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Devising a Legislative Solution to the Reverse Payment Dilemma: How Congress Can Balance Competition, Innovation, and the Public Policy Favoring the Settlement of Disputes Without Litigation

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**DEVisING A LEGISLATIVE SOLUTION TO THE REVERSE
PAYMENT DILEMMA: HOW CONGRESS CAN BALANCE
COMPETITION, INNOVATION, AND THE PUBLIC POLICY
FAVORING THE SETTLEMENT OF DISPUTES WITHOUT
LITIGATION**

INTRODUCTION

Central to any effective healthcare legislation is controlling the nation's rising healthcare costs.¹ In 2009, national health expenditures expanded by 5.7%, outpacing GDP growth and representing the single largest one-year increase in history.² Much of the bloated healthcare costs are attributable to the price-growth of prescription drugs.³ In 2008, American consumers, along with federal, state, and local governments, spent more than \$234 billion on prescription medications, an increase of 3.2% over the previous year.⁴ By 2019, the growth of prescription drug spending is expected to reach 7.7%, with increases in drug prices expected to account for approximately half of that growth.⁵

Despite sustained increases in prescription drug prices, generic versions of brand-name drugs have brought enormous benefits to consumers and governments by delivering medications at up to 80% below branded prices.⁶ The modern generic drug industry grew out of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.⁷

1. See Laura Meckler, *Obama's Health Expert Gets Political*, WALL ST. J., July 24, 2009, at A1 (highlighting concerns expressed in Congress that the proposed healthcare reform package will not do enough to keep healthcare costs from "spin[ning] out of control").

2. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE PROJECTIONS 2009–2019 *1 (2008) [hereinafter CMS REPORT], available at <http://www.cms.gov/NationalHealthExpendData/downloads/proj2009.pdf>.

3. *Id.* at *2–3.

4. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES AGGREGATE AMOUNTS AND AVERAGE ANNUAL PERCENT CHANGE, BY TYPE OF EXPENDITURE: SELECTED CALENDAR YEARS 1960–2008, available at <http://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf>.

5. CMS REPORT, *supra* note 2, at *3.

6. *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution: Hearings Before the S. Comm. on the Judiciary*, 110th Cong. 123 (2007) [hereinafter *Hearings*] (statement of the FTC).

7. Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 588 (2003). See also Drug Price Competition &

To promote generic competition, the Hatch-Waxman Act allows generic drug companies to challenge brand-name drug patents before their date of expiration, which helps ensure that invalid drug patents do not delay the introduction of generic competition into the market.⁸ In the 1990s alone, consumers saved nearly \$10 billion in the wake of successful patent challenges by drug manufacturers looking to market generic versions of just four blockbuster drugs: Prozac, Zantac, Taxol, and Plantinol.⁹

Settlement agreements between brand-name drug manufacturers and generic firms have limited the type of generic competition the Hatch-Waxman Act was designed to encourage. In the typical scenario, the brand-name manufacturer pays a would-be generic competitor a certain sum in exchange for the generic's agreement to drop its patent challenge and delay entering the market.¹⁰ Although the law encourages good-faith settlement of patent litigation, the Federal Trade Commission (FTC) has expressed significant concern that these settlement agreements allow patent-holders to purchase more reduced competition than patent rights can provide, thereby "disrupt[ing] the careful balance between patent protections and encouraging generic entry that Congress sought to achieve in the Hatch-Waxman Act."¹¹

For more than a decade, the FTC has battled these settlements in federal courts, and in 2007, it began pushing for a legislative solution.¹² Recently, with fresh support from the Obama administration¹³ and the Department of

Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of U.S.C.).

8. See FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4-5* (2002) [hereinafter *FTC 2002 STUDY*] (interpreting Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of U.S.C.)).

9. *Hearings*, *supra* note 6, at 18.

10. *Id.* at 1.

11. *Id.* at 4.

12. See generally *id.* (pushing for a legislative solution). The FTC suffered its most recent defeat in the case of *In re AndroGel Antitrust Litig. (No. II)*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010). There, the FTC and purchasers sued the manufacturers and suppliers of a testosterone replacement gel, AndroGel, alleging that the defendants entered into a reverse payment settlement, which thereby eliminated the potential for competition in the AndroGel market before 2015 in violation of the antitrust laws. *AndroGel*, 687 F. Supp. 2d at 1376. The district court determined that the proper framework for determining the legality of reverse payment settlements requires an examination of: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1377 (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005)). In applying this analysis, the district court held that the FTC failed to allege that the settlement agreements exceeded the scope of the brand-name patent. *Id.* at 1377.

13. See OFFICE OF MGMT. & BUDGET, *A NEW ERA OF RESPONSIBILITY: RENEWING AMERICA'S PROMISE 28* (2009), available at http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf (stating the new administration's intention of

Justice,¹⁴ Congress' efforts in devising a solution to the reverse payment dilemma have intensified.¹⁵ In early 2009, Senators Chuck Grassley and Herb Kohl introduced the Preserve Access to Affordable Generics Act, which was subsequently approved by the Senate Judiciary Committee.¹⁶ The proposed legislation makes presumptively unlawful any settlement resolving a patent infringement claim in which a generic challenger receives "anything of value" in exchange for its agreement not to "research, develop[], manufactur[e], market[], or s[ell]" its product for "any period of time."¹⁷ Then, it provides that this presumption can be overcome if the settling parties demonstrate that the "precompetitive benefits of the agreement outweigh the anticompetitive effects."¹⁸ In order to guide this analysis, the bill establishes an open-ended list of "competitive factors" to be considered by the fact finder.¹⁹

This Note analyzes the Grassley-Kohl response to the reverse payment dilemma. Part I illustrates the role of patent and antitrust law in the pharmaceutical industry, details the statutory provisions of the Hatch-Waxman Act, and examines the origin and evolution of reverse payment settlements. Part II outlines the key provisions of the Grassley-Kohl bill, concluding that, while a rebuttable presumption of illegality is the most appropriate legislative solution, the proposed legislation leaves important questions unanswered, namely, the proper scope of competitive factors to be weighed in determining whether the presumption of illegality has been overcome. Part III suggests that the competitive effects analysis under the proposed legislation should be broadened to the extent necessary to protect and promote the threefold interest in competition, innovation, and good-faith settlement of litigation.

barring "collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market").

14. See Brief for United States in Response to the Court's Invitation at 10, *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro IV), 544 F.3d 1323 (Fed. Cir. 2008) (No. 05-2851), 2009 WL 2429249 [hereinafter DOJ Brief] (advocating for a rule that would deem reverse payment settlements presumptively illegal).

15. Jon Leibowitz, Chairman, Fed. Trade Comm'n, Address at the Center for American Progress, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution) (June 23, 2009) ("[A]s Congress moves forward on health care reform, momentum to prohibit these agreements appears to be growing . . .").

16. S. 369, 111th Cong. § 1 (as reported by S. Comm. on the Judiciary, Oct. 15, 2009); see Press Release, Senate Comm. on Fin., Senate Committee Approves Grassley, Kohl Bill to Give Consumers Access to Lower-Priced Medicine (Oct. 15, 2009), available at <http://finance.senate.gov/newsroom/ranking/release/?id=fe363d3c-5478-4a54-9b39-811393985340>.

17. S. 369, § 3.

18. *Id.*

19. *Id.*

I. OVERVIEW OF PATENT & ANTITRUST LAW, THE HATCH-WAXMAN ACT, AND REVERSE PAYMENT SETTLEMENTS

Consumers rely on brand-name drug manufacturers to develop new medications.²⁰ At the same time, consumers rely on competition from generic firms to increase access to affordable medications once developed.²¹ Consequently, competition in the pharmaceutical industry invites the inevitable intersection of patent and antitrust policy.²² While the antitrust laws benefit consumers by prohibiting practices that unreasonably restrict competition between drug manufacturers,²³ the “legal monopoly” provided by the Patent Act benefits consumers by providing brand-name drug manufacturers, or “pioneers,” with the incentives to develop innovative medications.²⁴ The Hatch-Waxman Act encourages patent litigation as the “primary vehicle” through which the competing demands of patent and antitrust policy are to be reconciled.²⁵ The following section will examine the intersection of patent and antitrust law, the Hatch-Waxman Act, and reverse payment settlements.

A. *The Intersection of Antitrust and Patent Law in the Pharmaceutical Industry*

Justice Thurgood Marshall declared that the “[a]ntitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise.”²⁶ Economically, the antitrust laws are designed to prevent the acquisition of market power, the exercise of which allows an individual firm to restrict competition in order to raise prices above competitive levels to the detriment of consumers.²⁷ Section One of the Sherman Act declares “every contract, combination . . . or conspiracy, in restraint of trade” to be illegal.²⁸ Federal

20. JOHN R. THOMAS, CONG. RESEARCH SERV., RL 33717, PHARMACEUTICAL PATENT LITIGATION SETTLEMENTS: IMPLICATIONS FOR COMPETITION AND INNOVATION 22 (2008).

21. *Id.* at 22–23.

22. *See* Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1362 (Fed. Cir. 1999) (“The patent and antitrust laws are complementary, the patent system serving to encourage invention and the bringing of new products to market by adjusting investment-based risk, and the antitrust laws serving to foster industrial competition.”).

23. *See* THOMAS, *supra* note 20, at 12.

24. *See* Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (“The reason for the patent system is to encourage innovation and its fruits: new jobs and new industries, new consumer goods and trade benefits.”); *United States v. Studiengesellschaft Kohle*, 670 F.2d 1122, 1127 (D.C. Cir. 1981) (“The patent laws, authorized by the Constitution, were enacted by Congress to stimulate invention and reward innovation . . .”).

25. THOMAS, *supra* note 20, at 23.

26. *United States v. Topco Assocs.*, 405 U.S. 596, 610 (1972).

27. ANDREW I. GAVIL, WILLIAM E. KOVACIC & JONATHAN B. BAKER, ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS AND PROBLEMS IN COMPETITION POLICY 17 (Am. Casebook Ser., 2d ed. 2008).

28. 15 U.S.C. § 1 (2006).

courts have subsequently interpreted this provision as condemning “unreasonable” restraints of trade.²⁹

In order to determine whether a challenged practice violates § 1 of the Sherman Act, courts usually employ a “rule-of-reason” analysis, which takes into account the relevant history of the restraint, the facts relevant to the business, its condition before and after the restraint was imposed, and the restraint’s nature and effect.³⁰ This complex inquiry into challenged conduct involves substantial costs, in both time and judicial resources, which courts have alleviated through recognition of a *per se* rule of illegality.³¹ The *per se* rule is applied to categories of conduct “which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry” into anticompetitive effects or procompetitive justifications.³² Still, courts are careful not to depart from the rule-of-reason framework, since the *per se* rule does not permit any inquiry into procompetitive justifications.³³ Accordingly, “[i]t is only after considerable experience with certain business relationships that courts classify them as *per se* violations of the Sherman Act.”³⁴

The Patent Act confers upon the inventor, or “patentee,” the right to exclude others for a limited term from making, using, offering for sale, or selling the patented invention.³⁵ Although the right to exclude competition tends to result in higher prices and lower production than if competition were unrestrained, an expected legal monopoly increases long-term consumer welfare by providing pharmaceutical companies with the principal incentives to innovate.³⁶ In effect, it allows firms to recoup their front-end costs of

29. See, e.g., *Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 342–43 (1982).

30. *Chi. Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918); see *Maricopa*, 457 U.S. at 344 (“Once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it, it has applied a conclusive presumption that the restraint is unreasonable.”).

31. *Maricopa*, 457 U.S. at 343.

32. *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958). The categories of conduct deemed *per se* violations of the Sherman Act include price-fixing, market division, and group boycotts. *Id.*

33. *M & H Tire Co. v. Hoosier Racing Tire Corp.*, 733 F.2d 973, 977 (1st Cir. 1984).

34. *United States v. Topco Assocs.*, 405 U.S. 596, 607–08 (1972).

35. 35 U.S.C. § 271 (2006), *invalidated by Florida ex rel. Bondi v. U.S. Dept. of Health & Human Servs.*, No. 3:10-cv-91 (RV/EMT), 2011 WL 285683 (N.D. Fla. Jan. 31, 2011); see also *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (holding that patent laws are “an exception to the general rule against monopolies and to the right of access to a free and open market”)).

36. See Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 766–67 (2002) (pointing out that without patents, companies that invested in research and development at great risk may see their profits go to an after-market competitor).

discovery and development by preventing others from appropriating the value derived from that investment.³⁷

In order to enforce the right to exclude others from making, using, or selling the patented invention, the Patent Act grants the patentee the right to file an infringement action, at the attendant risk of its patent later being judged invalid or not infringed.³⁸ The filing of the infringement suit normally does not constitute a violation of the antitrust laws, even though it may have additional anticompetitive effects.³⁹ Antitrust liability does arise where a patentee brings in bad faith an infringement action (1) to enforce a patent it knows to be invalid, or (2) against a party it knows is not infringing its patent.⁴⁰ Nonetheless, with the Patent Act's provision permitting the filing of an infringement action, the Department of Justice observed that: "Congress thus struck a balance . . . between (1) encouraging innovation by providing for the enforcement of legitimate patent rights, and (2) protecting consumers' interest in a competitive marketplace by providing for the invalidation of undeserved patents."⁴¹ Likewise, in the pharmaceutical industry, the Hatch-Waxman Act encourages patent litigation between brand-name drug manufacturers and generic firms as the principal mechanism through which the competing interests in competition and innovation are to be reconciled.⁴²

B. Striking a Balance between Competition & Innovation: The Hatch-Waxman Prescription

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, more commonly known as the Hatch-Waxman Act.⁴³ Prior to its enactment, manufacturers seeking to market generic drugs had to undergo an FDA approval process comparable to that required of pioneer manufacturers, which involved highly expensive and time-consuming human clinical testing and safety studies.⁴⁴ These studies were required even if they duplicated those previously conducted on the brand-name drug.⁴⁵ Moreover, generic manufacturers could not begin the approval process until the pioneer's patent expired, because beginning earlier would constitute an act of

37. *Id.* at 767.

38. 35 U.S.C. § 281. The possible defenses against a charge of patent infringement include: 1) noninfringement, 2) unenforceability, and 3) invalidity. *Id.* § 282(1).

39. *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000).

40. 2 WILLIAM C. HOLMES, INTELLECTUAL PROPERTY AND ANTITRUST LAW § 38:03 (West 2004) (1983).

41. DOJ Brief, *supra* note 14, at 13.

42. THOMAS, *supra* note 20, at 9–10.

43. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of U.S.C.).

44. FTC 2002 STUDY, *supra* note 8, at 3–4.

45. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 n.2 (11th Cir. 2005).

infringement.⁴⁶ Thus, the timing and process of FDA approval effectively extended the life of the pioneer's patent.⁴⁷ The purpose of the Act, therefore, was to promote increased generic competition while still preserving the incentives for pioneer manufacturers to develop new medicines.⁴⁸

To encourage generic competition, the Hatch-Waxman Act relaxed the clinical testing procedures required of generic drug manufacturers seeking FDA approval.⁴⁹ Pharmaceutical medications, both pioneer and generic, must be approved as safe and effective prior to marketing.⁵⁰ In order for a pioneer drug manufacturer to demonstrate that its product is safe and effective, it must conduct human clinical trials and submit the results in a New Drug Application (NDA).⁵¹ For the generic drug manufacturer, however, the Hatch-Waxman Act establishes an expedited procedure.⁵² The generic firm does not need to conduct human clinical trials, provided that the active ingredient in the generic product is the bioequivalent of the brand-name drug.⁵³ Instead, it "must conduct tests that show the generic drug is the same as the pioneer drug and that it will be properly manufactured and labeled."⁵⁴ Then, it may submit those results in an Abbreviated New Drug Application (ANDA).⁵⁵

When the generic firm files the ANDA, it must make one of four certifications: (I) the pioneer manufacturer did not file a patent; (II) the pioneer's patent has expired; (III) the generic drug will not be marketed until expiration of the pioneer's patent; or (IV) the pioneer's patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."⁵⁶ If an ANDA filer makes a Paragraph IV certification, it must notify the patentee that it is seeking FDA approval to

46. FTC 2002 STUDY, *supra* note 8, at 4.

47. *Id.*

48. Weiswasser & Danzis, *supra* note 7, at 590.

49. *Id.*

50. Todd A. Rathe, Comment, *Medical Device Experimental Use Exception in Patent Infringement: Ely Lilly v. Medtronic*, 16 J. CORP. L. 625, 646 (1991).

51. Weiswasser & Danzis, *supra* note 7, at 587.

52. 21 U.S.C. § 355(j) (2006), *invalidated by Florida ex rel. Bondi v. U.S. Dept of Health & Human Servs.*, No. 3:10-cv-91 (RV/EMT), 2011 WL 285683 (N.D. Fla. Jan. 31, 2011); *see* CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xii (1998) [hereinafter CBO STUDY] (noting that the Hatch-Waxman Act "reduced the average delay between patent expiration and generic entry from more than three years to less than three months . . . [and] increased the proportion of brand-name drugs that face generic competition once their patents expire").

53. 21 U.S.C. § 355(j)(2)(A)(iv).

54. *Id.* § 355(j)(2)(A)(iv)-(v); H.R. REP. NO. 98-857, pt. 1, at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649.

55. H.R. REP. NO. 98-857, at 16.

56. 21 U.S.C. § 355(j)(2)(A)(vii).

market the generic drug.⁵⁷ Upon receipt of the notice, the patent-holder retains the right to sue the ANDA filer for patent infringement, because a Paragraph IV certification is considered a constructive act of infringement.⁵⁸ Then, if an infringement claim is asserted within forty-five days of receiving the ANDA filer's notice, the patent-holder is entitled to a thirty-month stay of FDA approval of the ANDA.⁵⁹

The purpose of the Hatch-Waxman Act's provision governing Paragraph IV certifications is to ensure that weak patents on brand-name medications do not escape invalidation and its fruits, generic competition and lower drug prices.⁶⁰ To encourage generic firms to make Paragraph IV certifications challenging the validity of a brand-name patent (or proving the non-infringement of the generic version), the Hatch-Waxman Act rewards the first Paragraph IV ANDA filer with 180 days of marketing exclusivity, during which the FDA cannot approve other ANDAs for the same drug.⁶¹ Thus, the "first-filer" enjoys a six-month market duopoly with the brand-name drug manufacturer, often worth millions of dollars.⁶² However, this "statutory bounty" is forfeited if the first ANDA filer fails to market the generic product by the later of the date that is (1) seventy-five days after the approval of its application is made effective or thirty months after it was submitted, whichever is earlier; or (2) seventy-five days after the date on which a court enters judgment that the NDA filer's patent is invalid or not infringed, a court signs a settlement agreement that includes a finding that the patent is invalid or not infringed, or the patent information is withdrawn by the NDA filer.⁶³

57. *Id.* § 355(j)(2)(B)(i).

58. *Id.* § 355(j)(5)(B)(iii).

59. *Id.* The FDA will withhold approval of the ANDA until the earliest of three alternative events: 1) the expiration of the thirty-month period beginning on the date of receipt of the ANDA filer's notice; 2) the date on which a court enters judgment that the patent is either invalid or not infringed; or 3) expiration of the patent term, if a court finds that the patent is valid and infringed. *Id.*

60. See FTC 2002 STUDY, *supra* note 8, at 7 (noting that the 180-day provision gives generic drug manufacturers who file under Paragraph IV a motive to either litigate or design around weak patents).

61. 21 U.S.C. § 355(j)(5)(B)(iv); see Weiswasser & Danzis, *supra* note 7, at 603.

62. 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, 450 (2008).

63. 21 U.S.C. § 355(j)(5)(D)(i). Alternatively, the statutory bounty is forfeited if the first ANDA filer: 1) withdraws the application; 2) withdraws or amends the Paragraph IV certification; 3) fails to obtain tentative approval of the application within thirty months after the date on which it was filed; or 4) enters into an agreement with another applicant, the FTC or the Attorney General files a complaint, and a finding is made by the FTC or a court that the agreement has violated the antitrust laws. *Id.* § 355(j)(5)(D)(i)(II)-(V).

Together with the numerous provisions designed to increase generic competition, the drafters of the Hatch-Waxman Act took measures to preserve the market incentives for innovation. First, the Hatch-Waxman Act provides that the patent term is “extended by the time equal to the [FDA] regulatory review period for the approved product.”⁶⁴ This allows the patentee to regain patent life lost as a result of the lengthy FDA-mandated testing and approval procedure.⁶⁵ It is intended to “create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval.”⁶⁶

In conjunction with patent term restoration, the Hatch-Waxman Act provides extended market exclusivity for new chemical entities (NCE) and new clinical investigations.⁶⁷ If the drug contains an NCE, the NDA holder is entitled to an additional five years of market exclusivity.⁶⁸ The effect of this provision is to prevent the submission of another patent application relying on the NDA’s safety and efficacy data.⁶⁹ If the NDA contains “reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant,” then the NDA holder is entitled to three additional years of market exclusivity.⁷⁰ The effect of this provision is to prevent for three years the final approval of an ANDA “for the conditions of approval of such drug.”⁷¹

In sum, the Hatch-Waxman Act has been largely successful in balancing the dual interests in innovation and competition in the pharmaceutical industry.⁷² That success, however, has not come without its problems. An unintended consequence of the Hatch-Waxman Act was to create strong incentives for brand-name drug manufacturers and Paragraph IV ANDA filers

64. 35 U.S.C. § 156(c) (2006). There are five eligibility requirements for patent term restoration: 1) the patent term has not yet expired; 2) the patent term has never been previously extended; 3) the application for extension is properly submitted; 4) the drug has been subject to a regulatory review period before its commercial marketing or use; and 5) the permission for the commercial marketing or use is the first permitted marketing or use of the drug. *Id.* § 156(a).

65. Weiswasser & Danzis, *supra* note 7, at 590–91.

66. H. R. REP. 98-857, pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

67. Weiswasser & Danzis, *supra* note 7, at 592–93.

68. *Id.* at 592. The statute provides five-year exclusivity to any new “active ingredient.” 21 U.S.C. § 355(j)(5)(D)(ii). The FDA has interpreted this provision as applying only to new “active moieties.” Weiswasser & Danzis, *supra* note 7, at 592. Thus, an NCE for purposes of the five-year exclusivity provision means “a drug that contains no active moiety that has been approved by FDA in any other application.” *Id.* (quoting 21 C.F.R. § 314.108(a)).

69. Weiswasser & Danzis, *supra* note 7, at 592.

70. 21 U.S.C. §§ 355(c)(3)(E)(iii), 355(j)(5)(F)(iii).

71. *Id.* §§ 355(c)(3)(E)(iii), 355(j)(5)(F)(iii).

72. *See* CBO STUDY, *supra* note 52, at xiii (concluding that the decline in revenues of pioneer drug companies resulting from increased generic competition has not made drug development, on average, unprofitable).

to enter potentially anticompetitive settlement arrangements using payments flowing in “reverse,” from the patent holder, or the plaintiff, to the alleged infringer, or the defendant.⁷³ These reverse payment settlements can delay the marketing of generic versions of blockbuster medications, potentially costing American consumers billions of dollars each year.⁷⁴

C. *A Side Effect of the Hatch-Waxman Act: Reverse Payment Settlements*

Litigation between a brand-name firm and Paragraph IV ANDA filer can end with either a finding of infringement, obstructing generic competition, or a finding of invalidity or non-infringement, allowing generic entry.⁷⁵ Like other forms of patent litigation,⁷⁶ however, the litigants may decide to settle rather than proceed to trial.⁷⁷ Paragraph IV settlements challenged as violations of the antitrust laws entail: 1) some form of payment by the pioneer to the generic firm; and 2) an agreement by the generic firm to delay marketing its product for some period of time.⁷⁸ Although the Patent Act grants pioneers holding a *valid* patent the right to exclude infringing competition, the possibility that a pioneer, lacking confidence in the strength of its patent, is intentionally evading a judgment of invalidity or non-infringement, thereby purchasing more reduced competition than the patent can provide, raises competitive concerns and forms the basis of possible antitrust liability.⁷⁹ The following section explores both the origins and evolution of reverse payment settlements.

73. See *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro II)*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003) (“[I]n creating an artificial act of infringement (the ANDA IV filing), the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry This statutory scheme affects the parties’ relative risk assessments and explains the flow of settlement funds and their magnitude.”) (citations omitted).

74. See FTC STAFF STUDY, *PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2* (2010) [hereinafter *FTC 2010 STUDY*] (estimating that reverse payment settlements cost consumers \$3.5 billion per year).

75. THOMAS, *supra* note 20, at 1.

76. Defendants-Appellees in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* stated the following:

In traditional patent litigation, the accused infringer is making, using, or selling the claimed invention and at risk of paying infringement damages. Such cases usually settle with the parties compromising on damages. The accused infringer usually pays to settle to reduce its risk of paying damages. But consideration also flows from the patent owner to the accused infringer because the innovator settles for less than its maximum provable damages. Thus, both parties compromise, discounting the claimed damages based on their risk assessments.

Brief of Defendants-Appellees at 26, *In re Ciprofloxacin Hydrochloride Antitrust Litigation (Cipro IV)*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097), 2008 WL 2446896.

77. See THOMAS, *supra* note 20, at 1.

78. *Id.*

79. DOJ Brief, *supra* note 14, at 22.

1. The “Natural Byproduct” of the Paragraph IV Certification Process

Generally, courts and legal scholars agree that reverse payment settlements arise out of the Hatch-Waxman Act’s unique statutory framework.⁸⁰ The Hatch-Waxman Act encourages pioneers to file an otherwise weak patent infringement claim against a Paragraph IV ANDA filer because the claim triggers the automatic thirty-month stay of FDA approval.⁸¹ Even if the pioneer asserts a weak infringement claim, the ANDA filer may still find it more advantageous to settle, rather than go to trial, because the total producer profits in a monopoly exceed the total producer profits in a duopoly, with the result that the pioneer’s possible loss at trial greatly exceeds the ANDA filer’s possible gain.⁸² Both parties will be better off, therefore, if the ANDA filer ceases its attempt to market the patented product and accepts a payment that is: 1) less than the pioneer’s possible loss at trial; and 2) more than the ANDA filer’s possible gain at trial.⁸³ In this scenario, the patent-holder is effectively paying the generic firm to stay out of the market, even though it may have a legal right to enter.⁸⁴

Even where a pioneer has a high probability of success at trial, it has an incentive to settle the litigation.⁸⁵ Professor Thomas Cotter stresses that an agreement by the ANDA filer not to enter the market guarantees monopoly profits for a risk-averse pioneer in the near-term.⁸⁶ Moreover, the generic challenger suffers no loss and avoids the possibility of having to pay damages for patent infringement.⁸⁷ Finally, for the pioneer, Professor Hemphill points out that reaching settlement with the first Paragraph IV ANDA filer de-incentivizes subsequent ANDA filers from challenging the patent, given that

80. *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro II), 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (“[S]o-called reverse payments are a natural by-product of the Hatch-Waxman process.”); Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1076 (2004) (“The Hatch-Waxman Act . . . contains several provisions the unintended consequence of which is to provide a greater incentive than would otherwise exist for the parties to some patent suits to agree to settlements involving reverse payments.”).

81. Cotter, *supra* note 80, at 1079–80.

82. *Id.* at 1080.

83. *Id.*

84. *Id.*

85. *See Schering-Plough v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (“Due to the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.”) (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003)).

86. *See Cotter, supra* note 80, at 1079.

87. *Id.*

the later-filing generic firms become ineligible for the highly lucrative 180-day exclusivity period.⁸⁸

2. The Evolution of Reverse Payment Settlements

Professor Hemphill traces the evolution in reverse payment settlements since 1984 by collecting and synthesizing publicly available information regarding the frequency and terms of settlement.⁸⁹ His study finds that early reverse payment settlements involved simple cash payments by brand-name firms to generic challengers.⁹⁰ In exchange for the payment, the generic firm agreed to delay marketing its product for the entire remainder of the patent term.⁹¹ From 1993 to 1997, Hatch-Waxman settlements for five different drugs included a cash payment in exchange for delayed generic entry.⁹²

In 1997, brand-name firms began engaging in side deals with generic challengers, rather than making outright cash payments in exchange for delayed entry.⁹³ Professor Hemphill shows that this evolution was likely a response to increased antitrust enforcement and a 1998 judgment, which concluded that a first-filing generic firm could retain its right to the 180-day exclusivity period even if it settled the litigation.⁹⁴ Subsequent to that decision, brand-name firms could offer a first-filing ANDA challenger payment in the form of “retained exclusivity,” that is, guaranteed access to the statutory bounty as a substitute for an outright cash payment.⁹⁵ Generic firms, therefore, became more willing to settle the litigation and agree to a later entry date, rather than proceed to trial and risk losing the right to duopoly profits.⁹⁶ In Hatch-Waxman settlements involving several blockbuster drugs, such as Provigil, Effexor XR, and Plavix, payment took the form of retained exclusivity.⁹⁷

88. See C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 635 (2009) (“[B]uying off the first filer is an effective means to remove the most potent entry threat.”). Not surprisingly, the majority of agreements that combine compensation with delayed entry occur between the pioneer and first-filer. See FTC 2010 STUDY, *supra* note 74, at 5.

89. Hemphill, *supra* note 88, at 645–47.

90. *Id.* at 657.

91. *Id.*

92. *Id.* at 649.

93. *Id.* at 649, 657–58.

94. Hemphill, *supra* note 88, at 658 (citing *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff’d*, 140 F.3d 1060 (D.C. Cir. 1998) (holding that the Hatch-Waxman Act does not include a “successful defense” requirement, nor does it require that the parties litigate the patent claim)).

95. *Id.*

96. *Id.* at 658–59.

97. *Id.* at 649.

Commentators have identified additional side deals, which entail payments by the patent-holder to the generic firm for IP licenses, for supplying raw materials, and for helping to promote and develop other products.⁹⁸ In a more sophisticated scenario, Professor Hemphill observes that pioneers disguise transfers of value for delayed entry by overpaying the generic firm for an unrelated product license.⁹⁹ For example, the generic firm may transfer for consideration an overvalued product license to the pioneer, allowing the pioneer to attribute its consideration to the product license rather than to the generic firm's delayed entry.¹⁰⁰

Recently, the FTC has expressed particular concern over agreements in which brand-name firms agree not to introduce "authorized generics" during the ANDA filer's 180-day exclusivity period.¹⁰¹ An "authorized generic," or "AG," is a generic version of a drug marketed by the *brand-name* firm.¹⁰² The Hatch-Waxman Act's 180-day exclusivity provision protects the generic entrant from other generic competition, but it does not protect generic firms from AG competition.¹⁰³ Accordingly, since AGs can substantially detract from the generic entrant's duopoly rents during the exclusivity period, an agreement by the pioneer to delay introduction of AG competition effectively amounts to a payment from the brand-name firm to the generic challenger.¹⁰⁴

As illustrated, reverse payment settlements continue to evolve in ways that increasingly obscure whether a payment for delay has been made. In an effort to give antitrust agencies "access to information about secret deals between drug companies," Congress provided in the 2003 Medicare Modernization Act (MMA) certain reporting requirements relating to reverse payment settlements.¹⁰⁵ Section 1112 of the MMA provides that settlement agreements between a pioneer and Paragraph IV ANDA challenger must be filed with the FTC and Department of Justice, provided that the agreement relates to: 1) the manufacture, marketing, or sale of the brand-name drug; 2) the manufacture, marketing, or sale of the generic drug; or 3) the 180-day exclusivity period.¹⁰⁶

98. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 78 (2009).

99. Hemphill, *supra* note 88, at 663–65.

100. *Id.*

101. See FTC 2010 STUDY, *supra* note 74, at 5.

102. *Id.* From 2004–2008, approximately 25% of settlement agreements involving first-filer generics involved both an agreement by the brand not to launch its AG and an agreement by the first-filer to delay market entry. *Id.*

103. *Id.*

104. See *id.*

105. Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 187–88 (2008) (quoting 148 CONG. REC. S11,340 (daily ed. Nov. 18, 2002) (statement of Sen. Patrick Leahy)).

106. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2065, 2461–62 (codified at 21 U.S.C. § 355, *invalidated by Florida ex*

An FTC Staff Study observes that, despite implementation of these statutory filing requirements, the MMA did not provide substantive standards relating to the legality of reverse payment settlements.¹⁰⁷ Unabated, brand-name drug manufacturers and generic firms continue to engage in potentially anticompetitive reverse payment settlements.

D. Reverse Payments in the Federal Courts and Congress' Options for Devising a Solution

The FTC has challenged, and continues to challenge, reverse payment settlements in federal courts. Yet the Second, Eleventh, and Federal Circuits—relying on the Congressional determination that “[a] patent shall be presumed valid”—have generally refused to condemn reverse payment settlements where the agreement has not exceeded the scope of the patent.¹⁰⁸ Unless the Supreme Court provides guidance on directly addressing anticompetitive concerns inherent in reverse payment settlements, Congress, with strong support from the FTC, will continue to work toward a legislative resolution on the proper scope of antitrust liability.¹⁰⁹ First, this section will examine the permissive approaches adopted by the federal courts determining the proper scope of antitrust liability. Second, it will explain the legislative options available to Congress, concluding that the codification of a rule-of-reason analysis is the most appropriate legislative solution.

1. The Federal Courts of Appeals Vary in their Analysis of Antitrust Liability

The Circuit Courts of Appeals have taken somewhat varied approaches to determining whether reverse payment settlements run afoul of the Sherman Act. The Eleventh Circuit held that reverse payment settlements should not be

rel. Bondi v. U.S. Dept of Health & Human Servs., No. 3:10-cv-91 (RV/EMT), 2011 WL 285683, (N.D. Fla. Jan. 31, 2011)).

107. THOMAS, *supra* note 20, at 10.

108. 35 U.S.C. § 282 (2006); *see, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro IV), 544 F.3d 1323, 1334 (Fed. Cir. 2008); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306–09 (11th Cir. 2003) (discussing the impact of subsequent invalidity on settlement agreements and holding that subsequent invalidity does not affect settlement agreements).

109. *See, e.g., Hearings, supra* note 6, at 140 (“The Commission strongly supports a legislative remedy for the problem of exclusion payment settlements”); *Pay to Delay: Are Patent Settlements that Delay Generic Drug Market Entry Anti-Competitive?: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 10 (2009) (statement of the FTC) (“[T]he Commission strongly supports H.R. 1706, which would prohibit these anticompetitive settlements.”); Leibowitz, *supra* note 15, at 11 (“Enacting legislation is always an uphill battle, but under these circumstances, I like our odds.”).

subject to either per se or rule-of-reason condemnation.¹¹⁰ Relying on the statutory presumption of patent validity, the Eleventh Circuit has found that a determination of “antitrust liability requires an examination of: 1) the scope of the exclusionary potential of the patent; 2) the extent to which the agreement exceeds that scope; and 3) the resulting anticompetitive effects.”¹¹¹ The Federal and Second Circuits have adopted this approach,¹¹² with the Federal Circuit further noting that, absent fraud before the Patent and Trademark Office (PTO) or evidence of sham litigation, it is not necessary that the court consider the validity of the underlying patent.¹¹³

In contrast, the Sixth Circuit held that a reverse payment settlement was a “classic example of a *per se* illegal restraint of trade.”¹¹⁴ Yet, as noted by one observer, the court did not expressly indicate that the mere existence of a reverse payment rendered the settlement per se unlawful.¹¹⁵ Instead, the court focused on the fact that the pioneer’s payment to the generic firm kept the generic version of the drug off the market, even after it obtained FDA approval.¹¹⁶ Moreover, the court expressed much concern with the generic firm’s refusal to give up its 180-day exclusivity period, which subsequently delayed entry of all third-party generic firms seeking FDA approval.¹¹⁷

Despite the different result reached in the Sixth Circuit, the decision can be reconciled on the unique facts of the case.¹¹⁸ The settlement reviewed by the Sixth Circuit, unlike the settlements reviewed in the other courts, restricted the generic firm’s ability to market drugs not covered by the patent claims, thereby reaching beyond the patent’s “exclusionary zone.”¹¹⁹ Consistent with the Solicitor General’s 2006 recommendation, therefore, the Supreme Court declined to decide the reverse payment issue because, in fact, no genuine split

110. See *Schering-Plough*, 402 F.3d at 1065; *Valley Drug Co.*, 344 F.3d at 1311 & n.27.

111. *Schering-Plough*, 402 F.3d at 1066 (quoting *Valley Drug Co.*, 344 F.3d at 1312).

112. See, e.g., *Cipro IV*, 544 F.3d at 1335; *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006).

113. See, e.g., *Cipro IV*, 544 F.3d at 1336.

114. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

115. Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 544 (2007).

116. *In re Cardizem*, 332 F.3d at 907.

117. *Id.*

118. See *Cipro IV*, 544 F.3d at 1335 (“[A]lthough the Sixth Circuit found a per se violation of the antitrust laws in *In re Cardizem*, the facts of that case are distinguishable from this case and from the other circuit court decisions.”).

119. See *id.* (finding that the agreement reviewed by the Sixth Circuit “clearly had anticompetitive effects outside the exclusion zone of the patent” because it delayed third-party generic manufacturers and provided that the ANDA filer would not market non-infringing versions of the generic drug at issue).

in the circuits existed.¹²⁰ Because the Supreme Court again denied certiorari in 2006,¹²¹ the FTC asked Congress to help devise a solution to the reverse payment dilemma in 2009.¹²²

2. The Legislative Options Available to Congress

Devising an approach for determining the scope of antitrust liability is not an easy task for Congress.¹²³ On one hand, the Hatch-Waxman Act provides a statutory framework ripe for anticompetitive settlement arrangements. As Professor Hemphill's longitudinal study reveals, brand-name firms rarely transact with generics outside of the Hatch-Waxman context for the products and services that form the basis of side deals, supporting the inference that the side deals are merely a device masking payment for delay.¹²⁴ Yet, as other scholars have noted, given the Hatch-Waxman's peculiar incentives, "[r]everse payments may be consistent with a high probability of success on the merits for Plaintiff, in which case they are no more offensive to competition policy than any other settlement of patent litigation."¹²⁵ Thus, many, but not all, reverse payment settlements run afoul of the Sherman Act. With all the difficulties inherent in determining the proper scope of antitrust liability, the Congressional Research Service concludes that lawmakers are left with three possible options: 1) await further judicial developments; 2) pass legislation imposing a per se rule of illegality; or 3) pass legislation codifying a rule-of-reason framework of analysis.¹²⁶ Congress, led by Senators Chuck Grassley and Herb Kohl, has decidedly settled on the third approach.

II. OVERVIEW OF THE GRASSLEY-KOHL BILL

In February 2009, Senators Grassley and Kohl introduced the Preserve Access to Affordable Generics Act, co-sponsored by Senators Russ Feingold, Dick Durbin, and Sherrod Brown.¹²⁷ The bill provided sweeping condemnation of reverse payment settlements, effectively codifying a per se

120. See Brief for the United States as Amicus Curiae at 16–20, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441 (arguing that there is no circuit split justifying Supreme Court review).

121. *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006).

122. See *supra* note 109 and accompanying text.

123. See Hemphill, *supra* note 88, at 632 (highlighting the difficulty in assessing the proper scope of antitrust liability for reverse payment settlements).

124. *Id.* at 633; see *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1073 (11th Cir. 2005) (citing *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 282–83 (6th Cir. 1898) (“Even restraints ancillary in form can in substance be illegal if they are part of a general plan to gain monopoly control of a market.”)).

125. Cotter, *supra* note 80, at 1080.

126. THOMAS, *supra* note 20, at 18–19.

127. S. 369, 111th Cong. (2009).

rule of illegality.¹²⁸ On October 15, 2009, however, the Senate Judiciary Committee voted to pass a compromise version of the bill, which provided for a rebuttable presumption of illegality, rather than a per se condemnation of reverse payment settlements.¹²⁹ Pursuant to the proposed legislation, a reverse payment settlement between a patent holder and an ANDA filer is deemed presumptively unlawful.¹³⁰ The settling defendants can rebut this presumption if they show by clear and convincing evidence that the agreement's procompetitive benefits outweigh its anticompetitive effects.¹³¹

A. The Grassley-Kohl Remedy: A Rebuttable Presumption of Illegality

The Grassley-Kohl bill provides that any agreement resolving or settling, on a final or interim basis, a patent infringement claim "shall be presumed to have anticompetitive effects and be unlawful if (i) an ANDA filer receives anything of value; and (ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time."¹³² The bill reaches any agreement entered into within thirty days of the actual settlement date, and any other agreement that is contingent upon or related to the settlement of the patent infringement claim.¹³³ The bill does not prohibit settlement agreements pursuant to which the NDA holder only pays the ANDA filer reasonable litigation expenses not to exceed \$7,500,000.¹³⁴

In addition, the Grassley-Kohl bill permits defendants to rebut the presumption of illegality.¹³⁵ To do so, the settling defendant must demonstrate with "clear and convincing evidence" that the settlement agreement will have procompetitive benefits that outweigh its anticompetitive effects.¹³⁶ In determining whether the settling parties have met this burden, the following competitive factors shall be considered by the fact finder:

- (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;

128. *Id.* § 29.

129. S. REP. NO. 111-123, at 7 (2010). In late 2009, an identical version of the bill was introduced by Senator Herb Kohl as an amendment to the healthcare reform package. *See* 155 CONG. REC. S12,335 (daily ed. Dec. 3, 2009) (statement of Sen. Herb Kohl).

130. S. 369, § 28(a)(2)(A).

131. *Id.* § 28(a)(2)(B).

132. *Id.* § 28(a)(2)(A).

133. *Id.* § 28(h)(2).

134. *Id.* § 28(d)(2).

135. S. 369, § 28(a)(2)(B).

136. *Id.*

- (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.¹³⁷

In weighing these competitive factors, the proposed legislation provides that the fact finder shall not presume that that generic "entry would not have occurred until the expiration of the relevant patent," or that a provision in the agreement providing for generic entry prior to patent expiration means that the agreement is procompetitive.¹³⁸ However, the legislation does provide that "such evidence may be relevant to the fact finder's determination" of the procompetitive benefits of the agreement.¹³⁹

B. A Rebuttable Presumption of Illegality is an Effective Legislative Solution

Codifying a presumption of illegality, which the settling defendants can rebut under a rule-of-reason framework, is the most appropriate legislative solution. The following analysis first will show that the presumption of illegality is consistent with recent scholarship, which demonstrates that reverse payment settlements inherently raise competitive concerns. Given the inherently anticompetitive nature of these settlements, as scholars point out, it is better that the defendants bear the burden of showing procompetitive benefits, as opposed to antitrust authorities and private plaintiffs, who lack easy access to such information. Second, this section will show that, in keeping with the public policy favoring settlement of litigation, the rule-of-reason framework embodied in the proposed legislation avoids false condemnation of pro-competitive agreements. Finally, this section will show that the bill is consistent with modern antitrust jurisprudence, which largely has abrogated the rigid per se rule in favor of a more precise focus on the anticompetitive effects of business practices challenged as violations of the antitrust laws.

In *California Dental Association v. Federal Trade Commission*, the Supreme Court discussed the intermediate "quick look" analysis of competitive

137. *Id.* § 28(b).

138. *Id.* § 28(c)(1).

139. *Id.* § 28(c)(2).

restraints.¹⁴⁰ The quick-look rests on the notion that certain business practices are so inherently anticompetitive that the Court, without an “elaborate industry analysis,” is justified in shifting the burden to the defendants to show procompetitive effects.¹⁴¹ Not only are reverse payment settlements inherently anticompetitive, as scholars observe, the complexity of reverse payment settlements has made it increasingly difficult for courts and the FTC to determine the reasonableness of reverse payments without launching a complex inquiry into the terms of the agreement and the business judgment of the settling parties.¹⁴² A reverse payment, for example, may be the sum of numerous side deals, including co-promotion agreements, IP licenses, supply agreements, no-authorized-generic provisions, and other development terms.¹⁴³ In this scenario, the settling parties should presumably have the records showing the multifarious settlement terms, particularly in light of the MMA reporting requirements.¹⁴⁴ It follows that any legislation should presume the illegality of the reverse payment settlement and then place the burden of bringing forth evidence of the payment’s reasonableness on the settling defendants, who have the most immediate access to such information.¹⁴⁵ The Grassley-Kohl bill appropriately adopts this approach.

Additionally, the Grassley-Kohl bill balances the public policy favoring settlement of litigation against the inherently anticompetitive nature of reverse payments. A legislative solution should recognize that settlement of patent infringement litigation is a voluntary, efficiency-enhancing arrangement that

140. 526 U.S. 756, 769–71 (1999) (ultimately holding that the lower court incorrectly applied the quick-look analysis to the case at hand).

141. *Id.* at 763 (quoting the lower court decision, 128 F.3d 720, 727 (9th Cir. 1997)) (citations omitted).

142. *See Carrier, supra* note 98, at 79 (noting that the increasingly nuanced form of settlements is making it harder for the FTC and antitrust plaintiffs to “track down evidence of payments for delay”); *Hearing on H.R. 1706, Protecting Consumer Access to Generic Drugs Act of 2009, Before the H. Comm. on Energy and Commerce and Subcomm. on Commerce, Trade, and Consumer Prot.*, 111th Cong. 9 (2009) (statement of C. Scott Hemphill). Hemphill adds that side deals involving a non-financial exchange of consideration may be facially absurd because it is clear that the brand-name firm does not need, for example, new drug development unrelated to its core business. *Id.* at 10. In other situations, however, the brand-name firm may be attempting to expand its core business, and the generic may have expertise in the matter relating to the side deal. *Id.*

143. In *Schering-Plough v. FTC*, for example, payment by the brand-name firm to the generic challenger comprised a three-part licensing deal, which called for Schering to pay \$60 million in initial royalty fees, \$10 million in milestone royalty payments, and 10% to 15% royalties on sales. 402 F.3d 1056, 1060 (11th Cir. 2005).

144. 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, 1061–62 (2008).

145. *Carrier, supra* note 98, at 79.

the law generally encourages.¹⁴⁶ Yet, as recently argued by the Department of Justice, a workable rule cannot encourage settlements to the extent that the patent-holder can evade entirely the risk of patent invalidation.¹⁴⁷ Along those lines, the Grassley-Kohl bill's rebuttable presumption of illegality prevents the patent-holder from "contract[ing] [its] way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract."¹⁴⁸ At the same time, it properly allows the settling defendants to rebut the presumption by setting forth evidence of the agreement's procompetitive benefits, if any exist.¹⁴⁹ Thus, the proposed legislation reconciles the conflicting interests in generic drug competition and settlement of litigation.

Finally, the proposed legislation's rule-of-reason framework is consistent with modern antitrust jurisprudence. Early cases arising under § 1 of the Sherman Act relied on a rigid dichotomy of competitive effects analysis, subjecting restraints of trade either to rule-of-reason or per se treatment.¹⁵⁰ Beginning in the late-1970s, however, the Supreme Court set out to place significant limits on the application of the per se rule¹⁵¹ and move "from a dichotomous categorical approach to a more nuanced and case-specific inquiry."¹⁵² Accordingly, it began to "reframe antitrust rules around core economic concepts of anticompetitive effect, market power, and efficiencies," thereby eroding the long-standing analytical dichotomy.¹⁵³ As a result, there has been a movement away from irrebuttable presumptions of

146. *See* *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[T]here is a compelling public interest and policy in upholding and enforcing settlement agreements voluntarily entered into because enforcement of settlement agreements encourages parties to enter into them—thus fostering judicial economy.") (internal quotations omitted).

147. *See supra* note 14 and accompanying text.

148. DOJ Brief, *supra* note 14, at 14.

149. *See supra* Part II.A.

150. *GAVIL ET AL.*, *supra* note 27, at 158–59; *see* *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 222 (1940) ("Whatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike.").

151. *See* *Cont'l T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 57 (1977) (rejecting the application of the per se rule as it applied to non-price vertical restraints); *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19–20 (1979) (de-classifying a blanket licensing arrangement as per se illegal "price-fixing" based on consideration of the arrangement's ability to generate economic efficiencies, such as increased output and lower costs); *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 99, 100 (1984) (refusing to apply a per se rule to an agreement by the NCAA limiting the number of intercollegiate football games that could be televised).

152. *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 33–34 (D.C. Cir. 2005).

153. *GAVIL ET AL.*, *supra* note 27, at 165.

unreasonableness to a more focused analysis of anticompetitive effects.¹⁵⁴ In light of these developments, codifying a per se rule banning reverse payment settlements would constitute a significant departure from modern antitrust policy. The Grassley-Kohl bill appropriately focuses on the anticompetitive effects, rather than pigeon-holing reverse payment settlements into the per se category of competitive restraints.

III. FILLING IN THE GAPS OF THE GRASSLEY-KOHL BILL

The proposed legislation leaves important questions unanswered. For one, it does not identify how the settling defendants can show that a reverse payment in excess of avoided litigation costs is procompetitive, leaving wide open the field of possible “competitive factors” to be considered by the fact finder. Moreover, its focus on the direction and timing of payment leaves open the possibility that creative lawyers can structure agreements that pass muster under the legislation.

The following analysis of the Grassley-Kohl bill proceeds by showing that a reverse payment settlement providing for generic entry prior to patent expiration should carry significant evidentiary weight. Then, it shows why the fact finder should consider the indirect costs of protracted litigation, as well as settings in which a reverse payment, although in excess of avoided litigation costs, may be otherwise reasonable. Next, it argues in favor of a limited inquiry into the merits of the patent claim as qualifying as a “competitive factor.” This section concludes by demonstrating why the bill’s narrow focus on the direction and timing of payment leaves much room for crafty lawyers to structure lawful agreements that have the same anticompetitive effects of a reverse payment settlement involving a basic cash payment, and proposes possible solutions.

A. *A Settlement Providing for Generic Entry Prior to Patent Expiration Should Carry Significant Evidentiary Weight*

The Grassley-Kohl bill provides that the fact finder “shall consider . . . the value to consumers of [generic] competition . . . allowed under the agreement.”¹⁵⁵ At the same time, however, it provides that the fact finder “shall not presume” that a generic entry date set before patent expiration (i.e., the value of competition to consumers) means that the agreement is procompetitive, although it “may be relevant” to the fact finder’s ultimate competitive effects determination.¹⁵⁶ Despite these seemingly contradictory

154. *See Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692 (1978) (holding that, regardless of whether the per se rule or rule-of-reason analysis is applied, “the purpose of the analysis is to form a judgment about the competitive significance of the restraint”).

155. S. 369, 111th Cong. § 28(b)(2) (2009).

156. *Id.* § 28(c)(2).

provisions, an agreement providing for generic entry prior to patent expiration should be highly “relevant” to the competitive effects analysis.

The aforementioned provisions in the Grassley-Kohl bill follow from the economic analysis of antitrust economist Carl Shapiro. According to Professor Shapiro, “consumers have a ‘property right’ to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts.”¹⁵⁷ Accordingly, a settlement providing for generic entry prior to patent expiration is anticompetitive when an earlier entry date was likely to prevail, had it not been for the reverse payment settlement.¹⁵⁸ Consistent with Professor Shapiro’s position, under the Grassley-Kohl bill, the fact finder cannot presume that an entry date set prior to patent expiration automatically means that the settlement is procompetitive.¹⁵⁹

Professor Shapiro’s position should not detract from the relevancy of a settlement provision providing for generic entry prior to patent expiration. For one, the Second Circuit rejected his position, finding “no legal basis for restricting the rights of patentees to choose their enforcement vehicle.”¹⁶⁰ Moreover, the court concluded that the “concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation.”¹⁶¹ For the litigants, having to answer to third parties claiming a property right in the outcome of litigation would reduce settlement options, thereby increasing the costs of litigation.¹⁶² Not only could this have the unintended effect of discouraging patent challenges by ANDA filers, restricting the litigants’ settlement options would, in effect, increase the cost of

157. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395–96 (2003). Professor Shapiro proposes that, as a rule, a reverse payment settlement “cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation.” *Id.* at 410.

158. *Contra In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro III), 363 F. Supp. 2d 514, 536 (E.D.N.Y. 2005) (noting, but rejecting, Plaintiff’s arguments that a payment to secure a later entry date is anticompetitive). Similarly, in *Schering-Plough*, the Commissioner’s basis for imposing antitrust liability for a reverse payment settlement was that in the absence of payments by the pioneer, the parties would have devised alternative settlement arrangements with earlier generic entry dates, a position that the Court rejected. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1071–72 (11th Cir. 2005).

159. S. 369, § 28 (c)(2).

160. *Cipro III*, 363 F. Supp. 2d at 531.

161. *Id.* See Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1040 (2004) (noting that consumers have no expectation to savings procured by infringement and that the gains made by protecting innovation may compensate for the loss in savings).

162. Schildkraut, *supra* note 161, at 1049.

patent enforcement, thereby reducing the economic value of patents.¹⁶³ This, in turn, could effectively reduce the incentives for innovation.¹⁶⁴

Ultimately, a settlement that provides for generic entry prior to patent expiration should weigh strongly in favor of a procompetitive arrangement, even in the presence of a large reverse payment. As articulated by the Supreme Court, the Sherman Act does not give antitrust authorities “*carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.”¹⁶⁵ Likewise, the Grassley-Kohl bill should not be applied in a manner that insists litigants construct settlements that yield consumer surplus to an extent that might have prevailed had litigation continued.

B. The Fact finder Should Consider the Indirect Costs of Protracted Patent Litigation in Ascertaining the Settlement’s Procompetitive Benefits

Legal scholars have noted that “[w]e should be loathe [sic] to adopt any principles that discourage the settlement of good faith litigation,” given that settlements are voluntary, efficiency-enhancing arrangements that public policy generally encourages.¹⁶⁶ Settlements preserve judicial resources, avoid unnecessary litigation costs, and increase social welfare “by facilitating the creation of wealth through consensual transactions.”¹⁶⁷ Per se condemnation of patent settlement litigation would require firms to engage in expensive and inefficient litigation—the direct costs of which would be passed on to consumers—to resolve a patent dispute, even though they might prefer to

163. See *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“A ban on reverse-payment settlements 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.”).

164. See JONATHAN ORSZAG & ROBERT WILLIG, A PRELIMINARY ECONOMIC ANALYSIS OF FTC CHAIRMAN LEIBOWITZ’S JUNE 23RD SPEECH 4 (June 24, 2009) (“The prospect of facing patent challenges and more frequent protracted litigation to defend patents may also discourage investments in innovation to develop new drugs in the first place.”), available at <http://www.compasslexecon.com/highlights/Documents/Orszag-Willig%20Statement%20Re%20FTC%20Reverse%20Payment%20Settlement%20Study.pdf>.

165. *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415–16 (2004).

166. Harry M. Reasoner & Scott J. Atlas, *The Settlement of Litigation as a Ground for Antitrust Liability*, 50 ANTITRUST L.J. 115, 123 (1981–1982); see also Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 749 (2002).

167. Crane, *supra* note 166, at 749. See also *Schlegal Mfg. Co. v. USM Corp.*, 525 F.2d 775, 783 (1975) (“The importance of encouraging settlement of patent-infringement litigation . . . cannot be overstated.”); Schildkraut, *supra* note 161, at 1042 (stating that settlements conserve public and private resources, “remove uncertainty and eliminate risk, lower capital costs and increase investment in the economy”).

settle.¹⁶⁸ To alleviate these concerns, under the Grassley-Kohl bill a settlement involving a reverse payment not in excess of \$7,500,000 is not deemed presumptively unlawful.¹⁶⁹

Although the bill accounts for the direct costs of litigation, it does not expressly encompass the less quantifiable, indirect costs that mandated litigation imposes on drug manufacturers and consumers. Professors Herbert Hovenkamp, Mark Janis, and Mark Lemley argue that reverse payments should be “limited to a good faith estimate of the out-of-pocket costs and attorney’s fees the patentee could expect to pay between the time of the settlement and the time the case was concluded.”¹⁷⁰ Yet, this view of litigation costs, accordingly to Professor Crane, overlooks “the many costs of litigation that firm managers consider in deciding whether to settle.”¹⁷¹

For one, Professor Crane correctly points out that firms incur the opportunity cost of redirecting their efforts to litigation, rather than the ordinary course of the business.¹⁷² Moreover, indirect social costs are imposed on the litigating parties and consumers as competitors can gain access to opposing firm’s trade secrets during discovery, including, for example, pricing lists, marketing studies, and customer lists.¹⁷³ Access to such information may allow the generic to free-ride off of the patent-holder’s internal research and development activities, the effect of which may, over time, destroy incentives to develop efficient means of production and distribution.¹⁷⁴ Additionally, calculating damages in a patent dispute often requires inter-party access to pricing, cost, and production information.¹⁷⁵ Subsequently, the mandatory sharing of such information can facilitate price-fixing and conscious parallelism, the very conduct antitrust rules are designed to prevent.¹⁷⁶ Finally, eliminating a generic challenger’s settlement options, should he be sued for infringement, may reduce the incentive to challenge brand-name patents in the first place, particularly for small pharmaceutical companies unable to

168. Crane, *supra* note 167, at 749; see *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro III), 363 F. Supp. 2d 514, 532 (E.D.N.Y. 2005) (“Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest . . . is, as a practical matter, tantamount to establishing a rule requiring litigants to continue to litigate when they would prefer to settle”) (citations omitted).

169. Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 3 (2009).

170. Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1760 n.177 (2003).

171. Daniel A. Crane, Response, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 703 (2004).

172. *Id.* at 703–04.

173. Crane, *supra* note 166, at 757–58.

174. *Id.* at 758.

175. *Id.* at 759.

176. *Id.* at 758.

withstand lengthy patent litigation.¹⁷⁷ Consequently, mandating litigation may indirectly result in less, not more, generic competition.

As illustrated, firms deciding to settle litigation take into account many costs that are not easily quantified. Under the proposed legislation, therefore, the fact finder should consider the indirect costs of mandating protracted litigation when conducting the competitive effects analysis.

C. The Fact Finder Should Consider Settings in Which Reverse Payments In Excess of Avoided Litigation Costs are Otherwise Reasonable

As noted earlier, the scope of antitrust liability for reverse payment settlements generally is based on the notion that, where a brand-name firm—faced with the risk of patent invalidation and an enormous decline in profits—makes a payment greatly in excess of avoided litigation costs, it is necessarily intending to exclude more competition than the patent could otherwise provide.¹⁷⁸ Consistent with this view, the Grassley-Kohl bill requires that the fact finder consider the possible loss in profits that the brand-name firm risked at trial, along with the amount of avoided litigation expenses. The bill, however, does not indicate the extent to which a reverse payment in excess of avoided litigation costs should be deemed anticompetitive.

The following analysis shows that the Grassley-Kohl bill should permit the fact finder to consider evidence of particular settings in which the reverse payment, although greatly in excess of avoided litigation costs, may be otherwise reasonable. Economists Robert Willig and John Bigelow demonstrate that the amount of consideration received by the ANDA filer does not reliably explain the anticompetitive nature of a settlement agreement.¹⁷⁹ Additional obstacles—differences in market information, disparate expectations of patent validity, and financially strapped litigants—often stand in the way of reaching a mutually beneficial agreement terminating

177. See ORSZAG & WILLIG, *supra* note 164, at 2 (“[O]verly simple economic models ignore important economic realities that can make reverse payment settlements procompetitive.”); Kristina Nordlander & Patrick Harrison, *Pharmaceutical Patent Settlements—A Presumption in Reverse*, GLOBAL COMPETITION POLICY, Aug. 2009, at 2, 5 (“The assessment of the financial and corporate policy-related advantages and disadvantages of a proposed settlement can be an extremely complex process for the parties themselves, let alone for a competition authority. As such, there are many pro-competitive and legitimate reasons why a payment or value transfer ‘in reverse’ might be made in the context of a settlement agreement . . .”).

178. DOJ Brief, *supra* note 14, at 25.

179. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (“[T]he size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy.”); Shapiro, *supra* note 157, at 407–08 (stating that naked cash payments from the patent holder to generic challenger are not necessarily anticompetitive when other factors, including asymmetric information, are brought into the analysis).

litigation.¹⁸⁰ In these settings, reaching settlement without a reverse payment may be impossible, even though the settlement would avoid unnecessary litigation costs and provide for generic entry prior to patent expiration.¹⁸¹ Under the proposed legislation, therefore, the fact finder should consider evidence that the reverse payment, although in excess of avoided litigation costs, was otherwise reasonable, in light of prevailing obstacles to reaching settlement.

1. Asymmetrical Information Regarding the Patent's Economic Value

Condemning an agreement based on the amount of payment, without factoring into the analysis asymmetrical information held by either party, may condemn settlements involving an otherwise reasonable payment.¹⁸² Willig and Bigelow show that a reverse payment may be required where the patent-holder has superior information about the economic value of the patent.¹⁸³

Oftentimes a brand-name firm will have superior information about the economic value of the patent, and the generic firm, although it does not possess such information, knows that the brand does. Consequently, the "known disparity of information influences the bargaining between them."¹⁸⁴ Willig and Bigelow point out that, if the brand-name firm knows that its patent has little economic value, it will offer the generic firm a relatively early date of entry, and from that offer the generic will infer that the brand-name patent is relatively weak.¹⁸⁵ Thus, the parties likely can reach an agreement without a

180. See Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 667 (2004) (discussing the likelihood that the pioneer has more information about the product's position in the market). See Opening Brief of Schering-Plough Corp. at 23, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688), 2004 WL 3557974 (summarizing the testimony of mediating experts that "many disputes cannot be settled within the four corners of the dispute itself. Parties disagree about the strength of their cases and frequently reach an impasse").

181. In *Schering Plough*, the FTC's economics expert conceded that "I don't know . . . whether the parties could have settled the lawsuit without a payment." Opening Brief of Schering-Plough Corp., *supra* note 180, at 45 (citing Complaint Counsel's economics expert).

182. John P. Bigelow & Robert D. Willig, "Reverse Payments" in *Settlements of Patent Litigation: Schering-Plough, K-Dur, and the FTC* (2005), in THE ANTITRUST REVOLUTION: ECONOMICS, COMPETITION, AND POLICY 248, 257-58 (John E. Kwoka, Jr. & Lawrence J. White eds., 5th ed. 2009).

183. *Id.* See also *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro III), 363 F. Supp. 2d 514, 536 (E.D.N.Y. 2005) ("[D]ue to the disparity between the brand-name manufacturer's and generic challenger's expected profits, there might not be any date that represents a reasonable litigation compromise for early (pre-patent expiration) entry by the generic challenger.").

184. Willig & Bigelow, *supra* note 180, at 660.

185. *Id.*

reverse payment because the brand's actual knowledge of the patent's economic value matches up with the generic's inference of that value.¹⁸⁶

On the other hand, if the patent-holder knows, and the generic is unaware, that no viable substitutes for the patented drug will become available in the near-term, the parties are unlikely to reach a settlement based solely on an agreed-upon entry date.¹⁸⁷ Since the value of the patent is high, given that no viable substitutes for the drug are available, the patent holder is unwilling to give up its monopoly and the generic is only willing to accept an entry date substantially earlier than expected through litigation.¹⁸⁸ Thus, a reverse payment, by signaling to the generic that the patent is strong, bridges the informational gap between the parties and leads to settlement of the litigation.¹⁸⁹ If the agreed-upon entry date is before the expected date of entry under litigation, then the reverse payment settlement is likely a procompetitive arrangement.¹⁹⁰

2. Varied Assessments of Success on the Merits

Where the parties have different expectations about the probability of success in litigation, according to Willig and Bigelow, a cash payment from the patent holder to the generic may facilitate a settlement.¹⁹¹ In a likely scenario, the generic entrant is overly optimistic about its chances of winning the patent litigation.¹⁹² The gap between the generic's predictions of success on the merits varies substantially from the patent holder's expectations, with the result that the parties are unable to agree on an acceptable date of entry.¹⁹³

If the gap in expectations is sufficiently wide, even the possibility of saved litigation expenses will not result in a mutually agreed-upon settlement.¹⁹⁴ However, a sufficiently large payment bridges the expectation gap and allows the parties to reach an agreement on the generic entry date.¹⁹⁵ If the agreed-

186. *Id.* at 660–61.

187. Bigelow & Willig, *supra* note 182, at 258.

188. *Id.*

189. *Id.*

190. *Id.*

191. Willig & Bigelow, *supra* note 180, at 672.

192. *Id.*

193. *Id.*

194. *Id.*

195. Willig & Bigelow provide the following economic analysis to explain this result:

To the [pioneer], moving the date of entry by one day later increases profit by the difference between one day's worth of monopoly and one day's worth of duopoly. To the [generic], though, moving the date of entry by one day later diminishes profit only by one day's worth of duopoly. Since monopoly profit exceeds the sum of the profits of the two duopolists . . . the difference between one day's worth of monopoly and one day's worth of duopoly is greater than one day's worth of duopoly. Consequently, each dollar the [pioneer] is willing to pay the [generic] extends the last entry date the [generic] is willing

upon entry date occurs before the date that would have prevailed through litigation, then the settlement can benefit both the settling parties and consumers.

3. Cash-Strapped Generics

Bigelow and Willig additionally show that a reverse payment may become necessary for the brand-name firm and generic challenger to reach a settlement when the generic challenger is in substantial need of cash.¹⁹⁶ Under such circumstances, the generic challenger, who needs financing and cannot otherwise obtain it from capital markets, may only agree to an entry date sufficient to secure an early stream of revenue from the marketing of the generic product.¹⁹⁷ The brand-name firm, however, may view its chances of success in litigation very positively, thus rejecting the generic's proposal for an early date of entry.¹⁹⁸ Unable to agree on an entry date without a reverse payment, the parties would undoubtedly proceed through costly litigation.¹⁹⁹ With a reverse payment that satisfies the entrant's need for cash and that accompanies an agreed-upon entry date, the parties may reach a mutually beneficial settlement.²⁰⁰ If, pursuant to the agreement, the entry date is set before the entry date that would prevail under litigation, the settlement benefits consumers as well.²⁰¹

In sum, the process by which parties reach a settlement agreement is extremely complex, particularly in the context of the Hatch-Waxman Act. Under the proposed legislation, therefore, the fact finder should not rely solely on the amount of payment and profits the litigants stood to gain or lose if litigation were to continue. Instead, the fact finder should carefully examine the settling parties' other motivations for entering into the reverse payment settlement, including informational asymmetries, disparate expectations of success at trial, and cash-strapped parties.

to accept by more days than the extension of the earliest date the [pioneer] is willing to accept. Thus, a large enough payment may enable the parties to reach an agreement . . .

Id. at 672–73.

196. Bigelow & Willig, *supra* note 182, at 257.

197. *Id.*

198. *Id.*

199. *Id.*

200. *Id.*

201. Bigelow & Willig, *supra* note 182, at 257.

D. *The Fact Finder Should Consider Whether the Reverse Payment Was Consistent with the Litigants' Assessments of the Merits of the Patent Claim*

A rule-of-reason analysis centers on whether, under all the circumstances, the pioneer's payment to the generic firm purchased more reduced competition than the underlying patent could otherwise provide.²⁰² Since the Grassley-Kohl bill provides that the settling defendants cannot carry this burden merely by showing that the agreement provided an entry date before patent expiration, the settling defendants must have other options available at their disposal. Consistent with the DOJ's recent proposal, the settling defendants should be able to show that the size of the payment reflected their contemporaneous evaluations of the strength of the patent claim.²⁰³

Applying the DOJ's proposal to the Grassley-Kohl bill would require a limited inquiry into the parties' subjective evaluations of the likelihood that the patent would be declared invalid. In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, however, the court declared that "it is inappropriate for an antitrust court . . . to conduct an after-the-fact inquiry into the validity of the underlying patent."²⁰⁴ Similarly, the United State Court of Appeals for the Federal Circuit, citing the statutory presumption of patent validity, disagreed with the Solicitor General that an analysis of antitrust liability requires a limited inquiry into the merits of the patent claim.²⁰⁵ Despite the courts' declarations, the proposed legislation permits the defendant to rebut the presumption that a reverse payment settlement agreement is illegal by demonstrating, under a rule-of-reason analysis, that the settlement agreement will have procompetitive benefits that outweigh its anticompetitive effects.²⁰⁶

To carry this burden, the brand-name drug manufacturer must be permitted to show that it was not purchasing more market exclusion than the patent could otherwise afford. Inevitably, this requires that the defendant come forward with evidence of its evaluation of the probable outcome of litigation.

As a final matter, determining the state of affairs in a "but-for" world can be difficult; precision may be impossible. Thus, consistent with the DOJ's proposal, under the Grassley-Kohl bill, precision should not be required. Instead, the litigants should be permitted to provide a less burdensome

202. See DOJ Brief, *supra* note 14, at 25 ("Liability properly turns on whether, in avoiding the prospect of invalidation that accompanies infringement litigation, the parties have by contract obtained more exclusion than warranted in light of that prospect.").

203. *Id.* at 28.

204. *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro III), 363 F. Supp. 2d 514, 530 (E.D.N.Y. 2005).

205. *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro IV), 544 F.3d 1323, 1337 (Fed. Cir. 2008).

206. S. 369, 111th Cong. § 28(a)(2)(B) (2009).

“reasonable explanation” that the reverse payment was consistent with their subjective evaluations of the strength of the patent claims.²⁰⁷ Although settling defendants have countered that assessing the relative strength of the patent is an amorphous concept, subject to speculation and doubt,²⁰⁸ as noted by one scholar, “the challenger and the patentee will have probably thought long and hard, and sought expert advice, about the strength of the IP case prior to settlement, so there should normally be relevant information and documents to guide the tribunal.”²⁰⁹

Assessing the parties’ relative assessments of the strength of the underlying patent claim poses procedural difficulties; settlement negotiations are protected by rules of confidentiality and are further subject to the attorney-client privilege. McMillan, Bram, and Tappan have proposed a rather ingenious three-part solution to this problem.²¹⁰ First, the plaintiffs can gather all publicly available information relating to the settlement and the underlying patent, including information published by the FDA, papers filed with the USPTO, annual reports filed with the SEC, and court documents filed with the FTC and DOJ.²¹¹ Second, to obtain additional, confidential information relating to settlement discussions, the antitrust plaintiffs can invoke Federal Rule of Evidence 408, which allows for the admissibility of evidence that is not offered to prove “‘liability for, invalidity of, or amount of a claim’ that was the subject of the negotiations.”²¹² Finally, and only if necessary, the plaintiffs can attempt to invoke the crime-fraud exception to the attorney-client privilege by making a prima facie showing of the defendants’ intent to violate the

207. See DOJ Brief, *supra* note 14, at 32.

208. The generic defendants in *Cipro III* expressed much concern with the Court’s questions pertaining to the defendant’s assessment of the patent’s strength. See Generic Defendants’ Responses to the Court’s February 22, 2005 Questions Relating to Summary Judgment at 5, *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro III), 363 F. Supp. 2d 514 (E.D.N.Y. 2005) (No. 1:00MDL1383DGT), 2005 WL 975866 (“Are we only considering some sort of ‘metaphysical’ strength of the patent under the patent laws, or are we also to factor in ‘false positives’ in the risk assessment—as this Court asks in another question, things like bias or incompetence or lack of patent law experience?”).

209. Ronald W. Davis, *Reverse Payment Patent Settlements: A View into the Abyss, and a Modest Proposal*, ANTITRUST, Fall 2006, at 26, 32 (2006).

210. Richard McMillan, Jr. et al., Essay, *Solving the Procedural Quagmire for Testing Reverse Payment Settlements*, 11 MINN. J. L. SCI. & TECH. 801, 827 (2010).

211. *Id.* at 819–20.

212. *Id.* at 821 (quoting FED. R. EVID. 408). The problem with using Rule 408 to obtain confidential documents and correspondence relating to settlement negotiations is that it may chill settlement negotiations and thereby undermine the policies behind the Rule. *Id.* at 822. The authors argue that “[o]nly companies that intend to effect an anti-competitive agreement would need to worry about such ‘chilling effects.’” *Id.* This argument, however, is convincing only if we assume the parties are confident in the patent’s relative weakness. Parties unsure about the patent’s strength may avoid entering settlement negotiations altogether.

antitrust laws.²¹³ Although the merits of this proposal are beyond the present analysis, it does provide a foundation on which scholars can develop a framework for overcoming the aforementioned procedural difficulties and clearly warrants further scholarly debate.

In sum, although the Hatch-Waxman Act created incentives for a brand-name firm to assert, and then settle, weak patent claims, the proposed legislation should not assume that in every case the brand-name firm is asserting a similarly weak patent claim. Instead, where the amount of payment substantially exceeds the settling parties' avoided litigation costs, the proposed legislation should permit the settling defendants to demonstrate that the payment is consistent with a high probability that the patent is valid and infringed.

CONCLUSION

Justice O'Connor stated that "[i]n the area of antitrust law, there is a competing interest, well represented in this Court's decisions, in recognizing and adapting to changed circumstances and the lessons of accumulated experience."²¹⁴ The Grassley-Kohl bill, with its open-ended list of "competitive factors," allows courts to evaluate with flexibility the competitive effects of reverse payment settlements, under all the circumstances, bearing in mind the competing interests in competition, innovation, and the public policy favoring the settlement of disputes without litigation. Ultimately, if the Grassley-Kohl bill, or similar legislation, is enacted, challenges in interpretation and application will remain, namely, devising the least costly process by which the settling defendants can establish their evaluation of patent strength without conducting a full-blown inquiry into patent validity. Nonetheless, the Grassley-Kohl bill is an effective legislative response to the reverse payment dilemma.

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213. *Id.* at 823. The authors admit that the crime-fraud exception is "reserved for exceptional circumstances." *Id.* at 826. Moreover, they noted that the analysis should never reach this step "unless and until the antitrust plaintiff ha[s] demonstrated a real basis for its claim," set forth evidence of an intent to violate the antitrust laws, and exhausted other less intrusive discovery tools. *Id.* at 824.

214. *State Oil Co. v. Khan*, 522 U.S. 3, 6, 20 (1997).

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