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I. INTRODUCTION

In recent years, the Federal Trade Commission (FTC) has closely scrutinized "reverse payment" patent settlements in which brand-name drug manufacturers make payments to generic manufacturers.[1] The FTC is concerned that such settlements harm consumers by delaying the market entry of lower-priced generic drugs.[2]

Despite a growing consensus among the courts that such settlements are

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1. *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing Before the H. Subcomm. on Com., Trade, and Consumer Prot.*, 111th Cong. 2, 8 (2009) (statement of J. Thomas Rosch, Comm'r, Fed. Trade Comm'n).

2. *Id.* at 2.

only anticompetitive under a narrow set of circumstances,[3] it is likely that antitrust scrutiny will continue to increase over the next several years. In 2007, then-Presidential Candidate Barack Obama raised specific concerns over such settlements in laying out his views on antitrust enforcement policy.[4] Jon Leibowitz, the current Chairman of the FTC, recently called eliminating anticompetitive patent settlements "one of the most important objectives for antitrust enforcement in America today."[5] Bills were introduced in both houses of Congress in early 2009 that would prohibit all settlements involving payments from brand-name to generic manufacturers.[6]

This article will present an analytical framework for evaluating the competitive effects of patent settlements between branded and generic pharmaceutical manufacturers, including those involving reverse payments, and demonstrate that such settlements can benefit consumers. While continued scrutiny of such settlements is important, broad brush treatments are inappropriate and only a more individualized evaluation can accurately determine the competitive effects of a particular settlement agreement.

II. COMPETITION IN THE PHARMACEUTICAL INDUSTRY

Consumers derive great benefit from both brand-name and generic drugs. Innovative brand-name pharmaceutical manufacturers benefit consumers by developing new drugs, while generic pharmaceutical firms benefit consumers by driving down drug prices through competition. Thus, the challenge of competition policy in this area (as in all highly innovative industries) is to strike the appropriate balance between providing incentives to encourage innovation, while stimulating competition to lower drug prices.

A. Innovation and Patent Protection

Innovation is the lifeblood of the pharmaceutical industry. In 2007, the pharmaceutical and biotechnology industries invested nearly $60 billion in research and development (R&D).[7] As described by the Congressional

3. Ken Letzler & Sonia Pfaffenroth, *Patent Settlement Legislation: Good Medicine or Wrong Prescription?*, 23 ANTITRUST 81, 82 (2009).

4. Senator Barack Obama, Statement for the American Antitrust Institute (Sept. 27, 2007) (transcript available at http://www.antitrustinstitute.org/Archives/pres01.ashx).

5. Comm'r Jon Leibowitz, Concurring decision regarding Federal Trade Commission v. Watson Pharmaceuticals (Feb. 2, 2009).

6. S. 369, 111th Cong. (2009); H.R. 1706, 111th Cong (2009). The current version of S. 369, as revised in committee, provides an exception "if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."

7. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL

Budget Office (CBO), "[t]he pharmaceutical industry is one of the most research-intensive industries in the United States. . .Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm."[8]

Since 1990, R&D by pharmaceutical manufacturers has led to the approval of an average of nearly thirty new drugs (molecular entities) and dozens of newly approved formulations or other modifications to existing drugs each year.[9]

The process of developing new drugs is lengthy, costly, and uncertain; as such, protection of the intellectual property rights underlying these innovations is critical to encouraging pharmaceutical manufacturers to continue to invest in R&D. Only a small fraction of medicines tested are eventually approved for patient use,[10] and only twenty to thirty percent of those approved eventually recoup their R&D investment.[11] The development of new drugs entails a considerable amount of time and money, and such costs are rising.[12] Recent studies estimate that the development of a new drug takes ten to fifteen years on average[13] and costs over $1.3 billion.[14] Strong protection of intellectual property rights, and the accompanying rewards, provides an incentive for pharmaceutical companies to make such a large, high-risk investment.

B. Generic Competition

Generic manufacturers often bring bioequivalent versions of brand-name drugs to market as soon as the brand-name drug loses patent protection, or when generic manufacturers are able to produce noninfringing generic

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INDUSTRY PROFILE 2008 at 2-3 (2008).

8. CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 7-9 (2006) [hereinafter CBO 2006].

9. FDA, CDER APPROVAL TIMES FOR PRIORITY AND STANDARD NMES AND NEW BLAS-CY 1993-2008 (2009).

10. Tufts Ctr. For the study of Drug Dev., *Backgrounder: How New Drugs Move throughout the Development and Approval Process*, Nov. 1, 2001 (indicating that only 1 of every 5,000 medicines tested is eventually approved).

11. JOHN M. VERNON, JOSEPH H. GOLEC & JOSEPH A. DIMASI, DRUG DEVELOPMENT COSTS WHEN FINANCIAL RISK IS MEASURED USING THE FAMA-FRENCH THREE FACTOR MODEL 3 (2009); Henry G. Grabowski, John M. Vernon & Joseph A. DiMasi, *Returns on Research and Development for 1990s New Drug Introductions*, 20 PHARMACOECONOMICS Suppl. 3, 23 (2002).

12. *See* Grabowski et al., *supra* note 11, at 19; Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 163 (2003).

13. CBO 2006, *supra* note 8, at 15; DiMasi et al., *supra* note 12, at 164.

14. Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL AND DECISION ECON. 469, 476 (2007) (including both cash outlays and costs of capitalization).

products.[15] Numerous economic studies have consistently found that the entry of a competing generic manufacturer typically leads to lower average drug prices, and that this price competition typically intensifies with the entry of additional generic manufacturers.[16] For example, the CBO concluded in a review of the evidence that:

> The dramatic rise in generic sales since 1984 has held down average prices for drugs that are no longer protected by a patent . . .[A]verage prices fall primarily because consumers switch from the higher-priced innovator drug to the lower-priced generics. To be on the receiving end of that switch, generic manufacturers compete with each other intensely in the area of price, partly because they sell identical products. The increased use of generic drugs has kept total spending on prescription drugs below what it might otherwise have been.[17]

Given the significant benefits to consumers that result from both innovation and lower prices, policy-makers have sought to facilitate generic competition within a framework intended to provide brand-name manufacturers with sufficient incentives to continue to innovate.

C. The Hatch-Waxman Amendments

1. Introduction

In 1984, Congress passed the Hatch-Waxman Amendments (Hatch-Waxman)[18] to the Federal Food, Drug, and Cosmetic Act of 1938, which sought to balance the benefits from innovation with those from generic entry.[19] Hatch-Waxman established the current framework for patent litigation in the pharmaceutical industry, a framework that, though modified since its inception, remains largely intact.[20] Any analysis of the economics

15. *See* Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry and Price Competition in Pharmaceuticals after the 1984 Drug Act*, 35 J.L. & ECON. 331, 331 (1992).

16. *See id.* at 335 (explaining that branded manufacturers may increase their prices in response to generic entry, but the net effect of lower generic prices and higher branded prices is generally to lower average prices for the molecule); *see also* Richard G. Frank & David S. Salkever, *Pricing, Patent Loss and the Market for Pharmaceuticals*, 59 S. ECON. J. 165, 173 (1992); Richard E. Caves, Michael D. Whinston, & Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, BROOKINGS PAPERS ON ECON. ACTIVITY, 1991, at 26; CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 13 (1998) [hereinafter CBO 1998].

17. CBO 1998, *supra* note 16, at 13.

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

19. *See* Caves et al., *supra* note 16, at 1-2.

20. Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491, 492 (2007)

of patent settlements must begin with an understanding of this framework.

2. FDA approval prior to Hatch-Waxman

Since 1962, the Food and Drug Administration (FDA) has required pharmaceutical companies to prove that new brand-name drugs are "safe and effective" prior to approval.[21] Brand-name drug manufacturers provide such evidence by conducting costly and lengthy clinical trials. This process of conducting clinical trials and obtaining FDA approval, however, decreases the effective life of pharmaceutical patents because FDA approval is typically granted several years after a patent is granted.[22] Before Hatch-Waxman, the FDA also required generic manufacturers to conduct their own safety and efficacy studies; generic manufacturers, however, could not begin such studies until patents on the brand-name drug had already expired.[23]

3. Overview of Hatch-Waxman

The intent of Hatch-Waxman was to alter the FDA approval process in two important ways:

(1) With an eye towards brand-name manufacturers, Hatch-Waxman sought to increase patent protection and to strengthen incentives for innovation.[24] Recognizing that the lengthy FDA approval process often substantially reduced the effective life of pharmaceutical patents, Hatch-Waxman allowed brand-name manufacturers to apply to extend the life of these patents in order to regain some of the patent life consumed by clinical trials and the FDA approval process.[25] Specifically, the brand-name manufacturer could apply for an extension on one patent equal to half of the time spent on clinical trials plus all of the time spent in FDA review, subject to a maximum extension of five years and a maximum effective patent life of 14 years.[26]

(2) With an eye towards generic manufacturers, the Hatch-Waxman attempted to foster competition by streamlining the approval process for generics, thereby reducing entry costs and speeding the generic product to market.[27] Specifically, Hatch-Waxman allowed generic pharmaceutical

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[hereinafter *Generic Competition*].

21. FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 3 (2002) [hereinafter FTC 2002].

22. CBO 1998, *supra* note 16, at 39.

23. *Generic Competition*, *supra* note 20, at 491-492.

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.*

companies to submit an Abbreviated New Drug Application (ANDA), simply referencing the safety and efficacy results submitted by the brand-name manufacturer, rather than requiring the performance of new clinical trials, so long as the generic drug could demonstrate "bioequivalence," which means that the rate and extent of absorption of the generic drug is not significantly different from that of the brand-name drug when administered with the same dosage.[28]

Brand-name manufacturers are required to file information about any relevant patents with the FDA. The ANDA filer must certify one of the following:

(1) the required patent information has not been filed by the brand-name manufacturer;[29]

(2) the patent has expired;[30]

(3) the patent will expire, identifying the expiration date;[31] or

(4) the patent is invalid and/or not infringed.[32]

The latter representation is known as a Paragraph IV certification.

Since Hatch-Waxman, competition from generic drugs has grown significantly; the market share of generics has grown from nineteen percent in 1984 to nearly sixty-seven percent today.[33]

4. Patent litigation under Hatch-Waxman

Hatch-Waxman established several important aspects of patent litigation between brand-name and generic manufacturers. First, an ANDA filer who makes a Paragraph IV certification that the existing patent is invalid or not infringed must notify the patent holder (and the branded manufacturer) of the basis for its assertion.[34] Under Hatch-Waxman, if a brand-name manufacturer files suit within forty-five days of receiving notice of a Paragraph IV certification, the brand-name company is granted an automatic stay of FDA final approval of the generic company's ANDA until the earliest of: (1) thirty months from the notification date; (2) a

28. *Id.*
29. Food, Drug & Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii) (2009).
30. *Id.*
31. *Id.*
32. *Id.*
33. *See* GENERIC PHARMACEUTICAL ASSOCIATION, CELEBRATING THE PAST, DEFINING THE FUTURE 1 (2009).
34. 21 U.S.C. §§ 355(j)(2)(B)(i)–(iii) (2009).

district court decision that the patent is invalid or not infringed; or (3) expiration of the patent.[35] This is commonly known as a "30-month stay." If the patent holder does not file suit within the forty-five day window, then the FDA may approve the ANDA immediately, provided all other requirements are met.[36]

Second, upon approval, the first generic pharmaceutical company to file an ANDA with a Paragraph IV certification for a particular drug is awarded a "180-day exclusivity period," during which time the FDA may not approve any Paragraph IV ANDAs filed subsequently for the same drug.[37] The start of the 180-day exclusivity period is triggered by commercial marketing of the first filer's product.[38] If the first filer does not exercise its exclusive rights in a timely fashion, forfeiture of its eligibility for exclusivity can occur.[39] The substantial profits available during the 180-day exclusivity period (in which the exclusive generic can both charge a higher price and capture a larger share of sales than it could in the face of competition from other generic manufacturers) provide generic firms with an additional incentive to be the first to challenge potentially invalid patents or to invent around the patented technology by developing a noninfringing alternative.

D. Patent Litigation and Settlement Agreements

ANDA filings frequently result in patent litigation. From 1998 to 2000, approximately twenty percent of filed ANDAs contained Paragraph IV certifications, where the generic manufacturer claimed that the brand-name manufacturer's patent(s) were invalid or not infringed.[40] A study by the FTC of ANDA filings between 1992 and 2000 found that a Paragraph IV certification resulted in patent litigation nearly seventy-five percent of the time.[41]

Most patent litigation is resolved through a settlement between the

35. *Id.*

36. 21 U.S.C. § 355(j)(5)(B)(iii) (2009).

37. 21 U.S.C. § 355(j)(5)(B)(iv) (2009). Under certain circumstances (e.g., two generic manufacturers file ANDAs containing a Paragraph IV certification for the same branded drug on the same day) the FDA may grant "shared exclusivity" in which both generic manufacturers can receive final approval simultaneously and potentially share the 180-day exclusivity period.

38. *Id.* For products subject to the prior law before 2003, the 180 days would also be triggered by a court decision of invalidity or noninfringement of the relevant patent. Food, Drug & Cosmetic Act, 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

39. Medicare Prescription Drug, Improvement, and Modernization Act of 2003. PUB. L. No. 108-173. § 1102. 117 Stat. 2066, 2457.

40. FTC 2002, *supra* note 21, at 10.

41. *Id.* at 9-10, 13.

parties.[42] From 1992 to 2000, nearly forty percent of litigations against the first ANDA filer resulted in a settlement.[43] Similarly, Barr, one of the largest generic manufacturers, has settled nearly half of the thirty patent cases that it has been involved with between 1993 and 2007.[44]

These settlements take many forms and can include the following types of provisions:

- An agreed-upon date at which time the generic manufacturer will enter the market (with or without royalty payments to the brand-name manufacturer);
- Cash payments from the brand-name manufacturer to the generic;
- Ancillary business transactions such as cross-licensing or supply agreements; and
- Agreement by the brand-name manufacturer not to launch or license an authorized generic for some period after generic entry.[45]

Pharmaceutical manufacturers that settle patent litigation are required to report information on settlements to the FTC and Department of Justice (DOJ), and the FTC publishes annual reports summarizing those settlements.[46]

The following table provides a summary of the FTC's classification of settlements that have been entered into over the last several years between brand-name and generic pharmaceutical manufacturers.[47]

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42. *See, e.g.*, Carl Shapiro, *Antitrust Limits to Patent Settlements*, 43 RAND J. of Econ., 391, 392 (2003).

43. FTC 2002, *supra* note 21, at 15-16.

44. *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it be Prohibited?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 4-23 (2007) (statement of Bruce L. Downey, Chairman and Chief Executive Officer, Barr Pharmaceuticals, Inc).

45. FTC 2002, *supra* note 21, at 25-26.

46. Medicare Prescription Drug, Improvement, and Modernization Act of 2003. PUB. L. NO. 108-173. §1102. 117 Stat. 2066, 2457.

47. BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION, DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2004 Fig. II (2004); BUREAU OF COMPETITION, 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 3 (2005); BUREAU OF COMPETITION, 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 3 (2006); BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION, DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY

			Settlements Not Allowing Immediate Generic Entry	
	Total Settlements	Settlements Allowing Immediate Generic Entry	With No Compensation to Generic	With Compensation to the Generic[48]
FY 2004	14	9	5	0
FY 2005	11	7	1	3
FY 2006	28	8	6	14
FY 2007	33	8	11	14
FY 2008				16
FY 2009				19

III. COMPETITIVE EFFECTS OF PATENT SETTLEMENTS: SHORT-RUN

A. Overview

1. Patent settlements reduce the direct and indirect costs of litigation

Patent settlements provide clear benefits by reducing litigation costs. In general, the cost of litigating includes (1) direct litigation costs, (2) indirect costs, such as requiring the attention of company executives, distracting them from the operation of the business, and (3) costs due to the uncertainty of litigation outcomes.[49] Further, there are additional costs to society as a whole, including increased congestion of the court system and the allocation of corporate resources towards dispute resolution as opposed to innovation and production activities.[50] Manufacturers generally pass on

2007 3 (2007); Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study, January 2010, p. 1.

48. As defined by the FTC, compensation to generic manufacturers may be in the form of cash, an ancillary business transaction, or an agreement by the brand name manufacturer not to launch or license an authorized generic for some period after generic entry. As discussed in more detail below, an ancillary business transaction does not constitute compensation where the transaction was conducted at fair market value. According to the FTC reports, many of these settlements also include compensation to the brand name manufacturer however the reports do not provide sufficient information to determine whether there was a net payment to the generic. BUREAU OF COMPETITION, 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 3 (2006).

49. James E. Bessen & Michael J. Meurer, *The Private Costs of Patent Litigation* 18-19 (Boston Univ. Sch. of Law Working Paper Series, Law and Econ., Working Paper No. 07-08, 2008).

50. Shapiro, *supra* note 42, at 394.

some portion of these costs to consumers, who ultimately suffer by paying higher prices.

2. Patent settlements have the potential to be anticompetitive

While patent settlements between brand-name and generic manufacturers have the potential to benefit consumers, they are also capable, under certain circumstances, of stifling competition and harming consumer interests. The potential for anticompetitive outcomes is increased when the settlement is with the first generic filer, rather than with a subsequent generic filer, and the first filer does not relinquish its exclusivity.[51] Under Hatch-Waxman, the first generic filer receives 180 days of marketing exclusivity.[52] This creates the potential for an anticompetitive effect to the extent that delaying entry by the first filer could delay entry by all other generics as well. Prior to 2003, when much of the concern over patent settlements in the pharmaceutical industry originated, first filing generic manufacturers that settled patent litigation were not required to relinquish their exclusivity.[53] Thus, a settlement with a first filer specifying an entry date well into the future could also prevent other generics from entering before that date.[54] Recognizing the potential anticompetitive effects of such a situation, the Medicare Prescription Drug, Improvement, and Modernization Act, a 2003 law, introduced additional restrictions on "parking" the 180-day exclusivity.[55] Importantly, the law was changed so that a generic manufacturer forfeits its exclusivity if (1) the brand-name and generic manufacturers reach a settlement agreement, (2) the settlement is challenged by the FTC or DOJ, and (3) the agreement is determined to violate antitrust law.[56] This change reduces the antitrust concerns regarding settlements.

The competitive effects of a particular settlement will depend greatly upon the strength of the underlying patent.[57] A patent gives the brand-name manufacturer the right, within certain boundaries, to exclude competition.[58]

51. FTC 2002, *supra* note 21, at 25-26.

52. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(B)(iv) (2009).

53. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(2)(D)(i)(V), 117 Stat. 2459 (2003) (addressing the anticompetitive concerns by voiding the 180-day exclusivity period in certain circumstances).

54. 21 U.S.C. § 355(j)(5)(B)(iv) (2009).

55. Pub. L. No. 108-173, § 1102(a)(2)(D), 117 Stat. 2458 (2003).

56. Pub. L. No. 108-173, § 1102(a)(2)(D)(i)(V), 117 Stat. 2459 (2003).

57. Some courts consider how a "reasonable person" would objectively evaluate the strength of the patent. *See, e.g., Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003).

58. Shapiro, *supra* note 42, at 395-96 (discussing patents as probabilistic property rights).

If the patent is quite strong, and likely to be found valid and infringed, then even a settlement with an agreed-upon entry date well into the future, but before the patent's expiration, may bring generic drugs to market sooner than the expected outcome from continued litigation. Moreover, there are frequently several generic manufacturers challenging a brand-name patent at any given time; where this is the case, a settlement agreement with the first-filing generic has even less potential for anticompetitive effect where the brand-name patent is weak. While the incentive may not be as strong as that of the first filer (due to the 180-day exclusivity), other generic manufacturers continue to have an incentive to challenge patents they believe are invalid or that they do not infringe.[59]

In contrast, if the patent is quite weak, and likely to be found invalid or noninfringed, then even a settlement with an entry date in the near future may delay generic entry and harm consumers. Considering the strength of a patent in real-world patent litigation is complex, but necessary. The next section presents an economic framework for this evaluation.

B. Economic Framework

1. Basic Model

Determining the scope of patent settlements that could raise antitrust concerns amounts to evaluating the following question: Which settlements would be in the economic interest of both the brand-name and generic manufacturer, but would harm consumers, relative to continuing litigation? Answering this question requires modeling the settlement decisions of both the brand-name and generic manufacturers, as well as evaluating the benefit to consumers from generic entry.

The standard economic model of settlements compares each party's potential economic benefit from settling to the potential economic benefits of pursuing litigation.[60] A comparison of the potential benefits determines the range of settlement terms that both parties would find preferable to continued litigation – in other words, those settlement terms that would feasibly lead to the end of the litigation.

Once the range of feasible settlements is established, one needs to

59. The 180-day exclusivity period provides motivation for generic manufacturers to bear the cost and risk associated with developing generic versions of brand name drugs and challenging brand name patents. But at the time of a settlement with the first-filing generic, many subsequent generic entrants may have already incurred many of these costs. Thus, even relatively small profits expected by a subsequent filer could provide the incentive to continue to challenge the brand name patent.

60. *See generally* Robert D. Cooter & Daniel L. Rubenfield, *Economic Analysis of Legal Disputes and Their Resolutions*, 28 J. ECON. LITERATURE 1067, 1067-1097 (1989) (general discussion of the settlement decision).

determine which of these settlements, if any, would benefit consumers.[61] After all, consumers are not a party to the settlements, and so one might imagine that there could be settlements, which benefit brand-name and generic manufacturers that do not benefit consumers.

For expositional purposes, we start with a highly simplified model of a patent settlement between brand-name and generic manufacturers. Assume:

- The parties are considering settlement at the beginning of Year 1
- The patent expires at the end of Year 10
- The generic manufacturer both believes that it has and in fact has a fifty percent chance of winning the patent case (and the brand-name manufacturer also has, and perceives, a fifty percent chance of winning)
- There are no costs to litigation and litigation is instantaneous
- Both parties are risk neutral.
- The only settlement tool available is the date of generic entry (*i.e.*, lump sum payments, royalty payments, and other business transactions are not allowed).[62]

As we describe below, many of these assumptions do not affect the conclusions, but rather allow for an easier grasp of the intuition underlying the economic model. Other assumptions, however, will have important effects on the conclusions. In the sections that follow, we will introduce real-world complexities and examine the implications of enriching the model.

Under these original assumptions, the expected outcome from litigation is generic entry at the end of Year 5. There is a fifty percent chance of immediate entry if the generic wins and a fifty percent chance of entry at the end of Year 10 if the brand-name wins. The settlement decision amounts to a comparison of the profits from settling to a simple average of the profits assuming immediate generic entry (fifty percent chance the generic wins) and the profits assuming generic entry in Year 10 (fifty percent chance the generic loses). Under the assumptions provided above, the simple average of profits from litigation is equivalent to the profits from

61. In this paper, the term "consumers" indicates those individuals that ultimately pay for prescription drugs. In reality, "consumers" are a combination of patients, private insurers, and government.

62. Other assumptions include: (1) Total prescriptions are constant in each year, as is the share of prescriptions by the brand name and generic manufacturers after generic entry; (2) there is no time value of money for either party; and (3) after entry, there will be only one generic competitor.

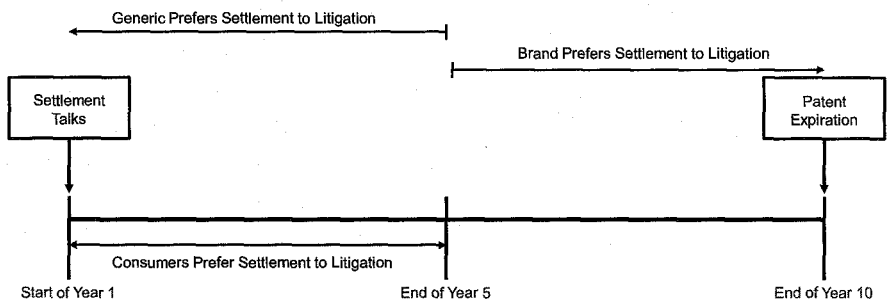
entry at the end of Year 5.

In this simple framework, the only tool the parties can use in settlement negotiations is the date of entry of the generic. As shown in Figure 1, the brand-name manufacturer would agree to a settlement with generic entry at any point after the end of Year 5, whereas the generic manufacturer would agree to a settlement with generic entry at any point up until the end of Year 5. Thus, no settlement can be mutually agreeable to the two parties. The settlement ranges of the two parties are contiguous, but do not overlap.

Of course, this simple model assumes away many complexities present in the real world – indeed, some of the very complexities that provide important incentives for litigating parties to settle. In the next section, we relax some of these assumptions and demonstrate that doing so leads to a range of reasonable conditions under which patent settlements can benefit consumers.

FIGURE 1

Settlement with Generic Entry Date



Note: There are no settlements that both the Brand and Generic prefer to Litigation.

2. Litigation costs

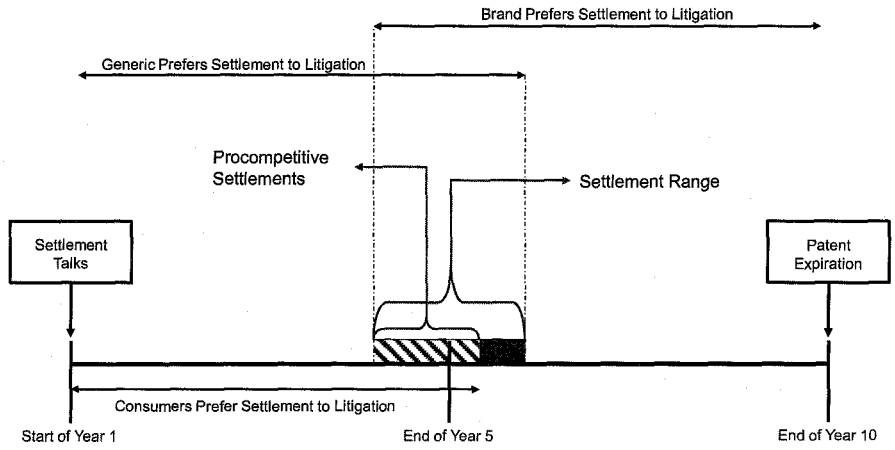
An important motivation for parties to settle litigation is that litigation is costly; the oversimplified model presented above ignores this motivation. We now introduce litigation costs into the model and show that it leads to a range of settlements that would be agreeable to both the brand-name and generic manufacturers, while also benefiting consumers

Figure 2 shows that the costs of litigation lead the brand-name manufacturer to be willing to accept settlements where the generic enters before the end of Year 5 (*i.e.*, earlier than the brand-name manufacturer would be willing to accept based only on the profits from winning or losing the litigation). Similarly, in order to avoid litigation costs the generic would be willing to accept settlements, which would have it entering after the end

of Year 5 (*i.e.*, later than it would be willing to accept based only on the chance of winning or losing the litigation). Thus, litigation costs expand the range of settlements that would be agreeable to both parties.[63] In this way, litigation costs create the possibility of some settlements – those that would lead the generic to enter before the end of Year 5 – that would benefit consumers relative to continued litigation. Accounting for the fact that part of litigation costs are passed on and ultimately borne by consumers broadens the range of procompetitive settlements.

FIGURE 2

Settlement with Generic Entry Date Litigation Costs



Of course, the particular size of settlement ranges shown in Figure 1 and Figure 2 is not meant to convey the relative likelihood of any particular type of settlement, but simply to demonstrate the economic logic that certain kinds of settlements exist. Indeed, what seems to be a clear distinction between procompetitive and anticompetitive in these diagrams in fact can be quite difficult to distinguish in the real world. Recall that our example assumes a fifty percent chance that the generic manufacturer will win the patent litigation, and that everyone knows that probability. In reality, the precise strength of the patent is unknowable to the antitrust analyst or even to the parties themselves. It will depend on a wide range of factors that

63. Because annual profits for the generic are lower than annual pre-generic entry profits for the brand name manufacturer, the generic would be willing to give up more time in the market to avoid those costs, assuming litigation costs for the brand name and the generic manufacturers are similar.

affect the outcome of litigation, including the documentary evidence, the quality of presentations by counsel, the testimony of company witnesses, the testimony of expert witnesses, and the particular judge and jury assigned to the case. Whereas settlements with entry after Year 5 could harm consumers under the assumptions we have presented, such settlements could in fact be procompetitive if the generic manufacturer's chance of winning the patent litigation was only, say, thirty percent.

3. Risk aversion

Another cost of litigation is the substantial uncertainty that litigation creates. Economists model the cost of uncertainty using the concepts of "risk aversion" and "risk premiums."[64] For example, a risk-averse economic actor will prefer to receive two dollars with certainty, rather than a fifty percent chance at one dollar and a fifty percent chance at three dollars. That is, risk-averse individuals prefer a certain outcome to uncertain outcomes with the same average or expected value but some degree of variance.[65] A risk premium is the amount of money that a party would pay to avoid taking a risk.[66] In the example above, the risk premium is the amount the individual would pay in order to receive the two dollars with certainty rather than the option with fifty-fifty odds. The concept of a risk premium allows us to model uncertainty in the same way we do other litigation costs – where the risk premium is the additional cost to the parties created by the uncertainty. Thus, just as in the discussion of litigation costs above, both brand-name and generic manufacturers would accept lower expected profits under a settlement, rather than risk an uncertain outcome in litigation. As shown in Figure 3, the effects of accounting for risk aversion are similar to with the effects of accounting for litigation costs.[67]

64. *See* ROBERT S. PINDYCK & DANIEL L. RUBINFELD, MICROECONOMICS, § 5.2 (7th ed. 2009).

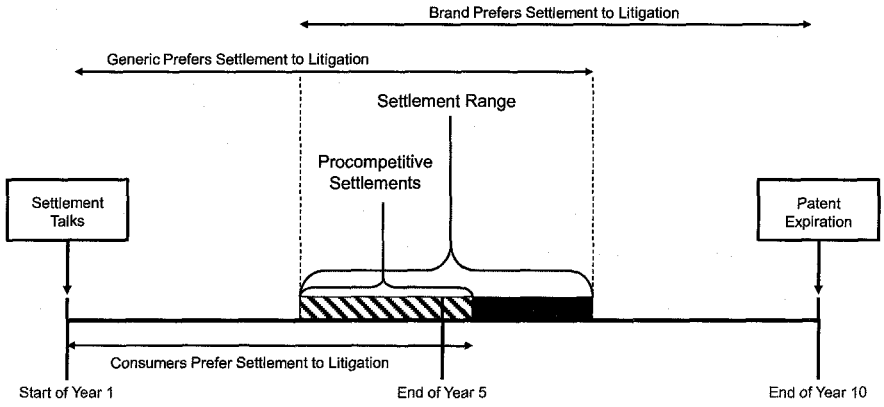
65. *See id.*

66. *Id.*

67. Similarly, if consumers are risk averse, accounting for this would broaden the range of procompetitive settlements.

FIGURE 3

Settlement with Generic Entry Date Risk Aversion and Litigation Costs



Is it reasonable to assume that large pharmaceutical companies are risk averse? After all, a basic tenet of financial economics holds that firms owned by (and effectively managed for) well-diversified shareholders should be risk neutral. The risk from a particular litigation can be largely eliminated through diversification—in this case, by investing in many projects or holding many stocks. However, this argument ignores two important realities. First, it ignores the so-called principal-agent problem that can exist between the managers of the firm (in this case, the executives with the power to choose between settling or continuing litigation) and the shareholders of the firm.[68] While the firm's shareholders may be risk neutral, because they can diversify their risks over many investments, managers whose jobs and salaries depend on their current employer may be risk averse.[69] Second, not all pharmaceutical companies – not even all brand-name manufacturers – are large firms owned by diversified shareholders. For some brand-name manufacturers, the financial health of the company may depend importantly on the success of a single drug line.

68. For a general discussion of the principal-agent problem see PINDYCK & RUBINFELD, *supra* note 64, at §17.4.

69. *See, e.g.*, Randall S. Thomas, *Should Directors Reduce Executive Pay?* 54 HASTINGS L.J. 437, 450 (2003).

4. Information asymmetries

Information asymmetries are another important component of settlement decisions.[70] Both the brand-name and the generic manufacturer are likely to have information that the other party does not possess. The generic manufacturer, for example, may have better information about its ability to manufacture a generic version of the brand-name product, such as knowledge that manufacturing problems will delay its entry beyond the point at which it receives FDA approval (or that make such entry less effective). The brand-name manufacturer would be unlikely to know of such problems at the time of the settlement discussions.

The brand-name manufacturer, on the other hand, may have better information about the expected size of the market for the product in the future. Brand-name pharmaceuticals generally have a limited life cycle; a brand-name drug often faces increasing competition from newer and often more effective brand-name products.[71] The brand-name manufacturer may, for example, have specific knowledge of a next-generation product in its development pipeline, which could substantially reduce the potential market for the litigated drug in the future.

These are just two examples of information asymmetries; there are many dimensions on which such asymmetries can exist. The parties may have private information that alters their probabilities of winning the patent litigation, about the competitive strategies (*e.g.*, pricing) they plan to employ after generic entry, or other factors.

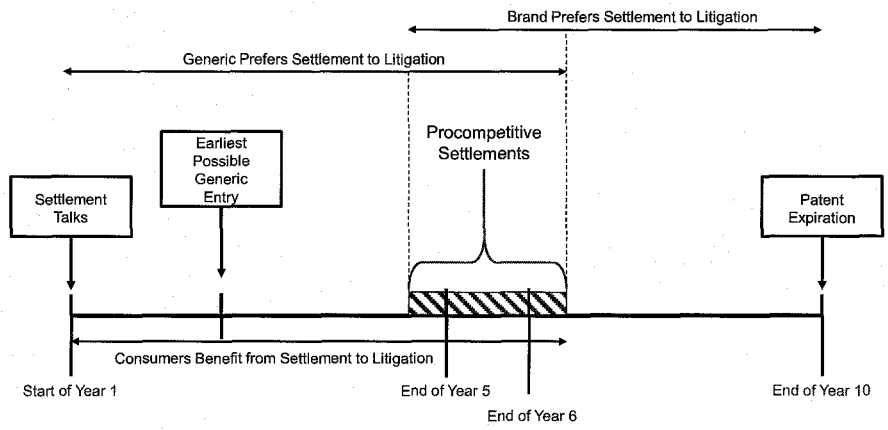
We now introduce a specific example of information asymmetry to our model. Assume that the generic manufacturer knows that, even if it wins the patent litigation, manufacturing issues will prevent it from launching until the beginning of Year 3 (two years from now). Assume also that the brand-name manufacturer is unaware of this.

70. *See, e.g.*, Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1073 (2004).

71. *See generally* Jayanta Bhattacharya, *A Simple Model of Pharmaceutical Price Dynamics*, 46 J. L. & Econ. 599 (2003).

FIGURE 4

Settlement with Generic Entry Date Information Asymmetry and Litigation Costs



In this case, as shown in Figure 4, the generic manufacturer would be willing to agree to a settlement with entry as late as Year 6 (even later factoring in litigation costs), which would give it an additional four years of generic profits relative to the scenario when it litigates and loses. This outcome splits the difference between the eight years of additional profits (Year 3 through Year 10) it would receive if it won the litigation, and the zero years if it lost. Similarly, consumers would be better off under a settlement with a date up to and including Year 6. The brand-name manufacturer, unaware that the generic has any production issues, has the same preferences it did in the initial example: It would agree to any settlement with generic entry as early as Year 5. Thus, as shown in Figure 4, procompetitive settlements with an entry date between Year 5 and Year 6 are feasible (and adding litigation costs or risk aversion to the model would only expand the range of procompetitive settlements).

Litigation costs, risk aversion, and information asymmetries are only three of the potential real-world complexities that can give rise to procompetitive patent settlements between the brand-name and generic manufacturer. For example, the preceding section has assumed that both parties have identical expectations as to the outcome of the litigation. It is highly likely, however, that the parties' expectations will differ at least to some extent – and perhaps greatly – and these differences can have important effects on the ability of the parties to reach settlement and the effects of those settlements on consumers. In the next section, we explore

these and other issues in the specific context of reverse payment settlements.

IV. COMPETITIVE EFFECTS OF REVERSE PAYMENT SETTLEMENTS: SHORT-RUN

A. Overview

While the potential for patent settlements to be procompetitive is generally recognized by economists, antitrust agencies, and the courts,[72] "reverse payment" settlements have generated extensive debate in recent years.[73] In these settlements, the parties settle the patent litigation and the brand-name manufacturer allows the generic manufacturer to enter at or after a particular date in the future (prior to the expiration of the patent) and pays some form of compensation to the generic manufacturer. That compensation can be in the form of cash payments or through a payment associated with some other business transaction (*e.g.*, a cross-licensing agreement) where the brand-name manufacturer might allegedly "overpay" the generic manufacturer or the generic manufacturer might allegedly "underpay" the brand-name manufacturer.[74]

The FTC and some antitrust scholars contend that these "reverse payments" are on their face evidence that the settlements are nothing more than a payment by the brand-name manufacturer to delay generic entry.[75] In this section, we show that such a perspective is flawed because reverse payment settlements can serve to increase or decrease competition and consumer welfare, depending upon the facts and circumstances surrounding the settlement. Thus, a *per se* rule against such settlements would be misguided. Indeed, a view allowing the possibility of reverse payments, with appropriate scrutiny in specific cases (as is available to the FTC under current law), has been adopted by most courts, and many scholars that have addressed this issue.[76]

B. Regulatory and Judicial Enforcement

1. History

The FTC began scrutinizing reverse payment settlements in the late

72. Shapiro, *supra* note 42, at 392-94.

73. Cotter, *supra* note 70, at 1069-70.

74. FTC 2002, *supra* note 21, at 28-29, 34.

75. Rosch, *supra* note 1, at 2.

76. *See, e.g.*, Letzler & Pfaffenroth, *supra* note 3, at 83; *see generally* Robert D. Willig & John P. Bigelow, *Antitrust Policy toward Agreements that settle Patent Litigation*, THE ANTITRUST BULLETIN, Fall 2004, at 655.

1990s.[77] Initial challenges were directed at settlements where brand-name manufacturers paid cash to generic manufacturers to settle patent litigation.[78] These challenges resulted in consent decrees.[79]

The FTC's most prominent challenge was against a settlement between Schering-Plough (Schering) and two generic manufacturers involving Schering's K-Dur (potassium chloride).[80] Schering settled patent litigation with both Upsher-Smith (Upsher) and ESI Lederle (ESI) in 1997.[81] The settlement agreement with Upsher included a related licensing agreement where Schering paid Upsher a sixty million dollars royalty for five Upsher drugs and provided a royalty-free license for Upsher to launch a generic potassium chloride product in 2001 (five years before Schering's patent expired in 2006).[82] The settlement agreement with ESI included a cash payment, as well as a fifteen million dollars royalty payment for two ESI products, and provided a royalty-free license for ESI to launch a generic potassium chloride product in 2004.[83]

The case has a long legal history, in which the disagreements over this issue are on full display. The FTC brought suit against the three companies, alleging that the royalty payments were simply disguised payments to delay generic entry and that the patent settlement agreements were anticompetitive.[84] In 2002, the FTC's Administrative Law Judge ruled that the appropriate legal standard was a "rule of reason" analysis, and that under such an analysis the patent settlement agreements at issue were not anticompetitive.[85] The FTC appealed this decision to the full Commission, which reversed the decision and concluded that the payments were indeed anticompetitive.[86] Schering and Upsher then appealed the Commission's opinion to the Eleventh Circuit Court of Appeals. The Eleventh Circuit reversed the Commission's decision, finding that ultimately the determination of competitive effects depends upon the strength of the patent.[87] The FTC appealed to the Supreme Court, which declined to hear the case.

77. FTC 2002, *supra* note 21, at 1.

78. *Id.* at 1.

79. *See* FTC Decision and Order, *In the Matter of Abbott Laboratories*, No. C-3945 (May 22, 2000); FTC Decision and Order, *In the Matter of Hoeschst, Carderm, and Andrx*, No. 9293 (May 8, 2001). These cases were often followed by private suits by direct and indirect purchasers.

80. *See generally*, *In re Schering-Plough Corp.*, 136 FTC 956 (2003).

81. *Id.* at 960, 962.

82. *Id.* at 961.

83. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1060 (11th Cir. 2005).

84. *Schering-Plough Corp.*, 136 FTC at 958-59.

85. *Id.* at 964.

86. *Id.* at 968.

87. *Schering-Plough Corp.*, 402 F.3d at 1076.

2. Current status

After these developments, reverse payment settlements are now treated quite differently by the various regulatory agencies and Courts. The FTC views reverse payment settlements as essentially *per se* illegal.[88] Despite the adverse ruling by the Eleventh Circuit in *Schering*, the FTC has continued to demonstrate an interest in challenging reverse payment settlements.[89] In contrast, the DOJ submitted a brief urging the Supreme Court *not* to hear the *Schering* case – a position at odds with the FTC's view.[90] Elsewhere, the DOJ has explained that ". . .settlements between an ANDA filer and the patent holder [even those with a reverse payment] also can benefit consumer welfare.[91] Accordingly, the DOJ does not believe *per se* liability under the antitrust laws is the appropriate standard."[92] In the Obama administration, the DOJ has modified its stance on reverse payment settlements and, while still acknowledging that they have the potential to be procompetitive, recommends that the burden of proof be on the manufacturers to demonstrate these procompetitive benefits.[93]

Courts that have evaluated these reverse payment settlements have also reached varying conclusions. In the *Cardizem* case, the Sixth Circuit embraced a standard of *per se* illegality.[94] In contrast, the other three circuit courts to address this issue have given reverse payment settlements significant latitude.[95] In both the *Schering* (described above) and *Valley Drug* cases, the Eleventh Circuit relied on a standard that acknowledges the potentially procompetitive nature of these settlements and that gives significant latitude so long as the patent litigation is not objectively baseless.[96] Similarly, the Second Circuit applied a rule of reason standard in

88. *See Schering-Plough Corp.*, 136 FTC at 968, 970 (prohibiting settlements under which the generic manufacturer receives anything of value but carving out an exception for payments up to $2 million linked to litigation costs).

89. Jon Leibowitz, Comm'r., Fed. Trade Comm'n., Oral Statement at the Hearing of the House Subcomm. on Com., Trade, and Consumer Prot., Comm. on Energy and Com. (May 2, 2007) (transcript available at http://www.ftc.gov/speeches/leibowitz/070502reversepayments.pdf).

90. Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit, Brief for the United States as Amici Curiae, at 1, 2, *Fed. Trade Comm'n. v. Schering-Plough Corp.*, et al., 548 U.S. 919 (2006), denied, No. 05-273 (June 26, 2006).

91. Letter from Brian A. Benczkowski, Principal Deputy Assistant Att'y Gen., Dep't. of Just. to Jon Kyl, U.S. Senator (Feb. 12, 2008).

92. *Id.*

93. Brief for the United States in Response to the Court's Invitation, *Arkansas Carpenters Health and Welfare Fund, et al. v. Bayer, AG, et al.*, 544 F.3d 1323 (2009).

94. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618 (E.D. Mich. 2002) (en banc), *reh'g denied*, 332 F.3d 896, 909 (6th Cir. 2003). The *Cardizem* case involved an interim settlement.

95. Letzler & Pfaffenroth, *supra* note 3, at 82.

96. *See Valley Drug Co., et al. v. Geneva Pharm., et al.*, 344 F3d 1294, 1304-12 (11th

the *Tamoxifen* case when affirming the trial court opinion that the settlements were not anticompetitive.[97]

Recently, the Federal Circuit applied a similar standard in the *Cipro* case.[98] In 1991, Bayer entered into an agreement with generic manufacturers Barr Labs, Hoechst Marion Roussel, and The Rugby Group settling patent litigation over Cipro.[99] Under the settlement agreement, Barr certified that it would not market its generic version prior to the expiration of Bayer's patent.[100] Bayer paid Barr a lump sum payment and agreed to either supply Barr with Cipro for resale, or make payments to Barr through December 2003.[101] Consistent with the decisions by the Second and Eleventh Circuits, the Federal Circuit concluded that a rule of reason approach was appropriate and that "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."[102] The appellate court affirmed the trial court's conclusion after a similar inquiry, that the plaintiffs had not shown that the agreement was anticompetitive.[103]

C. "Reverse Payment" and "Exclusion Payments" Are Misnomers

Before presenting our economic analysis of reverse payment settlements, it is useful to examine the "reverse payment" moniker itself. Such settlements were named by commentators who believe that a payment from the brand-name manufacturer to the generic manufacturer flows the "wrong" way. In a typical patent settlement, the alleged infringer pays the patent holder, while in a reverse payment settlement the patent holder (brand-name manufacturer) pays the alleged infringer (generic manufacturer).[104]

This label, however, is based on flawed logic. Hatch-Waxman creates an unusual circumstance in the pharmaceutical industry whereby the patent holder can sue the alleged infringer before the infringing products make it

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Cir. 2003) (case involved an "interim settlement" of a patent suit between Abbott and Geneva over generic Hytrin, the litigation continues but the generic manufacturer agrees not to launch "at risk" while the litigation is ongoing); *see generally*, James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments From Branded to Generic Drug Manufacturers*, 70 ANTITRUST L. J. 777, 777-818 (2003).

97. *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 386 (2d Cir. 2005).

98. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1331-32 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).

99. *Id.* at 1327.

100. *Id.* at 1328-29.

101. *Id.* at 1329.

102. *Id.* at 1336.

103. *Id.* at 1341.

104. Schildkraut, *infra* note 106, at 1033-34.

to market.[105]

In the typical patent case, the alleged infringer requires some compensation for abandoning the litigation.[106] In a typical case where the patent infringer has been on the market for a significant period of time and would owe significant damages if found liable, the parties may agree to a settlement where the infringer pays damages to the patent holder, but those damages are far less than the damages the patent holder is seeking. In this case, the patent holder pays the infringer to settle the lawsuit by accepting lower damages – this payment is obscured by the fact that some cash flows from the infringer to the patent holder. Reverse payment settlements can be thought of in the same way, but the Hatch-Waxman framework means the patent holder typically does not incur any damages from sales of the infringing products, and so the net payment flows from the brand-name manufacturer to the generic manufacturer. Since nothing nefarious can be gleaned from the simple fact that the payment flows in a particular direction, one must examine the underlying economics of these settlement agreements.

Similarly, the term "exclusion payments" does not accurately reflect the nature of many of these deals. If the brand-name manufacturer holds an ultimately valid patent, and the settlement allows the generic manufacturer to enter the market prior to patent expiration, then the generic was not "excluded" in any meaningful way. The patent itself provided the ability to exclude, not the payment.

D. Basic Economic Model

The framework presented above for an analysis of patent settlements can be used to evaluate reverse payment settlements as well. We start with the highly simplified case outlined in Figure 1 – no litigation costs, full information, and risk neutrality – and relax only the assumption requiring the only term of settlement to be the date of generic entry and allow settlements to include cash payments. How will this affect the range of settlements?

Monopoly profits will typically be larger than total profits when the brand and the generic are both in the market. Of course, brand-name pharmaceuticals are not necessarily monopolies before the entry of generics, as patents give only a limited right to exclude identical

105. Generic manufacturers can "enter at risk" – that is enter before final judgment in the patent litigation – but this is the exception rather than the rule. For example, Mr. Downey testified that Barr never enters at risk (Downey, *supra* note 44, at 24).

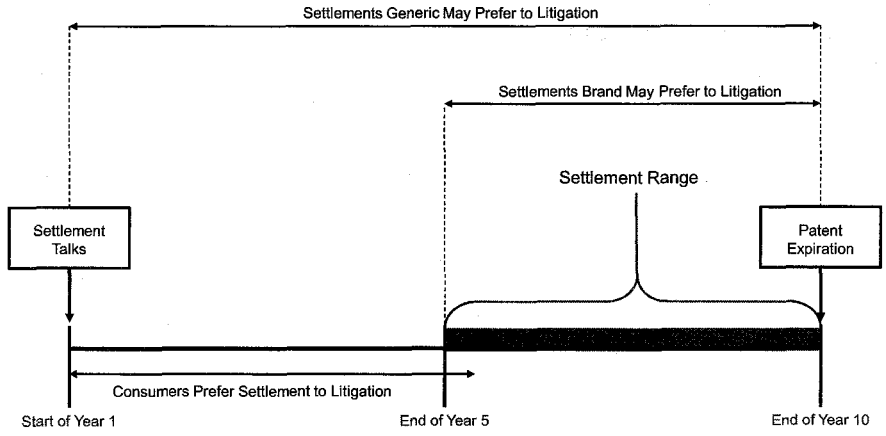
106. *See generally* Daniel A. Crane, *Correspondence: Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004); *see also* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004).

competition and, as such, they may compete with other similar products. Nonetheless, thinking about the analogy to monopoly profits can provide insight as to why the parties may have an incentive to agree to delay generic entry. A year of delay will be more valuable to the brand-name manufacturer, by allowing for an additional year of "monopoly" profits, than it costs the generic manufacturer, who only loses a year of contested profits. As a result, there will be settlements that delay entry beyond Year 5 that both parties prefer to litigation. As shown in Figure 5, this expands the range of settlements that the brand-name and generic manufacturers could potentially agree to, but only to include generic entry dates later than Year 5. Consumers will be worse off under these settlements. Of course, without knowing the precise strength of the patent, observed terms of a particular settlement agreement could be consistent with delayed generic entry, as shown in Figure 5, or with a procompetitive settlement where generic entry occurs sooner than would be expected through litigation.

Thus, a model that ignores real-world complexities can lead to the conclusion that a settlement with cash payments from the brand to the generic harms consumers. In the next section, we extend the basic model to account for the additional complexities that drive real-world settlements. This analysis demonstrates that relying on the overly simplistic framework discussed above can frequently lead one to draw incorrect conclusions as to the competitive effects of a patent settlement.

FIGURE 5

Settlement with Generic Entry Date and Cash Payment



E. Introducing Real-World Complexities to the Basic Model[107]

1. Overview

Expanding the model to account for other real-world factors demonstrates that settlements with reverse payments can be procompetitive. Under certain conditions, without the bargaining tool of a payment from the brand-name manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement, even if that settlement would benefit consumers.

Many economists that have written on this subject agree that when real-world complexities are taken into account, reverse payment settlements can be procompetitive.

Shapiro (2003) explained:

> This is not to say that such payments are necessarily anticompetitive if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as 'reverse cash payments' may be important in more complex settings for successful settlement.[108]

Bigelow and Willig (2009) share a similar view:

> It also follows from economic logic that the opportunity to employ reverse payments may be necessary for socially beneficial and procompetitive settlements to be reached, due to such common situations as asymmetric information, excess optimism, and differential cash needs between the parties to the patent dispute.[109]

Executives in the pharmaceutical industry have expressed similar views. For example, Bruce Downey, the CEO of generic manufacturer Barr Pharmaceuticals, testified to Congress that if a law were passed prohibiting reverse payments "there would be very, very few settlements."[110]

2. Cash payments with litigation costs and/or risk aversion

As described above, litigation costs and risk aversion can be important real-world factors to consider in evaluating patent settlements. Accounting for both litigation costs and risk aversion expands the range of settlement

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107. *See generally* Willig & Bigelow, *supra* note 76; John P. Bigelow & Robert D. Willig, *"Reverse Payments" in Settlements of Patent Litigation: Schering-Plough, K-Dur, and the FTC*, *in* THE ANTITRUST REVOLUTION: ECONOMICS, COMPETITION, AND POLICY 248 (5th ed. 2009) [hereinafter *Reverse Payments*].

108. Shapiro, *supra* note 42, at 408.

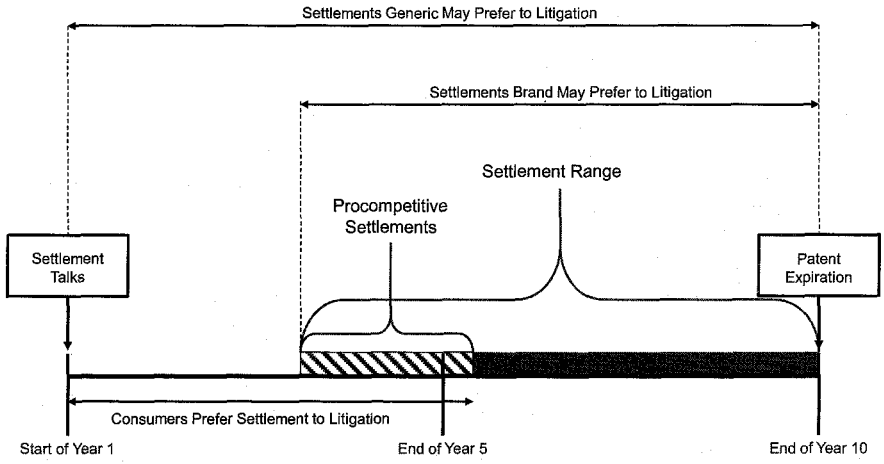
109. *Reverse Payments*, *supra* note 107, at 273.

110. Downey, *supra* note 44, at 28.

agreements that each party is willing to accept. As shown in Figure 6, these factors expand the range of potential settlements that brand-name manufacturers will accept (relative to Figure 5), and by creating incentives for brand-name manufacturers to settle on terms more favorable to consumers it becomes clear that settlements with reverse payments can be procompetitive.

FIGURE 6

Settlement with Generic Entry Date and Cash Payment Litigation Costs



3. Cash payments with a cash-strapped generic

Some observers have argued that, while reverse payment settlements can leave consumers better off than continued litigation, there is always a feasible alternative settlement without a payment that will leave consumers better off than either litigation or a reverse payment settlement.[111] Under this argument, a prohibition on reverse payment settlements would unambiguously leave consumers better off while still allowing the parties to reap the benefits of settlement.[112] This argument ignores the complexities of settlement negotiations.[113] In the presence of such complexities, additional

111. *See* Jon Leibowitz, Chairman, Fed. Trade Comm'n, at the Center for American Progress: "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution) (June 23, 2009).

112. *Id.*

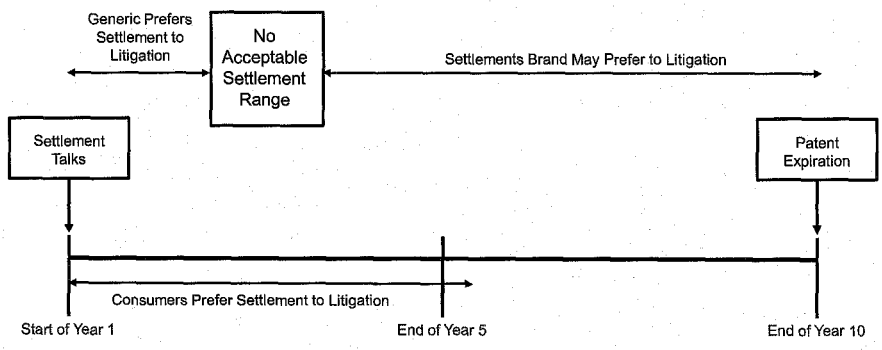
113. A related argument is that an alternative settlement with a different payment and a different entry date may be better for consumers. This is a stricter standard than the one

flexibility in negotiations may be *essential* to enabling a proconsumer settlement between the parties.[114] That is, under these circumstances, without a reverse payment the parties would be unable to reach a settlement at all.

Two real-world complexities ignored by the basic model are the time value of money and the possibility of liquidity constraints. The time value of money refers to the fact that individuals prefer a dollar received today to a dollar received in the future; thus they discount the value of future cash flows.[115] Imagine a small, cash-strapped generic entrant that is having a difficult time raising needed capital from the financial markets. As a result, the entrant discounts future profits very heavily; in other words, since it needs cash, it values near-term profits very highly. This generic manufacturer will only accept settlements that allow for relatively early entry, which under the conditions of the example illustrated in Figure 7a would not be acceptable to the brand-name manufacturer.

FIGURE 7A

Settlement with Generic Entry Date and No Cash Payment Cash-Strapped Generic and Litigation Costs/Risk Aversion



The latest entry date to which the cash-strapped generic would be willing to agree is earlier than the earliest date to which the brand-name manufacturer would be willing to agree. As a result, settlement talks would break down.

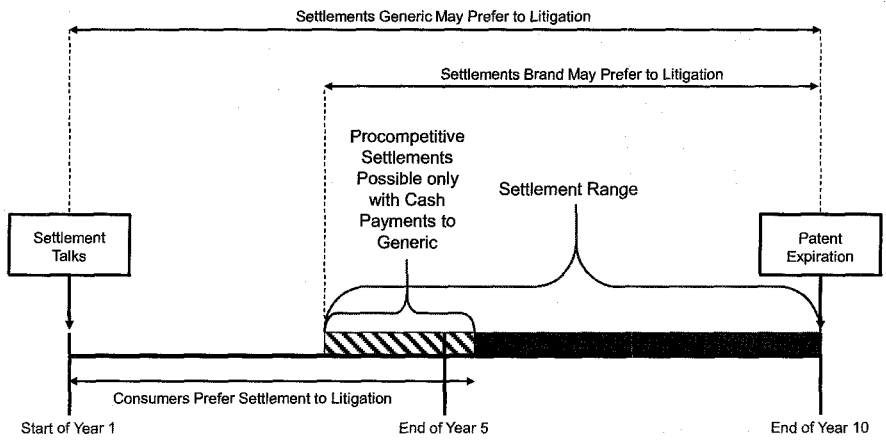
commonly used by antitrust regulators to evaluate agreements among competitors, which evaluates competition relative to a world without the agreement, rather than a world with an optimal agreement. See FED. TRADE COMM'N AND U.S. DEP'T OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS (April 2000).

114. *Reverse Payments*, *supra* note 107, at 248-74.

115. PINDYCK & RUBINFELD, *supra* note 64, at §15.1.

FIGURE 7B

Settlement with Generic Entry Date and Cash Payment Cash-Strapped Generic and Litigation Costs/Risk Aversion



A cash payment by the brand-name manufacturer may allow the brand-name and generic manufacturers to bridge the settlement gap shown in Figure 7a. The brand-name manufacturer would be willing to include a cash payment in the settlement in exchange for a later generic entry date. The generic manufacturer would be willing to accept later entry in exchange for a cash payment. As described above, the incremental profits that a brand-name manufacturer would receive because of postponed generic entry would be higher than the incremental profits that the generic manufacturer would lose from delaying its entry to a more competitive market. Thus, a given cash payment will expand the range of entry dates that the brand-name manufacturer is willing to accept later in time, but it will move the dates the generic is willing to accept to an even greater extent. Such a payment will bring the parties closer together, potentially bridging the settlement gap. As shown in Figure 7b, under these circumstances, reverse payments can lead to a range of settlements that would not have been otherwise feasible. Importantly, many of these newly conceivable settlements would benefit consumers by resulting in a generic entry date earlier than that expected through continued litigation.

4. Cash payments with an optimistic generic

Cash payments can also help bridge settlement gaps arising under other circumstances. For example, imagine a generic manufacturer that, despite actual odds of winning the patent suit of only fifty percent, believes that it

in fact has a seventy five-percent chance of winning. This mismatch of beliefs and actual probabilities could create a situation similar to that depicted in 7a, where (absent a reverse payment) the generic manufacturer would not be willing to accept any settlement terms the brand-name manufacturer would be willing to offer due to the generic manufacturer's unrealistic belief about its chance of winning. Just as with a cash-strapped generic, a reverse payment can potentially bridge the settlement gap and lead to a settlement that benefits consumers. Of course, it is possible that the brand-name manufacturer is also overly optimistic about its odds of success in the litigation, which would reduce the range of procompetitive settlements that a cash payment could generate. The point is not that these are the only scenarios that could play out, but rather that there are reasonable scenarios under which a patent settlement with a reverse payment can benefit consumers.

5. Cash payments with information asymmetries

Brand-name and the generic manufacturers rarely have access to identical information; each almost certainly possesses certain information that the other does not. Willig and Bigelow describe how this information asymmetry can create another circumstance where cash payments may facilitate a procompetitive settlement agreement that would not otherwise be feasible.[116]

Imagine that the brand-name manufacturer has private information about the effective life of the patent; for example, the prospects of future competition from other brand-name products. The generic entrant knows that the brand-name manufacturer is better informed about future competition, and therefore will interpret settlement offers from the brand-name manufacturer with this in mind.

Suppose there are two types of patents: "high-value" patents, where there is no chance that other brand-name competitors enter before the patent expires, and "low-value" patents, where there is a decent chance that such brand-name entry happens, significantly reducing the effective life, and the value, of the current patent. The brand-name manufacturer knows which type of patent it holds, while the generic manufacturer does not.[117] In the case of a low-value patent, agreeing to a compromise entry date may have little benefit to the generic because the market may be eliminated by future

116. Willig & Bigelow, *supra* note 76 at 661.

117. Economic models on this point often assume that the branded manufacturer knows the type of patent it holds with certainty. However, the results depend not upon this assumption (as there may be some uncertainty even on the part of the branded manufacturer) but only that the branded manufacturer will have better information on the type of the patent than the generic manufacturer.

competition; as a result, a generic may be wary of accepting a reasonable settlement offer because it worries that such a settlement may indicate that in fact the patent is low-value, and that the generic would be better off pursuing litigation.[118]

The problems created by information asymmetries can be overcome if the brand-name manufacturer is allowed to provide a cash payment to the generic manufacturer. In our example, only brand-name manufacturers with high-value patents would find it profitable to offer an up-front payment to the generic. Thus, the generic can interpret the reverse payment as a signal that the patent is high value, and have strong reason to believe that the settlement offer is in fact a good offer from a brand-name manufacturer with a high-value patent, rather than a poor offer from a brand-name manufacturer with a low-value patent. Here again, cash payments can facilitate settlements – including procompetitive settlements – that would not be reached if such payments were not allowed.

6. Collateral business agreements

Many settlements between brand-name and generic manufacturers involve collateral business agreements. These agreements may take a variety of forms, including:

- Brand-name manufacturer licenses products from the generic manufacturer;
- Generic manufacturer licenses products from the brand-name manufacturer;
- Generic manufacturer agrees to co-promote one or more of the brand-name manufacturer's products; and/or
- Generic manufacturer agrees to serve as supplier for the brand-name manufacturer.[119]

Such collateral agreements can be helpful in facilitating settlements by allowing the parties to get around some of the complexities discussed above that may otherwise pose obstacles to successful settlements like information asymmetries and differences in expectations.[120] Unlike cash, the parties' valuations of the components of a collateral business arrangement may be quite different. This difference in valuation could be used to offset different

118. Willig & Bigelow, *supra* note 76, at 668.

119. BUREAU OF COMPETITION, 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 (2007).

120. Willig & Bigelow, *supra* note 76, at 669.

expectations in the patent litigation to arrive at a settlement. In addition, these collateral agreements could in and of themselves benefit consumers, bringing together business partnerships that would not be possible with continued litigation. But while these collateral agreements can serve to facilitate settlements, they could also, in theory, contain "effective" payments that are designed to delay entry of the generic, if the generic manufacturer is over-compensated, or the brand-name manufacturer under-compensated.[121]

In recent years, patent settlements with collateral business agreements have received significant regulatory and legal scrutiny.[122] For example, as described above, the agreement between Schering and Upsher that was challenged by the FTC did not involve an isolated cash payment to the generic. Rather, in settling the patent dispute, Schering also licensed six different products from Upsher, including Upsher's Niacor SR, in exchange for royalty payments of $60 million.[123] The FTC argued that the $60 million royalty payments were well above the value of the licensed products, and that the payments were just another means to delay generic entry.[124]

Evaluating the competitive implications of settlements with collateral business arrangements is even more complicated than those with cash payments. Such an analysis first requires an evaluation of the collateral business transaction to determine a reasonable assessment of the market value of the transaction.[125] To the extent that it is clear from the evidence that the generic was over-compensated or the brand was under-compensated, the difference between the payment and the arms-length value of the transaction can be thought of in the same way as a "reverse payment." While collateral business transactions, just like reverse payments, can be anticompetitive, they may also serve to produce procompetition outcomes, some of which may not have been otherwise feasible.

V. LONG-RUN COMPETITIVE EFFECTS

The discussion to this point has focused on the short-run competitive effects of patent settlements. Clearly, patent settlements can be procompetitive, even when focusing on short-run competition; however, patent settlements can also have important long-term competitive effects.

121. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data & Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 663-665 (2009).

122. *Id.* at 135.

123. *Schering-Plough Corp.*, 402 F.3d, at 1068.

124. *See id*, at 1070 (FTC did not convincingly demonstrate that the $60 million was not simply a royalty payment within the range of fair market value for the licensed products).

125. Shapiro, *supra* note 42, at 408.

First, the scope of patent protection can affect future incentives for brand-name manufacturers to invest in additional R&D. Patents give patent holders the right to litigate claims against alleged infringers, and the right to settle such litigation, at least, as long as such a settlement does not exclude competition beyond that allowed by the patent.[126] Broad-brush limits on the types of patent settlements that are allowed by pharmaceutical manufacturers would likely result in a narrowing of the patent protection currently provided to patent holders.[127] As described above, such patent protection is an important component of pharmaceutical manufacturers' incentives to invest substantial sums in R&D and to introduce new medications. To the extent that limits on patent settlements reduce incentives to invest in pharmaceutical R&D, consumers may suffer significant adverse effects in the long-run, in the form of a smaller number of new medicines that become available.[128]

Second, the availability of procompetitive settlements can provide further incentives to generic manufacturers to challenge brand-name patents and bring lower-priced generic drugs to market.[129] Patent litigation can be expensive and risky, particularly for small firms. Restricting the range of settlement options will reduce the ability of generic manufacturers to settle these cases and increase the cost and risk of bringing a generic drug to market. On the margin, this will lower the incentives for generic pharmaceutical manufacturers to challenge brand-name patents in the first place.[130] Even if the effect on a particular generic manufacturer's decision is relatively small, the collective impact on future generic competition can be substantial.

VI. POLICY IMPLICATIONS AND CONCLUSIONS

Designing a workable framework that distinguishes procompetitive settlements from anticompetitive settlements is difficult, in part because, at its core, such a framework depends upon the validity of the patent claims. A settlement agreement whereby the generic manufacturer agrees to enter the market five years in the future, but also five years before the expiration of the patent, might be anticompetitive if the patent was weak (*i.e.*, if the generic had a high probability of winning at trial). However, the same

126. *Schering-Plough Corp.*, 402 F.3d at 1067.

127. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2nd Cir. 2006).

128. For a more extensive discussion of these effects, *see* James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L. J. 777-818 (2003).

129. Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

130. *See, e.g., id.*

settlement terms might be procompetitive if the patent was strong (*i.e.*, if the generic had a low probability of winning at trial). Ultimately, an evaluation of the competitive effects of a patent settlement must include an investigation into the merits of the patent litigation.

While antitrust economists generally agree with this line of argument, some analysts have suggested prohibiting settlements with "reverse payments;" several bills have been introduced in Congress that would do just that.[131]

However, as we explain above, under many circumstances, patent settlements between brand-name and generic manufacturers – even those involving reverse payments – can enhance competition and benefit consumers. An outright prohibition of reverse payment settlements would harm consumer welfare in a range of circumstances. Indeed, prohibiting settlements with cash payments could simply lead to a shift to settlements involving other business arrangements that are even more complicated to evaluate, making enforcement of potentially anticompetitive arrangements even more difficult to assess. Efforts to prevent settlements with any compensation, whether in the form of cash or collateral business arrangements, flowing from the brand-name manufacturer to the generic would similarly block many pro-consumer settlements. Of course, an outright prohibition on such settlements would reduce the uncertainty and litigation costs that may follow from antitrust challenges to such settlements; however, it is not at all clear that these savings would outweigh the harm created by eliminating potentially procompetitive settlements. "Quick look" or "safe harbor" approaches (whereby settlements with certain characteristics are presumptively anticompetitive or procompetitive, while leaving open the opportunity to rebut this presumption) could reduce these costs while still allowing procompetitive settlements.

Moreover, a restrictive policy approach that sought to bar reverse payment settlements would not only have short-term impacts by preventing procompetitive settlements, but may harm consumers in the long-run by reducing the incentives of brand-name manufacturers to continue to develop innovative new drugs, and reducing the incentives of generic manufacturers to challenge weak patents and bring generic drugs to market sooner.

Patent settlements between brand-name and generic pharmaceutical manufactures can be anticompetitive and should continue to be closely scrutinized by antitrust authorities and the courts; indeed, current law requires that the terms of any relevant patent settlement agreement be provided to the FTC and the DOJ. But painting all settlements with the same brush is likely to harm consumers. Instead, more individualized

131. Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009).

treatment is appropriate, whereby the competitive effects of a particular settlement are evaluated by applying an economic framework to the facts specific to that settlement.