

UNSETTLING DRUG PATENT SETTLEMENTS: A FRAMEWORK FOR PRESUMPTIVE ILLEGALITY[†]

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A tidal wave of high drug prices has recently crashed across the U.S. economy. One of the primary culprits has been the increase in agreements by which brand-name drug manufacturers and generic firms have settled patent litigation. The framework for such agreements has been the Hatch-Waxman Act, which Congress enacted in 1984. One of the Act's goals was to provide incentives for generics to challenge brand-name patents. But brand firms have recently paid generics millions of dollars to drop their lawsuits and refrain from entering the market.

These reverse-payment settlements threaten significant harm. Courts nonetheless have recently blessed them, explaining that the agreements reduce costs, increase innovation, and are reasonable based on the presumption of validity accorded to patents. Although scholars and the Federal Trade Commission have voiced strong arguments against courts' leniency, these have fallen on judicial deaf ears.

*In this Article, I apply the framework that the Supreme Court articulated in *Verizon Communications v. Law Offices of Curtis V. Trinko, LLP*,¹ which underscored the importance in antitrust analysis of a regulatory regime addressing the challenged activity. In particular, the Hatch-Waxman Act provides Congress's views on innovation and competition in the drug industry, freeing courts from the thorny task of reconciling the patent and antitrust laws. Unfortunately, mechanisms that Congress employed to encourage patent challenges—such as an exclusivity period for the first generic to challenge validity—have been twisted into barriers preventing*

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1. 540 U.S. 398 (2004).

competition. Antitrust can play a central role in resuscitating the drafters' intentions and promoting competition.

Given the Act's clear purpose to promote patent challenges, as well as the parties' aligned incentives and the severe anticompetitive potential of reverse payments, courts should treat such settlements as presumptively illegal. If the parties can demonstrate that the payments represent a reasonable assessment of litigation success, then they can rebut this presumption. If not, courts should conclude that the agreements violate the antitrust laws.

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INTRODUCTION

Consumers spend billions of dollars on prescription drugs. Senior citizens choose between medicine and food. Federal and state governments

suffer from rapidly growing expenses. General Motors estimates that it increases the price of its cars by \$1500 because of health-care costs.²

In short, a tidal wave of high drug prices is crashing across the U.S. economy. One explanation can be traced to the increase in agreements by which brand-name drug manufacturers and generic firms have settled patent litigation.³ The framework for such agreements has been the Hatch-Waxman Act,⁴ which Congress enacted in 1984. One of the Act's goals was to provide incentives for generics to challenge brand-name patents. But brand firms have recently paid generics millions of dollars to drop their lawsuits and refrain from entering the market.⁵

Of course, firms with valid patents can charge high prices and exclude competitors. That is the intended purpose of the patent system, and is especially needed for the difficult, expensive process of developing marketable drugs. At the same time, however, companies cannot lawfully use invalid patents to restrict competition. Challenges to invalid patents, in fact, benefit consumers and reduce prices.

Certain settlement agreements could be justified by objective assessments of the patent's validity. But in recent years, agreements have more frequently included large payments from brand patentees to generic challengers. These *reverse payments*, which differ from typical licensing payments that flow from challengers to patentees, may even exceed what the generic could have earned by entering the market. Further raising suspicion, many of the patents are not valid. In the 1990s, generics won nearly 75 percent of their challenges to patents on drugs such as Prozac, Zantac, Taxol, and Plantinol.⁶ Consumers saved almost \$10 billion from the introduction of generic competition on these four products alone.⁷

Reverse payments for generics to delay entering the market also are concerning because of the parties' aligned incentives. By delaying generic entry, the brand firm can increase its monopoly profits. It can then use a portion of these profits to pay the generic more than it would have received by

2. Eduardo Porter, *Japanese Cars, American Retirees; Makers Put Health and Pension Burdens Squarely on the Workers*, N.Y. TIMES, May 19, 2006, at C1. See generally Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Prepared Statement Before S. Comm. on the Judiciary, *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution*, at 1, Jan. 17, 2007, <http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf>.

3. See *infra* notes 83–94 and accompanying text.

4. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)).

5. See *infra* Part II.

6. See *infra* note 194 and accompanying text.

7. *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before the S. Comm. on Commerce, Science, & Transportation*, 107th Cong. 61 (2002) (statement of Kathleen D. Jaeger, President and CEO, Generic Pharm. Ass'n), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:90155.pdf. See generally Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Prepared Statement Before the S. Spec. Comm. on Aging, *Barriers to Generic Entry*, at 10, July 20, 2006 [hereinafter *Barriers to Generic Entry*], <http://www.ftc.gov/os/2006/07/P052103BarriersToGenericEntryTestimonySenate07202006.pdf>.

entering the market. From an antitrust perspective, these payments for delay threaten to divide markets, a particularly egregious offense eliminating competition between rivals.

Despite the concerns presented by reverse-payment settlements, courts have recently blessed them.⁸ They have explained that the agreements reduce costs and increase innovation. They have referred to settlements as “natural by-products” of the Act. And they have pointed to patents’ presumption of validity in demonstrating the agreements’ reasonableness. Although scholars and the Federal Trade Commission (FTC), which enforces the antitrust laws in the drug industry, have voiced strong arguments against courts’ leniency, these have fallen on judicial deaf ears.⁹

In this Article, I explain why settlement agreements with reverse payments should be presumptively illegal. I apply the framework that the Supreme Court articulated in *Verizon Communications v. Law Offices of Curtis V. Trinko, LLP*,¹⁰ which underscored the importance in antitrust analysis of a regulatory regime covering the challenged activity. In particular, the Hatch-Waxman Act provides Congress’s views on innovation and competition in the drug industry, freeing courts from the thorny task of reconciling the patent and antitrust laws.

The intersection of the patent and antitrust laws has presented courts with significant challenges. The foundation of the patent system is the right to exclude. This right allows inventors to recover their costs and obtain profits. Relatedly, it discourages “free riders” who imitate the invention and—because they have no costs to recover—undercut the price. The right to exclude, in short, is designed to increase invention.¹¹

But the very exclusion at the heart of the patent system might seem suspicious to the antitrust laws, which focus on harms to competition. These laws presume that competition leads to lower prices, higher output, and more innovation. They anticipate that certain agreements between rivals or conduct by monopolists prevents consumers from enjoying these benefits. There is no compass to guide courts that consider harms to competition that could arise from exclusion but are intended by the patent system.¹²

By encouraging generic patent challenges but also providing for patent-term extensions and marketing-exclusivity periods, the Hatch-Waxman Act offered a delicate balance between competition and innovation. Unfortunately, mechanisms that Congress employed to encourage patent

8. See *infra* Part II.

9. Commentators also have offered more deferential approaches. For example, some scholars have advocated treatment under the Rule of Reason (by which courts consider an agreement’s anticompetitive and procompetitive effects) because of conceivable reasons why settlements might not occur without payment from the brand to the generic firm. See *infra* notes 254–264 and accompanying text.

10. 540 U.S. 398 (2004).

11. Michael A. Carrier, *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation*, 56 VAND. L. REV. 1047, 1049–50 (2003).

12. *Id.* at 1050–53.

challenges—such as an exclusivity period for the first generic to challenge validity—have been twisted into barriers preventing competition. Antitrust can play a central role in resuscitating the drafters’ intentions and promoting competition.

Given the Act’s clear purpose to promote patent challenges, as well as the parties’ aligned incentives and the severe anticompetitive potential of reverse payments, courts should treat such settlements as presumptively illegal. If the parties can demonstrate that the payments represent a reasonable assessment of litigation success, then they can rebut this presumption. If not, courts should conclude that the agreements violate the antitrust laws. Such a conclusion applies not only to final settlements, which dispose of patent litigation, but also interim settlements, which do not end the litigation but tend to prolong it and delay entry.

Part I introduces the Hatch-Waxman Act, exploring its purpose, text, and mixed success. Part II discusses four representative cases illustrating courts’ increased leniency toward reverse-payment agreements. Part III demonstrates the flaws in judicial analyses. Part IV justifies a framework for presumptive illegality. It explains the importance of the relevant regulatory framework and demonstrates the ineffectiveness of the Act’s competition mechanisms. Part IV also describes the uniquely concerning aspects and potentially severe anticompetitive harm of reverse payments. Finally, it shows how the settling parties can rebut the presumption of illegality.

In short, this Article offers a new framework for the judicial treatment of reverse payments. Congress, of course, could enact other potential solutions. For example, recently-introduced legislation would prohibit agreements by which the generic firm receives “anything of value” in exchange for not researching, developing, manufacturing, marketing, or selling the generic product.¹³ The solution I offer, in contrast, directly addresses the courts’ erroneous decisions, offers a more appropriate framework for judicial analysis, and restores the Hatch-Waxman Act to its intended purposes.

I. HATCH-WAXMAN ACT

A. *General Purposes*

In 1984, Congress enacted the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act (Hatch-Waxman Act).¹⁴ In doing so, the legislature sought to increase generic competition and foster innovation in the pharmaceutical industry.

13. Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 29(a) (2009).

14. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)). The Act was originally called the Waxman-Hatch Act. Kevin J. McGough, *Preserving the Compromise: The Plain Meaning of Waxman-Hatch Market Exclusivity*, 45 FOOD DRUG COSM. L.J. 487, 487 (1990).

First, Congress sought to promote generic competition. Generic drugs have the same active ingredients, dosage, administration, performance, and safety as patented brand drugs.¹⁵ Despite the equivalence, generic manufacturers were required, at the time of the Act, to engage in lengthy and expensive trials to demonstrate safety and effectiveness. The Food and Drug Administration (FDA) approval process took several years, and because the required tests constituted infringement, generics could not begin the process during the patent term.¹⁶ They therefore waited until the end of the term to begin these activities, which prevented them from entering the market until two or three years after the patent's expiration. At the time Congress enacted Hatch-Waxman, there was no generic equivalent for roughly 150 drugs whose patent terms had lapsed.¹⁷

The drafters of the Act lamented the “practical extension” of the patentee’s “monopoly position” beyond expiration.¹⁸ Relatedly, they sought to ensure the provision of “low-cost, generic drugs for millions of Americans.”¹⁹ Generic competition would save consumers, as well as the federal and state governments, millions of dollars each year.²⁰ And it would “do more to contain the cost of elderly care than perhaps anything else this Congress has passed.”²¹

One of the tools used by the legislature to accelerate generic entry was a resuscitation of the experimental use defense. In the case of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,²² the Federal Circuit had held that the generic firm committed infringement by experimenting with the active ingredient in the brand’s patented sleeping pill so as to facilitate FDA testing. The court explained that the generic’s use was “solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”²³ In addition, it refused to interpret the defense to cover “scientific inquiry” when “that inquiry has definite, cognizable, and not insubstantial commercial purposes.”²⁴

Congress reversed this holding in the Hatch-Waxman Act. It exempted from infringement the manufacture, use, or sale of a patented invention for

15. FDA.gov, Generic Drugs: Questions and Answers, http://www.fda.gov/buyonlineguide/generics_q&a.htm (last visited May 18, 2009).

16. See CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 38 (1998) [hereinafter CBO STUDY].

17. H.R. REP. NO. 98-857, pt. 1, at 17 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2650.

18. H.R. REP. NO. 98-857, pt. 2, at 4 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2688.

19. 130 CONG. REC. 24427 (1984) (statement of Rep. Waxman).

20. See *infra* notes 83–87 and accompanying text.

21. 130 CONG. REC. 24427 (statement of Rep. Waxman).

22. 733 F.2d 858 (Fed. Cir. 1984).

23. *Id.* at 863.

24. *Id.*

uses “reasonably related to the development and submission of information” under a federal law regulating the manufacture, use, or sale of drugs.²⁵

Congress also sought to promote generic competition by creating a new process for obtaining FDA approval. Before Hatch-Waxman, generic companies that offered products identical to approved drugs needed to independently prove safety and efficacy.²⁶ One reason that generics chose not to bring products to the market after a patent’s expiration was the expense and time involved in replicating clinical studies. As discussed in more detail in the next section, the Act created a new type of drug application that allowed the generic to rely on the brand’s studies, thereby accelerating entry.²⁷

Also discussed below, the legislature increased competition by fashioning market exclusivity.²⁸ In particular, it encouraged generics to challenge invalid or noninfringed patents by creating a 180-day period of marketing exclusivity for the first generic firm to do so.

In addition to promoting generic competition, the Act increased incentives for innovation. Before 1962, companies had needed only to demonstrate a drug’s safety to gain FDA approval.²⁹ But amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) in 1962 required manufacturers to show not only that a drug was safe but also that it was effective for its intended use.³⁰ As a result, brand firms were required to undertake additional years of testing and clinical trials after the patent’s issuance. Such a development delayed commercialization and substantially eroded the effective patent term.³¹

The industry thus faced an “innovation crisis.” The number of new chemical entities entering human testing fell 81 percent from the late 1950s until the late 1970s.³² New drug compounds and dosage forms also decreased. Firms’ research and development declined because of increased

25. 35 U.S.C. § 271(e)(1)(2006). In 2005, the Supreme Court broadly interpreted the exception, finding that it covered activities that did not ultimately lead to information included in an FDA submission. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005).

26. Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 589–90 (2003).

27. *See infra* Section I.B.

28. *See infra* notes 61–62 and accompanying text.

29. Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 313 (2005).

30. Weiswasser & Danzis, *supra* note 26, at 588.

31. *Id.*

32. Maureen S. May et al., *New drug development during and after a period of regulatory change: Clinical research activity of major United States pharmaceutical firms, 1958 to 1979*, 33 CLINICAL PHARMACOLOGY THERAPEUTICS 691, 691 (1983).

investments but reduced returns.³³ And U.S. drug companies shifted their research overseas.³⁴

Much of this crisis was traced to the decline in the *effective patent life*, the period between FDA approval and patent expiration. This period was reduced as manufacturers engaged in more extensive tests, delaying the drug's marketing. Before the 1962 amendments, the effective patent life nearly matched the 17-year patent term.³⁵ By 1981, it had fallen to less than seven years.³⁶

The legislature thus extended the patent term. The extension currently amounts to half the time the drug is in clinical trials plus the period spent awaiting FDA approval after trials. The extension can last up to five years and, together with the remaining patent term, can give the patentee up to fourteen years of protection.³⁷

Congress also provided for periods of market exclusivity not based on patents. A company that offers a drug with a new active ingredient is entitled to either four or five years of exclusivity.³⁸ Because the FDA cannot receive generic applications during this period, the practical exclusivity period is extended by another two years, the time it typically takes the FDA to approve an application.³⁹ Similarly, new clinical investigations essential to approval receive three years of exclusivity.⁴⁰ The FDA has applied this form of exclusivity to new dosage forms, new uses, and adoption of over-the-counter status.⁴¹

Finally, Congress granted to patent holders an automatic 30-month stay of FDA approval. This period, explained more fully below,⁴² provides an additional exclusionary right benefiting brand firms who—even without

33. John R. Virts & J. Fred Weston, *Returns to Research and Development in the U.S. Pharmaceutical Industry*, 1 *MANAGERIAL & DECISION ECON.* 103, 110 (1980).

34. JOHN W. EGAN ET AL., *ECONOMICS OF THE PHARMACEUTICAL INDUSTRY* 105–06 (1982); see James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 *CATH. U. L. REV.* 433, 450 (1986).

35. Wheaton, *supra* note 34, at 451–52.

36. *Id.*

37. 35 U.S.C. § 156(c), (g)(6) (2006). See generally Weiswasser & Danzis, *supra* note 26, at 591.

38. 21 U.S.C. § 355(j)(5)(F)(ii) (2006). The exclusivity period is four years for generic filers certifying patent invalidity or noninfringement and five years for other generic failures. *Id.*

39. See JOHN R. THOMAS, *PHARMACEUTICAL PATENT LAW* 350 (2005). As described more fully below, other factors (including the brand firm's automatic stay and litigation) increase the delay. See *infra* notes 55–58 and accompanying text; *infra* Part II.

40. 21 U.S.C. § 355(c)(3)(E)(iii).

41. 35 U.S.C. § 156(c), (g)(6) (2006). See generally Weiswasser & Danzis, *supra* note 26, at 591.

42. See Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 *FOOD & DRUG L.J.* 195, 201 (1999).

obtaining a preliminary injunction—will not face generic competition for a period of time.⁴³

The Act's drafters emphasized the equilibrium between competition and innovation. Representative Henry Waxman underscored the "fundamental balance of the bill,"⁴⁴ and the Energy and Commerce Committee Report explained that allowing early generic challenges "fairly balanced" the exclusionary rights of patent owners with the "rights of third parties" to contest validity and market products not covered by the patent.⁴⁵ Similarly, the Judiciary Committee Report concluded that the Committee "has merely done what the Congress has traditionally done" in IP law: "balance the need to stimulate innovation against the goal of furthering the public interest."⁴⁶

In fact, the equilibrium was even more finely calibrated than the traditional balance between innovation and competition that underlies IP law. For Congress placed on the innovation side of the ledger not only patent term extensions but also (1) nonpatent market exclusivity for new chemical entities and new clinical investigations and (2) an automatic 30-month stay for brand firms that sued generics that had challenged the patent's invalidity or claimed noninfringement. According to one of the chief negotiators, the exclusivity period for new drugs "was the key to the compromise."⁴⁷

In short, Congress responded to the problems of insufficient generic entry and inadequate innovation through a carefully calibrated balance among patent term extension, nonpatent exclusivity, and generic competition.

B. Competition-Promoting Framework

Of the policies underlying Hatch-Waxman, generic competition has engendered the most attention and concern. The antitrust issues that have arisen under the statute have flowed from provisions intended to expedite generic entry. To understand the relevant framework, it is necessary to explore the provisions of the Act, as well as the process by which the FDA approves drugs. Neither of these offers the simplest regime ever created.

A company that wishes to market a new drug must receive approval from the FDA. To do so, it files a New Drug Application (NDA), which consists of thousands of pages and includes information on numerous categories, including clinical trial data.⁴⁸

43. FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 42* (2002) [hereinafter *GENERIC DRUG STUDY*], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

44. 130 CONG. REC. 24425 (1984) (statement of Rep. Waxman).

45. H.R. REP. NO. 98-857, pt. 1, at 28 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2661.

46. H.R. REP. NO. 98-857, pt. 2, at 30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2714.

47. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 *IDEA* 389, 406 (1999).

48. *GENERIC DRUG STUDY*, *supra* note 43, at 5; THOMAS, *supra* note 39, at 306.

The Hatch-Waxman Act allows generic firms to avoid the expensive and lengthy NDA process by filing an Abbreviated New Drug Application (ANDA). To do this, the applicant must show that its drug possesses the same active ingredient, route of administration, bioequivalence (rate and extent of drug absorption), and other characteristics of the brand.⁴⁹ If it can make this showing, it can rely on the brand's safety and effectiveness studies, dispensing with the need for independent preclinical or clinical studies.⁵⁰

Brand firms filing NDAs also are required to identify patents they believe would be infringed by the marketing of generic drugs.⁵¹ When the FDA approves the NDA, it lists the patents in a publication known as the Orange Book.⁵² Named for its orange cover (but now published in electronic form and accessible on the internet), the publication contains a list of all the drugs approved for marketing in the United States.⁵³

An ANDA applicant must provide one of four certifications for each patent listed in the Orange Book relating to the relevant NDA. It can certify that

- (I) no patent information appears in the Orange Book,
- (II) the patent has expired,
- (III) it will not seek approval until the patent expires, or
- (IV) the patent is invalid or will not be infringed by the generic drug.⁵⁴

For the first two certifications, the FDA can approve the ANDA immediately. For the third, approval is granted when the patent expires. It is the fourth certification that has resulted in settlement agreements raising anti-trust concern.

Upon filing such a certification, an ANDA applicant must provide notice within twenty days to the patent and NDA holders.⁵⁵ Such notice must detail support for its claim of invalidity or noninfringement.⁵⁶ If the patent holder (typically the brand firm) does not bring an infringement suit within forty-five days, the FDA may approve the ANDA as soon as the regulatory requirements are satisfied.⁵⁷

If, in contrast, the patent holder sues within forty-five days, it receives an automatic 30-month stay of FDA approval. The stay operates like a pre-

49. GENERIC DRUG STUDY, *supra* note 43, at 5.

50. *Id.*

51. THOMAS, *supra* note 39, at 15.

52. The technical name is "Approved Drug Products with Therapeutic Equivalence Evaluations." ELECTRONIC ORANGE BOOK (2009), <http://www.fda.gov/cder/ob/>.

53. THOMAS, *supra* note 39, at 327.

54. 21 U.S.C. § 355(j)(2)(A)(vii) (200). *See generally* THOMAS, *supra* note 39, at 313.

55. 21 U.S.C. § 355(j)(2)(B)(ii)–(iii). The 20-day limit was added in the 2003 amendments to the Act. Erika Lietzan & David E. Korn, *Issues in the Interpretation of 180-Day Exclusivity*, 62 FOOD & DRUG L.J. 49, 54 (2007).

56. 21 U.S.C. § 355(j)(2)(B)(iv)(II).

57. *Id.* § 355(j)(5)(B)(iii).

liminary injunction, preventing the ANDA applicant from marketing its product for a period of roughly thirty months (or less if a court determines that the patent is invalid or not infringed).⁵⁸ As a practical matter, the 30-month stay approximates the 25-month periods for (1) FDA approval of generic applicants filing paragraph IV certifications that are not sued and (2) the average period between the filing of a complaint and a district court decision.⁵⁹ Even though the generic has not entered the market, the paragraph IV certification is treated as an artificial act of infringement that allows the patentee to sue before entry.⁶⁰

To encourage challenges to potentially invalid drug patents, the Act grants a 180-day period of marketing exclusivity to the first applicant filing a “substantially complete” ANDA with a paragraph IV certification.⁶¹ During the period, which begins after the first commercial marketing of the drug, the FDA cannot approve other ANDAs for the same product.⁶²

C. 2003 Revisions

In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act.⁶³ Three of the Act’s most important changes addressed abuse of the Hatch-Waxman Act by limiting patent holders to a single 30-month stay, establishing *forfeiture events* causing ANDA applicants to lose the exclusive 180-day marketing period, and requiring parties to provide notice of settlement agreements to the antitrust enforcement agencies.

The single 30-month stay provision was a “centerpiece” of the amendments, designed to “allow[] lower-priced generic products to enter the market more quickly.”⁶⁴ Under the Hatch-Waxman Act, a brand firm could wait until a generic filed an ANDA and then list an additional patent in the Orange Book. If the generic then filed a paragraph IV certification, the brand could sue and receive another 30-month stay. As an example of such behavior, GlaxoSmithKline, by obtaining multiple 30-month stays, blocked

58. *Id.* The period could extend an additional twelve months depending on when the generic filed its paragraph IV certification. *Id.* § 355(j)(5)(F)(ii). See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1566 n.50 (2006).

59. GENERIC DRUG STUDY, *supra* note 43, at 39.

60. 35 U.S.C. § 271(e)(2)(A) (2006); see *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

61. 21 U.S.C. § 355(j)(5)(B)(iv). Multiple applicants that file paragraph IV ANDAs on the same day share exclusivity. See, e.g., *Lietzan & Korn*, *supra* note 55, at 55.

62. GENERIC DRUG STUDY, *supra* note 43, at 7. Until amended in 2003, the Hatch-Waxman Act included as a second trigger for the 180-day period a court decision finding invalidity or lack of infringement. See *Lietzan & Korn*, *supra* note 55, at 63.

63. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21, 26, and 42 U.S.C.).

64. H.R. CONF. REP. NO. 108-391, at 835 (2003), *reprinted in* 2003 U.S.C.C.A.N. 1808, 2187.

generic competition against its antidepressant drug Paxil for more than five years.⁶⁵

The 2003 revisions addressed this problem by limiting the stays to patents submitted to the FDA before submission of the ANDA.⁶⁶ To be sure, multiple 30-month stays are still possible. For example, a generic could file paragraph III and paragraph IV certifications on different patents and then, before the submission of the ANDA, change the paragraph III designation to paragraph IV.⁶⁷ Nonetheless, the change has reduced the problem's frequency.

The second modification was designed to limit abuse of the 180-day exclusivity period. The Medicare Act created various forfeiture events that resulted in generics forfeiting their 180-day exclusivity period. The events include the generic's:

- failing to market its drug within 75 days of FDA approval
- failing to market its drug within 75 days of a final judicial decision or consent decree finding the patent invalid or not infringed
- withdrawing its ANDA
- failing to obtain tentative FDA approval within 30 months of the filing of the ANDA
- witnessing the expiration of the patents entitling the applicant to exclusivity
- entering into an agreement found to violate the antitrust laws.⁶⁸

A close reading of the statute shows that these “use it or lose it” provisions do not necessarily trigger forfeiture as quickly as might be assumed. Simplifying greatly, the statute provides that the first filer loses exclusivity if it fails to market the drug by the later of (1) 75 days after FDA approval and (2) 75 days after an appellate court decision finding invalidity or noninfringement.⁶⁹ The exclusivity period thus would extend to the subsequent court decision, which could occur long after the FDA's approval.

65. GENERIC DRUG STUDY, *supra* note 43, at 51.

66. 21 U.S.C. § 355(j)(5)(B)(iii).

67. CTR. FOR DRUG EVAL. & RESEARCH, FDA, GUIDANCE FOR INDUSTRY: LISTED DRUGS, 30-MONTH STAYS, AND APPROVAL OF ANDAS AND 505(B)(2) APPLICATIONS UNDER HATCH-WAXMAN, AS AMENDED BY THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 8–9 (2004), available at <http://www.fda.gov/cder/guidance/6174dft.pdf>.

68. 21 U.S.C. § 355(j)(5)(D)(i).

69. *Id.* § 355(j)(5)(D)(i)(I) (referring to “decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed”); see also 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, 1023–24 (2008); Leibowitz, *supra* note 2. The forfeiture provisions apply only to ANDAs filed after December 8, 2003 for which no paragraph IV certifications were filed before the December 8 date. Medicare Prescription Drug, Improvement, and

Nonetheless, the changes reduce the likelihood of complete bottlenecks. This development is strengthened by the Federal Circuit's recent expansion of declaratory judgment actions. In 2007, this court made it easier for generics to file declaratory judgment actions against brand companies where (1) the brand listed patents in the Orange Book, (2) the generic filed a paragraph IV certification, and (3) the brand sued the generic on one or more of the patents.⁷⁰ Although courts have not addressed the availability of such actions when the brand does not sue the generic, the increased use of declaratory judgments could reduce bottlenecks.

Finally, the Act required brand and generic companies to file settlement agreements that concerned the 180-day exclusivity period or the production, sale, or marketing of a drug with the FTC and Department of Justice within ten days of the agreement.⁷¹ Representative Waxman sought to ensure the enforcement of the antitrust laws by requiring disclosure of "secret, anti-competitive agreements."⁷² Similarly, the Senate Judiciary Committee explained that the amendments were designed to "put an end to [the] exploitation" by which brand firms abused the Hatch-Waxman law by "[a]greeing with smaller rivals to delay or limit competition."⁷³

D. Mixed Success

On the whole, the Hatch-Waxman Act has been successful in increasing generic entry. Generic drugs, which made up 19% of prescriptions for drug products in 1984,⁷⁴ increased to 65% in 2008.⁷⁵ For the most popular drugs with expired patents, the share facing generic competition burgeoned from 35% in 1983 to almost 100% today.⁷⁶ And once a generic enters the market, the brand loses an average of 44% of its market, with one study finding generic penetration of approximately 75% after two months.⁷⁷

Modernization Act of 2003, Pub. L. No. 108-173, § 1102(b), 117 Stat. 2066, 2460 (codified as amended in scattered sections of 21, 26 and 42 U.S.C.).

70. Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1344 (Fed. Cir. 2007).

71. Medicare Modernization Act, §§ 1112–1113.

72. 146 CONG. REC. E1538 (daily ed. Sept. 20, 2000) (statement of Rep. Waxman).

73. S. REP. NO. 107–167, at 4 (2002).

74. See Kathleen D. Jaeger, President & CEO, Generic Pharm. Ass'n, Testimony Before the H.R. Comm. on Energy and Commerce, Oct. 9, 2002, available at <http://www.gphaonline.org/resources/2002/10/08/greater-access-affordable-pharmaceuticals-act>.

75. See Press Release, Generic Pharm Ass'n, GPhA Says New Study Shows that Hatch-Waxman is a Successful Model for Biogenerics Legislation Exclusivity Provisions Similar to Those in Hatch-Waxman Would Promote Competition and Innovation (Sept. 17, 2008), <http://www.gphaonline.org/media/press-releases/2009/02/12/gpha-says-new-study-shows-hatch-waxman-successful-model-biogenerics->

76. CBO STUDY, *supra* note 16, at 37.

77. *Id.* at xiii (44 percent); DOUG LONG, IMS, 2003 YEAR IN REVIEW: TRENDS, ISSUES, FORECASTS 35 (2004), available at <http://piapr.com/presentaciones/DougLong2003YIR Presentation.pdf> (75 percent).

These trends are amplified by health plans' encouragement or requirement of generic drugs.⁷⁸ Most states allow pharmacists that receive prescriptions for brand drugs to substitute generics.⁷⁹ Medicaid policies and managed-care plans also encourage such substitution.⁸⁰ And unlike the situation at the time of the Hatch-Waxman Act, when an average 3-year gap existed between patent expiration and generic entry, generics today enter the market almost immediately at the end of the patent term.⁸¹

Generic entry also saves consumers billions of dollars each year. As the FTC recently showed, reverse-payment settlements are forecast to cost consumers \$35 billion over ten years.⁸² Because generics have far lower development costs, they sell the drugs at a significant discount. The first generic entrant prices its product, on average, 5 to 25% lower than the brand drug.⁸³ The presence of a second generic lowers the price to approximately half the brand price.⁸⁴ In markets in which six or more generics enter, the price falls to a quarter of the brand price.⁸⁵ One survey showed that patients could save 52% in the daily costs of their medications by purchasing generic drugs.⁸⁶

The Hatch-Waxman Act also has been successful in increasing the patent term. Nearly half of the top twenty "blockbuster" drugs in 1997 received extensions of at least two years.⁸⁷ The average period of marketing rose from approximately nine years before Hatch-Waxman to about eleven-and-a-half years in the early 1990s.⁸⁸

Even though generic entry increased after the Act, prices also have recently increased. Prescription-drug spending is the fastest growing segment of health-care expenditures, increasing from approximately 6% in 1993 to

78. Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 23 (2005).

79. *Id.* at 23–24.

80. *See In re Schering-Plough Corp.*, 136 F.T.C. 956, 985 (2003), *vacated*, Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005).

81. CBO STUDY, *supra* note 16, at 38.

82. Jon Leibowitz, FTC Chairman, "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, at 8, <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>.

83. *See id.* at xiii; CTR. FOR DRUG EVAL. & RESEARCH, FDA, GENERIC COMPETITION AND DRUG PRICES (2006), http://www.fda.gov/CDER/ogd/generic_competition.htm.

84. *See* CBO STUDY, *supra* note 16, at xiii.

85. *See id.*

86. CTR. FOR DRUG EVAL. & RESEARCH, FDA, SAVINGS FROM GENERIC DRUGS PURCHASED AT RETAIL PHARMACIES (2004), <http://www.fda.gov/cder/consumerinfo/savingsfromgenericdrugs.htm>.

87. Engelberg, *supra* note 47, at 426.

88. CBO STUDY, *supra* note 16, at 39. The post-Hatch-Waxman term is based on drugs approved between 1992 and 1995 that received an extension.

almost 11% in 2003.⁸⁹ Senior citizens, despite making up only 13% of the population, account for 42% of all drug expenditures.⁹⁰ Between 2000 and 2004, the average price of the 100 most frequently dispensed retail prescriptions rose almost 25%, with the price for brand drugs rising three times faster than the price of generics.⁹¹

These price increases can be partially explained by agreements by which brand firms have settled patent-infringement disputes by paying generics to abandon their challenges and delay entering the market.⁹² Just as concerning, the companies have more frequently employed these agreements when enforcers and courts look the other way. In particular, the use of reverse payments plummeted after the FTC first declared its concern with these agreements in 2000 and skyrocketed after the courts bestowed their blessing in 2005.⁹³

In the years since the passage of the Hatch-Waxman Act, the drafters of the legislation have unequivocally expressed their disapproval of reverse-payment settlements. Representative Waxman explained that such agreements were an “unfortunate, unintended consequence” of the Act that “turned the . . . legislation on [its] head.”⁹⁴ Waxman emphasized that the purpose of the legislation was to promote generic competition, not allow generics “to exact a portion of a brand-name manufacturer’s monopoly profits in return for withholding entry into the market.”⁹⁵

Senator Hatch similarly found such agreements “appalling.” Hatch “concede[d], as a drafter of the law, that we came up short in our draftsmanship.” And his assessment mirrored that of Waxman in making clear that “[w]e did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition.”⁹⁶

89. U.S. GOV’T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: PRICE TRENDS FOR FREQUENTLY USED BRAND AND GENERIC DRUGS FROM 2000 THROUGH 2004 1 (2005).

90. FAMILIES USA, COST OVERDOSE: GROWTH IN DRUG SPENDING FOR THE ELDERLY, 1992–2010 2 (2000), available at <http://www.familiesusa.org/assets/pdfs/drugod852b.pdf>.

91. U.S. GOV’T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: PRICE TRENDS FOR FREQUENTLY USED BRAND AND GENERIC DRUGS FROM 2000 THROUGH 2004 4, 10 (2005).

92. Motion and Brief for Representative Henry A. Waxman as Amicus Curiae Supporting Petitioner at *2, 4, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2462026 (Waxman brief) (noting that brand-name drugs “account for most of the increase in drug costs”).

93. See *infra* notes 248–253 and accompanying text.

94. Waxman brief, *supra* note 92, at *v.

95. *Id.*; see also, e.g., Sheryl Gay Stolberg & Jeff Gerth, *Keeping Down the Competition; How Companies Stall Generics And Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, § 1, at 1.

96. 148 CONG. REC. S7566 (daily ed. July 30, 2002) (statement of Sen. Hatch).

II. CASE LAW

Four representative cases demonstrate courts' increasing leniency toward these agreements. In the first case, the court found the settlement to be *per se* illegal. But the next three applied much more deference.

A. Cardizem

The first case, *In re Cardizem CD Antitrust Litigation*,⁹⁷ involved a drug used to treat angina and hypertension and to prevent heart attacks and strokes.⁹⁸ In November 1995, the U.S. Patent and Trademark Office (PTO) issued a patent for the prescription drug Cardizem CD to Carderm, which licensed it to Hoechst Marion Roussel. The next month, Andrx Pharmaceuticals filed the first paragraph IV certification, asserting that its product did not infringe any patents covering Cardizem. In January 1996, Hoechst and Carderm sued Andrx for patent infringement. The complaint did not seek damages or injunctive relief, but triggered a 30-month stay during which the FDA was not able to approve Andrx's ANDA.

In September 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would finally approve the application when the 30-month stay expired in July 1998. Nine days after this announcement, and while the patent infringement litigation continued, the parties entered into an interim settlement. Andrx agreed not to market a bioequivalent or generic version of Cardizem (even those not at issue in the litigation) in the United States until it obtained a favorable, unappealable determination that the patent was not infringed.⁹⁹ By filing the first paragraph IV certification, Andrx received a 180-day period of marketing exclusivity. But by not entering the market, it never triggered this period, creating a bottleneck that blocked other paragraph IV filers from receiving FDA approval. In exchange for this promise, Hoechst agreed to pay Andrx \$40 million per year, which would increase to \$100 million per year if a court determined that the patent was not infringed.¹⁰⁰

The FDA issued its final approval of Andrx's ANDA in July 1998. Hoechst then began to pay Andrx to refrain from marketing the product. Two months later, Andrx reformulated its product, and the FDA approved this version the following year. Upon FDA approval, Hoechst and Andrx terminated their interim agreement and settled their infringement case, with Hoechst paying a final sum of \$50.7 million, for total payments of roughly \$90 million. Andrx then introduced its generic product, Cartia XT, which

97. 332 F.3d 896 (6th Cir. 2003).

98. The facts are taken from *id.* at 899–903.

99. Andrx also could market its generic version if it entered into a license agreement with Hoechst or if Hoechst entered into a license agreement with a third party. *Id.* at 902.

100. The \$100 million payment also would be made if Hoechst dismissed the infringement case or failed to refile the case after a court ruling that did not determine issues of validity, enforcement, or infringement. *Id.* at 903.

sold at a significantly lower price and captured a substantial share of the market.

The Sixth Circuit found that the agreement was *per se* illegal. It explained that the settlement guaranteed to Hoechst that “its only potential competitor” would “refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval.”¹⁰¹ And it focused on the effect of the Hatch-Waxman Act. “By delaying Andrx’s entry into the market,” the court continued, “the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx’s 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer.”¹⁰² The court also was concerned that the agreement prevented Andrx from marketing products not covered by the patent. It concluded that the settlement was “a horizontal agreement to eliminate competition . . . a classic example of a *per se* illegal restraint of trade.”¹⁰³

B. Schering-Plough

The second case dealt with a product used to treat high blood pressure and congestive heart disease. Schering-Plough manufactured an “extended-release microencapsulated potassium chloride product, K-Dur 20.” Although the active ingredient in K-Dur 20, potassium chloride, was not patentable, Schering owned a patent on the extended release coating of the drug.¹⁰⁴

In 1995, Upsher-Smith Laboratories sought FDA approval to market a generic version of K-Dur 20. Schering sued Upsher for patent infringement, and the parties settled the case immediately before trial was to commence in June 1997. The parties agreed that Upsher would not enter the market until September 1, 2001 and that Schering would license other Upsher products. In particular, Schering received licenses to five Upsher products, including a sustained-release niacin product used to reduce cholesterol.

In 1995, ESI Lederle also sought to market a generic version of K-Dur 20. Schering sued ESI for patent infringement, and the parties settled in 1998. They agreed that ESI could enter the market on January 1, 2004 (almost three years before the patent was to expire) and that Schering would pay ESI \$10 million if it received FDA approval by a certain date. Both Upsher and ESI remained off the market several years beyond their previous expectations.¹⁰⁵

In 2001, the FTC filed an administrative complaint alleging that Schering’s settlements with Upsher and ESI violated Section 5 of the Federal

101. *Id.* at 907.

102. *Id.*

103. *Id.* at 908.

104. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). The facts are taken from the opinion. *See id.* at 1058–62.

105. Petition for Writ of Certiorari at 8, *FTC v. Schering-Plough Corp. et al.*, 548 U.S. 919 (2006) (No. 05-273) [hereinafter *FTC Cert Petition*].

Trade Commission Act (FTC Act) and Section 1 of the Sherman Act. An Administrative Law Judge (ALJ) concluded that the settlements were lawful. The FTC's complaint counsel appealed this decision to the full Commission.¹⁰⁶

The Commission reversed the ALJ's decision and, in an exhaustive opinion, held that the settlements violated the FTC and Sherman Acts.¹⁰⁷ It found that the licenses Schering paid to Upsher and ESI greatly exceeded the value of the products it received.¹⁰⁸ Even though there were significant safety and market concerns with one product,¹⁰⁹ Schering (1) did not include its knowledgeable employees in the negotiations,¹¹⁰ (2) failed to request sales projections or research relating to the drug,¹¹¹ (3) never followed up on unfulfilled requests for information,¹¹² and (4) did not object when Upsher suspended its work.¹¹³ This lack of interest supported the Commission's conclusion that Schering paid the generics to delay entering the market.¹¹⁴

More generally, the FTC explained that it would invalidate settlements by which "the generic receives anything of value and agrees to defer its own research, development, production or sales activities."¹¹⁵ The Commission created exceptions to this prohibition for an "agreed-on entry date, without cash payments" and for payments less than \$2 million that could be linked to litigation costs.¹¹⁶

The Eleventh Circuit, in *Schering-Plough Corp. v. FTC*, reversed the FTC's condemnation. It concluded that "neither the rule of reason nor the *per se* analysis [was] appropriate" for the agreements.¹¹⁷ The emphasis on anticompetitive effects, in particular, was "ill-suited" for cases involving patents, which "[b]y their nature . . . create an environment of exclusion and . . . cripple competition."¹¹⁸ The court instead articulated a test that focused on "(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."¹¹⁹

106. *Schering-Plough*, 402 F.3d at 1061–62.

107. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1060–61 (2003).

108. *Id.* at 967.

109. *Id.* at 1038.

110. *Id.* at 1019.

111. *Id.* at 1037.

112. *Id.* at 1043.

113. *Id.* at 1051.

114. *Id.* at 1052.

115. *Id.* at 1062 (internal quotation marks omitted).

116. *Id.* at 987, 1062.

117. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

118. *Id.* at 1065–66.

119. *Id.* at 1066.

Pursuant to the first factor, the court found that Schering's patent gave it "the legal right to exclude Upsher and ESI from the market" until the generics proved the patent's invalidity or that their products did not infringe the patent.¹²⁰ Neither of the firms alleged the patent's invalidity or claimed that the infringement suits were "shams."¹²¹

Regarding the second factor, the court found that the agreements did not restrict competition beyond the scope of the patent. It found Schering's payment to Upsher for unrelated products to be "a bona fide fair-value payment."¹²² And it found that the ESI settlement reflected fifteen months of mediation as well as "the strength of Schering's case."¹²³ The court concluded that the settlement terms were "within the patent's exclusionary power," and that patentees "should not be in a worse position" than other parties in settling lawsuits.¹²⁴

On the third factor, the court found that any restrictions on competition were "ancillary restraints" necessary to settlement.¹²⁵ The agreement between Schering and Upsher applied only to products covered by the patent at issue. More generally, the court stated that reverse payments were "a natural by-product of the Hatch-Waxman process,"¹²⁶ and that patent litigation resulted in "a litany of direct and indirect costs" and "decrease[d] . . . innovation" by increasing uncertainty in developing patented products.¹²⁷

The court concluded that the agreements "fell well within the protections of the . . . patent" and thus were not illegal.¹²⁸ In the end, the court stated, it "cannot be the sole basis for a violation of antitrust law" for a brand firm with a patent to pay a generic competitor.¹²⁹

The FTC sought Supreme Court review of the Eleventh Circuit decision, and was backed by thirty-four states, the AARP, and a patent policy think tank.¹³⁰ Reflecting a rare disagreement between the agencies, the Justice Department recommended against granting certiorari. The agency suggested that the appropriate legal standard "should take into account the relative

120. *Id.*

121. *Id.* at 1068.

122. *Id.* at 1069.

123. *Id.* at 1071.

124. *Id.* at 1072.

125. *Id.*

126. *Id.* at 1074 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)).

127. *Id.* at 1075.

128. *Id.* at 1076.

129. *Id.*

130. Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 491 (2007).

likelihood of success of the parties' claims."¹³¹ The Supreme Court denied certiorari.

C. Tamoxifen

The third case involved tamoxifen, which was used to treat breast cancer and was "the most prescribed cancer drug in the world."¹³² Imperial Chemical Industries (ICI) received a patent on tamoxifen in August 1985, and Zeneca, a former ICI subsidiary, then obtained the rights to the patent and manufactured the drug. In December 1985, Barr Laboratories filed an ANDA with the FDA requesting approval to market a generic version of tamoxifen. In September 1987, Barr amended the ANDA to incorporate a paragraph IV certification.

In November 1987, ICI sued Barr and Barr's supplier for patent infringement. In April 1992, a district court declared ICI's patent invalid. It found that ICI had intentionally withheld crucial information from the PTO regarding safety and effectiveness tests. These tests showed hormonal effects "opposite to those sought in humans," which could have led to "unpredictable and . . . disastrous consequences."¹³³

ICI appealed to the Federal Circuit, and while the appeal was pending, the parties entered into a settlement agreement. Zeneca agreed to pay Barr \$21 million and Barr's supplier more than \$45 million if Barr withdrew its challenge to Zeneca's patent. Barr also agreed, by switching its paragraph IV certification to paragraph III, not to enter the market until Zeneca's patent expired in 2002. And it promised to revert to a paragraph IV certification, which could delay other generic challenges if a court declared the patent invalid. Finally, the parties agreed to file a motion to vacate the judgment invalidating Zeneca's patent.

In addition to the challenges to the validity of Zeneca's patent, consumers filed thirty lawsuits targeting the agreement between Zeneca and Barr. They claimed that the agreement allowed the parties to circumvent the district court's invalidation of the patent. The district court, however, granted the defendant's motion to dismiss, in part because the agreement's termination of the litigation "cleared the field for other generic manufacturers to challenge the patent."¹³⁴ In fact, however, the settlement removed the most

131. Brief for the United States as Amicus Curiae Supporting Respondents' Opposition to Petition for Writ of Certiorari at 11, *FTC v. Schering-Plough Corp. et al.*, 548 U.S. 919 (2006) (No. 05-273).

132. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193 (2d Cir. 2006). The facts are taken from the opinion. *See id.* at 193-99.

133. *Imperial Chem. Indus. v. Barr Labs.*, 795 F. Supp. 619, 622 (S.D.N.Y. 1992).

134. 466 F.3d at 197 (quoting *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 133 (E.D.N.Y. 2003)).

motivated challenger (the first-filing generic) and also delayed other generics' challenges.¹³⁵

The Second Circuit began its analysis by explaining that reverse payments did not constitute per se violations. The court was “not unaware” of the “troubling dynamic” in the cases that “[t]he less sound the patent or the less clear the infringement . . . the more a rule permitting settlement is likely to benefit the patent holder.”¹³⁶ But its concerns were assuaged by relying on the presumption of patent validity, which ensured that settlement was “merely an extension of the valid patent monopoly.”¹³⁷

On the issue of whether reverse payments were “excessive,” the court admitted that it seemed “suspicious” for a patentee to settle litigation against a potential generic manufacturer by paying “more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder.”¹³⁸ But it found the suspicion to “abate[] upon reflection.”¹³⁹

It concluded that as long as “the patent litigation is neither a sham nor otherwise baseless” or beyond the patent’s scope, a patentee can enter into a settlement “to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”¹⁴⁰ Zeneca’s patent litigation, claimed the court, was not baseless or fraudulent.¹⁴¹

The court then found that the agreement’s effects did not exceed the patent’s scope. First, the settlement did not restrict the marketing of noninfringing products. Because Zeneca’s patent “preclude[d] all generic versions of tamoxifen,” any competing version “would . . . necessarily infringe the patent.”¹⁴² Second, by concluding litigation, the agreement “opened the . . . patent to immediate challenge by other potential generic[s].”¹⁴³ Third, the settlement “did not entirely foreclose competition” since a license from Zeneca allowed Barr to market Zeneca’s version of tamoxifen eight months after the agreement became effective.¹⁴⁴ Even if the version distributed by Barr sold for only 5 percent less than Zeneca’s version, the court found that “[t]his was competition nonetheless.”¹⁴⁵

135. Hemphill, *supra* note 58, at 1584–86.

136. 466 F.3d at 211.

137. *Id.*

138. *Id.* at 208.

139. *Id.*

140. *Id.* at 208–09.

141. *Id.* at 213.

142. *Id.* at 214.

143. *Id.*

144. *Id.* at 215.

145. *Id.* at 216.

In the end, the court affirmed the lower court's order granting the defendant's motion to dismiss.

Judge Pooler filed a vigorous dissent. She stated that the majority's "sham" requirement was "not soundly grounded" in precedent and was "insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws."¹⁴⁶ In particular, she pointed to the important public interest in "having the validity of patents litigated," especially "in light of the recent trend toward capping the maximum amounts insurers and public benefit plans will spend on medications."¹⁴⁷ And she highlighted the difference between the interests of the parties and those of the public when "the patent has already been shown to be vulnerable to attack and the generic manufacturer is paid to keep its product off the market."¹⁴⁸

Judge Pooler concluded that a reasonableness standard should apply. Such a standard would rely primarily on the patent's strength at the time of settlement and secondarily on factors such as the size of the payment, the amount the generic firm would earn during its exclusivity period, and other anticompetitive effects. She concluded that the plaintiffs' pleading was adequate to survive a motion to dismiss because of their claims that (1) the patent's invalidity determination would have been affirmed on appeal, (2) Barr "received more than it would have through a victory on appeal," and (3) Barr agreed to "deploy its paragraph IV certification to defeat other potential generic entrants."¹⁴⁹ The judge concluded by contrasting the "factual record not yet in existence" in the case with the "full record" that courts had considered in other Hatch-Waxman cases.¹⁵⁰

D. Ciprofloxacin

The fourth case involved ciprofloxacin hydrochloride, the active ingredient in Cipro, a drug prescribed to treat bacterial illnesses.¹⁵¹ In 1987, the PTO issued a patent covering the compound, and Bayer's predecessor received marketing approval from the FDA.

In 1991, Barr Labs filed an ANDA for a generic version of Cipro, which included a paragraph IV certification that the patent was invalid and unenforceable. In 1992, Bayer sued Barr for patent infringement. Just before trial was scheduled to begin in 1997, the parties settled, with Bayer paying Barr \$49 million in return for Barr's agreement to convert its paragraph IV certification to paragraph III (thus not entering the market until after the

146. *Id.* at 224 (Pooler, J., dissenting).

147. *Id.* at 225–26 (Pooler, J., dissenting).

148. *Id.* at 226 (Pooler, J., dissenting).

149. *Id.* at 228 (Pooler, J., dissenting).

150. *Id.* at 232 (Pooler, J., dissenting).

151. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008). The facts are taken from *id.* at 1327–30. *See also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 518–19 (E.D.N.Y. 2005).

expiration of its patent). The parties also agreed that Barr would not manufacture a generic version of Cipro and that Bayer would supply Barr with Cipro for resale or make quarterly payments from 1998 until 2003. Four companies—Ranbaxy, Mylan, Schein, and Carlsbad—subsequently filed paragraph IV certifications. Bayer sued each for infringement.

The district court granted Bayer's motion for summary judgment. It found that Bayer had market power in the market for ciprofloxacin and that any adverse effects on competition from the agreement were "within the exclusionary zone" of the patent.¹⁵² It also rejected the argument that a patent's exclusionary power is limited by the possibility that it is invalid.

The Federal Circuit found no error in the district court's analysis. It offered multiple arguments in support of its conclusion that there was no liability. First, the agreements only "exclude[d] the defendants from profiting from the patented invention," thus falling "well within Bayer's rights as the patentee."¹⁵³ Second, "a patent is presumed to be valid," with patent law bestowing "the right to exclude others from profiting by the patented invention."¹⁵⁴ Third, a "long-standing policy in the law" favored settlements, with patent settlements, according to the court, frequently providing that the alleged infringer will not challenge patent validity.¹⁵⁵

Fourth, the court pointed to the "not unexpected" occurrence under Hatch Waxman of "a sizable exclusion payment from the patent holder to the generic manufacturer."¹⁵⁶ Fifth, it found "no evidence" that the settlements prevented challenges by other generic firms to the patent.¹⁵⁷ And sixth, the Federal Circuit concluded that the "essence of the inquiry" was "whether the agreements restrict competition beyond the exclusionary zone of the patent."¹⁵⁸ It found that the agreements did not do so, and that, in the absence of evidence of fraud before the PTO or sham litigation, the court "need not consider the validity of the patent."¹⁵⁹

In sum, the *Cardizem* court applied the most aggressive scrutiny to reverse-payment settlements. On the other hand, the *Schering*, *Tamoxifen*, and *Ciprofloxacin* courts, as discussed in the next section, applied an excessively deferential analysis that failed to appreciate the regulatory framework.

152. See 363 F. Supp. 2d at 523–41.

153. 544 F.3d at 1332–33.

154. *Id.* at 1337.

155. *Id.* at 1333.

156. *Id.* at 1333 n.11.

157. *Id.* at 1334.

158. *Id.* at 1336.

159. *Id.*

III. ANALYSIS OF COURTS' APPROACHES

Recent courts—in particular, the *Schering, Tamoxifen*, and *Ciprofloxacin* courts—have justified their conclusions on policies of secondary importance. In addition, they have insufficiently recognized both the Hatch-Waxman framework and potential antitrust harm of reverse-payment agreements.

The Hatch-Waxman Act reflects Congress's position on the balance between competition and innovation in the pharmaceutical industry. It was designed to solve specific problems. It addressed high drug prices and insufficient generic entry by promoting competition. It dealt with shortened effective patent terms resulting from changes in the FDA approval process by promoting innovation. This specific calibration displaces more general views on the patent and antitrust regimes.¹⁶⁰ Its explicit resolution is especially helpful given the difficulty of reconciling the patent and antitrust laws.

Recent courts, however, have ignored this specific guidance. They have taken upon themselves the Herculean task of reconciling competition and innovation. They have done this even though the legislature's preferred equilibrium appears before them on the silver platter of the Hatch-Waxman Act.

Courts, for example, have emphasized the benefits of settlement and, relatedly, the positive effects of settlements on innovation. At the same time, they have ignored the competition benefits of challenges to invalid patents. This gets it exactly backward. Innovation-based arguments for settlement do not appear in the Act's text or legislative history. On the other hand, even a cursory consideration of the statute underscores the importance of patent challenges.

Fleshing out these errors, Part III explores the five policies on which courts have relied in justifying their deference to reverse-payment agreements. These policies have emphasized (1) the importance of settlements, (2) the link between settlements and innovation, (3) the presumption of patent validity, (4) the scope of the patent, and (5) the "natural" status of reverse payments. An appreciation for the Hatch-Waxman framework demonstrates the secondary importance of these policies.

A. Importance of Settlements

First, courts have voiced a general policy in favor of settlement. They have recognized that settlements conserve resources, provide certainty that encourages investment, and result in licenses increasing competition.¹⁶¹ Settlements are particularly beneficial for patent litigation, which is lengthy,

160. See Hemphill, *supra* note 58, at 1614.

161. See *In re Schering-Plough Corp.*, 36 F.T.C. 956, 999–1003 (2003), *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005); U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY ¶ 2.3 (1995).

complex, and costly.¹⁶² For these reasons, the *Tamoxifen* court explained that “‘courts are bound to encourage’ . . . settlement[s].”¹⁶³ And the court in *Schering* found that “[t]he general policy of the law is to favor the settlement of litigation,” and that “the policy extends to the settlement of patent infringement suits.”¹⁶⁴

But reverse-payment agreements are not typical settlements. They are agreements that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme. Any general preference in the law for settlement was displaced by the Act’s specific framework.

A 180-day period of exclusivity for the first ANDA to challenge a patent only makes sense in the context of encouraging patent challenges. Moreover, the purpose of the exclusivity period, to ensure that a generic competitor could not “free ride” on a rival’s litigation efforts before the first filer recovered litigation costs, is not promoted if the litigation never produces a judgment benefiting other generics.¹⁶⁵

In addition, the 180-day period applies only to ANDA filers that seek to enter before the end of the patent term. It does not apply to certification challenges that target expired patents or delay approval until the end of the patent term. On the other side, the 30-month-stay provision reveals patentees’ incentives to file suit after receiving notice of a paragraph IV certification.¹⁶⁶

Finally, the 180-day bounty itself demonstrates the unique nature of these agreements. General patent settlements do not prevent other competitors from challenging the patent. In these cases, even if the settling defendant agrees not to challenge the patent, many others often wait in the wings to do so. In contrast, the Hatch-Waxman bounty creates a regulatory barrier to entry that can significantly delay other patent challenges. Competition’s central role is confirmed by the repulsion to reverse payments exhibited by Senator Hatch and Representative Waxman in the 2003 Medicare amendments debate.¹⁶⁷

In short, general patent-based policies in favor of settlements must give way to an industry-specific resolution that encourages patent challenges.

162. In 2007, in patent cases with more than \$25 million at risk, each party faced a median expense of \$5 million. AM. INTELLECTUAL PROP. LAW ASS’N, REPORT OF THE ECONOMIC SURVEY 2007 25 (2007).

163. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 202 (2d Cir. 2006) (citation omitted).

164. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

165. Engelberg, *supra* note 47, at 423.

166. FTC Cert Petition, *supra* note 105, at 4.

167. See *supra* notes 72–73 and accompanying text.

B. Settlements and Innovation

The second principle motivating courts is to defer to settlements so as not to harm incentives for innovation. The *Tamoxifen* court stated that rules “severely restricting” settlements could hamper the patent system’s goals by increasing uncertainty and delaying innovation.¹⁶⁸ Similarly, the court in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*¹⁶⁹ concluded that reduced settlement options would raise enforcement costs and “impair . . . incentives for disclosure and innovation.”¹⁷⁰ The district court in *Ciprofloxacin* found that the inability of brand-name firms to “control or limit their risk” through settlements could “chill[] efforts to research and develop new drugs” and lead to “severe consequences for consumers.”¹⁷¹ And the *Schering* court found that “the caustic environment of patent litigation” could reduce innovation by increasing the “uncertainty around the drug manufacturer’s ability to research, develop, and market the patented product.”¹⁷²

Any effects of settlements on innovation, however, are secondary in the context of the Hatch-Waxman Act. The Act, once again, offered a nuanced equilibrium between competition and innovation. To promote innovation, the drafters offered patent term extensions, nonpatent market exclusivity, and a 30-month stay of FDA approval for generics filing paragraph IV certifications. Nowhere in the Act or legislative history did the drafters ever link settlements to innovation. And since the Act’s passage, the drafters’ consistently negative reactions to such settlements have confirmed the absence of such a link.

C. Presumption of Patent Validity

Third, courts have upheld settlement agreements based on a presumption of patent validity. Section 282 of the Patent Act states that patents “shall be presumed valid.”¹⁷³ Courts have relied on this presumption to ascertain the validity that is so crucial to determining the appropriate antitrust treatment.¹⁷⁴ A settlement that allows generic entry before the end of the term of a valid patent promises to accelerate competition. In contrast, a settlement delaying entry beyond the date the generic could have entered on an invalid patent could allow the firms to divide the market.

168. 466 F.3d at 203.

169. 344 F.3d 1294 (11th Cir. 2003).

170. *Id.* at 1308.

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

172. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

173. 35 U.S.C. § 282 (2006).

174. Courts apply the same patentability requirements—subject matter, novelty, utility, non-obviousness, and enablement—in determining validity that the PTO applies in initially determining whether to grant a patent. *See id.* §§ 101, 102, 103, 112 (2006).

It is in this context that a substantive role for the procedural burden plays an outsized role. The *Tamoxifen* court, for example, found that the presumption of validity allows parties to settle “weak patent cases” even though “such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.”¹⁷⁵ The *Schering* court relied on the presumption in concluding that a brand firm would not suffer antitrust liability for exclusionary activity unless generics were able to prove a patent’s invalidity or noninfringement.¹⁷⁶ And the court in *In re Ciprofloxacin* asserted that “analysis of patent validity” is not “appropriate in the absence of fraud or sham litigation” since “a patent is presumed to be valid.”¹⁷⁷

Courts have also relied on the presumption in rebutting assertions by the FTC and commentators that patents are “probabilistic property right[s]”¹⁷⁸ or rights to “try to exclude” (as opposed to “right[s] to exclude”).¹⁷⁹ Such an argument highlights the uncertainty of patent rights and contends that settlements should not leave consumers in a worse position than they would have been through ongoing litigation. Consumers, in other words, have a “property right” to the competition that would have prevailed in litigation.¹⁸⁰

But courts have rejected these arguments, which “undermin[e] the presumption of validity that Congress has afforded patents.”¹⁸¹ They have found that settling parties are not required to “preserve the public’s interest in lower prices.”¹⁸² They have worried that the probabilistic approach would have adverse effects on patent licenses, “undermin[ing] the settled expectations of patentees and potential . . . licensees across countless industries.”¹⁸³ And they have made clear that “there is no support in the law” for “a public property right in the outcome of private lawsuits.”¹⁸⁴ Settling parties, in short, have “no duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the consumer.”¹⁸⁵

175. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 211 (2d Cir. 2006).

176. 402 F.3d at 1066–67.

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

178. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003); see also Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, 21 RES. L. & ECON. 475, 484 tbl.4 (2004).

179. Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 75 (2005). See generally Steven W. Day, Note, *Leaving Room for Innovation: Rejecting the FTC’s Stance Against Reverse Payments in Schering-Plough v. FTC*, 57 CASE W. RES. L. REV. 223, 233–36 (2006).

180. Shapiro, *supra* note 178, at 396.

181. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 533 (E.D.N.Y. 2005).

182. *Id.* at 541.

183. *Id.* at 533.

184. *Id.* at 531.

185. *Id.* at 532.

For four separate reasons, however, the Patent Act's presumption of validity is entitled to far less weight than courts have accorded it. First, it is only a procedural evidentiary presumption.¹⁸⁶ Patentees cannot, for example, rely on the presumption as substantive evidence in preliminary-injunction proceedings. As the Federal Circuit has explained, the presumption is a "procedural device" for allocating burdens of production and persuasion at trial, not "evidence which can be 'weighed' in determining likelihood of success" at the preliminary injunction stage.¹⁸⁷ "A presumption of validity," as scholars in a recent amicus brief colorfully analogized, "does not entitle a patentee to evade the test of patent litigation any more than a criminal defendant's presumption of innocence entitles him to avoid trial."¹⁸⁸

Second, the presumption should be entitled to the *least* amount of deference in situations in which the parties enter agreements that prevent validity from even being challenged. Patent litigation plays an important role in testing weak patents and ensuring that the public does not suffer the adverse effects of invalid ones.¹⁸⁹ The Supreme Court has recognized such an objective in several cases that have allowed licensees to challenge validity.¹⁹⁰ The presumption of validity should be particularly weak when the activity at issue precludes the testing of patents.

Third, confirming the fragile status of the presumption, the Hatch-Waxman Act's text and legislative history demonstrate the importance of invalidity challenges. Increasing generic competition was a primary goal of the legislation. That is why Congress provided a 180-day bounty to the first generic to challenge a patent's invalidity. Settlements preventing patent challenges are a particularly inappropriate setting for the presumption.

Fourth, empirical studies have consistently shown that a significant percentage of granted patents are invalid. Surveys have found that

- courts invalidated 46% of patents between 1989 and 1996;¹⁹¹
- the alleged infringer prevailed in 42% of the patent cases that reached trial between 1983 and 1999;¹⁹²

186. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).

187. *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992); *see* Hemphill, *supra* note 58, at 1602 n.181.

188. Corrected Brief for 28 Professors of Law, Business, and Economics as Amici Curiae Supporting Appellants at 12, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097).

189. *Id.*

190. *See* *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264 (1979); *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

191. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 *AIPLA Q.J.* 185, 205 (1998) (survey limited to cases resulting in a final judgment of validity).

192. Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 *MICH. L. REV.* 365, 385 (2000).

- in patent cases between 2000 and 2004, courts found that 43% of patents were invalid and 75% were not infringed.¹⁹³

In the context of generic challenges in particular, the rate of invalidity appears to be even higher. In a study of paragraph IV challenges between 1992 and 2000, the FTC found that the generic prevailed in 73% of the cases and that the brand-name companies won only 27% of the time.¹⁹⁴ These figures are consistent with a survey of Federal Circuit decisions from 2002 through 2004 that found that pharmaceutical patentees were successful on the merits in 30% of the cases.¹⁹⁵

This invalidity rate is particularly concerning, and the potential anticompetitive effects especially staggering, given the importance of the drugs that have been the subject of lawsuits. In the FTC study of challenges between 1992 and 2000, sales were far higher in the cases in which brand firms sued generics. For the seventy-five drug products subject to litigation, the first generic applicant gained \$190 million in median net sales the year it filed its ANDA.¹⁹⁶ In contrast, most of the twenty-nine new drug applications that were not subject to suit had net sales of less than \$100 million in the year of filing.¹⁹⁷

Lawsuits have been particularly prevalent on blockbuster drugs such as Cipro, Claritin, Paxil, Pravachol, Prilosec, Prozac, and Zoloft.¹⁹⁸ In fact, of the ten top-selling brand drugs in the United States in 2006, at least six (Nexium, Prevacid, Singulair, Effexor XR, Plavix, and Lexapro) were the subject of litigation under the Hatch-Waxman Act in 2008.¹⁹⁹

D. Patent Scope

The fourth framework on which courts have relied involves the patent's scope. Courts have tended to uphold reverse payments as a type of activity falling within the scope of the patent.

The court in *Ciprofloxacin* found that “[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone

193. Patstats.org, Univ. of Houston Law Ctr. Decisions for 2000–2004, Issue Codes 1–16, 23, 24, [http://www.patstats.org/Composite%20Table%20\(2000–2004\).html](http://www.patstats.org/Composite%20Table%20(2000–2004).html) (last visited May 18, 2009).

194. GENERIC DRUG STUDY, *supra* note 43, at 10, 16.

195. Paul M. Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 (2006).

196. GENERIC DRUG STUDY, *supra* note 43, at 14.

197. *Id.*

198. *Id.* at 10–11. See generally Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 331 (2005).

199. Corrected Brief for Federal Trade Commission as Amicus Curiae Supporting Appellants at 9, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097).

of the patent.”²⁰⁰ The court in *Schering* similarly concluded that reverse payments were “within the patent’s exclusionary power.”²⁰¹ The *Tamoxifen* court found that the settlement did not “unlawfully extend the reach” of the patent.²⁰² And the *Valley Drug* court sought to achieve “[a] suitable accommodation between antitrust law’s free competition requirement and the patent regime’s incentive system” by immunizing activity within the patent’s scope.²⁰³

The concept of scope, however, cannot do all the work courts require of it. The overriding question in these cases is whether the patent is valid. If it is, then an agreement allowing entry before the end of the patent term is within the scope. But if the patent is not valid, there is no scope at all.²⁰⁴ For that reason, judicial inquiries into the scope or “exclusionary potential” of the patent assume validity and thus eliminate antitrust concern. As stated above, the procedural presumption is not sufficient to prove substantive validity. In assuming the very validity it seeks to prove, therefore, scope is not an appropriate inquiry.

E. Natural Status

The fifth foundation on which courts have relied is the “natural” status of reverse payments under the Act. The *Schering* court explained that “[r]everse payments are a natural by-product of the Hatch-Waxman process” and that “patents, payments, and settlement are . . . all symbiotic components that must work together . . . for the larger abstract to succeed.”²⁰⁵ The *Tamoxifen* court noted that reverse payments were “particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them.”²⁰⁶ And the *Ciprofloxacin* court explained that “sizable” reverse payments are a “not unexpected” occurrence under Hatch Waxman.²⁰⁷

Courts are correct that reverse payments have accompanied settlement agreements under the Act. But that is a far cry from a conclusion that such a development is beneficial.²⁰⁸ In fact, it may reflect no more than the parties’ preference for sharing monopoly profits. To consider the point more broad-

200. *In re Ciprofloxacin*, 544 F.3d at 1336.

201. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

202. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006).

203. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003).

204. Andersen, *supra* note 69, at 1054–55.

205. 402 F.3d at 1074.

206. 466 F.3d at 206.

207. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 n.11 (Fed. Cir. 2008).

208. See Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758 (2003).

ly, we would not justify collusion in an industry based on rivals' effortlessly engaging in it. Similarly, the legality of reverse-payment settlements in no way depends on their frequency.

If the foundations of courts' reasoning are flawed, how should reverse-payment settlements be analyzed? In the next section, I offer a new framework justifying the presumptive illegality of these agreements.

IV. PROPOSAL

The framework I propose aims to bridge the gap between courts and commentators. As discussed above, courts have fastened on policies that are of secondary significance in the context of Hatch-Waxman. In contrast, the FTC and an array of commentators have sounded alarms about the concerning nature of reverse-payment settlements.²⁰⁹ But to date, they have not articulated a construct on which courts have relied in invalidating the agreements. For example, a focus on a right to "try to exclude" runs headlong into the presumption of patent validity on which courts have been transfixed.

My argument for presumptive illegality has five elements:

- (1) The existence of Hatch-Waxman's regulatory structure;
- (2) The regime's ineffectiveness in promoting patent challenges;
- (3) The severe anticompetitive harm of market allocation;
- (4) The uniquely concerning nature of reverse payments; and
- (5) A rebuttal for reverse payments reflecting reasonable assessments of patent validity.

Given the first four elements, the default position should be that such agreements are presumptively illegal. Because these agreements are not generally procompetitive in nature, deferential review under the Rule of Reason is not appropriate.²¹⁰ And because some agreements could conceivably be justified if the reverse payments reflected the parties' reasonable assessments of patent validity, per se illegality also is not appropriate at this time.²¹¹

209. See, e.g., *id.*; Hemphill, *supra* note 58; Shapiro, *supra* note 178.

210. Pursuant to the Rule of Reason, courts consider an agreement's anticompetitive and procompetitive effects. In the initial stage of analysis, a plaintiff must demonstrate an anticompetitive effect, typically by showing a defendant's market power. In most cases, plaintiffs cannot make this showing. See Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 B.Y.U. L. REV. 1265, 1268 (finding that courts dismissed 84 percent of Rule-of-Reason cases on the grounds that the plaintiff could not show a significant anticompetitive effect).

211. Courts apply per se treatment—essentially invalidating an agreement once its existence is shown—to price fixing, bid rigging, and market-allocation agreements, all of which are likely to lead to competitive harm and unlikely to offer benefits. See MICHAEL A. CARRIER, *INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW* 56 (2009).

A default position that reverse payments are presumptively anticompetitive recognizes the framework and increasing ineffectiveness of the Hatch-Waxman Act. It also acknowledges the potentially severe anticompetitive effects of reverse-payment settlements, which are particularly suspicious given the aligned incentives of the parties and windfalls received by generics.

An error-costs analysis of settlements confirms the propriety of the presumptive illegality approach. There are two types of errors in the antitrust analysis of settlements. Courts committing Type I errors wrongfully punish lawful activity such as reasonable payments on valid patents. Type II errors, in contrast, wrongfully allow illegal activity such as excessive payments on invalid patents.

In encouraging settlements and giving effect to the presumption of patent validity, courts have sought to minimize Type I errors. In the process, however, they have increased the frequency of Type II errors. This is a mistake. The Hatch-Waxman framework was designed to encourage patent challenges, reduce delay in entering the market, and promote generic competition. Type II errors, in allowing parties to delay entry on invalid patents, fly in the face of the Act's text and intent. The Act's preference for Type I errors confirms the propriety of presumptive illegality.

Having situated the default position most generally, the remainder of Part IV fleshes out each of the elements of the framework.

A. Regulatory Regime: Existence and Equilibrium

One of the most important antitrust developments in recent years has been the Supreme Court's attention to regulatory regimes in determining the appropriate analysis. As discussed in this Section, the Court has pointed to such regimes in the telecommunications and securities contexts in downplaying the need for antitrust enforcement.

The Supreme Court in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*²¹² considered the effect of a regulatory regime on the application of the antitrust laws. The Telecommunications Act of 1996 sought to break up local monopolies by requiring incumbent local exchange carriers (ILECs), which had state-provided monopolies in the provision of local phone service, to share their networks with competitors. The *Trinko* case arose when an AT&T customer alleged that Verizon discriminated against new entrants in the local market.²¹³

The Court found that the 1996 Telecommunications Act "deter[red] and remed[ied] anticompetitive harm."²¹⁴ As a result, it rejected the plaintiff's refusal-to-deal claim. The presence of the telecommunications regime sig-

212. 540 U.S. 398 (2004).

213. See generally Michael A. Carrier, *Of Trinko, Tea Leaves, and Intellectual Property*, 31 J. CORP. L. 357 (2006).

214. *Trinko*, 540 U.S. at 412.

nificantly reduced “the additional benefit to competition provided by anti-trust enforcement.”²¹⁵ In contrast, the Court continued, where “nothing built into the regulatory scheme . . . performs the antitrust function . . . the benefits of antitrust are worth its sometimes considerable disadvantages.”²¹⁶

In addition to considering the role of the telecommunications regime in fostering competition, the Court more generally described the relationship between antitrust and regulation. It explained that “[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue.”²¹⁷ In particular, courts must take “careful account” of “the pervasive federal and state regulation characteristic of the industry.”²¹⁸ The analysis also must “recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.”²¹⁹

Consistent with this approach, the Court in *Credit Suisse Securities v. Billing*²²⁰ concluded that the securities law regime “implicitly preclud[ed]” the application of the antitrust laws. In *Billing*, securities buyers challenged practices by which underwriting firms forced them to buy additional shares, pay high commissions, and purchase less desirable securities. The Court explained that the conduct fell “squarely within the heartland of securities regulations”²²¹ and that the Securities and Exchange Commission (SEC) had authority to supervise the activities and “continuously exercised” such authority.²²² It also pointed to the “complex, detailed line” separating permitted from forbidden activity and the existence of activity that could be punished under the antitrust laws but upheld under the securities laws.²²³

Just as the telecommunications and securities regimes presented comprehensive frameworks, the Hatch-Waxman Act offered an exhaustive scheme that prescribed Congress’s desired balance between competition and innovation in the drug industry. The drafters used patent-term extensions, market exclusivity, and 30-month stays to foster innovation. And they created a market exclusivity period and revived the experimental-use defense to promote generic competition. The Act, in short, constructed a delicate equilibrium that demonstrated the secondary relevance of settlement-related policies on which the courts have been riveted.

The drafters, for example, did not demonstrate any concern for the relationship between settlements and innovation. Innovation was an important

215. *Id.*

216. *Id.*

217. *Id.* at 411.

218. *Id.* (quoting *United States v. Citizens & S. Nat’l Bank*, 422 U.S. 86, 91 (1975)).

219. *Id.*

220. 127 S. Ct. 2383, 2387 (2007).

221. *Id.* at 2397.

222. *Id.* at 2393.

223. *Id.* at 2394.

objective of the statute, but it was fostered through other mechanisms, such as patent-term extensions and nonpatent market exclusivity.

The Act's policy encouraging validity challenges also displaced a general preference for settlements. Looking at the marketplace in 1984, the drafters saw high drug prices and few generics. They sought to increase competition and obtain early generic entry by implementing a market exclusivity period to encourage challenges to invalid and noninfringed patents. Reserving this period for generics that wished to enter during the patent term confirmed the importance of early entry and concern with settlements delaying entry.

Comparing Hatch-Waxman to the telecommunications and securities regimes that the Supreme Court has considered uncovers modest differences in goals, from promoting competition (the Hatch-Waxman and telecommunications regimes) to disclosing information (securities regulation). Another disparity involves the identity of the parties enforcing the regimes. While the telecommunications and securities acts rely on federal regulators, Hatch-Waxman depends on generic firms challenging invalid patents. As described more fully in the next section, however, this enforcement mechanism has been gutted in recent years as settlements have markedly reduced the regime's effectiveness. As a result, I employ the *Trinko* framework not to *limit* antitrust but to *justify* its aggressive application.

B. Regulatory Regime: Effectiveness

Before minimizing the need for antitrust, courts must find not only that a regulatory regime exists but also that it functions effectively.²²⁴ In *Trinko*, Justice Scalia explained that phone companies that provided local service were required to “be on good behavior” and not to discriminate in providing access to certain facilities before they could enter the long-distance market.²²⁵ In addition, firms that did not satisfy these conditions were subject to financial penalties, daily or weekly reporting requirements, and the suspension or revocation of long-distance approval.²²⁶ In *Credit Suisse*, the Court noted the SEC's active enforcement, pointing as one example to its detailed definitions of “what underwriters may and may not do and say during their

224. A contrary position might show less concern with an ineffective regulatory regime, as such a regime could reflect a deliberate underenforcement strategy rather than a need for antitrust oversight. See Philip J. Weiser, *The Relationship of Antitrust and Regulation in a Deregulatory Era* 21 (U. Colo. Legal Research Paper Series, Paper No. 06-19, 2006), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=814945. But deliberate underenforcement does not appear likely in the Hatch-Waxman context, as revealed by the drafters' hostile reactions to reverse-payment settlements.

225. 540 U.S. 398, 412 (2004).

226. See *id.* at 412–14. Even if the effectiveness of the telecommunications regime was weaker than the Court anticipated, at least the regulators were engaging in some actions that promoted competition. Carrier, *supra* note 213, at 369–70.

road shows” and bringing actions against underwriters who violated the regulations.²²⁷

In contrast, in the Hatch-Waxman setting, generic firms have recently been less effective in promoting competition. The drafters of the Act encouraged challenges to invalid or noninfringed patents. They believed that such challenges would lead to earlier market entry and lower prices for consumers. And they assumed that generics could enter the market immediately upon a judicial finding of invalidity.

Although generic entry has burgeoned in the quarter century since Congress enacted the law, generics are increasingly not serving their designated function.²²⁸ They are agreeing not to challenge patents and not to enter markets in exchange for payment. Many settlements even provide more money than the generic could have received by proving invalidity and entering the market.

The 180-day bounty, in particular, has been twisted from an incentive for the generic to challenge patents to a barrier to entry preventing challenge. By settling with the first to challenge under the 180-day bounty, the brand firm can significantly delay other generics’ entrance into the market.

In short, the Hatch-Waxman Act’s carefully balanced regulatory regime is not working as intended to promote competition.

C. Antitrust Harm

Just because the Act is not fulfilling its intended function does not mean that antitrust should offer assistance. As it turns out, however, the discipline can play a uniquely effective role in repairing Hatch-Waxman. Such a role is warranted given the severe anticompetitive dangers threatened by reverse-payment settlements. Of all the types of business activity, agreements by which competitors divide markets threaten the most dangerous anticompetitive effects.

Why does market division present more competitive concern than monopolization, agreements between suppliers and dealers, and price fixing? Because it restricts *all* competition between the parties on *all* grounds. Even price fixing allows the parties to compete on factors other than price. Where competitors divide markets, in contrast, consumers are robbed of competition on all grounds.

The Supreme Court has explained that “[o]ne of the classic examples of a *per se* violation . . . is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition.”²²⁹ Courts have consistently found territorial allocations between

227. 127 S. Ct. at 2393.

228. See Hemphill, *supra* note 58, at 1615; Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 19 (2004).

229. *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972).

competitors to be per se illegal.²³⁰ In *Palmer v. BRG of Georgia, Inc.*,²³¹ to pick one example, the Supreme Court applied per se illegality to an agreement by which competitors divided markets, agreeing not to compete in the other's territory.²³²

Settlement agreements by which brands pay generics not to enter the market threaten dangers similar to territorial market allocation. But instead of allocating geographic space, in which the parties reserve for themselves particular territories, they allocate time.²³³ The brand and generic, in other words, agree that the brand will not be subject to competition for a period of time, thereby dividing the market and preventing competition. When the patent is invalid, there is no justification—and thus significant anticompetitive harm—from the agreement.

Nor is it a defense that settlements block only potential competitors not certain to enter the market. The D.C. Circuit in the *Microsoft* case recognized that “it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will.”²³⁴ The leading antitrust treatise similarly explains that “the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition.”²³⁵

The anticompetitive harm at issue has human consequences. Artificially high prices result in patients not filling prescriptions or splitting pills in half.²³⁶ Decisions not to comply with doctors' orders because of high costs result in pain, more severe medical conditions, and even death.²³⁷ Such harms are magnified by the blockbuster nature of many of the drugs at the center of reverse-payment agreements.

Not all patent settlements, to be sure, constitute market-allocation agreements. If a patent is valid and infringed, the patentee could rely on the patent itself to restrict competition. In that case, an agreement that allows a generic to enter before the end of the patent term could increase competition. On the other hand, if a patent is invalid or not infringed, there is no legitimate justification for delaying competition. In such a setting, the agreement serves as a cover for market-allocation agreements.

230. ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 103 (6th ed. 2007).

231. 498 U.S. 46 (1990) (per curiam).

232. *Id.* at 49–50.

233. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 968–74 (2003), *vacated*, Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005).

234. *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc).

235. 12 HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2030b, at 213 (2d ed. 2005).

236. Brief for American Antitrust Institute as Amicus Curiae Supporting Petitioners at 8, *In re Tamoxifen Citrate Antitrust Litig.*, 127 S. Ct. 3001 (No. 06-830).

237. Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors*, 61 MED. CARE RES. & REV. 415, 420, 427–28 (2004).

The appropriate antitrust treatment of patent settlements thus depends on the validity of the patent and existence of infringement. But the most straightforward way to determine these issues, patent litigation, is not appropriate in this setting. Determining patent validity and infringement would require significant analysis and testimony on complex issues such as patent-claim interpretation and infringement analysis. Such inquiries, which could take weeks, cannot be inserted as mini-trials within antitrust cases.

In addition, an analysis of the merits of the patent infringement case would be unreliable. After a case settles, the parties' interests become aligned, with a generic firm lacking the incentive to vigorously attack a patent's validity or an infringement claim. In the *Schering* case, the generic had initially certified that the brand's patent was invalid or not infringed by its product. After settlement, the generic's views "dramatically changed," with the chief financial officer testifying that because of the risk posed by infringement damages, the company would not market its drug until the litigation was concluded.²³⁸

Finally, patent settlements in this setting create unique barriers to entry. Settlements outside the Hatch-Waxman setting typically do not prevent third parties from challenging patents. In the Hatch-Waxman context, in contrast, they delay, if not prevent, other challenges. Moreover, after the brand firm settles with the first generic filer, subsequent generics would be less motivated to pursue a challenge since they would be further behind in the approval process, would not be entitled to the market exclusivity period, and would receive a return dependent on the outcome of the first filer's suit.²³⁹ Such hurdles loom large given the costs of developing generic drugs and receiving FDA approval.

D. Reverse Payments

Even if a direct determination of validity and infringement is not appropriate, reverse payments offer another option for addressing these issues. Red flags of potential invalidity are raised when brands pay generics more than they ever could have gained by entering the market.

Further hoisting such flags are the parties' aligned incentives. Because the brand makes more by keeping the generic out of the market than the two parties would receive by competing in the market, the parties have an incentive to split the monopoly profits, making each better off than if the generic had entered. The generic, in fact, often gains more through settlement than through successful litigation. Generics have powerful incentives to file the first patent challenge but little incentive to pursue the litigation.²⁴⁰

238. *In re Schering-Plough*, 136 F.T.C. at 992–99.

239. Hemphill, *supra* note 58, at 1586.

240. Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III*, 30 SEATTLE U. L. REV. 377, 381 (2007).

Other types of agreements do not align the parties' incentives as directly. One example is a traditional licensing agreement by which a generic pays a brand to enter the market. This resembles the typical settlement that presents significantly less concern because it leads to more competition. And it presents different incentives, with the brand seeking higher royalties and the generic desiring lower payments.

Another example, though slightly more nuanced, involves the determination of the date of generic entry. Commentators have reasonably viewed the incentives of the parties as divergent, with a brand firm desiring late entry and a generic firm coveting early entry.²⁴¹ To the extent a generic firm prefers the certainty of an exclusivity period to its early commencement, the parties' incentives might be modestly more aligned.²⁴² The reverse-payment scenario, in contrast, does not offer any deviation from wholly aligned incentives.

In addition, reverse payments differ from other regulatory activity and settlements since the remedies are more likely to lie within courts' expertise. The Supreme Court in *Trinko* worried about courts' ability to craft remedies for unilateral refusals to deal, for which they would need to determine the assets to be shared and price charged for the shared assets.²⁴³ In contrast, courts are more likely to correctly analyze agreements between competitors.

They also are able to determine whether reverse payments represent an objective assessment of the transferred asset's value or an excessive payment to delay entry. Such an inquiry is easier than other obligations such as the reasonable-royalty calculation in determining patent damages. Courts calculating reasonable royalties construct a hypothetical licensing negotiation to determine what the infringer would have paid, considering factors such as the rate for similar patents, the importance of the invention, and expert testimony.²⁴⁴ In contrast to selecting a reasonable royalty from an infinite array of potential rates, the inquiry here begins with a single specified rate and asks whether it appears unreasonable. In the *Schering* case, the FTC demonstrated how to execute such an inquiry by exhaustively documenting the company's lack of interest in the transaction.²⁴⁵

Finally, as an empirical matter, reverse payments do not appear necessary to settle disputes between brands and generics. These payments disappear when challenged and reappear when the antitrust coast is clear. Between 1992 and 1999, 8 of the 14 final settlements between brands and

241. *E.g.*, Hovenkamp et al., *supra* note 208, at 1762.

242. Hemphill, *supra* note 58, at 1593.

243. HERBERT HOVENKAMP, *THE ANTITRUST ENTERPRISE: PRINCIPLE AND EXECUTION* 247–48 (2005).

244. *E.g.*, *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970). See generally Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 *TEX. L. REV.* 1991, 2018–19 (2007).

245. *In re Schering-Plough Corp.*, 36 F.T.C. 956, 1003–53, *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

generic first filers involved reverse payments.²⁴⁶ In 2000, the FTC announced that it would challenge such settlements.²⁴⁷ In the succeeding four years, between 2000 and 2004, *not one* of twenty reported agreements involved a brand firm paying a generic filer to delay entering the market.²⁴⁸ During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry.

In 2005, after the *Schering* and *Tamoxifen* courts took a lenient view of these agreements, the reverse-payment floodgates opened. In 2005, 3 of 11 final settlements (27%) between brand-name and generic firms included such payments.²⁴⁹ In 2006, 14 of 28 settlements (50%) contained these provisions.²⁵⁰ And in 2007, 14 of 33 settlements (42%) included such compensation.²⁵¹ Equally concerning, in the past two years roughly 70 to 80% of settlements between brand firms and first generic filers have involved reverse payments.²⁵²

Even if a direct determination of patent validity is not possible, strong evidence of invalidity is presented by payments from brands to generics that exceed what the generics could have gained by entering the market. Absent proof of consideration for a brand's significant payment to a generic, the quid pro quo for the payment would appear to be the generic's agreement to defer entry beyond "the date that represents an otherwise reasonable litigation compromise."²⁵³ Given the severe anticompetitive effects of market division, courts must search for such indicators.

246. BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2005 4 (2006) [hereinafter FY 2005 AGREEMENTS], available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

247. Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary, 65 Fed. Reg. 17506 (April 3, 2000), available at <http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm>.

248. FY 2005 AGREEMENTS, *supra* note 246, at 4.

249. BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006 4 (2007) [hereinafter FY 2006 AGREEMENTS], available at <http://www.ftc.gov/reports/mmact/MMAreport2006.pdf>.

250. FY 2005 AGREEMENTS, *supra* note 246, at 4.

251. BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2007 3 (2008) [hereinafter FY 2007 AGREEMENTS], available at <http://www.ftc.gov/os/2008/05/mmaact.pdf>.

252. *Id.* at 5 (11 of 16 agreements, or 69 percent); FY 2006 AGREEMENTS, *supra* note 249, at 6 (9 of 11 agreements, or 82 percent).

253. FTC Cert Petition, *supra* note 105, at 18.

E. Rebuttal

The last four sections have shown that the appropriate default position for reverse-payment settlements should be presumptive illegality. But because in certain cases payments could reflect an objective assessment of the patent's strength, the settling parties should have the opportunity to rebut this presumption. In offering such a rebuttal, I conservatively allow the parties to introduce arguments that have been offered in the economic literature. If judicial experience demonstrates that these arguments do not in fact justify the payments, then per se illegality might ultimately become a more appropriate treatment.

An agreement concerning the generic entry date, without any cash payment, often reflects the odds of the parties' success in patent litigation.²⁵⁴ By way of example, if there were ten years remaining in the patent term and the parties agreed there was a 60 percent chance that a court would uphold the patent's validity, the mean probable date of entry under litigation would occur in six years.²⁵⁵

A brand is likely to gain additional exclusivity by supplementing the parties' entry-date agreement with a payment to the generic. Continuing the example above, the brand could pay the generic to gain an additional three years (for a total of nine years) of exclusivity. The monopoly profits the brand earned in these three years would vastly exceed the reduced profits it would earn from sharing the market with the generic. Even with a payment to the generic, the brand would still come out ahead. And the generic would also benefit since the payment would exceed the profits it could have gained by entering the market.

In buying more exclusivity than the patent alone could provide, reverse payments tend not to reflect an objective assessment of validity. In most cases, the patentee would not pay more than its litigation costs unless it believed it was buying later generic entry than litigation would provide.²⁵⁶ That may not be the case, however, when the parties can demonstrate the reasonableness of the payment. Four potential settings in which the parties could show this include (1) payments no higher than litigation costs, (2) "cash-strapped generics," (3) parties with asymmetric information, and (4) otherwise reasonable payments.

First, if the payment is no higher than litigation costs, it is more likely to represent an objective assessment of patent validity. Once the brand sues the generic, each side must pay litigation costs. A reverse payment that does not exceed these costs does not present significant concern since the parties

254. Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 660 (2004).

255. See Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1043 (2004).

256. Shapiro, *supra* note 178, at 407–08.

would have been required to spend this money in any event.²⁵⁷ Litigation costs include a party's out-of-pocket costs and attorneys' fees from the time of settlement until the end of the case.²⁵⁸

Second, cash-strapped generics need to receive cash quickly. As a result, they could insist on entry earlier than the mean probable date of entry.²⁵⁹ But because the brand company does not share this view, the parties cannot reach a settlement solely along the dimension of time. The payment of money could bridge the gap, allowing the generic to accept a later entry date while providing it with needed cash.²⁶⁰

Third, informational asymmetries could justify reverse payments. One such asymmetry involves information about the patent's value. The brand firm could have better information than the generic about the state of the market and the period of time the patent will have economic value.²⁶¹ When the patent's value is high, bargaining may not lead to agreement since the brand does not wish to cede its valuable monopoly and the generic insufficiently appreciates an offer for modestly earlier entry. In this scenario, a reverse payment could bridge the gap. Although the parties could disagree over the valuation of potential entry dates, they do not differ on the valuation of cash.²⁶²

Fourth, in a more general defense, the parties could demonstrate the reasonableness of any payments. Such a showing could rely on factors such as (1) sales projections, (2) market analyses, (3) payments for similar products, and (4) the brand's interest in the product and due diligence. In the *Schering* case, the FTC conducted an exhaustive analysis on the issue, ultimately concluding that Schering's licenses greatly exceeded the value of the products it received.²⁶³

Each of these four scenarios could conceivably occur. As a result, per se illegality is not (at least yet) an appropriate treatment for reverse-payment settlements. But the identification of particular scenarios in which reverse payments could be justified is a far cry from a determination that they explain behavior in most cases. For that reason, commentators' arguments for why patentees might need to make reverse payments in certain situations do

257. The conclusion is slightly more nuanced since the brand also pays the generic's costs, which it would not otherwise have paid. Hemphill, *supra* note 58, at 1594–95.

258. Hovenkamp et al., *supra* note 208, at 1760 n.177.

259. Schildkraut, *supra* note 255, at 1059.

260. *Id.* at 1059–63.

261. Willig & Bigelow, *supra* note 254, at 660.

262. *See id.* at 661; *see also* James Langenfeld & Wenqing Li, *Intellectual Property and Agreements To Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Manufacturers*, 70 ANTITRUST L.J. 777, 796 (2003) (discussing situation of generic “hav[ing] private information on its ability to enter”).

263. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1003–53 (2003), *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

not demonstrate the propriety of Rule of Reason analysis as a default framework.

In fact, one model predicted that 92 percent of cases in which reverse payments were necessary to reach settlement were likely to reduce consumer welfare.²⁶⁴ Among the cases in which reverse payments were needed, the surplus loss from inefficient settlements was nearly thirty times the surplus gain from efficient settlements.²⁶⁵ And given the infrequent need for reverse payments to attain settlement, the model's authors concluded that less than one-half of 1 percent of efficient settlements would occur only because of reverse payments.²⁶⁶

The Hatch-Waxman framework, drafters' intentions, severe anticompetitive harms of market allocation, and uniquely concerning nature of reverse payments counsel placing the burden on the settling parties to show the reasonableness of the payments. As a final justification for putting the burden on the defendants, the settling parties are most likely to have the relevant information in their possession.

The parties must demonstrate the reasonableness of the payments, typically by producing sufficient evidence to place the payment in one of the four recognized categories. As the FTC has suggested, they must show that the justifications are cognizable and plausible.²⁶⁷ For example, if the parties rely on a defense of cash-starved generics, they must show that the generic actually was cash starved and that the support resulted in the generic entering the market earlier than it otherwise would have.²⁶⁸ If the parties can introduce such evidence, agencies and courts should uphold the settlement under the Rule of Reason. In such a case, the reasonableness of the payment reflects an objective likelihood of the patent's validity.

Putting the burden on the settling parties to demonstrate a payment's reasonableness also makes sense given the more nuanced agreements into which firms have recently entered. No longer are brand firms making simple cash payments for generics not to enter the market. Instead, they are paying generics for IP licenses, for the supply of raw materials or finished products, and for helping to promote products.²⁶⁹ They are paying milestones, up-front payments, and development fees for unrelated products.²⁷⁰ And, in the latest

264. Leffler & Leffler, *supra* note 178, at 484.

265. *Id.*

266. *Id.*; see also Reply Brief of Counsel Supporting Complaint at 31, *In re Schering-Plough*, 136 F.T.C. 956 (2003) (No. 9297) (F.T.C. Oct. 24, 2002) (explaining that even if a procompetitive settlement is conceivable, the parties naturally prefer a range of anticompetitive settlements).

267. *In re Schering-Plough*, 136 F.T.C. at 963–66.

268. *Id.* at 999–1003.

269. FY 2006 AGREEMENTS, *supra* note 249, at 4–5.

270. *Id.*

trend, they are agreeing not to launch authorized, brand-sponsored, generics.²⁷¹

Many of these provisions—such as a supply agreement by which a brand pays a generic *even if it does not supply the product*—exceed the fair market value for the item.²⁷² Of particular concern, side payments appeared in nearly all the settlements that restrained generic entry but few of the settlements that did not.²⁷³ Nor is the product provided by the generic typically even one that the brand had sought before the settlement.²⁷⁴ In other words, it is becoming harder for plaintiffs to track down evidence of payments for delay.²⁷⁵ To demonstrate the reasonableness of these side payments, it would be necessary for courts to examine product promotion expenses, supply invoices indicating the cost of raw materials, the value of IP licenses, and similar figures.²⁷⁶

It therefore makes sense to put the burden on the settling parties to provide evidence of the payments as well as their reasonableness. The parties would be more likely to possess this evidence and more likely to demonstrate the transaction's fair market value.

In short, the Act's regulatory barriers to entry and preference for patent challenges, together with the potential severe anticompetitive effects and uniquely concerning nature of reverse payments, supports a default position of presumptive illegality.

CONCLUSION

Reverse-payment agreements present complicated behavior lying at the intersection of patents, antitrust, the FDA process, and the Hatch-Waxman Act. Courts have ignored the guidance provided by the Act in emphasizing policies such as the importance of settlements and presumption of patent validity.

In this Article, I have shown the importance of Hatch-Waxman in providing Congress's specific views on the reconciliation of the patent and antitrust laws. The legislature's finely tuned equilibrium underscores the

271. FY 2007 AGREEMENTS, *supra* note 251, at 2. See generally C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Agency Rules to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009).

272. FY 2006 AGREEMENTS, *supra* note 249, at 5.

273. Prepared Statement of the FTC Before the Comm. on the Judiciary of the U.S. Senate, *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution*, at 17 (Jan. 17, 2007), http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

274. C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey* 15 (2007), available at <http://ssrn.com/abstract=969492>.

275. For a recent attempt to do so, see the FTC's 2008 complaint against Cephalon, which alleged "side-term inducements" (such as licenses to IP, supply agreements, and codevelopment deals) to generics so they did not challenge its sleep-disorder drug Provigil. Complaint ¶ 56, FTC v. Cephalon, Inc., No. 1:08-cv-00244-RMC (D.D.C. Feb. 13, 2008).

276. Andersen, *supra* note 69, at 72–74.

importance of generic competition and patent challenges and minimizes the policies favoring settlement. As the Supreme Court reminded us in *Trinko*, courts must consider the applicable regulatory regime in determining the appropriate antitrust scrutiny. Such consideration is particularly necessary given the Act's increasing ineffectiveness as reverse-payment settlements reduce generic competition and patent challenges.

Antitrust can ameliorate this deficiency. Given the severe anticompetitive harm presented by market division and the significant questions presented by reverse-payment agreements, aggressive antitrust scrutiny is appropriate. In fact, given the inability of antitrust courts to directly determine patent validity, the proxy of unjustified settlements provides the best available evidence of invalidity.

Courts should treat reverse-payment settlements as presumptively anti-competitive. The settling parties can demonstrate that the payments are reasonable and reflect an objective assessment of the patent's validity. But in the vast majority of cases, presumptive illegality will resuscitate the generic competition at the heart of the Act. Given the importance of the drugs subject to reverse payments and the far-reaching effects of skyrocketing health-care costs, a more justified and aggressive framework for such agreements would offer significant benefits.