) process enabled generic manufacturers to avoid the costly and lengthy process of developing data establishing the safety and efficacy of their drugs and to obtain FDA approval merely by showing their drugs to be the "same" as, and "bioequivalent" to, the listed drug." *Id.* at 585-86.

³ See *infra* Part II.

Propelled by the Hatch-Waxman Act, generic drugs have proven enormously popular. The share of U.S. prescriptions filled by generics has surged from 19% of total prescription volume in 1984⁴ to 75% in 2009.⁵ Much of this popularity is due to the cost savings provided by generic drugs. One recent study reported that generics saved U.S. consumers more than \$824 billion from 2000 to 2009, including \$139 billion in 2009 alone.⁶ However, in recent years, a surge of patent litigation settlements between pharmaceutical patent holders and generic challengers has produced what appear to be anticompetitive results and deprived consumers of the savings intended by the Hatch-Waxman Act.

The Federal Trade Commission (FTC)⁷ and a host of scholars argue that certain settlements of patent litigation encouraged by the Hatch-Waxman Act significantly contribute to escalating drug prices.⁸ These settlements are referred to as *reverse payment* or *pay-for-delay* settlements because, rather than the potentially infringing generic manufacturer making a payment to the patent holder, the patent holder pays the generic company to drop its lawsuit and refrain from or delay entry into the market. Despite this practice, recent court decisions have not found these settlements to be anticompetitive if the scope of the original patent was not exceeded.⁹ In an effort to act where the judiciary has not, legislation was considered in Congress last year that would severely limit settlements of patent litigation between pharmaceutical patent holders and generic challengers.¹⁰

In Part II, this article will focus on the Hatch-Waxman Act and its historic role in promoting generic pharmaceuticals. Part III will explain

⁴ *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Entry Prior to Patent Expiration: Hearing Before the Subcomm. on Health of the Comm. on Energy and Commerce*, 107th Cong. 75 (2002), available at <http://www.gphaonline.org/resources/2002/10/08/greater-access-affordable-pharmaceuticals-act> (Testimony of Kathleen D. Jaeger, President and CEO, Generic Pharmaceutical Association).

⁵ John Jannarone, *Generics Game Will Get Tougher*, WALL ST. J., Apr. 5, 2010, at C8.

⁶ GENERIC PHARM. ASS'N, SAVINGS ACHIEVED THROUGH THE USE OF GENERIC PHARMACEUTICALS: 2000 – 2009 (July 2010), http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010_0.pdf.

⁷ Jon Leibowitz, Comm'r, 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 1* (June 23, 2009), <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>. FTC Commissioner Jon Leibowitz announced that eliminating reverse-payment settlements of pharmaceutical patent disputes was one of the FTC's highest priorities. *Id.*

⁸ See, e.g., Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009).

⁹ See *infra* Part IV.

¹⁰ S. 3677, 111th Cong. Sec. 746 (2010).

reverse payments and the controversy surrounding the settlements. Part IV will review the decisions of the federal circuit courts that have addressed the legality of pharmaceutical reverse-payment settlements and describe the escalating utilization of reverse payments subsequent to judicial approval of the settlements. Part V explores the proposed and, as yet, unsuccessful legislative attempts to severely restrict settlements by introduction of the Preserve Access to Affordable Generics Act. Part VI analyzes the advantages and disadvantages of reverse payment settlements and the effects of possible restriction or elimination of settlements. In Part VII, this article concludes with a recommendation for a legislative compromise that utilizes many of the features of the Preserve Access to Affordable Generics Act while still conserving opportunities for litigants to establish the merits and legality of beneficial settlements.

II. THE HATCH-WAXMAN ACT: A CAREFUL BALANCE BETWEEN COMPETING INTERESTS

Congress passed the Hatch-Waxman Act to facilitate the development of a vigorous and healthy generic drug industry. The drafters of this legislation were cognizant of the need to foster innovation by brand manufacturers within the pharmaceutical industry and, at the same time, encourage the entry of generic pharmaceuticals into the market.¹¹ This delicate balance is necessary to reconcile the contradictory worlds of patents and competition. Patent laws were created by Congress as exceptions to the rules of competition and generally provide innovators with a twenty-year monopoly.¹² Innovators seeking patents must disclose their ideas in the patent application which then provides a base on which other innovators can build.¹³ However, in return for this disclosure, patent holders are protected for a specific period of time from infringers, who could use this now-public information to compete. This period of patent exclusivity shields the pioneer companies, potentially allowing these innovators to recover investments (which may run into the hundreds of millions of dollars) and reap justly

¹¹ John R. McNair, *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, 120 (2007). "The dual purposes of the Hatch-Waxman Act are to reimburse pharmaceutical patent holders for time lost due to the long review period needed to achieve FDA approval and to encourage generic drugs to enter the market by enacting procedures that expedite and incentivize their introduction." *Id.*

¹² 35 U.S.C. § 154(a)(2) (2010). "[S]uch grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States." *Id.*

¹³ *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5 (1966).

deserved profits sufficient to encourage future innovation.¹⁴ The sensitive, yet essential, balancing of these equally compelling interests requires a thorough understanding of not only the complex subject matter involved, but also the impact on the complex healthcare marketplace.

Prior to the passage of the Hatch-Waxman Act, a company seeking to introduce a generic drug into the U.S. marketplace was generally required to re-establish the safety and efficacy of the drug.¹⁵ This necessitated a repetition of the lengthy and expensive Food and Drug Administration (FDA) trials and testing processes that were required of the pharmaceutical company that first developed the drug and originally filed a New Drug Application (NDA). However, any FDA-required testing by a generic challenger during the exclusivity period of the original pharmaceutical patent could trigger an actionable patent infringement claim.¹⁶ Thus, fear of litigation and resulting potential liability often precluded testing until the original patent term expired. As a practical matter, the lengthy FDA approval process, combined with the inability of generic manufacturers to begin testing until after the patent expiration date, provided the pharmaceutical brand manufacturer with an effective patent protection period that far exceeded the life of the actual patent.¹⁷

The Hatch-Waxman Act was designed to end this unofficial patent extension and save consumers millions of dollars by speeding up the entry of generic medicines into the market.¹⁸ Hatch-Waxman encourages and facilitates generic entry in three very significant ways. First, if a drug is tested by a potential generic manufacturer in order to provide information to the FDA, the Act shields the aspiring generic manufacturer from an infringement claim.¹⁹ This protection greatly accelerates the introduction of

¹⁴ Pamela J. Clements, *The Hatch-Waxman Act and the Conflict Between Antitrust Law & Patent Law*, 48 IDEA 381, 383 (2008). “Patents grant potential monopolies to innovators in an effort to encourage innovation by allowing them to charge higher prices to recoup money spent on research and development. The goal of antitrust law, however, is to increase and punish businesses for anticompetitive acts, including monopolies.” *Id.*

¹⁵ Weiswasser & Danzis, *supra* note 2, at 589-90.

¹⁶ *Roche Prods., Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 863 (Fed. Cir. 1984). “Bolar’s intended use . . . to derive FDA required test data is thus an infringement of the [original] patent [U]nlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter’s business is a violation of the rights of the patentee.” *Id.*

¹⁷ *Carrier*, *supra* note 8, at 42. “[B]ecause the required tests constituted infringement, generics could not begin the process during the patent term. They therefore waited until the end of the term to begin these activities, which prevented them from entering the market until two or three years after the patent’s expiration.” *Id.*

¹⁸ *Id.*

¹⁹ 35 U.S.C. § 271(e)(1) (2010). “It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” *Id.*

approved generics into the market. Second, the Act provides new guidelines that allow generic manufacturers to file Abbreviated New Drug Applications (ANDAs) with the FDA that piggyback off the approval tests of the branded counterparts.²⁰ By completing an ANDA, a generic drug company need only show that the generic is a bioequivalent of the original medicine, effectively allowing generics to save hundreds of millions of dollars and eliminating several years in the development process, and thus providing savings for consumers.²¹ Finally, Congress included an incentive provision in the Act to encourage generic companies to take advantage of the new rules and enter the market as soon as possible. The first generic manufacturer to substantially submit a completed ANDA is granted 180 days of exclusivity, essentially barring all other generics from the market for half a year.²² This provision provides the opportunistic generic manufacturer extraordinary profits akin to those originally provided to the patent holder. However, these profits will clearly be tempered by the competition the first generic will face from the brand manufacturer, as the brand name pharmaceutical will have benefited from several years of advertising and market recognition by the time of the successful generic challenge.

However, brand owners were not forgotten in the Act. Congress recognized that, even after being granted a patent, several years of trials and tests may be necessary before the innovator receives the FDA clearance needed to market the new drug. This time lag was eroding the patent system's incentives to innovate and severely limiting a company's return on its investment. The legislators rebalanced the system by granting extended patent terms for up to five years to compensate for the patent time lost while the drug was in clinical trials and awaiting FDA approval.²³

Additionally, Congress provided a protective process to deal with the anticipated lawsuits between brand-name and generic pharmaceutical companies. For example, in order to protect the rights of patent holders, the Act requires the ANDA applicant to file a certification that (I) the patent information has not been filed, (II) the patent has expired, (III) the patent will expire on a specified date, or (IV) the patent is invalid or will not be infringed on by the generic drug.²⁴ Regulations and timelines regarding litigation were also written into the Act. When a generic manufacturer files an ANDA and challenges an existing patent, the innovator company must be given notice and then has forty-five days to file a patent infringement

²⁰ 21 U.S.C. § 355(j) (2010).

²¹ See Weiswasser & Danzis, *supra* note 2, at 593-606 (discussing the approval process for generic drugs).

²² 21 U.S.C. § 355(j)(5)(B)(iv).

²³ 35 U.S.C. § 156(c)(g)(6) (2010).

²⁴ 21 U.S.C. § 355(j)(2)(A)(vii).

lawsuit.²⁵ Upon the filing of such a suit, the ANDA is then frozen for thirty months while a court determines the original patent's validity.²⁶ The FDA cannot approve this ANDA (or any subsequent ANDA) while the initial patent is under dispute.²⁷

III. REVERSE PAYMENTS: HATCH-WAXMAN'S UNINTENDED SIDE EFFECT

Reverse payment settlements and the potential to negate the intended benefits of the Hatch-Waxman Act by seriously delaying generic competition are at the heart of the current controversy. The issue of reverse payments occurs when ANDAs are filed and challenged using the above referenced *paragraph IV certification*, attesting that the generic drug either does not infringe on an existing patent or that the patent is invalid.²⁸ As previously explained, such a filing automatically opens the door for the pioneer drug company to file a patent infringement cause of action. But, with the passage and implementation of this legislation, Congress seemingly did not anticipate the creative drafting of settlement agreements by pharmaceutical companies. A key component in many of these compromise agreements has been the pioneer company paying millions of dollars to the generic company to stay out of the market. As Representative Waxman noted two decades after passing the original bill, the intent of the legislation was to promote generic competition, not to encourage generic manufacturers "to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market."²⁹

IV. CIRCUIT COURTS PROVIDE SECOND OPINIONS ON REVERSE PAYMENT SETTLEMENTS

A. Sixth Circuit: *In re Cardizem CD Antitrust Litigation (2003)*

Given the new operating system under Hatch-Waxman and the FTC's disapproval of reverse payment settlements,³⁰ it was only a matter of time

²⁵ *Id.* at § 355(j)(5)(B)(iii).

²⁶ *Id.*

²⁷ *Id.* at § 355(j)(5)(B)(iv).

²⁸ *Id.*

²⁹ Motion and Brief of Representative Henry A. Waxman as Amicus Curiae in Support of Petitioner at 1, *Fed. Trade Comm'n v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2462026.

³⁰ Leibowitz, *supra* note 7, at 5. In a 2009 speech, FTC Commissioner Jon Leibowitz proclaimed, "The FTC is continuing to bring cases to protect consumers from these anticompetitive settlements, and we hope the trend in courts will change." *Id.*

before lawsuits advanced to final judgment. In 2003, the Sixth Circuit became the first federal circuit court to hear this issue with the *In re Cardizem CD Antitrust Litigation* case.³¹ HMR, the brand manufacturer of Cardizem CD, sued Andrx (generic) for patent infringement after Andrx filed a paragraph IV certification.³² The parties subsequently entered into an agreement in which the generic agreed not to enter the market until either (1) Andrx obtained a favorable decision in the lawsuit, (2) the brand and the generic entered into a licensing agreement, or (3) the brand entered into a licensing agreement with a third party.³³ When Andrx received FDA approval, the generic further agreed not to transfer the 180-day exclusivity period, in exchange for payments of \$40 million per year from HMR.³⁴ By not entering the market, the 180-day exclusivity period never started, which delayed the entry of other generic competitors.³⁵ The Sixth Circuit invalidated the settlement, holding:

There is simply no escaping the conclusion 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 a *per se* illegal restraint of trade 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.³⁶

B. Eleventh Circuit: *Schering-Plough Corp. v. FTC* (2005)

Two years later, the Eleventh Circuit heard a similar case but reached the opposite conclusion.³⁷ The holding in *Schering-Plough Corp. v. FTC* established what would become the judicial branch's majority view that reverse payments are not *per se* illegal.³⁸ The court showed a willingness to consider the totality of circumstances instead of adhering to the bright line rule espoused by the Sixth Circuit.³⁹ The Eleventh Circuit outlined three

³¹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

³² *Id.* at 901-02.

³³ *Id.* at 902.

³⁴ *Id.*

³⁵ *Id.* at 907.

³⁶ *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 908.

³⁷ *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005).

³⁸ *Id.* at 1065. "We think that neither the rule of reason nor the *per se* analysis is appropriate in this context." *Id.*

³⁹ *See id.* at 1066 (explaining why consideration of the various factors involved is a better approach). "What is required here is an analysis of the extent to which the patent laws prevent antitrust liability for such exclusionary effects." *Id.*

factors that must be weighed when evaluating antitrust liability: “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”⁴⁰ Under the settlement agreement, Schering (innovator) agreed to pay Upsher (generic) \$70 million in royalty fees and payments plus another 10-15% of sales in royalties to stay out of the market for four years. A distinguishing characteristic of this agreement was the fact that Schering also secured licenses for five additional Upsher products (including one that the company valued between \$245 and \$265 million).⁴¹ This added consideration strengthened the notion that the settlement was not *per se* illegal, but merely a normal business transaction. The court also found value in contrasting the bounds of the original patent with the entry date provided in the settlement agreement. “What patent law does not do, however, is extend the patentee’s monopoly beyond its statutory right to exclude.”⁴² Although the terms of the settlement did delay Upsher, the generic product still would have entered the market almost three years before Schering’s original patent was due to expire.

C. Second Circuit: *In re Tamoxifen Citrate Antitrust Litigation* (2006)

Other federal circuits that have subsequently heard similar cases agreed with the Eleventh Circuit. When the Second Circuit issued its ruling in *In re Tamoxifen Citrate Antitrust Litigation* in 2006, it simplified the issue: “If the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the Tamoxifen patent, they would succeed in alleging an antitrust violation.”⁴³ In this case, Barr (generic) filed an ANDA a mere four months after Imperial Chemical Industries (ICI) obtained a Tamoxifen patent which was later transferred to Zeneca.⁴⁴ Under the main terms of the agreement, in exchange for \$21 million and a license to sell some of Zeneca’s products, Barr consented to refrain from marketing its generic until the original Tamoxifen patent expired.⁴⁵ Because this agreement did not extend beyond the original patent term, the court held that it was not anticompetitive.⁴⁶

⁴⁰ *Id.*

⁴¹ *Id.* at 1059-60.

⁴² Schering-Plough Corp., 402 F.3d at 1067 (citing *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992)).

⁴³ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 200 (2d Cir. 2006).

⁴⁴ *Id.* at 193.

⁴⁵ *Id.* at 193-94.

⁴⁶ *Id.* at 216. “In the absence of any plausible allegation that the reverse payment provided benefits to Zeneca outside the scope of the tamoxifen patent, the plaintiffs have not stated a claim for relief with respect to the Settlement Agreement.” *Id.*

D. *Federal Circuit: In re Ciprofloxacin Hydrochloride Antitrust Litigation (2008)*

The Federal Circuit, the court with exclusive jurisdiction over appeals regarding U.S. patent law,⁴⁷ concurred with the Second and Eleventh Circuits in 2008 with its *In re Ciprofloxacin Hydrochloride Antitrust Litigation* decision.⁴⁸ Each of the negotiated settlements featured monetary payments from Bayer to generic manufacturers (including Barr, HMR, Rugby, Apotex, and Bernard Sherman), in exchange for an agreement not to challenge Bayer's patent or manufacture a generic version of the patented medication until Bayer's patent expired.⁴⁹ In total, Bayer paid out just under \$400 million to keep Barr and the partner companies out of the market, even though Barr filed its ANDA twelve years before Bayer's patent was due to expire.⁵⁰ The Federal Circuit considered the findings of the Sixth, Eleventh and Second Circuits over the previous five years and followed the trend of upholding such settlements as long as the patent holder was not given extra rights unauthorized by the original patent. The Federal Circuit reasoned, "[T]he 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."⁵¹

In summary, a majority of federal circuit courts (Second, Eleventh and Federal Circuit) has held that a reverse payment settlement is lawful if it does not restrain competition past the time the patent was permitted to preempt competitors. The direction of the flow of payments between the parties was not found to be the determinative factor by the courts.⁵²

E. *Aftermath of Reverse Payment Litigation*

In an effort to monitor such reverse payment settlements between name-brand and generic drug manufacturers, Congress passed legislation in 2003 requiring pharmaceutical companies to file settlement agreements with the

⁴⁷ 28 U.S.C. §§ 1295(a)(1), 1338(a) (2010).

⁴⁸ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

⁴⁹ *Id.* at 1328-29.

⁵⁰ *Id.* at 1328.

⁵¹ *Id.* at 1333.

⁵² Michael A. Carrier, *Innovation for the 21st Century: A Response to Seven Critics*, 61 ALA. L. REV. 597, 611 (2010). "Dan Crane explores settlement agreements by which brand-name pharmaceutical companies pay generic firms to drop patent challenges and delay entering the market. Professor Crane is right that the direction of the payment, by itself, is not what is suspicious about brand drug firms' payments to generics for delay." *Id.*

FTC.⁵³ The reports generated from these filings provide evidence that reverse payment settlements are increasing in popularity. During the year after the legislation was passed, fourteen agreements were reported between innovators and generics, but none of the agreements included reverse payments in exchange for delayed market entry. In 2005 (coinciding with the Eleventh Circuit's decision in *Schering*, which held such settlements were not an antitrust violation), three of sixteen such agreements included reverse payments.⁵⁴ By 2008, sixteen of sixty-six similar agreements contained some type of payment from the innovator to the generic.⁵⁵ In just the first nine months of 2010, a total of twenty-one reverse payment settlement cases were filed, more than any prior full year.⁵⁶ The judicial *laissez faire* attitude toward pharmaceutical reverse payment settlements has created a flood of litigants opting for this alternative, and the FTC projects that, if left unchecked, these settlements will deprive United States consumers of \$35 billion in lost generic cost savings over the next ten years.⁵⁷

V. PROPOSED REMEDY OF THE 111TH CONGRESS

Language very similar to the frequently proposed, and yet to be enacted, Preserve Access to Affordable Generics Act⁵⁸ was included as part of the unsuccessful Fiscal Year 2011 Financial Services and General Government Appropriations Bill (S. 3677).⁵⁹ If this federal legislation had been enacted, it would have severely limited the ability of brand-name and generic drug manufacturers to settle patent litigation. The Act would have created a presumption that pharmaceutical patent infringement settlements are anticompetitive and unlawful if the ANDA filer receives any value and

⁵³ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in relevant part at 42 U.S.C. § 1395, 21 U.S.C. § 355), available at

<http://www.ftc.gov/os/2004/01/04106pharmrules.pdf>.

⁵⁴ Leibowitz, *supra* note 7, at 4-5.

⁵⁵ BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FED. TRADE COMM'N UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2008 3 (2008), <http://www.ftc.gov/os/2010/01/100113mpdim2003rpt.pdf>.

⁵⁶ *FTC Testimony: Stopping "Pay for Delay" Drug Settlement Agreements is a Top Competition Priority: New Data Show the Number of Potential Anticompetitive Settlements is on the Rise* (July 27, 2010), <http://www.ftc.gov/opa/2010/07/antitrust.shtm>.

⁵⁷ FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 6 (2010), <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

⁵⁸ *See, e.g.*, S. 27, 112th Cong. (2011); S. 369, 111th Cong. (2009); S. 316, 110th Cong. (2007); H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2006).

⁵⁹ S. 3677, Sec. 746(a)(1)(B).

agrees to limit research, development or sales.⁶⁰ An exception would have been granted for agreements with procompetitive benefits that outweigh anticompetitive effects, if the parties established this benefit by clear and convincing evidence.⁶¹ In response to the reluctance of the federal courts to consider factors other than whether the settlement postpones generic entry beyond the expiration of the original patent, the proposed legislation expressly prohibited the fact finder from determining the settlement to be legitimate solely because it permits generic entry prior to the expiration of the patent.⁶² Additionally, the legislation provided further clarification of the factors a court should consider in making such a determination. The factors expressly to be considered in determining whether a settlement is procompetitive or anticompetitive 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.⁶³

Failure to use these seven factors to clearly establish that a settlement is procompetitive would subject the settling parties to civil penalties of up to three times the value received that is attributable to the illegal settlement⁶⁴ and loss of the 180-day exclusivity period by the generic manufacturer.⁶⁵ An exception was included for a settlement providing for early entry of the

⁶⁰ *Id.* at § 28(a)(2)(A).

⁶¹ *Id.* at § 28(d).

⁶² *Id.* at § 28(c).

⁶³ *Id.* at § 28(b)(1-7).

⁶⁴ S. 3677, Sec. 746(a)(1)(B); § 28(g)(1).

⁶⁵ *Id.* at § 28(h)(2)(c).

generic with payments to the generic not exceeding reasonable litigation costs and in no case exceeding \$7.5 million.⁶⁶ Many considered this proposed legislation to be excessive, including several Senators who signed a bipartisan opposition letter, arguing that the *de facto* ban on settlements will have a chilling effect on drug patent challenges due to the expense of litigation and the absence of the ability of settlements to allow generic competition much sooner than litigation would provide.⁶⁷

The proposed legislation, however, would focus the fact finder's attention on the true economic factors of the settlement. These factors ensure that time delays, payment size, potential lost earnings and other circumstances indicate whether the settlement is essentially a collusive split of unmerited excessive profits. The required consideration of the interests of consumers is also appropriate in any Hatch-Waxman analysis, as consumers are the intended beneficiaries of not only Hatch-Waxman but also of the antitrust laws.

VI. A DIAGNOSIS OF REVERSE PAYMENTS: TO PRESERVE OR REVERSE

A. *Why Preserving the Status Quo Is Healthy*

The Hatch-Waxman Act provides oversight of a delicate balance between competition essential for the protection of the consuming public and patent rights critical for encouraging innovation in health care. While generics have proven enormously successful under the care of Hatch-Waxman, that success only makes it all the more important that changes that may affect the status quo be weighed carefully. An absolute ban, or actions tantamount to an absolute ban, on settlements with reverse payments could potentially create many negative consequences, both for consumers and innovators.

⁶⁶ *Id.* at § 28(d)(1-3).

⁶⁷ Letter from Arlen Specter, Orrin Hatch, et al, U.S. Senators, to Harry Reid, U.S. Senate Majority Leader (July 28, 2010), *available at* <http://www.fdalawblog.net/files/patent-settlement---letter-to-majority-leader-reid-july-2010.pdf>.

Banning settlements means that most generic drug manufacturers will not have the incentive to challenge drug patents and thus the consumer market will effectively wait a longer period of time for cheaper generics to come to the market An outright ban of such settlements will potentially eliminate billions of dollars of consumer savings and cause an exponential rise in the average costs of consumer medication.

The most obvious negative impact of a limitation on the ability of litigants to resolve a dispute through a reverse payment settlement is the loss of time and money, not only by the parties, but also by the publicly funded courts. As Judge Fay of the Eleventh Circuit stated, “Litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.”⁶⁸ Another negative consequence is that extra and excessive litigation costs must ultimately be passed on to the consumer at some point. These savings explain why ninety-five percent of patent infringement cases are resolved through the settlement process.⁶⁹

Additionally, the public may be denied the savings provided by a settlement allowing for early generic entry. If, instead, the parties litigate, the brand may prevail and naturally exercise the full remaining time provided by its patent. The loss of realistic settlement options will also counteract the Hatch-Waxman incentives for generic challenges by signaling to generics that, instead of the prospect for a reasonably quick, lucrative settlement with an early entry into the market, the only possible outcome of a challenge is a lengthy, protracted, expensive battle against well financed international pharmaceutical corporations with no guaranteed favorable result. This may simply be a risky battle that few generic manufacturers have the fortitude or finances to undertake. In fact, the CBO (Congressional Budget Office) has estimated that the loss of settlement incentives would raise drug prices by \$2 billion between 2010 and 2019.⁷⁰ Such a loss of incentives will destroy the benefits to the consumer along with the targeted anticompetitive settlements. In *Schering*, the Eleventh Circuit quoted a passage from Judge Posner to illustrate how a ban on reverse payment settlements would actually *decrease* competition:

If any settlement agreement can be characterized as involving "compensation" to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden "reverse payment," we shall have no more patent settlements A prohibition on reverse-payment settlements would “reduce the

⁶⁸ *Schering-Plough Corp.*, 402 F.3d at 1073 (citing *Valley Drug Co. v. Geneva Pharm. Inc.*, 344 F.3d 1294, 1309 (2003)).

⁶⁹ Jean Olson Lanjouw & Mark Schankerman, *Enforcing Intellectual Property Rights, Conference on New Research on the Operation of the Patent System*, sponsored by the U.S. National Academy of Sciences (2001).

⁷⁰ BRET DICKEY, JONATHAN ORSZAG & ROBERT WILLIG, A PRELIMINARY ECONOMIC ANALYSIS OF THE BUDGETARY EFFECTS OF PROPOSED RESTRICTIONS ON “REVERSE PAYMENT” SETTLEMENTS 6 (2010), <http://www.compasslexecon.com/highlights/Documents/Dickey%20Orszag%20Willig%20CBO.pdf>.

incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.⁷¹

Settlements also provide the certainty that is essential to ensure efficient business operations and continued U.S. innovation and competitiveness. The so-called *Pay-for-Delay* agreements are a byproduct of the system Congress established.⁷² Furthermore, the FTC is already provided with notice of reverse payment settlements and may challenge any egregious settlements in court under the antitrust laws. The courts are the appropriate forum to weigh the advantages and disadvantages of the settlements on a case-by-case basis and ensure that the public interest is being preserved. This retention of the status quo is especially appropriate when dealing with such a delicate balance as the Hatch-Waxman Act. An abrupt change, such as the direct reversal of the court system's recent findings that settlement virtues outweigh the vices, risks undermining the pharmaceutical innovation and cost savings that the current Hatch-Waxman environment is so successfully providing.

B. *Why Reverse Payment Settlements Are Bad Medicine*

The Hatch-Waxman Act was designed to encourage generic pharmaceutical manufacturers to challenge existing pharmaceutical patents and, when the proposed generic did not infringe a patent or the patent was found invalid, to provide consumers with lower-cost generics as quickly as possible. A 2002 FTC study indicated that generics were successful in seventy-three percent of these challenges and the savings to consumers was enormous.⁷³ Of course, the consumer savings due to generic availability directly reduce the extraordinary profits a brand manufacturer receives from the patent monopoly. In response, pharmaceutical companies that hold invalid or indefensible patents immediately consider reverse payment settlements to limit future losses. The reverse payment option offers former adversaries the opportunity to compromise and collude in order to circumvent Hatch-Waxman's intended benefits to consumers. Collusion is an enormous temptation when the original litigants have the opportunity to split

⁷¹ Schering-Plough Corp., 402 F.3d at 1074-75 (quoting *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (Posner, Circuit J., sitting by designation)).

⁷² *Id.* at 1074 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 251 (E.D.N.Y. 2003)). "The Commission's inflexible compromise-without-payment theory neglects to understand that '[r]everse payments are a natural by-product of the Hatch-Waxman process.'" *Id.*

⁷³ FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 13 (2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

a pool of monopoly profits that greatly exceeds the expected combined returns of both the brand-name and the generic manufacturers, as compared with the uncertainty surrounding the infringement challenge proceeding to a judicial decision. The potential losers in these arrangements are other generic drug manufacturers who are kept out of the market and consumers who, in the case of a major pharmaceutical drug, may be deprived of millions or billions of dollars in savings that competition provides.

The FTC asserts that generics enter the market, on average, seventeen months sooner in the absence of a reverse payment settlement,⁷⁴ and mature generic markets save consumers eighty-five percent over brands protected by a patent monopoly.⁷⁵ If these settlements are abolished, the combination of early generic entry and generic cost savings is expected to save the public \$35 billion over the next ten years.⁷⁶ With the majority of courts favoring the public policy aspects of settlements, pharmaceutical patent holders and challenging generics are increasingly turning to reverse payment settlements to augment profits.

VII. OUR PRESCRIPTION: A COMPROMISE PROPOSAL

The Hatch-Waxman Act was enacted to balance the often contradictory goals of supporting pharmaceutical innovation and facilitating the entry of generic drugs into the market. The Act's intended balance is being distorted by reverse payment settlements that often delay generic entry far beyond the entry point that successful patent litigation would have provided. Congress can restore balance to this critical area by passing legislation that retains several of the key elements of the Preserve Access to Affordable Generics Act but also refrains from a *de facto* ban on pharmaceutical reverse-payment settlements.

Legislation should be enacted that voids the 180 days of generic exclusivity whenever a pharmaceutical reverse payment settlement is reached.⁷⁷ Additionally, all related stays or injunctions prohibiting other generic manufacturers from filing ANDAs should be removed immediately upon such a settlement. These provisions would subject the patent in question to immediate challenges by other generic manufacturers and thus reduce the incentives for the original two litigants to engage in delaying activities, market-sharing and other anticompetitive activities. While this proposal might result in the elimination of most of these controversial

⁷⁴ FED. TRADE COMM'N, *supra* note 57, at 4.

⁷⁵ *Id.* at 8.

⁷⁶ *Id.* at 6.

⁷⁷ See S. 27, 112th Cong. § 5 (2011) (deleting the section of federal law that includes the 180-day exclusivity period).

settlements, it is less severe than the total elimination of all settlements, while still preserving the public interest. This proposal allows a litigation escape valve that may prove valuable to some litigants who seek an alternative to expensive litigation or a time-consuming resolution of their dispute. When incentives inspired by Hatch-Waxman are withdrawn and the parties abandon the litigation process, balance is returned to the system.

There are valid reasons for allowing settlements of pharmaceutical patent infringement claims, including settlements with reverse payments. The Preserve Access to Affordable Generics Act enters dangerous territory if it includes a shift in the burden of *clear and convincing proof* to the settling parties and imposes triple damage awards so potentially devastating as to essentially be a ban on any reverse payments in excess of reasonable litigation expenses. While an effective ban on pharmaceutical reverse payment settlements will ensure that the public interest is not betrayed by collusion, the ban ignores the potential benefits of pharmaceutical dispute settlements. The settlement of these disputes can result in earlier generic access to the market, tremendous savings of litigation expenses (both for the parties and the public), an economical exit path from lengthy and expensive litigation and may serve as an inducement to the filing of the very patent challenges sought to be fostered by the Hatch-Waxman Act.

Thus, we propose the removal of the Hatch-Waxman incentives rather than impose the damage provisions of the Preserve Access to Affordable Generics Act, which are so potentially costly and likely to eliminate all settlements, good or bad. Instead, we propose that compromise legislation be enacted that will preserve the settlement option to the greatest extent possible, while clearly removing the overwhelming incentives for pharmaceutical patent litigants to delay generic entry and betray consumers.

Additionally, there are other key provisions of the Preserve Access to Affordable Generics Act that merit preservation. First, the exemption for reverse payment settlements of less than the generic manufacturers' estimated litigation expense, not to exceed \$7.5 million, provides shelter for reasonable settlements and needs to be included in any legislation limiting reverse payment settlements. The limited payouts indicate that various factors, other than inducements to delay generic entry, are the primary motivation for the settlement and, thus, there is little, if any, risk to market competition which is outweighed by the benefits of the settlement. Second, the seven listed characteristics for court review of settlements are essential for determining the true nature of the settlement and should be preserved. Instead, the seven listed factors⁷⁸ will focus court attention on the actual economics of the settlements. If the seven factors were not reviewed by the court, owners of patents that are likely invalid or indefensible may simply

⁷⁸ S. 3677, Sec. 746(a)(1)(B) § 28(b)(1-7).

collude with their generic challengers to split the monopolistic patent profits. Care would only need to be taken to not delay generic entry beyond the life of the otherwise impotent patent.

The public interest is preserved by continuation of the requirement that the FTC must be notified of the pharmaceutical settlement, the adoption of the new criteria regarding economic factors for courts to consider when reviewing settlements and, finally, the removal of the artificial incentives (the 180 days of first generic exclusivity and the automatic stay of challenges by other generics) provided by the Hatch-Waxman Act to incentivize generic challenges and to compensate brands for generic challenges. These changes, if enacted in successful legislation, allow as much opportunity for settlement as possible while ensuring the removal of incentives to collude, conspire or deny the public the benefits of the Hatch-Waxman Act. In an imperfect system where the interests of the general public, pharmaceutical innovators, brand-name manufacturers, insurance companies and the federal government are all at stake, we believe this proposal is the most fair and reasonable solution.