

An Economic Assessment of Patent Settlements in the Pharmaceutical Industry

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December 2008⁴

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⁴ The authors thank Jamie Mullins of Compass Lexecon for his excellent research assistance. This study was supported by funding from the Pharmaceutical Research and Manufacturers of America (PhRMA). The views and opinions expressed in this study are solely those of the authors and do not necessarily reflect the views and opinions of PhRMA or any of the organizations with which the authors are or have previously been associated. Compass Lexecon has served as economic consultants to branded and generic manufacturers regarding the competitive effects of patent settlements.

Executive Summary

- Consumers benefit from the availability of innovative new products and from lower prices. In the pharmaceutical industry, both the development of new medicines and price competition from manufacturers of generic drugs provide substantial consumer benefits. Competition policy towards the pharmaceutical industry must therefore represent a balance between protecting incentives for manufacturers of branded drugs to innovate and facilitating entry by manufacturers of lower-priced generic drugs.
- The current framework for patent litigation between branded and generic pharmaceutical manufacturers, established by the Hatch-Waxman Amendments in 1984, is an important component of this balance. Generic manufacturers must notify branded manufacturers before launching a potentially infringing generic product, providing branded manufacturers an opportunity to sue for patent infringement before the generic enters the market. In many cases, litigation is resolved with a settlement between the parties. These settlements may include the following types of provisions:
 - A negotiated date upon which the generic manufacturer will enter the market (with or without royalty payments to the branded manufacturer);
 - Cash payments from the branded manufacturer to the generic;
 - Business transactions between the branded and generic manufacturer such as cross-licensing or supply agreements; and
 - Agreement by the branded manufacturer not to launch or license an authorized generic for some period after generic entry.
- In recent years, settlements between branded and generic manufacturers have received increased scrutiny from the Federal Trade Commission (FTC) due to concerns that some settlement agreements harm consumers by delaying the entry of lower-priced generic drugs. This paper presents an analytical framework for evaluating the competitive effects of these settlements.
- On the one hand, settlements of litigation – including patent settlements – can provide clear competitive benefits. Litigation imposes substantial costs upon the litigating parties and on society as a whole. Settlements also reduce risk associated with litigation. Because settlements can lower costs and uncertainty, economists agree that settlements can be procompetitive.
- On the other hand, under certain conditions, patent settlements between branded and generic manufacturers can be anticompetitive. Ultimately, the competitive effects of a particular settlement will depend importantly upon the underlying strength of the patent. If the patent is 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 patent expiration may bring generic drugs to market sooner than continued litigation and generate lower prices for consumers. In contrast, if the patent is weak, and likely to be found invalid and/or non-infringed, then even a settlement with an entry date not

far in the future may delay generic entry and harm consumers. Assessing the strength or weakness of a patent in real-world patent litigation is complex – indeed, the precise strength of a patent is subject to the vagaries of the litigation system and is ultimately unknowable even to the parties themselves. Nevertheless, such an assessment is necessary at some level in assessing whether a patent settlement is pro- or anticompetitive.

- While the procompetitive nature of patent settlements is generally recognized by economists, antitrust agencies, and the courts, one category of settlements – so called “reverse payment” settlements – has generated extensive debate in recent years. In these settlements, the parties settle the patent litigation and the branded manufacturer (1) allows the generic manufacturer to enter at or after a particular date in the future (prior to the expiration of the patent) and (2) pays some form of compensation to the generic manufacturer. That compensation can be in the form of cash or through some other business transaction (*e.g.*, a cross-licensing agreement) which provides a conduit through which the branded manufacturer might allegedly “overpay” the generic manufacturer.
- The FTC and some antitrust scholars contend that such “reverse payments” are on their face evidence that the settlements are nothing more than a payment by the brand manufacturer to delay generic entry. They argue that in what one might think of as the “typical” patent settlement case, the defendant (an alleged patent infringer) makes a payment to the plaintiff (the holder of the patent). But in “reverse payment” settlements, they argue that the payment flows the “wrong” way, from the patent holder (branded manufacturer/plaintiff) to the defendant (the generic manufacturer and alleged infringers).
- A “reverse payment” is a misnomer based on flawed logic. In contrast to a “typical” patent case, where the alleged infringer is already selling a product and the patent holder is suing for damages, in patent suits between branded and generic pharmaceutical manufacturers, the generic has typically not entered the market and the branded manufacturer is suing for a remedy akin to injunctive relief. In this case, there is no *a priori* expectation that a payment should flow from the generic manufacturer to the branded manufacturer.
- The use of highly simplified economic models can inappropriately lead to the conclusion that “reverse payment” settlements will always reduce competition. But overly simple economic models ignore important economic realities that can make reverse payment settlements procompetitive. Such realities include, but are not limited to, (a) risk aversion, (b) information asymmetries, (c) differences in expectations, and (d) differences in discount rates. In fact, under certain conditions, without a payment from the branded manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement – even if that settlement would benefit consumers.

- For example, suppose that both the branded and generic manufacturers are overly optimistic about their chances of success in the patent litigation – say the branded manufacturer believes that there is a 75-percent chance that it will win the litigation and the generic manufacturer believes that there is a 75-percent chance that it will win. In this case, the parties will be unable to reach a settlement based upon entry date alone. A reverse payment, however, can facilitate a settlement that is agreeable to both parties and, given the actual chance of success in the patent litigation based on the strength of the underlying patent, provide benefits to consumers relative to continued litigation.
- Other examples of circumstances in which settlement is not possible without compensation between the parties will be discussed in more detail in the report.
- Moreover, competition policy towards patent settlements can have important effects both on the incentives of branded manufacturers to innovate and on the incentives of generic manufacturers to challenge branded patents. Taking some potentially procompetitive settlement options off the table would narrow the patent protection provided to branded manufacturers and, on the margin, lower incentives to invest in new medicines in the future. This would also reduce the ability of generic manufacturers to settle such cases and increase the cost and risk of bringing a generic drug to market. On the margin, this will lower the incentives of generic pharmaceutical manufacturers to challenge branded patents in the first place. Even if the effect on a particular generic manufacturer’s decision is relatively small, the collective impact on future generic competition can be substantial.
- Despite the contention by some that reverse payment settlements should be treated as *per se* illegal, courts, the Department of Justice (DOJ), and many economists have concluded that patent settlements between pharmaceutical manufacturers can be procompetitive and should be given considerable latitude.
 - Decisions by the Second, Eleventh, and most recently the *Cipro* decision by the Federal Circuit Court of Appeals have all concluded that patent settlement agreements between branded and generic pharmaceutical manufacturers – even agreements involving reverse payments – are appropriately treated under a rule of reason standard and are not anticompetitive as long as the agreement is not beyond the exclusionary scope of the patent and the litigation is not objectively baseless.
 - The DOJ has stated that “...settlements between an ANDA filer and the patent holder [even those with a reverse payment] also can benefit consumer welfare. Accordingly, the Department of Justice does not believe *per se* liability under the antitrust laws is the appropriate standard.” Economists have reached similar conclusions.
- Designing a workable framework that distinguishes procompetitive settlements from anticompetitive settlements is difficult – in part because at its core it depends upon

the validity of the patent claims. What is clear is that under many circumstances, patent settlements between branded and generic manufacturers – even those involving reverse payments – can benefit competition and consumers. An outright prohibition of reverse payment settlements would harm consumer welfare in a range of circumstances. Patent settlements between branded and generic pharmaceutical manufactures can be anticompetitive and should continue to be closely scrutinized by the antitrust authorities and the courts. Indeed, current law requires that the terms of any patent settlement agreement between a branded pharmaceutical company and a generic applicant be provided to the FTC and the DOJ. But painting all settlements with the same brush is likely to harm consumers. Instead, more individualized treatment is appropriate, whereby the competitive effects of a particular settlement are evaluated by applying an economic framework, such as that presented here, to the facts specific to that settlement.

I. COMPETITION IN THE PHARMACEUTICAL INDUSTRY

Innovative branded pharmaceutical firms can benefit consumers by developing new drugs. Generic pharmaceutical firms can benefit consumers by offering competition that drives down prices. Thus, the challenge of competition policy in this area (as in all highly innovative industries) is to benefit consumers by striking the appropriate balance between providing sufficient rewards to encourage innovation, followed after a time by a transition to a more competitive market with lower 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”).⁵ As described by the Congressional Budget Office (“CBO”):

The 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.⁶

Since 1990, R&D by pharmaceutical manufacturers has led to the approval of an average of roughly 30 new drugs (molecular entities) and dozens of newly approved formulations or other modifications of existing drugs each year.⁷

Protection of the intellectual property underlying these innovations is critical to providing incentives for pharmaceutical manufacturers to continue to invest in, and develop, new drugs. The research and development process is lengthy, costly, and uncertain. Only a tiny fraction of medicines tested are eventually approved for patient

⁵ Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2008*, March 2008, pp. 2-3. See also Congressional Budget Office, “Research and Development in the Pharmaceutical Industry,” October 2006, pp. 7-9 (“CBO 2006”).

⁶ CBO 2006, p. 9.

⁷ U.S. Food and Drug Administration, “CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type” (<http://www.fda.gov/cder/rdmt/pstable.htm>); U.S. Food and Drug Administration, “CDER Drug and Biologic Approvals for Calendar Year 2005” (<http://www.fda.gov/cder/rdmt/InternetNDA05.htm>); U.S. Food and Drug Administration, “CDER Drug and Biologic Approvals for Calendar Year 2006” (<http://www.fda.gov/cder/rdmt/InternetNDA06.htm>); U.S. Food and Drug Administration, “CDER Drug and Biologic Approvals for Calendar Year 2007” (<http://www.fda.gov/cder/rdmt/InternetNDA07.htm>).

use,⁸ and only 20 to 30 percent of those approved eventually recoup their R&D investment.⁹ Development of a new drug entails considerable time and expense. These development costs have been rising significantly. Recent studies estimate that the average new drug took 10 to 15 years¹⁰ and cost over \$1.3 billion (including both direct costs and opportunity costs) to develop.¹¹ Strong protection of intellectual property, and the potential rewards that come with it, provide incentives for pharmaceutical companies to undertake such large development costs.

B. Generic Competition

After a branded drug loses patent protection (or a generic manufacturer is able to produce a non-infringing generic version), generic manufacturers often bring bioequivalent versions of branded drugs to market. Numerous economic studies have consistently found that entry of a competing generic manufacturer typically leads to lower average prices, and that this price competition typically intensifies with the entry of additional manufacturers.¹² For example, the CBO concluded in a review of the evidence that:

⁸ For example, one report indicates that only 1 of every 5,000 medicines tested is eventually approved (Tufts Center for the Study of Drug Development. "Backgrounder: How New Drugs Move Throughout the Development and Approval Process," November 1, 2001).

⁹ Vernon, John M., Golec, Joseph H., and DiMasi, Joseph A. "Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three Factor Model," *Tufts Center for the Study of Drug Development Working Paper*, 2008, p. 3 (concluding that 20 percent cover their R&D expenses); Grabowski, Henry G., Vernon, John M., and DiMasi, Joseph A. "Returns on Research and Development for 1990s New Drug Introductions," *PharmacoEconomics*, 20(3), March 2002, p. 17 (concluding that 30 percent do).

¹⁰ CBO 2006, p. 20. See also DiMasi, Joseph A., Hansen, Ronald W., and Grabowski, Henry G. "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 22(2), March 2003, pp. 164-165,.

¹¹ DiMasi, Joseph A., and Grabowski, Henry G. "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics*, 28, 2007, pp. 469-79. See also CBO 2006, and Adams, Christopher P., and Brantner, Van V. "Estimating the Cost of New Drug Development: Is It Really \$802 Million?" *Health Affairs*, 25(2), 2006, pp. 420-428.

¹² See, for example, Grabowski, Henry G. and Vernon, John M. "Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law and Economics*, 35, October 1992, pp. 331-350. Other articles reaching similar findings include: Frank, R. G. and Salkever, D. S. "Pricing, Patent Loss and the Market for Pharmaceuticals," *Southern Economic Journal*, 59(2), 1992, pp. 165-179; Caves, Richard E., Whinston, Michael D., and Hurwitz, Mark A. "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics*, 1991, pp. 1-48; Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, pp. 28-33 ("CBO 1998"). As Grabowski and Vernon (1992) and others have found, branded manufacturers may increase

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.¹³

As the next section discusses, given the significant consumer benefits that result from both innovation and lower prices, policy-makers have sought to facilitate generic competition within a framework intended to provide branded manufacturers sufficient incentives to innovate.

C. The Hatch-Waxman Amendments

1. Introduction

In 1984, the U.S. Congress passed the Hatch-Waxman Amendments (“Hatch-Waxman”)¹⁴ to the Federal Food, Drug, and Cosmetic Act of 1938, which sought to balance the importance of innovation and generic entry. Hatch-Waxman established the current framework for patent litigation in the pharmaceutical industry, and although this framework has been modified since 1984, it largely remains intact. Any analysis of the economics 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 branded drugs are “safe and effective” prior to approval. Branded drug manufacturers provide such evidence by conducting costly and lengthy clinical trials. The process of conducting clinical trials and obtaining FDA approval decreases the effective life of pharmaceutical patents substantially, because

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.

¹³ CBO 1998, p. 13.

¹⁴ More formally, the law was known as the Drug Price Competition and Patent Term Restoration Act of 1984.

approval is typically received many years after a patent is granted.¹⁵ Before Hatch-Waxman, the FDA also required generic manufacturers to conduct their own safety and efficacy studies. Generic manufacturers could not begin their safety and efficacy studies until patents on the brand-name drug had expired.

3. Overview of Hatch-Waxman

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

On the one hand, Hatch-Waxman sought to increase patent protection and to strengthen the incentives of branded manufacturers to innovate. Recognizing that the lengthy FDA approval process often substantially reduced the effective life of pharmaceutical patents, Hatch-Waxman allowed branded manufacturers to apply to extend the life of these patents to regain some of the patent life lost by clinical trials and the FDA approval process.¹⁶

On the other hand, Hatch-Waxman attempted to encourage generic competition. It streamlined the approval process for generic manufacturers, thereby reducing the costs of obtaining FDA approval and speeding their time to market. More specifically, Hatch-Waxman allowed generic pharmaceutical companies to submit an Abbreviated New Drug Application (ANDA), simply referencing the safety and efficacy results submitted by the branded company rather than conducting 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. Branded manufacturers were required to file

¹⁵ CBO 1998, p. 39.

¹⁶ Specifically, the branded 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. See Grabowski, Henry G. and Kyle, Margaret, “Generic Competition and Market Exclusivity Periods in Pharmaceuticals,” *Managerial and Decision Economics* 28, 2007, p. 492. Additionally, regardless of whether a new drug has patent protection, upon approval of an NDA for a New Chemical Entity, a drug will receive a 5-year term of exclusivity from the FDA. During this exclusivity period an ANDA that references the brand manufacturer’s NDA cannot be submitted (except after four years if there is a patent challenge). See: “Frequently Asked Questions on Patents and Exclusivity,” *U.S. Food and Drug Administration*, <http://www.fda.gov/cder/ob/faqs.htm#How>.

information about any relevant patents with the FDA. In addition, the ANDA filer must certify one of the following:

- (1) the required patent information has not been filed by the branded manufacturer
- (2) the patent has expired;
- (3) the patent will expire, identifying the expiration date; or
- (4) the patent is invalid and/or not infringed.

The latter representation is known as a Paragraph IV certification.

Since Hatch-Waxman, competition from generic drugs has grown significantly. The generic share of prescriptions has grown from 19 percent in 1984 to nearly 67 percent today.¹⁷

4. Patent litigation under Hatch-Waxman

Hatch-Waxman established several important aspects of patent litigation between branded 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. Under Hatch-Waxman, if a branded manufacturer files suit within 45 days of receiving notice of a Paragraph IV certification, the branded company is granted an automatic stay of FDA final approval of the generic company's ANDA until the earliest of: (1) 30 months from the notification date; (2) the district court decides the patent is invalid or not infringed; or (3) the patent expires. This is commonly known as a "30-month stay." If the patent holder does not file suit within the 45-day window, then the FDA may approve the ANDA immediately, provided all other requirements are met.

Second, the earliest 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

¹⁷ See, for example, Generic Pharmaceutical Association (GPhA), "Annual Report 2008: Generics: The Right Choice for Better Health," 2008, p. 6; GPhA, "Industry History" (available at <http://www.gphaonline.org/Content/NavigationMenu/AboutUS/History.htm>).

subsequently for the same drug.¹⁸ The start of the 180-day exclusivity period is triggered by commercial marketing of the first filer's product.¹⁹ If the first filer does not exercise its exclusivity in a timely fashion, a variety of circumstances can lead to the forfeiture of its eligibility for exclusivity.²⁰ The substantial profits available during the 180-day period of exclusive marketing (in which the exclusive generic can charge a higher price than it could in the face of competition from other generic manufacturers and capture a larger share of sales) provide generic firms with an additional incentive to be first to challenge potentially invalid patents or to invent around the patented technology by developing a non-infringing alternative.

D. Patent Litigation and Settlement Agreements

ANDA filings frequently result in patent litigation. From 1998 to 2000, roughly 20 percent of filed ANDAs contained Paragraph IV certifications, where the generic manufacturer claimed that the branded manufacturers' patent(s) were invalid or not infringed.²¹ A study by the FTC of ANDA filings between 1992 and 2000 found that a Paragraph IV certification resulted in patent litigation nearly 75 percent of the time.²²

In general, the vast majority of patent litigation is resolved through a settlement between the parties.²³ Settlements between branded and generic pharmaceutical manufacturers are common. From 1992 to 2000, nearly 40 percent of litigations against the first ANDA filer resulted in settlement.²⁴ Similarly, Barr, one of the largest generic

¹⁸ 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.

¹⁹ 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.

²⁰ "Medicare Prescription Drug, Improvement, and Modernization Act of 2003," §1102 (a)(2)(D)(i)(I)(aa)(AA) ("2003 MMA").

²¹ Federal Trade Commission. "Generic Drug Entry Prior to Patent Expiration: An FTC Study," (2002), p. 10 ("FTC 2002").

²² FTC 2002, pp. 13-15.

²³ See, for example, Shapiro, Carl. "Antitrust Limits to Patent Settlements." *RAND Journal of Economics*, 43(2), 2003, pp. 391-411 ("Shapiro (2003)").

²⁴ FTC 2002, pp. 15-16.

manufacturers, has settled nearly half of the 30 patent cases that it has been involved with (and the vast majority of cases that are not still pending) in the last 15 years.²⁵

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

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

Pharmaceutical manufacturers settling patent litigation are required to report information on those settlements to the FTC and DOJ, and the FTC publishes annual reports summarizing those settlements.²⁶ The following table provides a summary of the FTC’s classification of settlements that have been entered into over the last several years between branded and generic pharmaceutical manufacturers.²⁷

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

²⁵ Testimony of Bruce Downey, “Paying Off Generics to Prevent Competition With Brand Name Drugs: Should It Be Prohibited?” *Hearing Before the Committee on the Judiciary, United States Senate, Serial No. J-110-4, 2007*, p. 23. (“Testimony of Bruce Downey”) Specifically, Mr. Downey testified that this has been true during his tenure as CEO, which began in 1993.

²⁶ This requirement was created by the 2003 MMA and effective in FY 2004.

²⁷ Federal Trade Commission, “Summary of Agreements Filed in FY 2004,” Figure II; Federal Trade Commission. “Summary of Agreements Filed in FY 2005,” p. 3; Federal Trade Commission. “Summary of Agreements Filed in FY 2006,” pp. 3-4; Federal Trade Commission, “Summary of Agreements Filed in FY 2007,” p. 3 and Figure III.

²⁸ As defined by the FTC, compensation may be in the form of cash, an ancillary business transaction, or an agreement by the branded manufacturer not to launch or license an authorized generic for some period after generic entry. According to the FTC reports, many of these settlements also include compensation to the branded manufacturer – the reports do not provide sufficient information to determine whether there was a net payment to the generic.

II. COMPETITIVE EFFECTS OF PATENT SETTLEMENTS: SHORT-RUN

A. Overview

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

Settlements of litigation provide clear potential benefits. After all, litigation imposes substantial costs. Costs to litigating parties include (1) direct litigation costs such as legal fees, (2) indirect costs such as requiring attention of company executives and distracting them from their responsibilities of running the business, and (3) indirect costs due to uncertainty.²⁹ Additional costs to society as a whole include increased congestion of the court system and corporate resources focused on private dispute resolution as opposed to innovation and production activities. Moreover, as firms generally pass on at least some portion of costs incurred, consumers ultimately bear some of these costs.

2. *Patent settlements have the potential to be anticompetitive*

While patent settlements between branded and generic manufacturers have clear potential benefits, they also can harm competition and consumers under certain conditions. The potential for anticompetitive effects is increased when the settlement is with the first generic filer, rather than a subsequent generic filer, and the first filer does not relinquish its exclusivity. As described above, under Hatch-Waxman, the first generic filer receives 180 days of marketing exclusivity. This creates the potential for 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, a settlement agreement did not affect 180-day exclusivity. 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 (unless a subsequent-filing generic obtained a court decision that its product did not infringe or that the patent was invalid. Recognizing the potential anticompetitive effects of such a situation, a 2003 law introduced additional restrictions on “parking” the 180-

²⁹ See, for example, Shapiro (2003), p. 394; Bessen, James E. and Meurer, Michael J., “The Private Costs of Patent Litigation,” *2nd Annual Conference on Empirical Legal Studies Paper*, February 1, 2008, p. 2.

day exclusivity. Importantly, the law was changed such that if the branded and generic manufacturers reach a settlement agreement, the settlement is challenged by the FTC or DOJ, and the agreement is determined to violate the antitrust laws, then the generic manufacturer forfeits its exclusivity.³⁰ This change substantially lessens the antitrust concerns with such settlements.

Ultimately, the competitive effects of a particular settlement will depend importantly upon the strength of the underlying patent.³¹ A patent gives the branded manufacturer the right, within certain boundaries, to exclude competition.³² 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 patent expiration may bring generic drugs to market sooner than the expected outcome from continued litigation and generate lower prices for consumers. 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 continue their challenge of patents they believe are invalid or that they do not infringe.³³

In contrast, if the patent is quite weak, and likely to be found invalid and/or non-infringed, then even a settlement with an entry date not far in the future may delay generic entry and harm consumers. Considering the strength of a patent in real-world patent litigation, at least to some extent, is complex, but necessary. The next section presents an economic framework for this evaluation.

³⁰ 2003 MMA.

³¹ Some courts have considered not the subjective assessments of the parties but what a “reasonable person” would think. *See, e.g., Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 992-993.

³² See Shapiro (2003) for a discussion of patents as probabilistic property rights.

³³ The 180-day exclusivity provides a motivation for generic manufacturers to bear the cost and risk associated with developing generic versions of branded drugs and challenging branded 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 branded patent.

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 branded and generic manufacturer, but would harm consumers, relative to continuing litigation? Answering this question requires modeling the settlement decisions of both the branded and generic manufacturers, as well as evaluating the benefit to consumers from generic entry.

The standard economic model of settlements compares each settling party's economic gains from settling to its economic gains from continuing the litigation.³⁴ One then compares these two sets of settlement terms to determine 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 determine which of these settlements, if any, would benefit consumers.³⁵ After all, consumers are not a party to the settlements, and so one might imagine that there could be settlements which benefit branded and generic manufacturer that do not benefit consumers.

For expositional purposes, we start with a highly simplified model of a patent settlement between branded and generic manufacturer. 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 50 percent chance of winning the patent case (and the branded manufacturer also has, and perceives, a 50 percent chance)
- There are no costs to litigation

³⁴ For a general discussion of the settlement decision, see Cooter, Robert and Rubinfeld, Daniel L., "Economic Analysis of Legal Disputes and their Resolution," *Journal of Economic Literature*, September 1989, pp. 1067-1097.

³⁵ In this paper, the term "consumers" is used to represent those that ultimately pay for prescription drugs. In reality, this is a combination of patients, private insurers, and government.

- 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).³⁶

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 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 or average outcome from litigation is generic entry at the end of Year 5. There is a 50 percent chance of immediate entry if the generic wins and a 50 percent chance of entry at the end of Year 10 if the brand wins. The settlement decision amounts to a comparison of the profits from settling to a simple average of the profits assuming immediate generic entry (50 percent chance the generic wins) and the profits assuming generic entry in Year 10 (50 percent chance the generic loses). Under the assumptions provided above, the simple average of profits from litigation is equivalent to the profits from 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 branded 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.

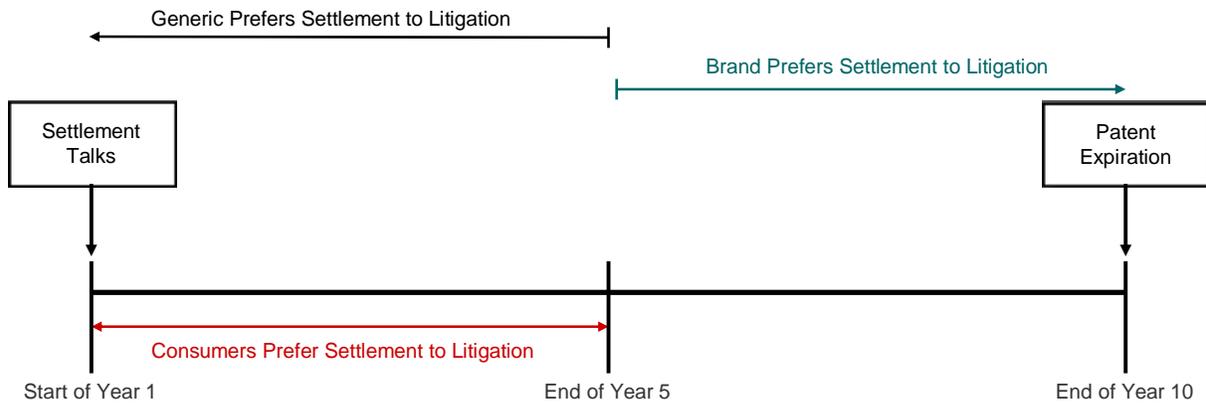
Of course, this simple model assumes away many complexities present in the real world – indeed, some of the very complexities that provide important incentives for litigating parties to settle. In the next section, we relax some of these assumptions and

³⁶ Other assumptions include: (1) Total prescriptions are constant in each year, as is the share of prescriptions by the branded and generic manufacturers after generic entry. (2) There is perfect information, so both parties know the ultimate chance of winning. (3) Both parties are risk neutral. (4) There is no time value of money for either party. (5) After entry, there will be only one generic competitor.

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



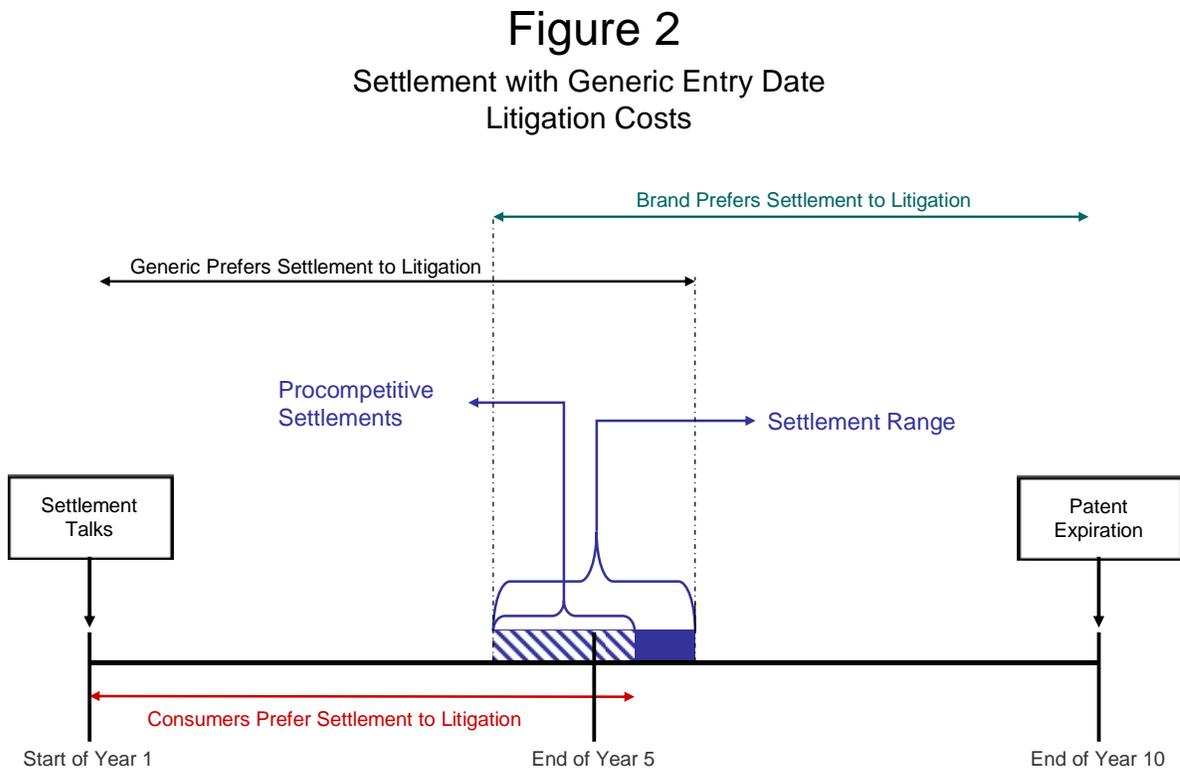
Note: There are no settlements that both the Brand and Generic prefer to Litigation

2. Litigation costs

A primary motivation for parties to settle litigation is that it 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 branded and generic manufacturers and could also make consumers better off.

Figure 2 shows that, because litigation is costly, the brand-name manufacturer would be willing to accept settlements where the generic enters before the end of Year 5 (*i.e.*, earlier than it would be willing to accept based only on the profits from winning or losing the litigation), because the brand-name manufacturer would avoid these costs. Similarly, 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). These litigation costs enlarge the range

of settlements that would be agreeable to both parties.³⁷ 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. Accounting for the fact that part of litigation costs are ultimately borne by consumers broadens the range of procompetitive settlements.



Of course, the particular size of settlement ranges shown in these figures 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 is in fact quite difficult to distinguish in the real world. Recall that our example

³⁷ Because annual profits for the generic are lower than annual pre-generic entry profits for the branded manufacturer, the generic would be willing to give up more time in the market to avoid those costs, assuming litigation costs for the brand and the generic are similar.

assumes a 50 percent chance that the generic manufacturer will win the patent litigation – and that everyone knows that probability. But the precise strength of the patent is not knowable to the antitrust analyst or even the parties themselves. It will depend on a wide range of factors that 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, 30 percent.

3. *Risk aversion*

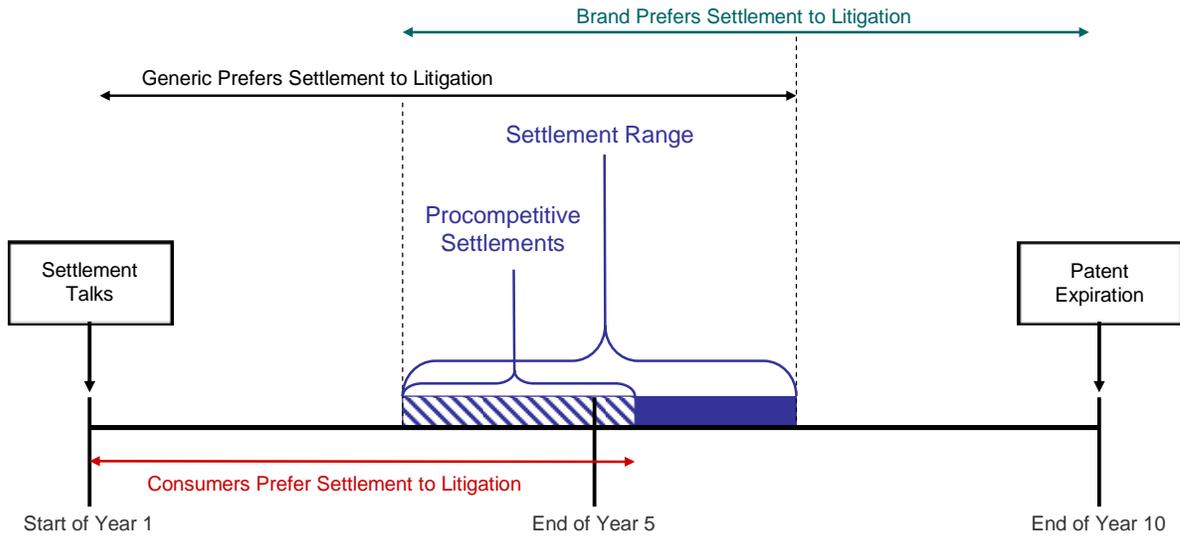
Another cost of litigation is the substantial uncertainty that it creates. Economists model the cost of uncertainty using the concepts of “risk aversion” and “risk premiums.”³⁸ For example, a risk-averse economic actor will prefer to receive \$2 with certainty, rather than a 50 percent chance at \$1 and a 50 percent chance at \$3. That is, risk-averse individuals prefer a certain outcome to uncertain outcomes with the same average or expected value but some degree of variance. A risk premium is the amount of money that a party would pay to avoid taking a risk. In the example above, the risk premium is the amount the individual would pay in order to receive the \$2 with certainty rather than the option with 50-50 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 branded and generic manufacturers would accept lower expected profits under a settlement relative to continued litigation to avoid heightened uncertainty. As shown in Figure 3, the effects are similar to those with litigation costs.³⁹

³⁸ See Pindyck, Robert and Rubinfeld, Daniel. *Microeconomics*, 5th Edition, 2001, Section 5.2.

³⁹ 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 a large firm and/or a firm owned by (and effectively managed for) well-diversified shareholders should be risk neutral. The risk from a particular litigation can be effectively 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 decision-making power over the decision to settle or continue litigating) and the shareholders of the firm.⁴⁰ While the firm’s shareholders may be risk neutral, because they can diversify their risks over many investments, managers whose jobs and salaries depend to some extent on their current employer may be risk averse, instead. Second, not all pharmaceutical companies – not even all branded manufacturers – are large firms

⁴⁰ For a general discussion of the principal-agent problem see, for example, Rubinfeld, Daniel L. and Robert S. Pindyck, *Microeconomics*, 5th Edition, 2001, pp. 609-613.

owned by diversified shareholders. For some branded manufacturers, the financial health of the company may depend importantly on the success of a single drug line.

4. *Information asymmetries*

Information asymmetries are another important component of settlement decisions. Both the branded 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 branded product. For example, a generic manufacturer may have manufacturing problems that delay its entry beyond the point at which it receives FDA approval (or that make such entry less effective). The branded manufacturer would be unlikely to know of such problems at the time of the settlement discussions.

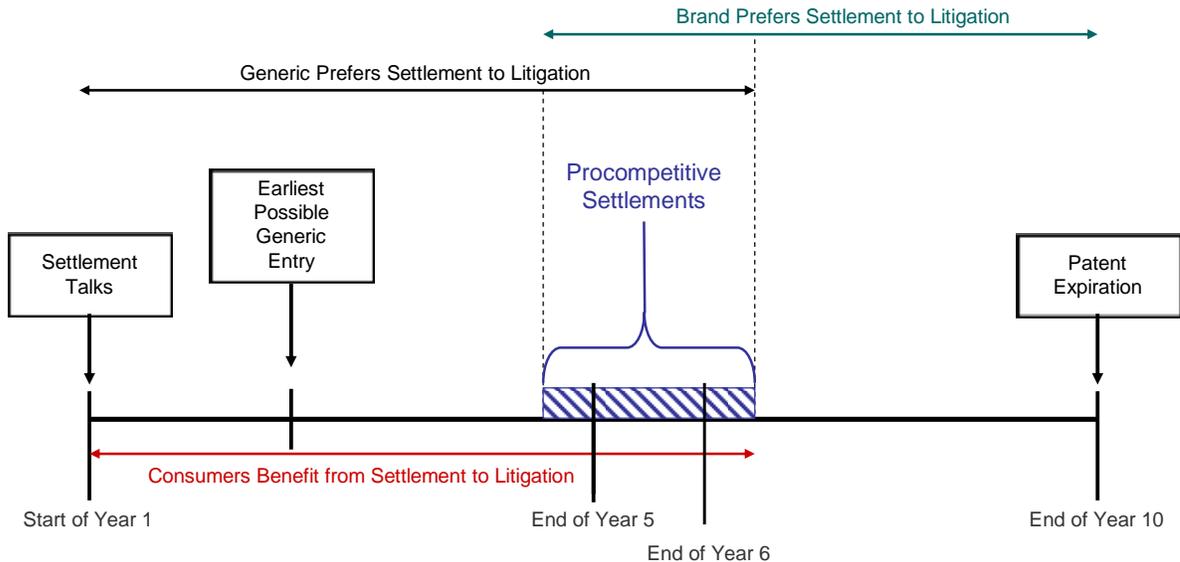
The branded manufacturer, on the other hand, may have better information about the expected size of the market for the product in the future. Branded pharmaceuticals generally have a limited life cycle; a branded drug often faces increasing competition from newer and often more effective branded products. The branded 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 branded manufacturer is unaware of this.

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 branded 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 branded 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.

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

A. Overview

While the possibility of the procompetitive nature of patent settlements is generally recognized by economists, antitrust agencies, and the courts, one category of settlements – so-called “reverse payment” settlements – has generated extensive debate in recent years. In these settlements, the parties settle the patent litigation and the branded manufacturer (1) allows the generic manufacturer to enter at or after a particular date in the future (prior to the expiration of the patent) and (2) 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 branded manufacturer might allegedly “overpay” the generic manufacturer or the generic manufacturer might allegedly “underpay” the branded manufacturer.

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 manufacturer to delay generic entry. 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, the DOJ, and many scholars that have addressed this issue.

B. Regulatory and Judicial Enforcement

1. History

The FTC began scrutinizing reverse payment settlements in the late 1990s. Its initial challenges were directed at settlements where the brand-name manufacturer paid cash to the generic manufacturer to settle patent litigation. These challenges resulted in several consent decrees.⁴¹

The FTC's most prominent challenge was against Schering-Plough ("Schering") and two generic manufacturers relating to Schering's K-Dur (potassium chloride). Schering settled patent litigation with both Upsher-Smith ("Upsher") and ESI Lederle ("ESI") in 1997. The settlement agreement with Upsher included a related licensing agreement where Schering paid Upsher a \$60 million royalty for five Upsher drugs and provided a royalty-free license for Upsher to launch a generic potassium chloride product in 2001 (Schering's patent expired in 2006). The settlement agreement with ESI included a cash payment, as well as a \$15 million royalty payment for two ESI products, and provided a royalty-free license for ESI to launch a generic potassium chloride product in 2004.

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. 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.⁴² The FTC appealed this decision to the full Commission, which reversed the decision and concluded that the payments were indeed anticompetitive.⁴³ 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

⁴¹ 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). Many of these cases were followed by private suits by direct and indirect purchasers.

⁴² Initial Decision, *In the Matter of Schering-Plough Corp.*, et al, 136 F.T.C. 956, 1092 (2002) (No. 9297).

⁴³ Opinion of the Commission, *In the Matter of Schering-Plough Corp. et al*, 136 F.T.C. at 957.

ultimately the determination of competitive effects depends upon the strength of the patent.⁴⁴ The FTC appealed to the Supreme Court, which declined to hear the case.

2. *Current status*

After these developments, reverse payment settlements are now treated quite differently by the various regulatory agencies and Courts. The FTC has clearly expressed that it views reverse payment settlements as essentially *per se* illegal.⁴⁵ Despite the adverse ruling by the Eleventh Circuit in *Schering*, the FTC has continued to demonstrate an interest in challenging reverse payment settlements.⁴⁶ The DOJ submitted a brief urging the Supreme Court *not* to hear the *Schering* case – a position at odds with the FTC’s view.⁴⁷ 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. Accordingly, the Department of Justice does not believe *per se* liability under the antitrust laws is the appropriate standard.”⁴⁸

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.⁴⁹ In stark contrast, the other three circuit courts to address this issue have given reverse payment settlements significant latitude. 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 would give significant latitude as long as the branded patent litigation was not objectively baseless.⁵⁰

⁴⁴ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

⁴⁵ See, for example, Opinion of the Commission, *In the Matter of Schering-Plough Corp. et al*, 136 F.T.C. at 957, prohibiting settlements “under which the generic receives ‘anything of value’” (carving out an exception for payments up to \$2 million linked to litigation costs).

⁴⁶ See, e.g., Oral Statement of FTC Commissioner Jon Leibowitz, Hearing of the House Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, May 2, 2007.

⁴⁷ On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit, Brief For The United States As Amicus Curiae, *FTC v. Schering-Plough Corp. et al*, 548 U.S. 919 (2006) (No. 05-273).

⁴⁸ U.S. Department of Justice, Office of the Assistant Attorney General, Letter to the Honorable Jon Kyl, February 12, 2008.

⁴⁹ *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.* (In re Cardizem CD Antitrust Litig.), 332 F.3d 896 (6th Cir. Mich. 2003).

⁵⁰ The *Valley Drug* case involved an “interim settlement” of a patent suit between Abbott and Geneva over generic Hytrin. See *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294 (11th Cir. Fla. 2003). Whereas the focus of our paper is on final settlements – where the settlement resolved the litigation – in an interim

Similarly, the Second Circuit applied a rule of reason standard in the *Tamoxifen* case when affirming the trial court opinion that the settlements were not anticompetitive.⁵¹

Recently, the Federal Circuit applied a similar standard in the *Cipro* case.⁵² In 1991, Bayer entered into an agreement with generic manufacturers Barr Labs, Hoechst Marion Roussel, and The Rugby Group settling patent litigation over Cipro. Under the settlement agreement, Barr certified that it would not market its generic version prior to the expiration of Bayer's patent. 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. 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." The appellate court affirmed the trial court's conclusion after a similar inquiry, that the plaintiffs had not shown that the agreement was anticompetitive.

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 baptized by commentators who believe that a payment from the branded manufacturer to the generic manufacturer flows the "wrong" way. In a typical settlement of a patent lawsuit, this argument points out, the alleged infringer pays the patent holder (a lump-sum payment and/or a license fee), while in a reverse payment settlement the patent holder (branded manufacturer) pays the alleged infringer (generic manufacturer).

But this label is based on flawed logic. Hatch-Waxman creates an unusual circumstance in the pharmaceutical industry where the patent holder (branded

or "partial" settlement, the litigation continues but the generic manufacturer agrees not to launch "at risk" while the litigation is ongoing. For a more complete discussion of the competitive implications of interim settlements, see Langenfeld, James and Li, Wenqing. "Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers," *Antitrust Law Journal*, 70, 2003, pp. 777-818.

⁵¹ *In Re: Tamoxifen Citrate Antitrust Litigation*, 29 F.3d 370 (2d Cir. 2005).

⁵² *In Re: Ciproflaxin Hydrochloride Antitrust Litigation* (Fed Cir. 2008).

manufacturer) can sue the alleged infringer (generic manufacturer) before the alleged infringer markets a product.⁵³

In the typical patent case – indeed, in any patent case – the alleged infringer is going to require some compensation for abandoning the litigation.⁵⁴ 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 just obscured by the fact that on net 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 branded 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 branded manufacturer holds an ultimately valid patent, and the parties settlement allows the generic manufacturer to enter the market prior to patent expiration (but after the generic manufacturer preferred to enter), 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

⁵³ 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 (Testimony of Bruce Downey, p. 24).

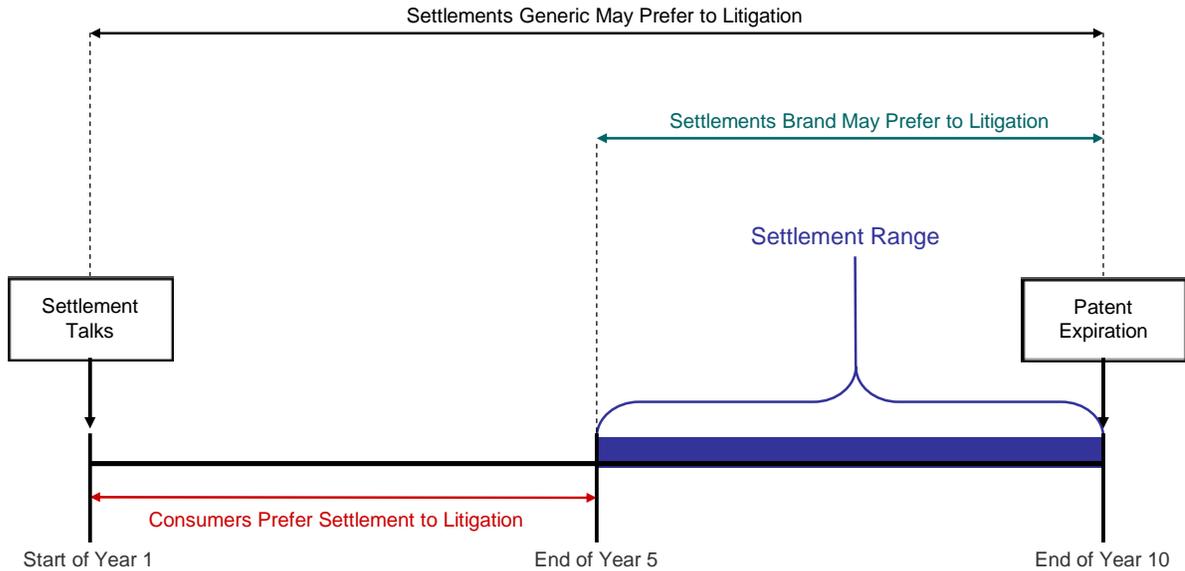
⁵⁴ Crane, Daniel A. “Correspondence: Ease Over Accuracy in Assessing Patent Settlements,” *Minnesota Law Review*, 88, 2004, pp. 698-711; Schildkraut, Marc G. “Patent-Splitting Settlements and the Reverse Payment Fallacy,” *Antitrust Law Journal*, 71(3), 2004, pp. 1033-1068.

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 (profits when only the brand is in the market), will typically be larger than profits when the brand and the generic are both in the market. Of course, branded pharmaceuticals are not necessarily monopolies before the entry of generics, because patents give only a limited right to exclude identical competition and because they may compete with other branded or generic manufacturers. Nonetheless, thinking about analogy to monopoly profits can provide intuition as to why the parties may have an incentive to agree to delay generic entry. A year of delay will be worth more to the branded manufacturer (because it gains a year of “monopoly” profits) than it costs the generic manufacturer (because it loses a year of contested profits), so 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 and generic manufacturers could potentially agree to, but only to include generic entry dates later than Year 5. Consumers will be clearly 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 with 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 can harm consumers. In the next section, we extend the basic model – as we did in the earlier section – 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 Model⁵⁵

1. Overview

Expanding the model to account for other real-world factors demonstrates that settlements with reverse payments can be procompetitive. In fact, under certain conditions, without the bargaining tool of a payment from the branded 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.

⁵⁵ This section draws on the work of Robert Willig and John Bigelow. See Willig, Robert D. and Bigelow, John P., “Antitrust Policy Toward Agreements that Settle Patent Litigation,” *The Antitrust Bulletin*, pp. 655-698, (Fall 2004); Bigelow, John P. and Willig, Robert D., “‘Reverse Payments’ in Settlements of Patent Litigation: Schering Plough, K-Dur and the FTC,” *The Antitrust Revolution: Economics, Competition, and Policy*, 5th Edition (2008) (“Bigelow and Willig (2008)”).

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.⁵⁶

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.⁵⁷

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.”⁵⁸

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

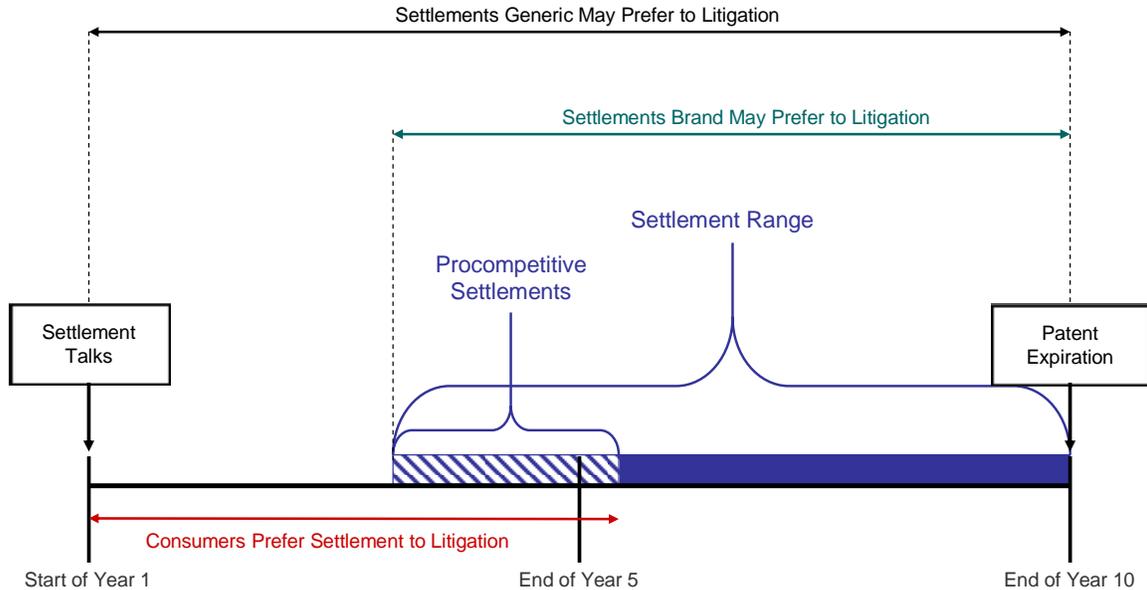
As described above, litigation costs and risk aversion can be important real-world factors to consider in evaluating patent settlements. Accounting for litigation costs and/or risk aversion expands the range of settlement agreements that each party is willing to accept. As shown in Figure 6, these factors expand the range of potential settlements that branded manufacturers will accept (relative to Figure 5), and by creating incentives for branded manufacturers to settle on terms more favorable to consumers it becomes clear that settlements with reverse payments can be procompetitive.

⁵⁶ Shapiro (2003), p. 408.

⁵⁷ Bigelow and Willig (2008), p. 35.

⁵⁸ Testimony of Bruce Downey, p. 28.

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 (where the parties simply agree on an entry date) that will leave consumers better off than either litigation or a reverse payment settlement. 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. This argument ignores the complexities of settlement negotiations.⁵⁹ In the presence of such complexities, additional flexibility in negotiations may be *essential* to enabling a

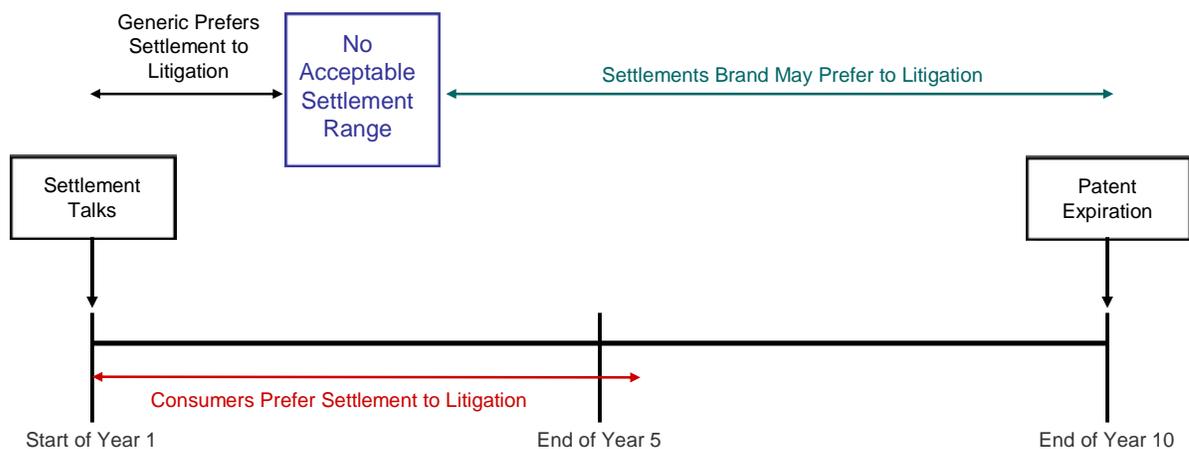
⁵⁹ A related argument is that an alternative settlement with a different payment and a different entry date may be better for consumers. However, this argument ignores the fact that antitrust regulators consider the implications to competition of an agreement among competitors (such as a reverse payment settlement) versus a but-for world without the agreement, not against an optimal agreement. See Department of Justice and Federal Trade Commission, “Antitrust Guidelines for Collaborations Among Competitors,” April 2000, p. 4, 7, and 10.

pro-consumer settlement between the parties. 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 dollar received in the future; thus they discount the value of future cash flows. 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 branded manufacturer.

Figure 7a

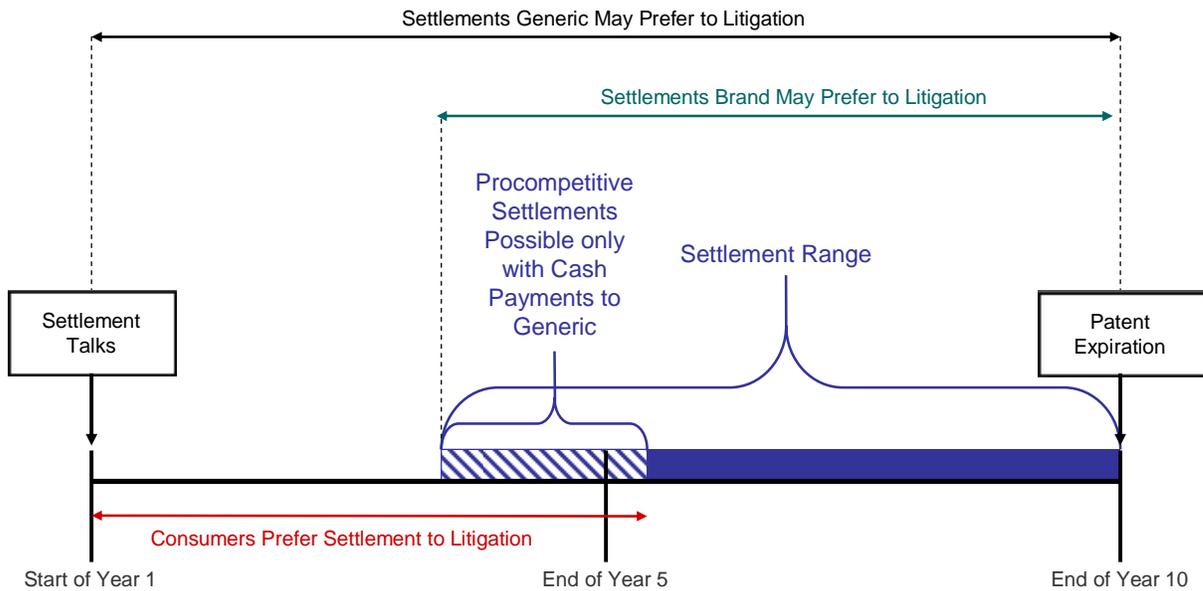
Settlement with Generic Entry Date and No Cash Payment
Cash-Strapped Generic and Litigation Costs/Risk Aversion



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

Figure 7b

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



A cash payment by the branded manufacturer may allow the branded and generic manufacturers to bridge the settlement gap shown in Figure 7a. The branded 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 branded 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 move the range of entry dates that the branded manufacturer is willing to accept later in time, but it will move the dates the generic is willing to accept by an even greater amount. Such a payment will bring the parties closer together and could bridge the settlement gap between the two parties. 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 with 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 50 percent, believes that it in fact has a 75 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 branded manufacturer would be willing to offer because the generic manufacturer has an unrealistic belief about its chance of winning if it holds out and continues to litigate. 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 branded 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. Our point here 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

The sets of information known by the brand and the generic manufacturer almost certainly differ significantly, and often in important ways. Willig and Bigelow (2004) describe how this information asymmetry can create another circumstance where cash payments can facilitate a procompetitive settlement agreement that would not otherwise be feasible.

Imagine that the branded manufacturer has private information about the effective life of the patent – for example, about the prospects of future competition from other branded products that would reduce or eliminate demand for the product at issue in the patent litigation. The generic entrant knows that the branded manufacturer is better informed about future competition, and therefore will interpret settlement offers from the branded manufacturer with this in mind.

Suppose there are two types of patents: “high-value” patents, where there is no chance that other branded 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 branded manufacturer knows which type of patent it holds, but the generic manufacturer does not.⁶⁰ 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 competition. So a generic may be wary of accepting a reasonable settlement offer because it worries that that settlement may indicate that in fact the patent is low value – and the generic would be better off continuing to litigate.

The problems created by information asymmetries can be overcome if the branded manufacturer is allowed to provide a cash payment to the generic manufacturer. In our example, only branded 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 branded manufacturer with a high-value patent, rather than a poor offer from a branded 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 branded and generic manufacturers involve collateral business agreements. These agreements may take a variety of forms, including:

- Branded manufacturer licenses products from the generic manufacturer;
- Generic manufacturer licenses products from the branded manufacturer;
- Generic manufacturer agrees to co-promote one or more of the branded manufacturer’s products; and/or

⁶⁰ 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.

- Generic manufacturer agrees to serve as supplier for the branded manufacturer.

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. 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 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 for what it is providing or the branded manufacturer is under-compensated for what it is providing.

In recent years, patent settlements with collateral business agreements have received significant regulatory and legal scrutiny. 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 five different products from Upsher, including Upsher's Niacor SR, in exchange for royalty payments of \$60 million.⁶¹ 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.⁶²

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. To the extent that it is clear from the evidence that the generic was over-compensated or the brand was under-compensated,

⁶¹ *Schering-Plough v. FTC*, 402 F.3d, at 1060.

⁶² Ultimately, the Appeals Court concluded that the 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. See *Schering-Plough v. FTC*, 402 F.3d, at 1068.

then 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.” Collateral business transactions, just like reverse payments, therefore can be anticompetitive, but they can also serve to produce procompetitive outcomes, some of which may not have been otherwise feasible.

IV. 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. Patent settlements can also have important long-run competitive effects. First, the scope of patent protection can affect future incentives for branded manufacturers to invest in additional R&D. Patents give patent holders, such as branded pharmaceutical manufacturers, 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. 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. 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.⁶³

Second, the availability of procompetitive settlements can provide further incentives to generic manufacturers to challenge branded patents and bring lower-priced generic drugs to market. 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 of generic pharmaceutical

⁶³ For a more extensive discussion of these effects, see Langenfeld, James and Li, Wenqing, “Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers,” *Antitrust Law Journal*, 70, 2003, pp. 777-818.

manufacturers to challenge branded patents in the first place.⁶⁴ Even if the effect on a particular generic manufacturer's decision is relatively small, the collective impact on future generic competition can be substantial.

V. POLICY IMPLICATIONS AND CONCLUSIONS

Designing a workable framework that distinguishes procompetitive settlements from anticompetitive settlements is difficult – in part because at its core this depends upon the validity of the patent claims. A settlement agreement whereby the generic manufacturer agrees to enter in, say, five years – but five years before patent expiration – might be anticompetitive if the patent was weak (*i.e.*, if the generic had a high probability of winning at trial). But the same 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 cannot avoid at least some 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.” Bills have been introduced in at least the last two Congressional sessions that would do just that.⁶⁵

However, as we explain above, under many circumstances, patent settlements between branded and generic manufacturers – even those involving reverse payments – can benefit competition and 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 with other business arrangements which are even more complicated to evaluate, which makes enforcement of potentially anticompetitive arrangements even more difficult to assess. Efforts to prevent settlements with any compensation (whether in the form of cash or compensation from other business arrangements) flowing from the branded manufacturer to the generic would similarly block many pro-consumer settlements. Of

⁶⁴ See, for example, Judge Posner's opinion in *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994.

⁶⁵ See, for example, Preserve Access to Affordable Generics Act, S.361, 110th Cong. (2007).

course, an outright prohibition on such settlements would reduce the uncertainty and litigation costs that may follow from antitrust challenges to such settlements. But 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 branded 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 branded and generic pharmaceutical manufactures can be anticompetitive and should continue to be closely scrutinized by the 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 treatment is appropriate, whereby the competitive effects of a particular settlement are evaluated by applying an economic framework, such as that presented here, to the facts specific to that settlement.