Walmart

July 24, 2013

The Honorable Amy Klobuchar
U.S. Senate Committee on Judiciary
Chairwoman, Subcommittee on Antitrust, Competition Policy and Consumer Rights
Washington, D.C. 20510

Dear Chairwoman Klobuchar:

As one of the nation's largest providers of health benefits and a leading provider of affordable prescription drugs, we take seriously our commitment to saving our customers and associates money so that they can live better. As such, Walmart is pleased to support S. 214, The Preserve Access to Affordable Generics Act.

This bipartisan legislation, led by you and Senator Grassley, would establish a presumption that brand name/generic manufacturer patent settlements or "pay for delay" agreements are on their face unlawful if the filer receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug for any period of time.

This language clarifies that payments from brand name to generic manufacturers are anti-competitive, and will help to save consumers billions on future drug costs by assisting the Federal Trade Commission (FTC) as it brings actions in such matters. As you are aware, the FTC has recently stated that it believes these agreements are costing American consumers $3.5 billion annually.

Walmart is committed to reducing the cost of health care for all Americans. As part of our commitment, we launched a $4 generic drug program in 2006 saving our pharmacy customers more than $3.5 billion in the last 7 years. In 2010, we partnered with Humana to provide a new Medicare Part D offering that we estimate is saving seniors hundreds of dollars a year. Yet, roadblocks remain to market entry of generic drugs, reducing our ability to provide affordable medicines to even more of our customers. S. 214 presents an effective solution to the anti-competitive, anti-consumer impacts of pay-for-delay settlements, and would allow us to build on the 300 prescriptions currently covered in Walmart's affordable pharmacy program.

We thank you for your leadership in increasing the affordability of health care for all Americans, and look forward to working with you to ensure the timely passage of The Preserve Access to Affordable Generics Act.

Sincerely,

E. Ivan Zapien
Vice President, Federal Government Relations

Cc: The Honorable Charles Grassley
U.S. Senate
Washington, D.C. 20510

AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
Executive Vice President, CEO

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July 23, 2013

The Honorable Amy Klobuchar
United States Senate
302 Hart Senate Office Building
Washington, DC 20510

Dear Senator Klobuchar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express support for S. 214, the "Preserve Access to Affordable Generics Act." The AMA has policy, passed by physicians in our House of Delegates representing all states and national medical specialties, supporting the Federal Trade Commission (FTC) in its efforts to stop "pay-for-delay" arrangements by pharmaceutical companies. We appreciate your efforts to clarify and strengthen the FTC's authority to bring an end to tactics that delay the entry of generics into clinical practice.

The cost to the health care system and individual patients of anti-competitive settlement agreements between brand and generic manufacturers is substantial. Brand-name firms have used exclusion agreements to delay the entry of generics by an average of seventeen months and to terminate patent challenges that could otherwise generate billions of dollars in patient savings. The lack of low cost treatment options reverberates throughout the entire health care system and can exact a heavy toll on the uninsured. Even for those patients who are insured, but who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment or not having any treatment at all. Due to the foregoing, the AMA has supported the FTC's efforts to bring an end to pay-for delay arrangements by most recently joining with other organizations in filing a friend-of-the court brief in the U.S. Supreme Court. While the Court held that such agreements are illegal, the decision placed a very high burden on the FTC in challenging such agreements. S. 214 would unambiguously restore the congressionally intended balance between the Hatch-Waxman Act's provisions to spur innovation while also fostering competition through the development of generic drugs.

Sincerely,

James L. Madara, MD

March 12, 2013

The Honorable Amy Klobuchar
302 Hart Senate Office Building
Washington, DC 20515

Dear Senator Klobuchar:

The Academy of Managed Care Pharmacy (AMCP) is pleased that you have introduced S. 214, the "Preserve Access to Affordable Generics Act," which would prohibit brand-name and generic drug manufacturers from entering into generic exclusion agreements. AMCP believes that such agreements deny patients access to affordable generic drugs, unnecessarily raising prescription drug costs for patients, employers, health plans and taxpayers.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's almost 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

While AMCP realizes that appropriate incentives must be retained in order for brand-name manufacturers to recoup their investment in research and development of brand-name drugs, the use of strategies that can unnecessarily delay the entry of generic drugs into the marketplace must be prohibited. If there was concern regarding either the safety or efficacy of a generic drug, a delay would be warranted. However, it appears that most frequently, brand-name manufacturers and generic manufacturers come to legal agreements that delay the entry of generic competitors for reasons other than safety and efficacy. AMCP believes these agreements must be addressed in order to streamline the generic approval process and allow patients greater access to generic drugs.

AMCP's staff would be pleased to work with you and your staff to support passage of this legislation. Please do not hesitate to contact me or AMCP's Vice President of Government Affairs, Lauren Fuller, at 703-683-8416, or by email at lfuller@amcp.org, whenever we may be of assistance. Thank you again for your efforts to ensure access to safe and affordable prescription medications.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

NERA
Economic Consulting

A NERA Perspective

Antitrust Insights

Spring 2005

A Publication of National Economic Research Associates

From the Editor:

In the US, the growth in spending on prescription drugs has exceeded that of any other single category of health care spending. This is due, in large part, to increases in pharmaceutical research and development spending, which has led to new and sometimes more expensive medicines, as well as broader insurance coverage for prescription drugs, which is one of the main drivers of demand. To spur competition at the retail level without compromising manufacturers' incentives to innovate, the US Congress passed the Hatch-Waxman Act in 1984, which was designed to encourage the entry of generic drugs. Since the Act was passed, generic entry has played an increasingly important role in keeping drugs affordable.

In this issue of Antitrust Insights, *Sumanth Addanki, a Senior Vice President in NERA's White Plains office, tackles one of the most important economic, legal, and public policy issues surrounding competition in this industry—the rationale and competitive effects of an agreement between a generic and branded drug manufacturer to settle a patent dispute, where the settlement involves a payment from the patent holder (i.e., the branded manufacturer) to the alleged infringer (i.e., the generic manufacturer). The Federal Trade Commission (FTC) has challenged these types of agreements, claiming that these so-called "reverse payments" necessarily serve to delay generic entry. Sumanth explains why the FTC's "bright line" rule about such agreements is not appropriate, as it is based on a fundamentally invalid assumption, one that ignores the risks of litigation and the parties' desire to avoid or reduce these risks. Therefore, as Sumanth points out, the FTC's rule could invalidate procompetitive agreements as well as anticompetitive ones. The FTC's test, he argues, is no substitute for case-by-case analysis.*

Sumanth specializes in antitrust, intellectual property and the evaluation of commercial damages. He has analyzed the competitive consequences of numerous mergers and has frequently presented the results of his analyses to the US antitrust agencies and courts. Many of Sumanth's antitrust inquiries have focused specifically on intellectual property and its unique role in the analysis of market power and competitive effects.

I hope you enjoy this issue.

—Lawrence Wu, Editor

Schering-Plough and the Antitrust Analysis of Patent Settlement Agreements in Pharmaceutical Markets

By Sumanth Addanki [1]

The Court of Appeals for the Eleventh Circuit dealt the Federal Trade Commission (FTC) a blow in March 2005, when it resoundingly rejected the Commission's conclusions in *In the Matter of Schering-Plough Corporation*.[2] The Commission's Opinion had concluded that agreements entered into by the Schering-Plough Corporation (Schering) in settlement of patent litigation against Upsher Smith and ESI Lederle violated the antitrust laws. Those conclusions, in turn, rejected the earlier findings of the Administrative Law Judge (ALJ) who, after a nine-week trial, had concluded that the agreements were *not*, in fact, anticompetitive. In reversing the FTC Opinion, the Eleventh Circuit reinstated the ALJ's findings for the most part. And, in the most recent twist in this convoluted controversy, the FTC has moved (in April 2005) for *en banc* reconsideration of the Eleventh Circuit's ruling.

The ultimate outcome of the FTC's unremitting efforts is yet to be determined, but the agency's reverses stem in large part from fundamental flaws in its analytic approach to the matter. Although the shortcomings in the FTC's approach were pointed out at the trial of the matter before

[1] The author served as an economic expert witness for Schering-Plough in the FTC's administrative proceeding against Schering-Plough and Upsher Smith. The opinions expressed here are based on the Expert Report that he filed in 2001 and expert testimony that he delivered at the hearing in 2002. Needless to say, they do not necessarily reflect the opinions of any other economists at NERA. Some of these ideas have been discussed in Schildkraut, Mark, "Patent-Splitting Settlements and the Reverse Payment Fallacy," *Antitrust Law Journal*, 71, 2004; and Willig, J. and Bigelow, J, "Antitrust Policy Toward Agreements that Settle Patent Litigation," *Antitrust Bulletin*, Fall 2004.

[2] FTC vs. Schering-Plough et al., US Court of Appeals for the Eleventh Circuit, March 8, 2005.

"The FTC argued that the appropriate measure of any 'anticompetitive effect' of a given settlement agreement is the amount of time by which it delays entry relative to alternative settlements or litigation."

the ALJ, the FTC did not respond to the substance of these criticisms during the trial. Curiously, the Commission's subsequent Opinion overturning the ALJ also failed entirely to address these shortcomings. Perhaps the most important of these—and the one that is discussed here—is that the FTC's analytic framework—and, more important, the simple "bright line" test that the FTC urges for future analyses of such agreements—are neither usable nor defensible.

Background

Schering held a patent on a micro-encapsulated extended-release potassium chloride supplement which it marketed in the US as K-Dur 20. In late 1995, Upsher Smith, a generic drug manufacturer, applied for Food and Drug Administration (FDA) approval to market a generic version of the product. Schering sued for patent infringement and, after protracted litigation, the parties agreed to a settlement in June 1997. Under the settlement, Upsher was permitted to enter the market no earlier than September 2001 (the patent will expire in 2006) and Schering licensed several other Upsher products in development (products unrelated to potassium chloride), for which it agreed to pay $60 million.

The FTC declared that the licenses to other Upsher products were a sham and that the $60 million payment was nothing more than a bribe that Schering paid Upsher to delay its entry into the marketplace, to the detriment of consumers. The FTC further proposed a "bright line" litmus test under which any settlement which incorporates a so-called "reverse payment," i.e., a payment by the patentee to the alleged infringer, would be regarded as anticompetitive on its face.

The FTC's Three-Part Test for Anticompetitive Settlements

Through the testimony of its economic expert, the FTC claimed that a simple three-step test is sufficient to determine whether an agreement that settles a patent infringement case is anticompetitive: (i) does the patent holder (plaintiff) have monopoly power? (ii) is there a threat to that monopoly power? and (iii) is there a payment to the potential entrant (defendant) to delay market entry by the defendant? If the answer to all these questions is affirmative, the FTC asserted that the agreement must be anticompetitive, and that it would necessarily make consumers worse off than they could have expected to be had the matter been resolved through litigation.

Meet Our Antitrust and Competition Policy Experts

The following economists contributed to this edition of *Antitrust Insights*:

:: ***Lawrence Wu, Vice President/Editor (San Francisco, +1 415 291 1007, and White Plains, +1 914 448 4054)***
:: ***Sumanth Addanki, Senior Vice President (White Plains, +1 914 448 4060)***

The next edition of *Antitrust Insights* will feature:

:: ***G. Steven Olley, Senior Consultant (White Plains, +1 914 448 4139)***

The proposed test was defended as follows. To begin with, the FTC argued that the appropriate measure of any "anticompetitive effect" of a given settlement agreement is the amount of time by which it delays entry relative to alternative settlements or litigation; according to the FTC, this measure is reasonable because consumers are better off the sooner the generic entrant enters the market. The FTC then argued that settlements that involve payments from patentee to infringer are necessarily anticompetitive: on the one hand, if the parties could reach a settlement without a side payment, the settlements reached with side payments are "more anticompetitive," i.e., result in later generic entry, than the settlement that those same parties would have reached otherwise. On the other hand, when payments are necessary for settlement even to be feasible, such payments in the "wrong" direction, from incumbent to entrant, lead to outcomes "more anticompetitive"—i.e., later entry dates—than either party expects under litigation.

The Proposed Test is Useless as a Means of Identifying Anticompetitive Settlements

The FTC's Reasoning

The fatal flaw in the foregoing reasoning lies in the argument that settlements that involve payments to the generic entrant will necessarily result in entry dates later than might be expected under litigation. In essence, the FTC argues as follows. Suppose for simplicity that the litigation has reached a stage where discovery is complete, so that the parties have learned all that they could expect to learn prior to trial about their odds of winning at trial; suppose further that both parties agree that each one's chances of prevailing in the litigation are roughly 50 percent. Then, each party expects that, if they continued to litigate, the probability of the defendant prevailing and entry occurring virtually immediately is 50 percent, while the probability of the patentee prevailing and of entry being delayed until expiration of the patent is, also, 50 percent.[3] Therefore, the FTC argues, the "expected" time to entry under

"The FTC argued that settlements reached with side payments are 'more anticompetitive,' i.e., result in later generic entry, than the settlement that those same parties would have reached otherwise."

[3] I will assume, following the FTC and its economic expert, and only for purposes of the present discussion, that the outcome of the trial will be made known relatively quickly, so that, should the generic manufacturer prevail, its entry would not be subject to any additional delay. In fact, of course, this assumption is frequently unrealistic, and it appears unrealistic in the instant case, as discussed more fully below.

"Economists have long understood that most individuals are 'risk averse' in that they value outcomes that are inherently uncertain less than outcomes that can be known with certainty."

litigation (i.e., the probability-weighted average of the two entry dates under the two alternative outcomes) is approximately one-half of the term remaining on the patent.[4] Any settlement that results in an entry date *later* than this benchmark would, then, be deemed anticompetitive.

The FTC further argues that if the parties agreed that their respective chances of prevailing were 50 percent each, they would not agree, absent side payments, to any settlement that specified an entry date different from this benchmark date; the patentee, according to this view, would accept no date earlier than the benchmark, whereas the entrant would accept no date later than the benchmark, each party reasoning that it could expect to do at least as well should it pursue the litigation to its conclusion. Therefore, the FTC concludes, any payment from patentee to entrant must necessarily be a "bribe" to persuade the entrant to delay its entry.

The Role of Risk and Risk Aversion

A crucial flaw in this chain of reasoning lies in the assertion that the patentee would not settle for an entry date earlier than the benchmark (i.e., the expected, or probability-weighted average, date of entry under litigation). The implicit assumption here is that the patentee would view a *date certain* entry of, say, four years in the future as exactly equivalent to engaging in litigation whose *expected* entry date is also four years in the future (because, say, it offers equal odds of entry today or entry eight years hence).

The problem with this assumption is that it is frequently violated in practice. There are many sound (and commonly occurring) economic reasons why a patentee may be willing to settle for an entry date earlier than that expected under litigation. Among these is risk and people's attitudes toward risk. Economists have long understood that most individuals are "risk averse" in that they value outcomes that are inherently uncertain less than outcomes that can be known with certainty. Our everyday experience is replete with examples of this. Companies whose fortunes are more volatile (i.e., risky) have to offer higher *expected returns* to their investors than do companies that are less risky. The interest rates on corporate bonds reflect the same reality: companies whose prospects are regarded as more risky (and whose ratings by bond rating services like Moody's reflect that assessment) have to offer higher interest rates in order to attract investors than do companies that are regarded as less risky.

[4] For instance, if the patent at issue has eight years to run, the probability of instantaneous entry is 50 percent—reflecting the likelihood that the infringer prevails in the lawsuit. However, because there is also a 50 percent chance that the patentee will prevail, the probability that entry would be deferred for eight years is also 50 percent, which means that the expected time to entry under litigation is four years (a 50 percent chance of zero and a 50 percent chance of eight years).

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Paying for Certainty

The immediate implication of this, of course, is that an individual who is risk-averse might well be willing to sacrifice some portion of his/her expected return from a venture, if, in exchange, he/she could reduce the uncertainty associated with that venture. A patentee who has built a substantial business around a patent is very likely to be risk-averse in exactly that fashion: when choosing between a settlement and pursuing litigation to its final outcome, the patentee would recognize that the nonzero probability associated with "losing it all" creates very real risk, regardless of the expected value associated with litigation. If, as in our example above, the expected date of entry associated with litigation were four years (because there was equal likelihood of immediate entry or entry after eight years, upon patent expiration), the risk-averse patentee would be willing to sacrifice some of this expected value in exchange for reducing the uncertainty attendant upon litigation. In other words, the risk-averse patentee would be willing to settle for a "date certain" *earlier* than the expected date under litigation so as to avoid the risk associated with the litigation. In effect, the patentee's risk aversion could make the settlement more favorable to consumers than the expected outcome under litigation.

Of course, such a settlement could also be attractive to the entrant, because it would permit entry sooner than might have been expected under litigation. The problem is that the would-be infringer may well also find that its liquidity position does not permit it to "wait out" the period until that entry date.[5] In other words, while attractive, the settlement may not be feasible for the entrant without some sort of cash infusion that would help it to survive until the entry date at issue (even though it is earlier than the expected outcome under litigation). In this situation the only path to a settlement could well be one in which the patentee provides such a cash infusion. Why? Simply because, without the infusion, even though the patentee would be willing to entertain a definite entry date earlier than the expected outcome of litigation, that earlier date would remain infeasible for the entrant. Or, to put it differently, any date that the entrant would regard as feasible (absent the cash infusion) would be too early for the patentee to accept, given its odds of prevailing in the lawsuit (even allowing for risk aversion). Thus, the only alternative to the settlement with a cash payment might, in fact, have been litigation, under these circumstances; a settlement without a cash payment might not be feasible at all.

"When choosing between a settlement and pursuing litigation to its final outcome, the patentee would recognize that the nonzero probability associated with 'losing it all' creates very real risk."

Note that this does *not* mean that the resulting date of entry would be later

[5] Note that the potential entrant may well have the cash resources to wait until the outcome of litigation is known but not enough to survive until the mathematical "expected outcome" of the litigation. For instance, suppose that the patent at issue has 12 years to run, each side has a 50 percent chance of winning, and that the litigation will take 3 years to complete. Under these assumptions, the "expected" entry date is the weighted average of 3 years and 12 years, which is 7 years and-a-half. The entrant may well be able to survive for 3 years but not for 7 years or longer.

"The FTC's proposed test is useless as a litmus or 'bright line' test. Its critical assumption that the patentee would never agree to a settlement that embodied an entry date earlier than the date that might be expected under litigation is fundamentally invalid."

than the expected outcome of the litigation. In fact, the date agreed upon by the parties—even with the cash payment—may well be *earlier* than the date that might be expected under litigation. This, of course, is the crucial question: is the entry date specified in the settlement earlier than or later than the benchmark entry date that might be expected under litigation? In this example, whether or not it is earlier than the benchmark date depends upon the degree of risk aversion of the patentee, the amount of the payment required and the returns that each party expects to earn under the alternatives.

Implications

What this means is that the FTC's proposed test is useless as a litmus or "bright line" test. Its critical assumption that the patentee would never agree to a settlement that embodied an entry date earlier than the date that might be expected under litigation is fundamentally invalid. The invalidity of this underlying assumption, of course, necessarily nullifies the proposed test. Moreover, it is important to note that the risk aversion discussed above represents only one of several possible reasons why the FTC's key assumption could easily be violated. For instance, the patentee might simply be pessimistic about its case; the judge or magistrate may have placed particular pressure on the patentee to settle; litigation costs, including out-of-pocket costs as well as the significant opportunity costs that litigation imposes on senior management time and attention, could be a factor.[6] Therefore, contrary to the FTC's assertion that a payment from patentee to potential entrant is necessarily anticompetitive, agreements that provided for payments from the patentee to the entrant *could*, in fact, be procompetitive.

A More Appropriate Test

What, then, is the analyst to do? In many situations, the monopoly power portion of the proposed test—if properly applied—could obviate the need for further inquiry. If there is no monopoly power present, there is no need for any further inquiry; the agreement could not be anticompetitive in its effect.[7] Assume, however, that further analysis establishes that the patentee possesses monopoly power and that, for any of a number of reasons, including those discussed earlier, a settlement without cash payments is not feasible.[8] In that case, as even the FTC's economic expert conceded, the appropriate test is whether or not settlement resulted in an agreed-upon entry date later than what might have been expected under litigation.

[6] There are certainly other reasons why the FTC's assumptions may be violated. Among other things, there might be antitrust counterclaims that would be disposed of concurrently with the patent litigation, which could bear on the parties' incentives to settle.

[7] Because of other fundamental flaws not discussed here, the FTC erroneously concluded that Schering's K-Dur 20 possessed monopoly power. As I showed in my testimony—adopted by the trial court—appropriate application of the monopoly power test indicated clearly that there was no such power in this case.

[8] Even the FTC's economic expert acknowledged that such situations could arise.

It seems eminently reasonable to suppose that, to establish whether or not this occurred, one must evaluate the likely outcomes of the patent case, as well as each party's odds of prevailing in litigation. These facts would help establish what the expected outcome would have been under litigation. However, the FTC explicitly disavowed the need for any such investigation. Rather, the FTC proposed *inferring*—based on economic argument—that the settlement with cash payments *could not* have resulted in an earlier entry date than might be expected under litigation. But, as I have discussed at length above, the fundamental underpinnings of the proposed economic reasoning may not be satisfied, for a number of possible reasons. Therefore, the "inferential" conclusions are unsupportable; some alternative means must be found to evaluate whether or not the settlement is anticompetitive in its effect.

The correct approach to this is, in fact, the obvious one stated above. Any assessment of the likely competitive effects of the settlement—relative to the litigation alternative—should be based squarely on the facts surrounding the underlying patent case itself. Suppose, again, that the expected (or agreed-upon) entry dates offer a reasonable yardstick with which to evaluate the competitive effects of a given settlement. The objective facts elicited in the patent infringement case—presumably including findings regarding patent claim construction and the like—may constitute the best available information regarding the relative odds that each party would have prevailed in the underlying patent suit. Thus, an agreement that, say, splits the remaining patent term in half, could be viewed as relatively procompetitive if the objective facts uncovered in the litigation suggest that the expected time to entry under litigation was longer, i.e., that the patentee had the better of the case. Analogously, if the patentee had monopoly power, such a settlement might be viewed as anticompetitive if the objective facts suggested that the patentee had relatively low odds of prevailing.

"Any assessment of the likely competitive effects of the settlement—relative to the litigation alternative—should be based squarely on the facts surrounding the underlying patent case itself."

In this connection, it is important to recall that the assumption underlying these discussions is that entry would be virtually instantaneous should the entrant prevail in the litigation. In actual fact, even a victory could result in deferred entry, either because

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"In those situations in which a properly applied test indicates that the patentee possesses monopoly power, it is necessary to evaluate whether the settlement agreement at issue, on balance, delayed entry beyond the date that might have been expected under litigation."

of appeals or because the entrant's approvals (or other FDA permissions) were still pending. In that case, the expected time to entry would exceed one-half the time remaining on the patent even if the odds of the entrant prevailing were 50 percent. Therefore, any empirical evaluation of whether or not a given agreement is anticompetitive requires that we inquire not only about the odds of each party prevailing, but also about the likely entry dates under alternative litigation outcomes.

To recapitulate, in those situations in which a properly applied test indicates that the patentee possesses monopoly power, it is necessary to evaluate whether the settlement agreement at issue, on balance, delayed entry beyond the date that might have been expected under litigation; such an evaluation would, necessarily, involve an assessment of the facts surrounding the underlying patent case in order to ascertain the outcomes that the cases could have generated, as well as the relative likelihood of each of those outcomes in litigation. Only then could one establish whether or not the agreement resulted in an entry date that is later than the date that might have been expected under litigation. The FTC's proposed "inferential" approach fails to meet this burden.

In Conclusion: There Are No Shortcuts!

In articulating its attack on Schering's agreement with Upsher, the FTC proposed a seductive-sounding analytic shortcut: the FTC suggested that detailed analysis of the agreement's competitive effects was superfluous because payments from patentee to entrant automatically signal anticompetitive effects. That argument, as we have seen, is unfounded. There are sound economic reasons why parties may find it necessary to include a payment in an agreement whose ultimate effect is, nevertheless, procompetitive. Therefore, this "shortcut" is, in fact, entirely unhelpful. The FTC's proposed approach cannot substitute for a detailed investigation of the facts of the case; only such a detailed investigation can establish whether the settlement agreement at issue was procompetitive or anticompetitive relative to the likely outcome of litigation.

An Economic Assessment of Patent Settlements in the Pharmaceutical Industry

Bret Dickey[*]
Jonathan Orszag[**]
Laura Tyson[***]

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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[*] Bret Dickey is a Senior Vice President with Compass Lexecon, an economic consulting firm.

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.

[**] Jonathan Orszag is a Senior Managing Director and member of the Executive Committee of Compass Lexecon. He is also a Fellow at the University of Southern California's Center for Communication Law & Policy and a Senior Fellow at the Center for American Progress. Previously, he served on President Clinton's National Economic Council and as the Assistant to the Secretary of Commerce and Director of the Office of Policy and Strategic Planning.

[***] Laura D'Andrea Tyson is Professor of Business Administration and Economics at the Haas School of Business at the University of California, Berkeley. Dr. Tyson served with cabinet rank in the first Clinton Administration, first as chair of the White House Council of Economic Advisers, then as National Economic Adviser to the President and chair of the National Economic Council. She is the former dean of the London Business School and the Haas School of Business.

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

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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]

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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

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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.

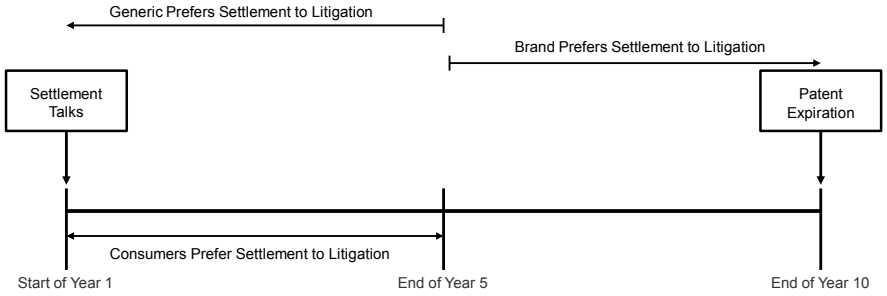
entry at the end of Year 5.

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

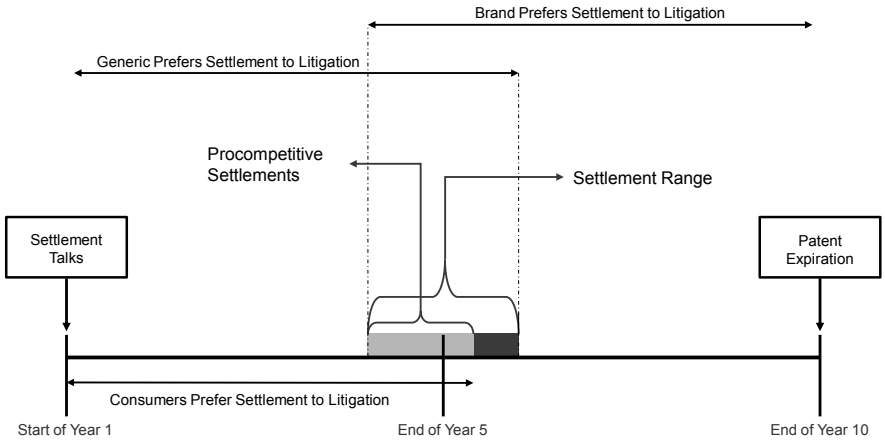
An important motivation for parties to settle litigation is that litigation is costly; the oversimplified model presented above ignores this motivation. We now introduce litigation costs into the model and show that it leads to a range of settlements that would be agreeable to both the brand-name and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

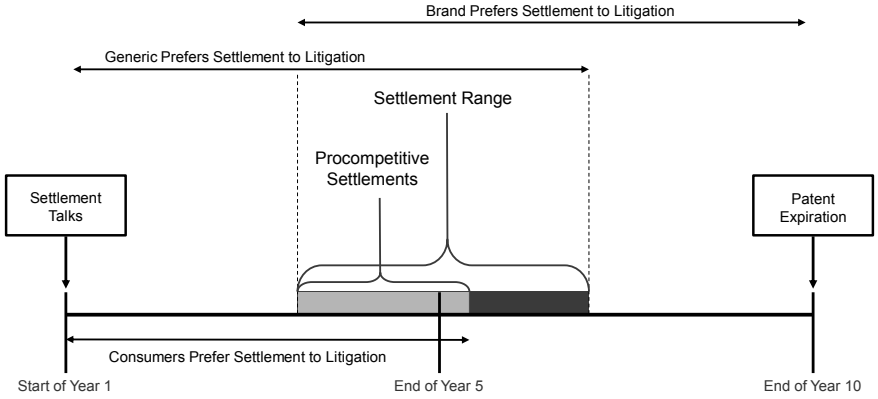
65. *See id*.

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.

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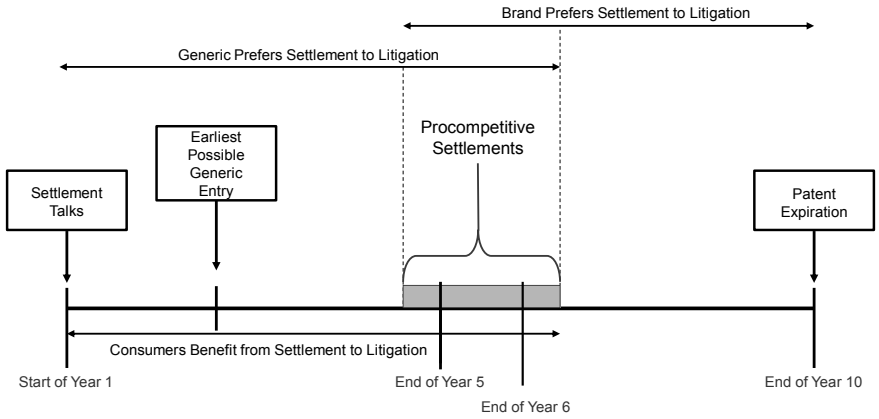
70. *See, e.g.*, Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1073 (2004).

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.

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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).

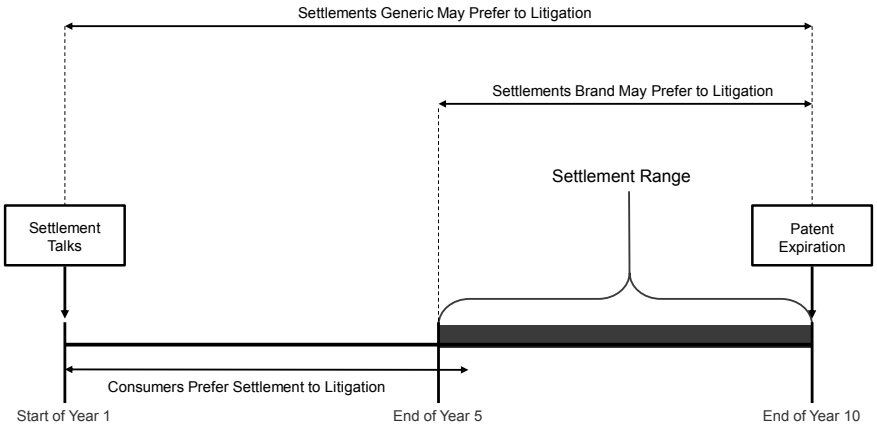
106. *See generally* Daniel A. Crane, *Correspondence: Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004); *see also* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004).

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.

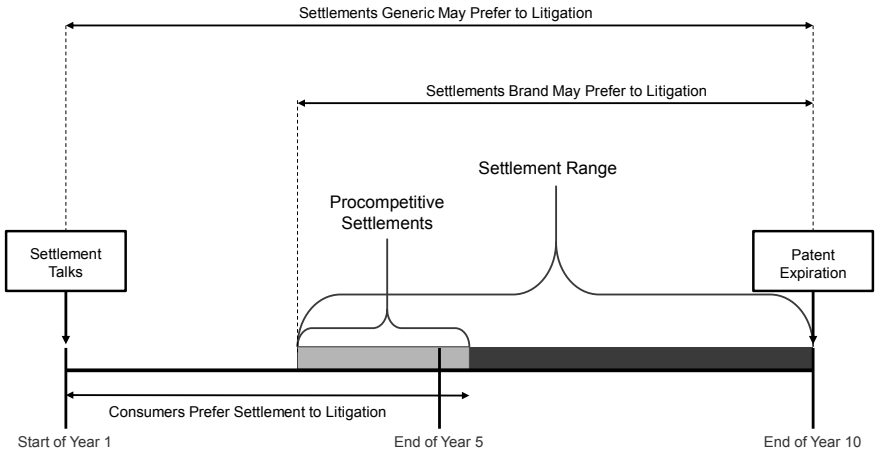
109. *Reverse Payments*, *supra* note 107, at 273.

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*.

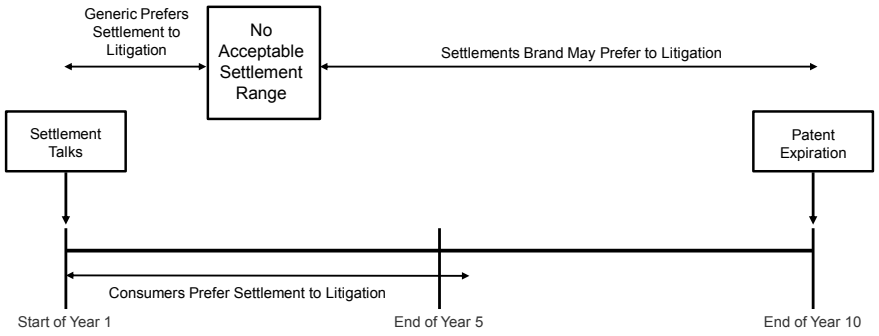
113. A related argument is that an alternative settlement with a different payment and a different entry date may be better for consumers. This is a stricter standard than the one

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.

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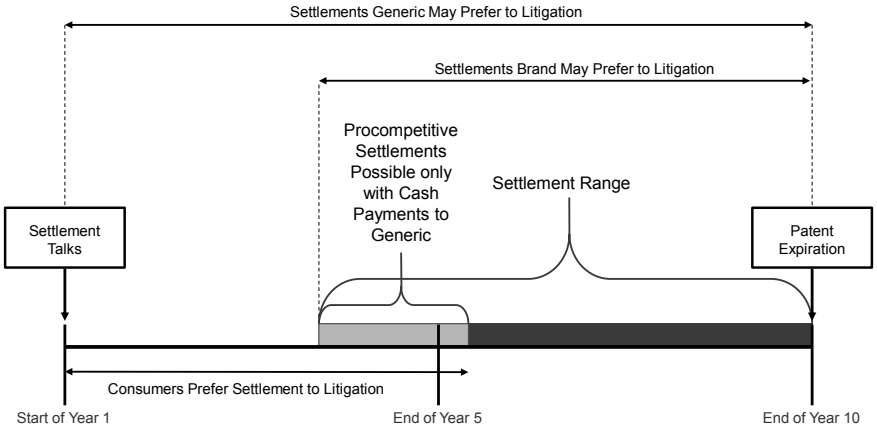
commonly used by antitrust regulators to evaluate agreements among competitors, which evaluates competition relative to a world without the agreement, rather than a world with an optimal agreement. See FED. TRADE COMM'N AND U.S. DEP'T OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS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

Sumanth Addanki & Alan J. Daskin, *Patent Settlement Agreements*, *in* 3 ISSUES IN COMPETITION LAW AND POLICY 2127 (ABA Section of Antitrust Law 2008)

Chapter 85

PATENT SETTLEMENT AGREEMENTS

Sumanth Addanki and Alan J. Daskin*

Various commentators have argued that while agreements in settlement of patent litigation are generally procompetitive, they can harm consumers if they include so-called "reverse payments" from the incumbent patentee to the would-be entrant. Therefore, they suggest, settlements that include reverse payments should be condemned. We show that this proposed filter is not particularly useful: in fact, settlement agreements that include such terms are not necessarily anticompetitive. Moreover, seemingly innocuous agreements—i.e., ones that exclude such terms—may well turn out to be anticompetitive and to harm consumers.

1. Introduction

The interface between antitrust and the laws governing intellectual property presents interesting and challenging questions to students, practitioners, and policy makers alike. The analysis of agreements that firms enter into in order to settle patent disputes, in particular, has a rich history in the antitrust literature, including the *Antitrust Guidelines for the Licensing of Intellectual Property*,[1] numerous scholarly articles,[2] and important recent court decisions.[3] Not surprisingly, as thinking on the subject has evolved, ideas about what constitutes anticompetitive patent settlements have evolved as well.

In this chapter, we demonstrate that the competitive effects of settlement agreements may not be as obvious as they seem: apparently anticompetitive agreements may actually benefit consumers, while seemingly innocuous or beneficial settlements may harm consumers. In Section 2 below, we consider one example of the former type of settlement, one that includes a so-called "reverse payment" from the incumbent patentee to the would-be entrant. While some commentators suggest that such settlements are presumptively anticompetitive, we show that such a general presumption is invalid. In Section 3, we consider examples of licensing agreements that seem to have beneficial (or, at worst, neutral) effects on consumers; we demonstrate that they may in fact harm consumers.

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1. U.S. DEP'T OF JUSTICE & FEDERAL TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132.
2. *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, ANTITRUST BULL. 655 (2004); Robert Kneuper, *Four Economic Principles Underlying the FTC's Position Against Reverse Payments in Patent Settlement Agreements*, ANTITRUST SOURCE (Jan. 2006), www.antitrustsource.com.
3. See, among others, the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), and the Supreme Court's denial of the FTC's petition for certiorari, 126 S. Ct. 2929 (2006).

2. Reverse payments need not be anticompetitive

In recent years, the Federal Trade Commission (FTC) and various economic and legal commentators have argued that settlement agreements that include reverse payments are inherently anticompetitive and should be condemned. In this section, we demonstrate that such blanket condemnations are unwarranted.

2.1. A proposed litmus test for anticompetitive settlements

The FTC, in its enforcement actions, publications, and public statements, has endorsed a "bright line" litmus test under which any settlement that incorporates a so-called reverse payment—i.e., a payment by the patentee to the alleged infringer—"raises a red flag . . . and mandates a further inquiry."[4] While this approach has not been universally accepted, other commentators have apparently endorsed it.[5]

The FTC's position appears to be that the following three-step test is sufficient to determine whether an agreement that settles a patent infringement case is anticompetitive: (1) Does the patent holder (plaintiff) have monopoly power? (2) Is there a threat to that monopoly power? and (3) Is there a payment to the potential entrant (defendant) to delay entry by the defendant?[6] If the answer to all these questions is

4. Schering-Plough Corp., FTC Docket No. 9297, at 29 (Dec. 18, 2003) (opinion of the Commission) [hereinafter *FTC Schering Opinion*]. In an earlier filing in that case, the FTC stated, "[Respondents] never directly respond to our contention that paying a potential competitor to accept an entry date is a payment not to compete and presumptively anticompetitive." Reply Brief in Support of Complaint at 26, *available at* http://www.ftc.gov/os/adjpro/d9297/index.shtm. According to the Commission's opinion in the case, "Complaint Counsel made an alternative argument that the settlement agreements in issue should be characterized as either *per se* illegal or presumptively anticompetitive. Translated into the terms of the structure outlined above, their claim was that the nature of the restraint is sufficiently troublesome to obviate specific proof of market effects." *FTC Schering Opinion* at 12 (footnote omitted). In 2000, David Balto, then Assistant Director of the Office of Policy and Evaluation in the FTC's Bureau of Competition, wrote, "Typically in patent infringement cases the payment flows from the alleged infringer to the patent holder. A payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement." David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 335 (2000) (footnote omitted). In a recent speech, Jon Leibowitz expressed concern about what he called "exclusion payments." Jon Leibowitz, FTC Commissioner, Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!, Remarks at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust (Apr. 24, 2006).

5. For varying degrees of endorsement, see, e.g., Keith B. Leffler & Cristofer I. Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case; An Argument for Per Se Condemnation of Payments by the Patent Holder*, ECON. COMM. NEWSL. (ABA Section of Antitrust Law), Spring 2002, at 26-35; Merril Hirsh & Dan Zoloth Dorfman, *I Didn't Say Orphan Often: The Benefits of a Bright-Line Rule Barring Brand to Generic Payments in Hatch-Waxman Patent Settlements*, 19 ANTITRUST HEALTH CARE CHRON. 2 (Summer 2005); and 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 (2004).

6. This three-part test stems from the testimony of Professor Timothy Bresnahan, the FTC's economic expert in its proceedings against Schering-Plough and its correspondents. *See FTC Schering Opinion*, at 15. Addanki, who served as the economic expert for Schering-Plough, addressed these and other issues in his expert report, which was filed in September 2001.

affirmative, the FTC asserts that the agreement must be anticompetitive, that it would necessarily make consumers worse off than they could have expected to be had the matter been resolved through litigation.

The proposed test is defended as follows. To begin with, the FTC argues that the appropriate measure of any "anticompetitive effect" of a given settlement agreement is the amount of time by which it delays entry relative to alternative settlements or litigation, because consumers are better off the sooner the entrant enters the market.[7] The FTC then argues that settlements that involve payments from the patentee to the alleged infringer are necessarily anticompetitive, because, if the parties could reach a settlement without a side payment, the settlements reached with side payments are "more anticompetitive," i.e., result in later entry, than the settlement that those same parties would have reached otherwise.[8]

On the other hand, the argument goes, when payments are necessary for settlement even to be feasible, such payments in the "wrong" direction, from incumbent to entrant, lead to outcomes "more anticompetitive"—i.e., later entry dates—than either party expects under litigation. This conclusion rests on the following argument: Suppose for simplicity that the litigation has reached a stage where discovery is complete, so that the parties have learned all that they could expect to learn prior to trial about their odds of winning at trial; suppose further that both parties agree that each one's probability of prevailing in the litigation is roughly 50 percent. Then each party expects that, if they continued to litigate, the probability that the defendant will prevail and entry will occur virtually immediately is 50 percent, while the probability that the patentee will prevail and entry will be delayed until expiration of the patent is also 50 percent.[9] Therefore, the argument goes, the "expected" time to entry under litigation (i.e., the probability-weighted average of the two entry dates under the two alternative outcomes) is approximately one-half of the term remaining on the patent.[10] Any settlement that results in an entry date *later* than this benchmark would then be deemed anticompetitive.

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7. This formulation is not strictly correct; risk aversion and discounting (the economic reality that a dollar today is worth more than a dollar payable in the future, even setting aside inflation), among other things, mean that a "date certain" entry four years in the future, for instance, is not equivalent, from the consumer's standpoint, to a lawsuit under which the expected outcome is an entry date four years into the future. It is certainly entirely possible to incorporate these features into an economic model, but we have not done so here, because their inclusion greatly complicates the exposition without materially changing our qualitative results. In any event, much of the public debate has been framed (simplistically) in terms of entry dates.

8. "The issue of exclusion payments has been the subject of significant debate, but the Commission's position is clear. Where a patentholder makes a payment to a challenger to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed *either* because a settlement with an earlier date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition." *Barriers to Generic Entry: Hearing Before the Sen. Special Comm. on Aging*, 109th Cong. 18 (2006) (statement of FTC) (footnote omitted).

9. For simplicity of exposition only, we assume that the outcome of the trial will be made known relatively quickly, so that, should the alleged infringer prevail, its entry would not be subject to any additional delay.

10. For instance, if the patent has eight years to run, the probability of instantaneous entry is 50%, but the probability that entry would be deferred for eight years is also 50%, so the expected time to entry under litigation is four years (50% probability of zero and 50% probability of eight years).

The argument further holds that if the parties agreed that their respective odds of prevailing were 50 percent each, neither side would agree, absent side payments, to any settlement that specified an entry date different from this benchmark date; the patentee, according to this view, would accept no date earlier than the benchmark, whereas the entrant would accept no date later than the benchmark, each party reasoning that it could expect to do at least as well should it pursue the litigation to its conclusion. Therefore, the argument for the proposed test concludes, any payment from patentee to entrant must necessarily be a "bribe" to persuade the entrant to delay its entry.[11]

2.2. The proposed test cannot be used to identify anticompetitive settlements

One crucial flaw in this chain of reasoning lies in the assertion that the patentee would not settle for an entry date earlier than the benchmark (i.e., the expected, or probability-weighted average, date of entry under litigation). The logical flaw stems from the implicit assumption that the patentee would view a *date certain* entry of, say, four years in the future as exactly equivalent to engaging in litigation whose *expected* entry date is also four years in the future (because, for example, it offers equal odds of entry today or entry eight years hence).

The problem with this assumption is that it is frequently violated in practice. There are many sound economic reasons why a patentee may be willing to settle for an entry date earlier than that expected under litigation. Among these are risk and people's attitudes toward risk. Economists have long understood that most individuals are "risk averse," in that they value outcomes that are inherently uncertain less than outcomes that can be known with certainty. Everyday experience is replete with examples. Companies whose fortunes are more risky have to offer higher *expected returns* to their investors than do companies that are less risky. The interest rates on corporate bonds reflect the same reality: companies whose prospects are regarded as more risky (and whose ratings by bond rating services like Moody's reflect that assessment) have to offer higher interest rates in order to attract investor interest than do companies that are regarded as less risky.

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11. According to Carl Shapiro, for example:

> Consumers benefit from a negotiated entry date *t* if and only [if] *t* [is earlier than the entrant's expected date of entry under litigation]. Assuming that duopoly profits are less than monopoly profits, however, there is little reason to expect the firms to find such entry dates mutually attractive. If the firms are risk neutral, a reasonable assumption for large, publicly traded firms if not individual managers at those firms, and ignoring litigation costs, there are simply no gains from settlement under these conditions when the only available instrument is the entry date . . . . To the extent that the patentholder believes the patent is stronger than does the challenger, settlement is made even more difficult, as the patentholder will insist on a later entry date and the challenger will not agree to wait so long to enter.
>
> In this simple model, a naked cash payment flowing from the patentholder to the challenger (in excess of avoided litigation costs) is a clear signal that the settlement is likely to be anticompetitive. Presumably, the patentholder would not pay more than avoided litigation costs unless it believed that it was buying later entry than it expects to face through the litigation alternative.

Shapiro, *supra* note 2, at 407-08.

The immediate implication, of course, is that an individual who is risk averse might well be willing to sacrifice some portion of his expected return from a venture, if, in exchange, he could reduce the uncertainty associated with that venture. A patentee who has built a substantial business around a patent is very likely to be risk averse in exactly that fashion: when choosing between a settlement and pursuing litigation to its final outcome, the patentee would recognize that the nonzero probability associated with "losing it all" creates very real risk, regardless of the expected value associated with litigation. If, as in our example above, the expected date of entry associated with litigation were four years (equal likelihood of immediate entry or entry after eight years, upon patent expiration), the risk averse patentee would be willing to sacrifice some of that expected value in exchange for reducing the uncertainty attendant upon litigation. In other words, the risk averse patentee would be willing to settle for entry by the would-be entrant at a date certain *earlier* than the expected date under litigation. In effect, the patentee's risk aversion could make the settlement more favorable to consumers than the expected outcome under litigation.

Of course, such a settlement could also be attractive to the entrant, because it would permit entry sooner than might have been expected under litigation. The problem is that the would-be infringer may well also find that its liquidity position does not permit it to "wait out" the period until that entry date. In other words, while attractive, the settlement may not be feasible for the entrant without some sort of cash infusion that would help it to survive until the entry date at issue (even though that date is earlier than the expected date of entry under litigation). In this situation, the only path to a settlement could well be one in which the patentee provides such a cash infusion. Without the infusion, even though the patentee would be willing to entertain a definite entry date earlier than the expected outcome of litigation, that earlier date would remain infeasible for the entrant. Any date that the entrant would regard as feasible (absent the cash infusion) would be too early for the patentee to accept, given its odds of prevailing in the lawsuit (even allowing for risk aversion). Thus, the only alternative to the settlement with a cash payment might, in fact, have been litigation.

Note that this does *not* mean that the resulting date of entry would be later than the expected outcome of the litigation. In fact, the date agreed upon by parties—even with the cash payment—may well be *earlier* than the date that might be expected under litigation. That, of course, is the crucial question: is the entry date specified in the settlement earlier or later than the benchmark entry date that might be expected under litigation? In this example, whether it is earlier than the benchmark date depends upon the degree of risk aversion of the patentee, the amount of the payment required and the returns that each party expects to earn under the alternatives.[12]

The proposed test, therefore, is inappropriate as a litmus or bright line test. Its critical assumption that the patentee would never agree to a settlement that embodied an entry date earlier than the date that might be expected under litigation is fundamentally

12. As Shapiro notes, "This is not to say that such payments [from the patentholder to the challenger] 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." Shapiro, *supra* note 2, at 408 (footnote omitted).

invalid. The invalidity of this underlying assumption, of course, necessarily nullifies the proposed test. Moreover, the risk aversion discussed above represents only one of several possible reasons why the test's key underlying assumption could easily be invalid. For instance, the patentee might simply be unduly pessimistic about its case; the judge or magistrate may have placed particular pressure on the patentee to settle; or litigation costs, including out-of-pocket costs as well as the significant opportunity costs that litigation imposes on senior management time and attention, could be a factor. There are certainly other reasons as well why the assumptions may be violated.[13] Therefore, contrary to the arguments made by proponents of the litmus test, agreements that provide for payments from the patentee to the entrant *could*, in fact, be procompetitive.[14]

3. Agreements without reverse payments may be anticompetitive

Just as reverse payments may have procompetitive effects, license agreements with payments flowing from the licensee to the licensor may have anticompetitive effects. Thus, the direction of the flow of payments will not, in and of itself, indicate the effect of the agreement on customers.

3.1. A seemingly innocuous license agreement

In the last section, we demonstrated that license agreements that embody reverse payments from patentee to alleged infringer may, in fact, be procompetitive, so that the bright line test for anticompetitive agreements does not work. Unfortunately, the obverse does no better: license agreements that appear perfectly normal—with royalties flowing in the "right" direction—may, nevertheless, be anticompetitive in their effect: they may lead to market outcomes that are inferior, from the standpoint of customers, to the expected outcomes of litigation.[15]

First, however, consider the following agreement, reached in settlement of patent litigation between Patco (the patent holder) and Mitou (an alleged infringer): Mitou will pay Patco 14 percent of its net revenues in royalties each year. If Mitou's net sales exceed $100 million in any year, in recognition of the marketing and market development efforts undertaken by Mitou, it will earn a credit of $10 million against its royalty obligations that year, reducing its net payment by that amount. Is there anything about this agreement that could raise antitrust concerns?

Certainly, on its face, this seems like an eminently procompetitive settlement: Mitou will enter the market right away; the royalty rate is not obviously overly onerous; and, moreover, by rewarding Mitou for beating certain sales goals, the agreement seems to

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13. Among other things, there might be antitrust counterclaims that would be disposed of concurrently with the patent litigation, which could bear on the parties' incentives to settle.
14. Appendix A provides an analytical development of this point.
15. For a discussion suggesting that it is not obvious what the "correct" direction is for payments to flow in patent settlements, see Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 769-76 (2002). *See also* Kevin D. McDonald, *Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea*, 15 ANTITRUST HEALTH CARE CHRON. 2 (Winter 2002).

provide explicit incentives for increasing output. Could an antitrust enforcer ask for more?

Unfortunately, things are not quite so simple. In fact, this seemingly benign, apparently procompetitive agreement may actually be quite the opposite! It may actually be *worse* from the standpoint of customers than the expected outcome of litigation.[16]

3.2. Understanding the parties' incentives

To see why, it is helpful first to understand the economic incentives facing the three interested parties—patentee, potential entrant, and customer—under the alternative scenarios of continued litigation and settlement via a license. To keep things simple, assume for now, as before, that litigation would be instantaneous and costless and that the probability that the patentee will prevail is known in advance by both parties. In other words, there is no disagreement about the odds of the outcomes and we do not need to concern ourselves with delays due to discovery, appeals and the like.

In this stylized world, litigation could yield two possible outcomes: first, the patentee could prevail, which we will further assume means that for the remaining life of the patent, the patentee will preserve its "monopoly," in that no further entry will occur; second, the alleged infringer could prevail, in which case entry would occur instantaneously to provide competition to the patentee. Should the patentee prevail, the would-be entrant gets nothing for its trouble, and the patentee retains its pretrial profitability. Should the patentee lose, entry occurs immediately, and the entrant and patentee share the market opportunity. Litigation, therefore, represents a lottery with two possible outcomes; the value of the lottery to each firm is simply the mathematical expected value—the probability-weighted average—of the values of the two outcomes.

Finally, what about the effects on the customer? The customer—like the would-be entrant—benefits from entry, although the benefits garnered by the customer are not the same as the profits that will be earned by the entrant. However, the expected value of the litigation outcome from the customer's standpoint is calculated using the same principles: it is simply the probability-weighted average of the two possible market price/quantity outcomes that could result from litigation.

Let us turn now to the alternative scenario, in which the patentee licenses the would-be entrant for immediate entry in exchange for running royalty payments. This scenario differs from the litigation alternative—for each of the three parties—in two key respects. First, there is no longer any uncertainty, so there is no need to weight outcomes by the probability of their occurrence. Rather, the definite outcome is that entry will occur, the market opportunity will be shared by patentee and entrant, and the customer will enjoy the benefit of the competition between them. The second important difference is that, unlike the litigation outcome in which the patentee loses, competition between patentee and entrant—and, hence, the market outcome of that competition—will be fettered somewhat by the royalty payable by the entrant to the patentee. That is because the royalty will, in effect, represent additional *variable* cost to the entrant: each additional unit sold by the entrant will result in added costs to the entrant, who now incurs

16. *See* Appendix B for analytical details.

production and distribution costs *as well as* the additional royalty obligation engendered because of that unit.

These added costs impair the competitiveness of the entrant, to the patentee's benefit. The direct effect of this diminished competitiveness is that market prices will be higher—and market quantities lower—than if the entrant were unhindered by any ongoing royalty obligations. All else equal, the higher the royalty rate, the greater will be the additional cost imposed on the entrant, and the higher the resulting market price. Again, the effect on the customer, while quantitatively distinguishable from the effect on the entrant, moves in the same direction. Note that the royalty rate of interest is the one that would apply to an additional unit that the licensee might contemplate producing; it is the *incremental* royalty rate that counts in influencing the licensee's behavior and, hence, market price and quantity.

To sum up, litigation can result in two outcomes—the patentee's prevailing and retaining its "monopoly" or the patentee's losing and facing unfettered competition from the alleged infringer—and the value of this litigation "lottery," to patentee, would-be entrant, and customer alike, is simply the probability-weighted average of the value that each party realizes under the alternative outcomes. Settlement via a license, in contrast, results in immediate entry and competition by the entrant, although that competition (and its resulting impact on patentee and customer) is somewhat attenuated by the added cost that the license imposes on the entrant.

3.3. Impact of the parties' incentives on the feasibility, private value, and public value of settlement

Armed with this understanding of the parties' incentives, we are ready to explore the circumstances under which settlements are feasible, and then to assess whether feasible settlements will necessarily inure to the benefit of the customer. In what follows, for simplicity, we will focus on potential agreements under which the licensee (alleged infringer) pays a running royalty to the licensor (patentee) and exclude complications such as lump sum payments (in either direction), cross-licenses, and other trappings that may well come into play in real life.

The condition under which a given license agreement is feasible is simple enough to state: an agreement is feasible if it offers the litigants—patentee and alleged infringer alike—an alternative that each prefers to continued litigation. We assume, moreover, that a party will prefer the settlement agreement if that party's total profits under the agreement are no lower than the mathematical expectation (the probability-weighted average) of the value of litigation.[17]

Let P represent the probability that the patentee prevails in the lawsuit, let $PROFIT_{DE}$ represent the entrant's profit under a pure duopoly (i.e., the situation in which the parties do not settle and the patentee loses the lawsuit), let $PROFIT_{DP}$ represent incumbent patentee's profit under the same scenario, and let $PROFIT_{MP}$ represent the patentee's profit in the event that it wins the lawsuit and retains its patent monopoly. Finally, let R

17. In other words, we will not deal with the possibility that one or both parties may be risk averse. Adding that feature does not change the basic outcome or conclusions of the model considered here, but it does needlessly complicate its exposition.

denote the royalty payment under the settlement, and let $PROFIT_{LE}$ and $PROFIT_{LP}$ represent profits that the entrant and patentee, respectively, earn under the license agreement, prior to any royalty payments. Feasibility then requires the following:

$$PROFIT_{LE} - R > (1 - P)* PROFIT_{DE}$$

and

$$PROFIT_{LP} + R > P * PROFIT_{MP} + (1 - P)* PROFIT_{DP}$$

The first of these simply states that the profit earned by the entrant/licensee, after paying its royalty obligations, has to exceed the expected value to the entrant of the litigation alternative—the profits that it would earn as an unfettered duopolist weighted by the probability that it would attain that state. The second is the corresponding condition for the patentee/licensor: its profits plus its royalty receipts must exceed *its* expected value of litigation—the value of a victory weighted by the probability of that outcome *plus* the correspondingly weighted value of a litigation loss.[18]

Examination of these feasibility conditions yields some useful insights. In particular, the test for feasibility is a *total profit* test for each party. In other words, if a license agreement yielded each party total profits that exceeded what that party could expect to get under the litigation alternative, that agreement would be feasible and plausible, *regardless of the incremental royalty rate it contained.* But recall from the last section that the licensee's incentives to expand (or contract) its output are determined by the *incremental* royalty rate that it faces, not the total royalty obligation engendered by the license.

There is no reason, therefore, to suppose that a license agreement that satisfies the parties (because it meets the total profit criterion that each party's total profits are at least as great as it could expect under litigation) would create the appropriate incentives for the licensee to expand its output enough to make the licensing outcome superior—from the customers' standpoint—to continued litigation. And that, indeed, is why the agreement between Patco and Mitou may, in fact, be less competitive—and therefore less beneficial to customers—than continued litigation. Because the agreement allows a lump-sum reduction in Mitou's royalty obligation to Patco, it embodies a higher incremental rate than would license terms that offered the same *total* royalty obligation but with no credit or lump-sum reduction.

There are, of course, other ways to effect the same divergence between the incremental royalty rate and the total royalty obligation: sliding scales, where the royalty rate increases with licensed output, and royalty "holidays" for the first portion of licensed output are but two. As one example of the latter, a settlement between Patco and Mitou might allow the entrant to sell 200 units annually royalty-free and require royalty payments of $70 per unit for any additional units sold. Under some conditions, such an agreement would reduce consumer welfare relative to the litigation alternative.[19]

Does this mean, then, that we should proscribe, as a matter of policy, license agreements that embody such terms, on the grounds that such arrangements probably

18. There is only one term on the right-hand side of the first inequality, because the would-be entrant earns no profits if it loses the litigation.

19. *See* Appendix B for analytical details.

spring from sinister motives and are likely to be anticompetitive? Unfortunately for the policy maker (but fortunately for potential litigants, because licensing terms of this type are quite commonplace), there is no such easy solution. The mere fact that the credit (or sliding scale or royalty holiday) means that the license's incremental rate can be made higher (and remain attractive to Mitou because the *total* royalty obligation is still superior to litigation) does not, in and of itself, make the license agreement anticompetitive relative to the litigation alternative; it simply creates the wedge between total and incremental royalty rates that makes such an outcome more plausible. In a variety of situations, however, depending on market demand conditions and the parties' relative cost structures, such terms may be necessary in order for there to be an agreement at all, *and* the resulting agreement may well be superior to litigation from the customers' standpoint! In other words, it would be unwise to adopt a blanket proscription on agreements that embodied such terms. Such a policy could preclude many procompetitive and beneficial agreements, resulting in more (and, from the customers' standpoint, less favorable) litigation.

4. Principled analysis requires evaluating monopoly power and litigation odds

What, then, is the correct analytical approach to deal with agreements that appear facially anticompetitive, perhaps because they include a reverse payment, or agreements that appear entirely innocuous but may depress output and elevate price relative to the expected outcome of litigation? As it turns out, the correct analytical framework for dealing with both of these problems is the same.

In many situations, the monopoly power portion of the FTC's proposed test—if properly applied—could obviate the need for further inquiry. If there is no monopoly power present, there is no need for any further inquiry; the agreement could not be anticompetitive in its effect.

Assume, however, that further analysis establishes that the patentee does have monopoly power. In that case, the appropriate test is whether customers are better off under the settlement than they would have been (in expectational terms) under litigation.[20] In evaluating a settlement agreement with a so-called reverse payment and an agreed date of entry, for example, the appropriate test is whether the settlement resulted in an agreed-upon entry date later than what might have been expected under litigation.

To establish whether or not this occurred, one must evaluate the likely outcomes of the patent case, as well as each party's odds of prevailing in litigation. These facts would help establish what the expected outcome would have been under litigation.[21]

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20. Shapiro suggests a similar approach: "I propose and explore . . . the following simple antitrust rule: a patent settlement cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation." Shapiro, *supra* note 2, at 396.

21. The FTC has stated, however, that "we believe that it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements." Schering-Plough Corp., FTC Docket No. 9297, at 35 (Dec. 18, 2003).

The best source of information about the likely competitive effects of the settlement—relative to the litigation alternative—is likely to be found in the facts surrounding the underlying patent case itself. The objective facts elicited in the patent infringement case—presumably including findings regarding patent claim construction and the like—may constitute the best available information regarding the relative odds that each party would have prevailed in the underlying patent suit. Thus, an agreement that, say, splits the remaining patent term in half, could be viewed as relatively procompetitive if the objective facts uncovered in the litigation suggest that the expected time to entry under litigation was longer—i.e., that the patentee had a stronger case. Analogously, if the patentee had monopoly power, such a settlement might be viewed as anticompetitive if the objective facts suggested that the patentee had relatively low odds of prevailing.

Several practical points are worth noting. First, the court needs to determine the likely outcomes of the patent case and the *objective* odds that each party will prevail in the litigation, *not* the parties' *subjective* estimates of those odds. Consequently, there would generally be no need to examine privileged documents to estimate those odds. Second, it is not generally necessary to estimate those odds with tremendous precision. If the proposed settlement splits the remaining patent term in half, for example, the court need only determine if the expected time to entry under litigation would have been longer, not whether the patentee's probability of prevailing in the litigation is 0.6, 0.7, or 0.75.

In this connection, it is important to recall that the assumption underlying these discussions is that entry would be virtually instantaneous should the entrant prevail in the litigation. In actual fact, even a victory by the entrant could result in deferred entry, either because of appeals or because the entrant's entry would be delayed by the need to undertake various investments or seek regulatory approvals, among other sources of delay. In that case, the expected time to entry would exceed one-half the time remaining on the patent even if the probability of the entrant's prevailing were 50 percent. Therefore, any empirical evaluation of whether or not a given agreement involving delayed entry and reverse payments is anticompetitive requires that we inquire not only about the odds of each party prevailing, but also about the likely entry dates under alternative litigation outcomes.

Analogously, the assessment of whether a seemingly innocuous license agreement—one in which entry is immediate and the payments flow in the "right" direction—is in fact procompetitive (i.e., results in lower prices or higher consumer surplus than the expected outcome of litigation), depends on the same fact-specific investigation outlined above. If the patentee has no monopoly power, the inquiry can end. But if the patentee is found to possess monopoly power, evaluation of the competitive effects of the license vis-à-vis the litigation alternative *must* consider the likely outcomes under litigation as well as the likelihood that the patentee would have prevailed in the lawsuit.

Thus, in those situations in which a properly applied test indicates that the patentee possesses monopoly power, analysis of the competitive effects of a settlement agreement would necessarily involve an assessment of all of the pertinent facts surrounding the underlying patent case, in order to ascertain the outcomes that the case could have generated as well as the relative likelihood of each of those outcomes in litigation. Only

then could one establish whether or not the agreement resulted in an outcome that was superior—whether in terms of entry dates or in terms of prices and quantities prevailing in the marketplace—than the outcomes that might have been expected under litigation.

Although analysis of the underlying patent case is by no means trivial, other commentators—both economists and attorneys—have reached similar conclusions about the need to conduct such analysis. Carl Shapiro, for example, notes:

> I would like to highlight one key practical problem with the approach advocated and analyzed here: typically, to compare consumer surplus under a settlement with consumer surplus from ongoing litigation requires an informed judgment as to the strength of the patent(s) at issue . . . . Except in special cases . . . , there does not appear to be any way around the need to assess patent strength directly if one is trying to determine whether a settlement benefits consumers.[22]

Similarly, in an amicus brief regarding the FTC's petition for certiorari in the Schering-Plough case, the Solicitor General and the Department of Justice stated that "the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful. Rather, an appropriate legal standard should take into account the relative likelihood of success of the parties' claims, viewed *ex ante.*"[23] In a footnote, the brief added, in part, "A court would not need to conduct a full trial on the merits of the patent claims in order to make a determination regarding the likelihood of a patent owner's litigation success. Rather, a court could conduct a limited examination into the relative merits of the patent claims and other relevant factors surrounding the parties' negotiations."[24]

5. Conclusion

Various commentators have suggested the use of relatively simple "red flags" (and corresponding "safe harbors") to vet proposed agreements designed to settle patent litigation. For instance, some have argued that the presence of a reverse payment from patentee to licensee should be a litmus test: agreements that embody these payments should be deemed likely to be anticompetitive, while agreements that do not can be presumed, all else equal, to be innocuous. We have examined the economic incentives facing the parties involved—patentee, licensee/entrant, and customer—and concluded that such tests are unhelpful. Agreements that involve reverse payments may, in fact, be procompetitive relative to litigation, while apparently innocuous agreements that involve no such payments may, in fact, be anticompetitive relative to the litigation alternative. There is, therefore, no substitute for closer, fact-specific analysis of the agreement and its context. This, in turn, underscores two important realities: first, the agreement cannot be anticompetitive if the patentee lacks monopoly power; second, it is difficult to assess the competitive effects of a license agreement in a vacuum. The agreement can only be evaluated relative to the expected outcome of litigation; therefore, a principled

22. Shapiro, *supra* note 2, at 397.
23. Amicus Brief for United States at 11, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273).
24. *Id.* n.1.

antitrust analysis must necessarily examine the likely outcomes of the litigation alternative in some detail.

Appendix A

1. Introduction

This appendix develops a model in which an incumbent patentee (P) and a would-be entrant (E) individually decide whether to pursue patent infringement litigation brought by the patentee or settle the case without litigation by agreeing that the entrant will defer entry to some date certain in the future. In the model below, we show that there are certain values for the parameters of interest for which there is no feasible settlement that involves only an agreed-upon date of entry for E. For such parameter values, the latest date for entry by entrant E that would induce E to settle is earlier than the earliest date that would induce patentee P to settle. We show, however, that the parties *can* reach a settlement in which (1) P pays E a lump sum, (2) each party prefers to settle rather than litigate, and (3) the agreed-upon date for entry by E is earlier than the expected date of entry under litigation.

2. Basic assumptions and outline of the model

1. The current date is $t = 0$; the patent will expire at $t = 2T$. In all cases, after expiration of the patent (for $t > 2T$), free entry ensures that all suppliers, including both P and E, earn zero economic profits.
2. At time $t = 0$, each party decides unilaterally whether it prefers to settle or litigate.
3. Unless both parties prefer to settle, they litigate at $t = 0$; each party's probability of winning is 0.5. The decision in the litigation—unknown to the parties before they choose between settlement and litigation—is instantaneous.
4. If the parties do litigate,
    - If E wins the litigation,
        - — E enters immediately (at $t = 0$) and earns profits at a rate of π_E^D (D for *duopolist* and E for *entrant*)[25] from $t = 0$ to $t = 2T$; and
        - — P earns profits at a rate of π_P^D (D for *duopolist* and P for *patentee*) from $t = 0$ to $t = 2T$.

25. For the numerical examples/simulations below, we have assumed that the entrant's and the patentee's rates of duopoly profit (i.e., their rates of profit before expiration of the patent if both are selling the product) are equal. In the algebraic development of the model, however, we allow for more generality, allowing for different values of (and using different notation for) the two firms' rates of profit. The model, therefore, allows for more elaborate examples/simulations in which the duopolists' rates of profit are not equal.

- If *P* wins the litigation,
  - — *E* cannot enter until $t = 2T$. Since its economic profits will be 0 after $t = 2$T—and, by assumption, it will have to incur ongoing expenditures from $t = 0$ until $t = 2T$ to maintain its viability (see below)—*E* never enters. It "earns" profits at a rate 0, therefore, starting at $t = 0$ (just after resolution of the litigation in favor of the patentee).
  - — *P* earns profits at a rate π^m (*m* for *monopolist*) from $t = 0$ to $t = 2T$ (and 0 thereafter).

5. If the parties each prefer to settle, *E* enters at $t = t^*$.
   - *P*
     - — earns profits at a rate of π^m from $t = 0$ to $t = t^*$, and
     - — earns profits at a rate of π_P^D from $t = t^*$ to $t = 2T$ (and 0 thereafter).
     - — In addition, *P* pays *E* a lump sum payment of *B* at $t = 0$. (In the model below, *B* can, of course, be zero.)
   - *E*
     - — receives the lump sum payment of *B* at $t = 0$;
     - — "earns" profit at a rate of $-\pi_R$ from $t = 0$ to $t = t^*$ (i.e., *E* must make ongoing expenditures at a rate of π_R to remain viable until it enters at $t = t^*$); and
     - — earns profit at a rate of π_E^D from $t = t^*$ to $t = 2T$ (and 0 thereafter).
6. The patentee is risk-averse: The utility of the present value of the patentee's profits is given by $U\left[PV(profits)\right] = \ln\left[PV\left(profits\right)\right]$.

3. The patentee's decision

In this section, we develop expressions for the present value of the patentee's stream of profits under settlement and under litigation. We then develop an expression for the break-even date t_P^* at which the patentee is indifferent between settling and litigating.

3.1. The patentee's profits from settlement

If the parties settle, the present value of the patentee's stream of profits is

$$\pi^m \int_0^{t^*} e^{-rt}dt + \pi_P^D \int_{t^*}^{2T} e^{-rt}dt - B$$

$$= \frac{\pi^m}{r}\left(1 - e^{-rt^*}\right) + \frac{\pi_P^D}{r}\left(e^{-rt^*} - e^{-2rT}\right) - B \quad \text{(A1)}$$

26. The patentee's and entrant's discount rates need not be equal—and, in general, they will not be equal. To minimize notational clutter, however, we omit subscripts on *r* in the general development of the model below. In the numerical examples/simulations that follow, moreover, we assume equal discount

The interpretation of the first two terms in Equation (A1) is straightforward: $\frac{\pi^m}{r}\left(1-e^{-rt^*}\right)=\frac{\pi^m}{r}-\frac{\pi^m}{r}e^{-rt^*}$ gives the value (at $t=0$) of a perpetuity at rate π^m starting at $t=0$ *minus* the value (at $t=0$) of a perpetuity at rate π^m starting at $t=t^*$; $\frac{\pi_P^D}{r}\left(e^{-rt^*}-e^{-2rT}\right)$ gives the value of a perpetuity at rate π_P^D starting at $t=t^*$ *minus* the value of a perpetuity at rate π_P^D starting at $t=2T$.

3.2. The patentee's profits from litigation

If the parties litigate, the present value of the patentee's stream of profits takes one of two values, each with probability ½. The present value of *P*'s stream of profits is

$$\pi^m\int_0^{2T}e^{-rt}dt=\frac{\pi^m}{r}\left(1-e^{-2rT}\right)\text{ if }P\text{ wins the lawsuit }or \tag{A2}$$

$$\pi_P^D\int_0^{2T}e^{-rt}dt=\frac{\pi_P^D}{r}\left(1-e^{-2rT}\right)\text{ if }E\text{ wins the lawsuit} \tag{A3}$$

3.3. Conditions under which the patentee is indifferent between settlement and litigation

The patentee will be indifferent between settlement and litigation when his utilities from those two options are equal. Using Equations (A1), (A2), and (A3), the patentee will be indifferent when

$$\ln\left[\frac{\pi^m}{r}\left(1-e^{-rt^*}\right)+\frac{\pi_P^D}{r}\left(e^{-rt^*}-e^{-2rT}\right)-B\right]=\left(\frac{1}{2}\right)\ln\left[\frac{\pi^m}{r}\left(1-e^{-2rT}\right)\right]+\left(\frac{1}{2}\right)\ln\left[\frac{\pi_P^D}{r}\left(1-e^{-2rT}\right)\right]$$

Exponentiating both sides of the equation and simplifying the right side,

$$\frac{\pi^m}{r}\left(1-e^{-rt^*}\right)+\frac{\pi_P^D}{r}\left(e^{-rt^*}-e^{-2rT}\right)-B=\left(\frac{1-e^{-2rT}}{r}\right)\sqrt{\pi^m\pi_P^D} \tag{A4}$$

If *B* is constrained to be 0—i.e., we restrict our attention to settlements that do not include lump sum payments between the parties—then the third term on the left side of Equation (A4) drops out. We can then simplify Equation (A4) and solve for t_P^*, the patentee's break-even value of t^* at which he is indifferent between litigation and settlement when $B=0$:

$$\pi^m\left(1-e^{-rt^*}\right)+\pi_P^D\left(e^{-rt^*}-e^{-2rT}\right)-\left(1-e^{-2rT}\right)\sqrt{\pi^m\pi_P^D}=0$$

$$\Rightarrow t_P^*=\left(\frac{-1}{r}\right)\ln\left[\frac{\left(1-e^{-2rT}\right)\sqrt{\pi^m\pi_P^D}+\left(\pi_P^D\right)e^{-2rT}-\pi^m}{\pi_P^D-\pi^m}\right] \tag{A5}$$

rates for the two parties. Generalization of the model to allow for different discount rates for the two parties is straightforward and obvious.

For given values of the parameters in the expression on the right side of Equation (A5), the patentee

- will prefer settlement to litigation if $t^* > t_P^*$,
- will prefer litigation to settlement if $t^* < t_P^*$, and
- will be indifferent between litigation and settlement if $t^* = t_P^*$.

4. The entrant's decision

In this section, we develop expressions for the present value of the entrant's stream of profits under settlement and under litigation. We then develop an expression for the break-even date t_E^* at which the entrant is indifferent between settling and litigation.

4.1. The entrant's profits from settlement

If the parties settle, the present value of the entrant's stream of profits is

$$-\pi_R \int_0^{t^*} e^{-rt}\,dt + \pi_E^D \int_{t^*}^{2T} e^{-rt}\,dt + B$$

$$= \left(\frac{\pi_R}{r}\right)\left(e^{-rt^*} - 1\right) + \left(\frac{\pi_E^D}{r}\right)\left(e^{-rt^*} - e^{-2rT}\right) + B \qquad \text{(A6)}$$

Note that an increase in t^* affects both of the first two terms of Equation (A6). By delaying the entry of *E,* an increase in t^*

- reduces the present value of *E*'s duopoly profits (the second term), *and*
- increases the duration of *E*'s net outflows required before its entry, thereby increasing the magnitude of the first term in Equation (A6), which is negative.

4.2. The entrant's profits from litigation

If the parties litigate, the present value of the entrant's stream of profits takes one of two values, each with probability ½. The present value of *E*'s stream of profits is

$$0 \text{ if } P \text{ wins the lawsuit } \textit{or} \qquad \text{(A7)}$$

$$\pi_E^D \int_0^{2T} e^{-rt}\,dt = \left(\frac{\pi_E^D}{r}\right)\left(1 - e^{-2rT}\right) \text{ if } E \text{ wins the lawsuit} \qquad \text{(A8)}$$

4.3. Conditions under which the entrant is indifferent between settlement and litigation

The entrant will be indifferent between settlement and litigation when the present values of his profits from those two options are equal. Equating the expression in Equation (A6) and the expected value of the two expressions in Equations (A7) and (A8), the entrant will be indifferent when

$$\left(\frac{\pi_R}{r}\right)\left(e^{-rt^*} - 1\right) + \left(\frac{\pi_E^D}{r}\right)\left(e^{-rt^*} - e^{-2rT}\right) + B = \left(\frac{\pi_E^D}{2r}\right)\left(1 - e^{-2rT}\right) \qquad \text{(A9)}$$

If B is constrained to be 0—i.e., we restrict our attention to settlements that do not include lump sum payments between the parties—the third term on the left side of Equation (A9) drops out. We can then simplify Equation (A9) and solve for t_E^*, the entrant's break-even value of t^* at which he is indifferent between litigation and settlement when $B = 0$:

$$\left(\pi_R\right)\left(e^{-rt^*}-1\right)+\left(\pi_E^D\right)\left(e^{-rt^*}-e^{-2rT}\right)=\left(\frac{\pi_E^D}{2}\right)\left(1-e^{-2rT}\right)$$

$$\Rightarrow t_E^*=\left(\frac{-1}{r}\right)\ln\left[\frac{\pi_R+\left(\frac{\pi_E^D}{2}\right)\left(1+e^{-2rT}\right)}{\pi_R+\pi_E^D}\right] \tag{A10}$$

For given values of the parameters in the expression on the right side of Equation (A10), the entrant

- will prefer settlement to litigation if $t^* < t_E^*$,
- will prefer litigation to settlement if $t^* > t_E^*$, and
- will be indifferent between litigation and settlement if $t^* = t_E^*$.

5. For some sets of parameter values, there is no feasible settlement without a payment *B*

As noted in the introduction to this appendix, it is possible to find sets of parameter values for which there is no feasible settlement without a payment B but for which the parties *can* reach a settlement in which (1) P pays E a lump sum, (2) each party prefers to settle rather than litigate, and (3) the agreed-upon date for entry by E is earlier than T, the expected date of entry if the parties litigate.

To see one such example, consider the following set of parameter values:[27]

$$\begin{aligned}\pi^m &= 4\\ \pi_P^D &= \pi_E^D = 1.5\\ \pi_R &= 0.5\\ T &= 2\\ r_P &= r_E = 0.2\ \left(20\%\right)\end{aligned} \tag{A11}$$

Note, of course, that the two parties' discount rates, r_P and r_E, *could* differ. To make the point below, however, we need not specify different values for r_P and r_E.

Plugging those values into the expressions in Equations (A5) and (A10) gives $t_P^* = 1.173$ and $t_E^* = 1.157$. In words, if $B = 0$,

- the patentee will settle (rather than litigate) only if the settlement date is *later* than $t_P^* = 1.173$, while

27. The values listed for π^m and π^D are the monopoly and Cournot duopoly profits, respectively, if demand is given by $Q = 16p^{-2}$ and both parties have constant marginal costs of 1. (To verify those results, see the discussion in Appendix B, which discusses such a Cournot model.)

- the entrant will settle (rather than litigate) only if the settlement date is *earlier* than $t_E^* = 1.157$.

Clearly, without some sort of payment *B,* there is no settlement date that will induce both parties to settle; without a payment *B,* therefore, they will litigate.

But there are an *infinite* number of feasible settlements—settlements that both parties prefer to litigation—once we allow a nonzero payment *B* from the patentee to the entrant. It is easy to show, for example, that *both* parties will prefer settlement to litigation if the entrant enters at $t^* = 1.5$ and the patentee pays the entrant $B = 0.6$. In fact, for entry by *E* at $t^* = 1.5$ (and the parameter values indicated in Equation (A11) above), it is possible to show that both parties will prefer settlement to litigation as long as $0.526801 < B < 0.62549$.[28] Similarly, for entry by *E* at $t^* = 1.75$ (and the parameter values indicated in Equation (A11) above), it is possible to show that both parties will prefer settlement to litigation as long as $0.888103 < B < 1.077116$. In that case, for example, a payment of $B = 1$ would induce both parties to settle.

Note that in both sets of examples in the previous paragraph, the parties can reach a settlement with certain entry by the entrant at a date t^* that is earlier than

$$\left(\frac{1}{2}\right)(0+2T) = \left(\frac{1}{2}\right)\left[0+(2)(2)\right] = 2,$$

the expected date of entry under litigation.

Appendix B

This appendix develops several models that lie behind various examples in the text of this chapter. In particular, we develop models that show how the settlement agreements between Patco and Mitou may harm consumers, even though the parties may prefer settlement to litigation in both cases.

1. Notation

This section sets out briefly the notation used below.

Q = total market outupt
q_P = the patentee's output
q_E = the entrant's output
η = the elasticity of market demand; demand is isoelastic: $Q = Kp^{-\eta}$; equivalently, $p = (Q/K)^{-1/\eta}$
K = a multiplicative constant (a scale factor)
c_P = the patentee's constant marginal cost of production (normalized to 1)

28. For a given value of t^*, we can find the break-even value of *B* at which the patentee is indifferent between settlement and litigation by solving Equation (A4) for *B* in terms of the other parameters, including t^*. Similarly, for a given value of t^*, we can find the break-even value of *B* at which the entrant is indifferent between settlement and litigation by solving Equation (A9) for *B* in terms of the other parameters, including t^*.

c_E = the entrant's marginal cost of production (assumed to be constant)
ϕ = the probability that the patentee wins the litigation if the parties litigate

In general, the subscripts *P* and *E* refer to the patentee and entrant, respectively. To distinguish variables in the litigation scenarios from those in the settlement scenarios, we use superscripts *L* and *s*, respectively.

2. Basic overview of the models

2.1. Litigation

If the parties decide to litigate—i.e., they do not reach a settlement—there are two possible outcomes:

- The patentee wins the lawsuit. In that case, the would-be entrant is not allowed to enter, and the patentee prices the product as a monopolist.
- The patentee loses the lawsuit. In that case, the entrant enters, and the parties compete as Cournot duopolists.

2.2. Settlement

If the parties decide to settle, they compete as Cournot duopolists. We consider two alternative types of settlement if the parties decide to settle: a royalty that is a linear function of the entrant's revenue (i.e., an ad valorem royalty) and a royalty specified as a certain dollar amount per unit sold by the entrant (i.e., a specific royalty). We provide further details about these settlements in the discussion below.

3. Solution of the models

3.1. Litigation

SCENARIO 1: THE PATENTEE WINS THE LAWSUIT

In this case, the patentee behaves as a monopolist in choosing the profit-maximizing quantity. Specifically, the patentee chooses the monopoly price p_m to maximize

$$\pi_P(p_m) = (p_m - c_P)q_P = (p_m - 1)Q = (p_m - 1)Kp_m^{-\eta} = K\left(p_m^{1-\eta} - p_m^{-\eta}\right) \tag{B1}$$

The first-order conditions are then

$$\frac{\partial \pi_P}{\partial p_m} = K\left[(1-\eta)p_m^{-\eta} + \eta p_m^{-\eta-1}\right] = 0 \Rightarrow p_m = \frac{\eta}{\eta - 1} \tag{B2}$$

At that price, the monopoly patentee's profits are given by

$$\begin{aligned} \pi^m \equiv \pi_P(p_m) &= (p_m - 1)Q = (p_m - 1)(K)(p_m)^{-\eta} \\ &= K\left(\frac{1}{\eta - 1}\right)\left(\frac{\eta}{\eta - 1}\right)^{-\eta} \end{aligned} \tag{B3}$$

SCENARIO 2: THE PATENTEE LOSES THE LITIGATION

In this case, the patentee and entrant compete as Cournot duopolists. To compute the Cournot duopoly price and the parties' profits, we use the general expression for the Cournot oligopoly price for a market with N firms in which firm i's marginal cost is constant at c_i:

$$p = \frac{\eta \sum_{i=1}^{N} c_i}{\eta N - 1}, \tag{B4}$$

where N is the number of firms.[29] (Note incidentally that with $N = 1$ and $c_P = 1$, which apply if the monopolist *wins* the lawsuit, the expression in Equation (B4) simplifies to the expression for p_m in Equation (B2).)

In the duopoly case at hand, the Cournot duopoly price is just a special case of Equation (B4):

$$p^L = \frac{\eta\left(1 + c_E\right)}{2\eta - 1}, \tag{B5}$$

where the superscript L refers to the outcome under *litigation*. We can then compute total quantity demanded by substituting that price into the demand function:

$$Q^L = K\left(p^L\right)^{-\eta} \tag{B6}$$

To compute the quantities produced by each party, note that in this model (see note 29),

$$\frac{q_i}{Q} = \eta\left(1 - \frac{c_i}{p}\right) \Rightarrow q_i = \eta\left(1 - \frac{c_i}{p}\right)Q, \tag{B7}$$

so the quantities produced by the patentee and entrant, respectively, can be computed using the following expressions:

$$q_P^L = \eta\left(1 - \frac{c_P}{p^L}\right)Q^L = \eta\left(1 - \frac{1}{p^L}\right)\left(K\right)\left(p^L\right)^{-\eta} \tag{B8}$$

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29. Let Q and q_i denote total market quantity and the quantity supplied by firm i, respectively. Firm i maximizes profits $\pi_i = pq_i - c_i q_i$. Defining $\lambda_i = d\sum_{j \neq i} q_j / dq_i$, the first-order condition for firm i is as follows:

$$\frac{\partial \pi_i}{\partial q_i} = p + q_i p'(Q)\left(1 + \lambda_i\right) - c_i = 0$$

If firms behave in Cournot fashion ($\lambda_i = 0$ for all i), the latter equation implies

$$\frac{q_i}{Q} = \eta\left(1 - \frac{c_i}{p}\right)$$

Following Roger Clarke & Stephen W. Davies, *Market Structure & Price-Cost Margins*, 49 ECONOMICA 277 (1982), we can sum both sides of the latter equation over the N firms and solve for p:

$$p = \frac{\eta \sum_{i=1}^{N} c_i}{\eta N - 1}$$

$$q_E^L = \eta\left(1-\frac{c_E}{p^L}\right)Q^L = \eta\left(1-\frac{c_E}{p^L}\right)(K)\left(p^L\right)^{-\eta} \tag{B9}$$

Finally, we can use the expressions in Equations (B5), (B8), and (B9) above to generate expressions for the parties' profits in the Cournot duopoly equilibrium:

$$\pi_P^L = \left(p^L - c_P\right)q_p^L = \left(p^L - 1\right)q_P^L \tag{B10}$$

$$\pi_E^L = \left(p^L - c_E\right)q_E^L \tag{B11}$$

The parties' *expected* profits from litigation are then just weighted averages of their profits in Scenarios 1 and 2, with weights ϕ and $(1 - \phi)$, respectively.

3.2. Settlement 1: An ad valorem royalty

If the parties decide to settle, they compete as Cournot duopolists, taking account of the effect of the royalty on their profits. In the discussion below, we consider two alternative types of settlements. We first consider a settlement in which the entrant pays the patentee a linear royalty given by

$$\alpha + \beta\left(\textit{entrant revenue}\right),$$

where α and β are parameters.

THE PATENTEE'S PROBLEM

The patentee chooses q_P^s to maximize

$$\pi_P^s = \left(p^s - c_P\right)q_P^s + \alpha + \beta p^s q_E^s = \left(p^s - 1\right)q_P^s + \alpha + \beta p^s q_E^s \ ,$$

where the superscript *s* on price and quantities indicates *settlement* price and quantities, and π_P^s denotes the patentee's profits in the settlement equilibrium. The patentee's first-order condition, therefore, is

$$\begin{aligned}
&\frac{\partial \pi_P^s}{\partial q_P^s} = p^s - 1 + q_P^s p' + \beta q_E^s p' = 0 \\
&\Rightarrow p^s + \left[q_P^s + \beta q_E^s\right]p' = 1 \\
&p^s + p^s\left(\frac{q_P^s}{Q}\right)p'\left(\frac{Q}{p^s}\right) + \beta p^s\left(\frac{q_E^s}{Q}\right)p'\left(\frac{Q}{p^s}\right) = 1 \\
&\frac{q_P^s}{Q^s} = \frac{\eta\left(1-\frac{1}{p^s}\right)-\beta}{1-\beta}
\end{aligned} \tag{B12}$$

THE ENTRANT'S PROBLEM

The entrant chooses q_E^s to

$$\max_{q_E^s} \pi_E^s = \left(p^s - c_E\right) q_E^s - \alpha - \beta p^s q_E^s$$

The entrant's first-order condition, therefore, is

$$\frac{\partial \pi_E^s}{\partial q_E^s} = p^s - c_E + q_E^s p' - \beta\left(p^s + q_E^s p'\right) = 0$$

$$\Rightarrow (1-\beta)\left(p^s + q_E^s p'\right) = c_E \tag{B13}$$

$$p^s + p^s\left(\frac{q_E^s}{Q}\right)\left(\frac{Q}{p^s}\right)p' = \frac{c_E}{1-\beta}$$

$$\frac{q_E^s}{Q} = \eta\left[1 - \frac{c_E}{p^s(1-\beta)}\right] \tag{B14}$$

THE EQUILIBRIUM PRICE WITH A LINEAR ROYALTY

We can then add the expressions for the two firms' shares in Equations (B12) and (B14) to solve for the equilibrium price in the settlement scenario as a function of demand elasticity, the firms' marginal costs, and β:

$$\frac{\eta\left(1-\frac{1}{p^s}\right)-\beta}{1-\beta} + \eta\left[1 - \frac{c_E}{p^s(1-\beta)}\right] = 1$$

$$\Rightarrow p^s = \frac{\eta(1+c_E)}{2\eta - (1+\eta\beta)} \tag{B15}$$

THE PARTIES' PROFITS

Having derived the expression for the equilibrium price p^s in Equation (B15) as a function of c_E, η, and β—and, therefore, the equilibrium quantity through the demand function $Q = Kp^{-\eta}$—as well as expressions for the firms' equilibrium shares in Equations (B12) and (B14), we are now in a position to compute the parties' profits under settlement.

3.3. Settlement 2: A specific (per unit) royalty

In this case, we consider a settlement in which the entrant pays the patentee a per unit royalty. We first outline the model in which the per unit royalty is fixed at a certain level, regardless of the quantity sold by the entrant (i.e., the royalty = aq_E, where a is a parameter); we refer to such a royalty as a one-tier per unit royalty. We then outline

another version of the model, the version mentioned in the text, in which the per unit royalty increases once the entrant's quantity exceeds a certain threshold; we call that structure a two-tier per unit royalty.

THE ONE-TIER PER UNIT ROYALTY

If the parties decide to settle, they compete as Cournot duopolists, taking account of the effect of the royalty on their profits. The formal solution of the model is, of course, very similar to the solution of the Cournot model in Scenario 2 of the Litigation outcome (see note 29 and the previous section of the text).

THE PATENTEE'S PROBLEM

The patentee chooses q_P^s to maximize

$$\pi_P^s = (p - c_P)q_P + aq_E = (p-1)q_P + aq_E \ ,$$

where the superscript s in π_P^s denotes the patentee's profits in the *settlement* equilibrium. The patentee's first-order condition is

$$\frac{\partial \pi_P^s}{\partial q_P} = p + q_P p' - 1 = 0$$

Since the patentee's first-order condition does not depend on q_E, we can use the general expression for firm i's share in such a model (see note 29) to rewrite the patentee's first-order condition as follows:

$$\frac{q_i}{Q} = \eta\left(1 - \frac{c_i}{p}\right) \Rightarrow \frac{q_p}{Q} = \eta\left(1 - \frac{1}{p}\right) \tag{B16}$$

THE ENTRANT'S PROBLEM

The entrant chooses q_E to maximize

$$\pi_E^s = (p - c_E)q_E - aq_E = q_E(p - c_E - a)$$

The entrant's first-order condition, therefore, is

$$\frac{\partial \pi_E^s}{\partial q_E^s} = p - c_E - a + q_E p' = 0$$

Formally, the entrant's problem is equivalent to the problem faced by a firm with marginal cost $c_E + a$. Therefore, we can rewrite that first-order condition, using the general expression for firm i's share in such a model (see note 29), as follows:

$$\frac{q_i}{Q} = \eta\left(1 - \frac{c_i}{p}\right) \Rightarrow \frac{q_E}{Q} = \eta\left(1 - \frac{c_E + a}{p}\right) \tag{B17}$$

THE EQUILIBRIUM PRICE WITH A ONE-TIER PER UNIT ROYALTY

We can then add the expressions for the two firms' shares in Equations (B16) and (B17) to solve for the equilibrium price in the settlement scenario as a function of demand elasticity, the firms' marginal costs, and *a:*[30]

$$\frac{q_P}{Q}+\frac{q_E}{Q}=\eta\left(1-\frac{1}{p}\right)+\eta\left(1-\frac{c_E+a}{p}\right)=1$$

$$\Rightarrow 2\eta-\eta\left(\frac{1+c_E+a}{p}\right)=1$$

$$p^s=\frac{\eta\left(1+c_E+a\right)}{2\eta-1} \qquad \text{(B18)}$$

OVERVIEW OF THE TWO-TIER PER UNIT ROYALTY

The structure and the solution of the model with a two-tier per unit royalty are very similar to their counterparts for the model with a one-tier per unit royalty, so we provide a briefer outline for the two-tier model.

If the parties decide to settle, the entrant pays the patentee a royalty of a per unit for each unit up to a threshold quantity $\tilde{q}$; for each unit beyond that threshold, the entrant pays a royalty of $a+b$ per unit. Formally,

$$\text{Royalty} = \begin{cases} aq_E & \text{if } q_E \le \tilde{q} \\ aq_E + b\left(q_E-\tilde{q}\right)=\left(a+b\right)q_E-b\tilde{q} & \text{if } q_E > \tilde{q} \end{cases}$$

With that settlement structure, the patentee's first-order condition is the same as in the model of the one-tier per unit royalty: although the patentee's profit function depends on q_E, its first-order condition does not. In the settlement equilibrium, therefore, the patentee's share is given by Equation (B16).[31]

The relevant version of the entrant's first-order condition depends on whether the entrant's equilibrium quantity exceeds the threshold $\tilde{q}$. Since we have already considered the one-tier model, we focus here on parameter values for which q_E does exceed $\tilde{q}$. In that case, the entrant's first-order condition is similar to its first-order condition in the one-tier model—see Equation (B17)—except that $a+b$ replaces *a:*

$$\frac{q_E}{Q}=\eta\left(1-\frac{c_E+a+b}{p}\right) \qquad \text{(B19)}$$

Similarly, the equilibrium price is given by Equation (B18), except that $a+b$ replaces *a:*

30. As expected, the expression for p^s is a special case of the general expression for equilibrium price in the Cournot model discussed in note 29.

31. Because the *entrant's* first-order condition with a two-tier royalty is different from its first-order condition with a one-tier royalty (see the discussion below), the equilibrium settlement price will also differ for the two types of royalties.

$$p^s = \frac{\eta\left(1 + c_E + a + b\right)}{2\eta - 1} \tag{B20}$$

Having derived the expression for the equilibrium price p^s in Equation (B20) as a function of c_E, η, a, and b—and, therefore, the equilibrium quantity through the demand function $Q = Kp^{-\eta}$—as well as expressions for the firms' equilibrium shares in Equations (B16) and (B19), we are now in a position to compute the parties' profits under settlement.

4. The parties' preferences for settlement or litigation

If each firm is risk neutral, it will prefer settlement to litigation if its equilibrium profits under settlement exceed its expected profits under litigation. The parties' expected profits under litigation depend on the probability that the patentee will win the litigation, which we denote by ϕ; we assume that both parties have the same estimate of ϕ.

The patentee will prefer settlement to litigation if

$$\pi_P^s > E\left(\pi_P^L\right), \text{ i.e., if}$$

$$\pi_P^s > \varphi\pi^m + \left(1 - \varphi\right)\pi_P^L$$

$$\Rightarrow \varphi < \frac{\pi_P^s - \pi_P^L}{\pi^m - \pi_P^L}\ , \tag{B21}$$

where π^m, π_P^L, and π_P^s are functions of the underlying parameters (η, c_E, etc.). For given values of those underlying parameters, Equation (B21) indicates the values of ϕ for which the patentee would prefer settlement.[32]

The entrant will prefer settlement to litigation if

$$\pi_E^s > E\left(\pi_E^L\right), \text{ i.e., if}$$

$$\pi_E^s > \varphi\left(0\right) + \left(1 - \varphi\right)\pi_E^L$$

$$\Rightarrow \varphi > \frac{\pi_E^L - \pi_E^s}{\pi_E^L}\ , \tag{B22}$$

where π_E^L and π_E^s are functions of the underlying parameters. For given values of those underlying parameters, Equation (B22) indicates the values of ϕ for which the entrant would prefer settlement.

5. Consumer surplus

If demand is isoelastic ($Q = Kp^{-\eta}$), as assumed, and $\eta > 1$, consumer surplus at any price p is given by

32. More generally, given values of all but one of the underlying parameters, Equation (B21) generates the range of values for the other parameter for which the patentee would prefer settlement.

$$\int_p^{\infty} Kx^{-\eta}\,dx = \frac{Kx^{1-\eta}}{1-\eta}\Bigg|_{x=p}^{x=\infty} = \frac{Kp^{1-\eta}}{\eta-1} \tag{B23}$$

Using Equation (B23) and the appropriate expressions for price in the various scenarios considered above, we can compute expected consumer surplus under litigation and consumer surplus under settlement for any particular parameter values. To compute expected consumer surplus under litigation, we use the same estimate of ϕ as the parties.

6. Choice of parameter values

It is now possible to show that settlements that both parties prefer to litigation and that look quite innocuous may well harm consumers.

6.1. Settlement 1: The ad valorem royalty

Suppose, for example, the settlement includes an ad valorem royalty of the type considered in Settlement 1, with the following parameter values:

$$\eta = 3$$
$$K = 1{,}000$$
$$c_P = 1$$
$$c_E = 1.1$$
$$\alpha = -10$$
$$\beta = 0.14$$
$$\varphi = 0.5$$

If Q is measured in millions of units, these parameters correspond to the example cited in the text: a royalty rate of 14 percent per dollar of the entrant's gross revenue, with a rebate of $10 million if the entrant's revenue exceeds $100 million. (In equilibrium, given these parameter values, that condition will be satisfied.) The reader can verify that both Equations (B22) and (B21) are satisfied—i.e., both parties prefer this settlement to litigation—but expected consumer surplus is higher under litigation than consumer surplus under this settlement.

6.2. Settlement 2: The two-tier per unit royalty

Alternatively, suppose the settlement includes a two-tier per unit royalty of the sort considered in Settlement 2, with the following parameter values:

$$\eta = 2$$
$$K = 1{,}000$$
$$c_P = 1$$
$$c_E = 1$$
$$a = 0$$
$$b = 0.07$$

$$\tilde{q} = 200$$
$$\varphi = 0.1$$

If prices are denominated in thousands of dollars, those parameter values correspond to the last example cited in the text: royalty-free sales of the first 200 units, with royalties of $70 per unit for any additional units sold. For those parameter values, in equilibrium, q_E does exceed $\tilde{q}$, so the entrant does pay a two-tier royalty, and both parties prefer settlement to litigation. Expected consumer surplus under litigation, however, is actually higher than consumer surplus in the settlement equilibrium. Thus, as indicated in the text, although the parties would prefer to settle, settlement will actually harm consumers.

Note also that for some parameter values there is no one-tier per unit royalty that both parties would prefer to litigation.[33] To effect a settlement that both parties—and consumers—prefer to litigation, therefore, a two-tier royalty or some other royalty structure may be necessary.

33. For example, if $h = 2$, $c_P = 1$, $c_E = 0.95$, $a = 0.01$, $b = 0.1$, $\tilde{q} = 200$, and $\phi = 0.15$, it is possible to show that there is no *one*-tier per unit royalty that both parties would prefer to litigation.

ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

STATEMENT FOR THE RECORD

GEORGE P. SLOVER
CONSUMERS UNION

BEFORE THE

SUBCOMMITTEE ON ANTITRUST,
COMPETITION POLICY, AND CONSUMER RIGHTS
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ON

PAY-FOR-DELAY DEALS: LIMITING COMPETITION AND COSTING CONSUMERS

JULY 23, 2013

Introduction

Consumers Union, the policy and advocacy arm of Consumer Reports,[1] commends the Subcommittee for holding this important hearing, and we appreciate the opportunity to present our views.

The availability of affordable generic alternatives to patented brand-name pharmaceutical drugs has saved consumers substantial sums over the years, totaling many billions of dollars. Consumers benefit in two ways – they pay less for the generic drug; and because the prices are lower, the drug is affordable and available to more consumers.

Consumer Reports has been very active in informing consumers of the benefits of generic alternatives and how to shop around for the best deals on the medicines they need.

In 2004, Consumer Reports launched a free public education initiative, "Consumer Reports Best Buy Drugs," to provide consumers with reliable, easy-to-understand advice about the safest, most effective, and lowest-cost prescription drugs available. We currently provide information for 26 different classes of medicine, and we will likely add more classes as we go forward. Consumers can use this information to check to see if there is a safe, effective, and low-cost alternative to a medicine they are taking. We encourage consumers to talk to their doctors about this information.

We also publish articles periodically in our magazine explaining the cost-saving benefits of generic alternatives, and alerting readers, with specific examples, of how prices for some common generic drugs can vary widely depending on the retail pharmacy.

The Promise of Hatch-Waxman and the Problem of Pay-For-Delay

We were strong supporters of the abbreviated new drug application process established under the Hatch-Waxman Act in 1984. Experience has borne out our prediction that it would create powerful incentives for brining new generic alternatives to market. These incentives included not only the less costly and more expedited path to FDA approval, but also a special 180-day exclusivity period, under which the first generic alternative to a brand-name drug would have 180 days in the market to itself, as the sole alternative to the brand-name drug, before competing approved generic alternatives would be permitted to enter the market.

During the 180-day period, the generic would sell for less than the brand-name drug did under monopoly conditions, but still for more than under fully competitive conditions. A typical

[1] Consumers Union is the public policy and advocacy division of Consumer Reports. Consumers Union works for telecommunications reform, health reform, food and product safety, financial reform, and other consumer issues. Consumer Reports is the world's largest independent, not-for-profit product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications

price reduction during the 180-day period might be 20 to 30 percent, as compared to a reduction of 80 percent or more under full competition. For a major drug, the additional benefit of this 180-day period to the first generic could be in the hundreds of millions of dollars – a powerful financial incentive to be the first to develop a generic alternative and apply for FDA approval expeditiously, while still shortening the time before the market would be opened to full competition.

But the amount of money at stake for the brand-name drug maker in protecting its monopoly for as long as possible – potentially billions of dollars over the life of its patent – also creates powerful incentives for the brand-name drug manufacturer to find a way to delay competitive entry. And the ways entry has been delayed have not been limited to the time-honored way established under the patent laws, defending its patents vigorously in court, and prevailing against the generic manufacturer for infringement. They have also included the less honorable way, of inducing the generic manufacturer to voluntarily delay introduction of its competing product, thereby prolonging the period during which it can charge monopoly prices to consumers who need the drug and have no alternative.

Because the additional monopoly profits the brand-name drug maker can reap from staving off competition far exceed the profits the generic drug maker could reasonably expect to gain by competing, the brand-name drug maker can pay the generic drug maker more for agreeing not to compete than the generic drug maker can earn by competing, and still come out way ahead. Looked at another way, what the brand-name gives up in monopoly profits if the generic enters the market doesn't all go to the generic. A significant portion of it goes to consumers in cost savings as a result of competition.

And those consumer cost savings can increase even more dramatically once the 180-day exclusivity period ends and full competition arrives. Of course, when that happens, both the brand-name and the first generic have to accept reduced profits.

So putting off the beginning of the 180-day period, and the competitive free-for-all that follows it, for as long as possible is a big win for the companies who enter into this anticompetitive scheme. But it is a big loss for consumers.

And it's not as if pay-for-delay is necessary to enable parties to settle costly patent litigation under Hatch-Waxman. If there is no payoff in exchange for delay, what the generic and the brand-name drug makers are left to negotiate over is when the generic will enter the market. If the generic drug maker is willing to agree to delay entry for X years if it gets a payment of $10 million a month while it waits, it stands to reason that it will not be willing to wait that long if it gets no money while it waits. Whatever period of delay the parties eventually agree to, it will be a shorter period without the payoff, and consumers will begin to benefit from competition sooner. The addition of the pay-off just skews the negotiations in the anticompetitive direction.

And as if those anticompetitive temptations weren't already too powerful, a drafting issue in the Hatch-Waxman Act has perversely made the incentive to agree to a payoff for delaying generic competition even harder to resist. The special 180-day exclusivity period, as interpreted by the courts, is awarded to the first generic drug for which an application is filed with the FDA, regardless of what happens after the filing. This interpretation allows the generic who is first at the filing gate to grab the 180-day exclusivity period, "park" it, take the payoff from the brand-name drug for delaying introduction of its competing alternative drug, sometimes for years, and still get the full benefit of the 180-day exclusivity period down the road.

This interpretation also makes it easier for the generic and brand-name drugmakers to make their pay-for-delay agreement succeed, because it denies the 180-day exclusivity period to other generic drug makers who might come after.

From the beginning, the Federal Trade Commission vigorously challenged pay-for-delay settlements as violating the antitrust laws, and for a number of years, that largely stopped them. But in the 2005 *Schering-Plough* decision and the 2006 *In re Tamoxifen* decision, two circuit courts, dismissed the antitrust challenge, even while readily acknowledging that the pay-for-delay settlement in question was anticompetitive. The courts reasoned that the patent underlying the settlement had to be presumed to be valid and, assuming that it was valid, the pay-for-delay settlement enjoyed the same antitrust immunity as the patent as long as it did not go beyond the scope and life of the patent.

In other words, the courts ruled that patent law principles and legal policies favoring settlements over litigation required them to look the other way, in defiance of common sense.

These court rulings threatened to give free rein to pay for delay, ignoring the obvious question: why would the brand-name drug manufacturer be willing to pay tens or even hundreds of millions of dollars to delay entry of a generic alternative when it really believes it is already protected from entry by a valid, enforceable patent?

As long as these court rulings stood, anticompetitive pay-for-delay settlements were effectively immune from legal challenge. As these settlements came roaring back into vogue, Consumers Union joined with others in calling – including in testimony before this Subcommittee in January 2007 – for a legislative solution addressing both the antitrust immunity and the 180-day exclusivity period.

The Supreme Court's Actavis Decision

We are pleased that the Supreme Court has now ruled, in *Federal Trade Commission v. Activis, Inc.*, that pay-for-delay settlements are subject to the antitrust laws, that they cannot hide behind a smokescreen of dubiously presumed patent validity. The Court's opinion does not go as far as it could have. The Court certainly had reason enough to pronounce these settlements

presumptively unlawful, to be given a "quick-look" analysis that then puts the evidentiary burden on the two drug companies to justify their anticompetitive agreement and explain, if they can, how it is somehow actually precompetitive and pro-consumer. But the opinion nevertheless goes far enough to subject these agreements to meaningful scrutiny under the antitrust laws. That's a great step forward.

And there is plenty in the Supreme Court's opinion to lead the lower courts to find most if not all pay-for-delay agreements to be in violation of the antitrust laws. Even though the Court directs that these agreements be evaluated under the rule of reason, it also notes that rule of reason analysis is not uniformly wide open, that there is a "sliding scale" of how much proof may be required. So if the lower courts follow these aspects of the Supreme Court's opinion, the end result may ultimately not be noticeably different from a quick look.

Under the best scenario, this decision can now open the way for vigorous antitrust enforcement against pay-for-delay agreements, creating a strong deterrent against them and spurring increased competition through properly directed, healthy incentives for robust development and introduction of affordable generic alternative medications.

But questions remain as to how the lower courts will apply the decision. For one thing, now that presumed patent validity is not an absolute bar to antitrust liability, will drug makers defend their pay-for-delay agreement by proving that the patent is valid, and infringed by the generic? The Supreme Court emphasizes that its opinion should not be read "to require the courts to insist, contrary to what we have said, that the Commission need litigate the patent's validity." The lower courts could decide, on that basis, that patent validity is not relevant in a pay-for delay settlement, or that there is a strong legal presumption that the patent is invalid, or not infringed, if the two companies are willing to agree to pay-for-delay. But it is not clear yet how the courts will treat that question.

And that is only one of a number of questions the lower courts will need to address, any of which could help determine how strong a deterrent this decision will ultimately create. And it will be many months, even years, before all those questions are resolved. Rule-of-reason litigation is time-consuming and costly. So while this decision provides an important and welcome opening, it is far from a complete and immediate solution to pay-for-delay.

A Role for Legislation and Continued Oversight

So there is still a beneficial role for legislation. Two bills in particular, sponsored by members of this Subcommittee, are constructive and well-considered and warrant support. They address pay-for-delay from two different angles – one strengthens the enforcement deterrent against it, the other reduces the incentive to engage in it.

The first bill, S. 214, the Preserve Access to Affordable Generics Act, amends the Federal Trade Commission Act to strengthen the antitrust enforcement deterrent against pay for delay. This bill was introduced in February, months before the Supreme Court announced its decision. But it touches on many of the same issues now confronting the lower courts in the wake of that decision.

The bill takes a measured and balanced approach. It does not conclusively deem all pay-for-delay settlements automatically anticompetitive; it makes them presumptively anticompetitive, with the opportunity for the settling parties to show that their agreement is actually pro-competitive on balance. That test is a bit stronger than the rule of reason, closer to the "quick look" advocated by the Federal Trade Commission and the Department of Justice in *Actavis*. But as we note above, in light of the guidance given by the Supreme Court, the two tests may not be very different in practice. And the factors set forth in the bill are consistent with those identified by the Supreme Court as important.

The bill would thus establish a structure for enforcing the antitrust laws against pay-for-delay settlements very close to what the Federal Trade Commission and others have been advocating, and essentially consistent with the Supreme Court's guidance. Furthermore, the Federal Trade Commission has made clear that it intends to continue its vigorous enforcement in this area. But even assuming the lower courts adopt every aspect of the structure set forth in the bill, it will likely take years to get there definitively. So supporting this legislation could hasten the establishment of a clear and strong antitrust deterrent.

The second bill, S. 504, the Fair and Immediate Release of Generic Drugs Act, amends the Hatch-Waxman Act to reduce the incentive to delay for pay. This bill targets the 180-day exclusivity period as it has been interpreted by the courts. Under this bill, the first-to-file generic drug maker would share exclusivity with other generic drug makers who successfully complete the application process and resolve the patent issues in time to enter the market during that period.

Furthermore, under this bill any generic drug maker who agrees to a delayed entry date in exchange for payment or other consideration does so at considerable risk, as it would now be held to that date. It will no longer be able to "accelerate" its entry if another generic drug maker qualifies and prepared to enter the market, as it can under current law; instead, it will now be required to wait until either that agreed-upon delayed entry date, or until after the other qualifying generic has enjoyed its full 180-day exclusivity period, whichever comes first. By then, there could be several competing generics in the market ahead of it.

The combination of these two changes could neutralize the anticompetitive incentive to grab the 180-day exclusivity period and "park" it as part of a pay-for-delay settlement. The exclusivity period would then be able to fulfill its intended purpose, as a true reward for bringing a cost-saving generic alternative *on* the market *sooner*, not a bargaining chip to be used to keep all generic alternatives *off* the market until *later*.

And to the extent these changes could result in more than one generic sharing in the 180-day exclusivity period, that would further hasten the day when consumers benefit from even more competition.

Competitive development of affordable generic alternatives has suffered from too much incentive to stall competition, and from too little countervailing deterrence in the way of antitrust enforcement. Both sides of the problem need to be addressed. Both of these bills would make significant improvements.

It may also be time to revisit other well-intentioned incentives created 30 years ago by the Hatch-Waxman Act, and consider whether they are now creating unintended anticompetitive side effects that outweigh any continued usefulness for innovation. For example, the brand-name drug maker can automatically delay generic entry for 30 months by suing a generic challenger for patent infringement.– even after having previously settled with another generic challenger. These special incentives may well have been useful in an era of fledgling start-up generic pioneers. With today's generic drug industry populated by large, well-established companies, it is time to reconsider whether they still make sense for competition and consumers.

Finally, while there are important generic drugs in the development pipeline, and there will continue to be new drugs for which generic alternatives can be developed, we also need to pay attention to biologic drugs. These drugs, created by biological processes rather than chemical synthesis, are becoming increasingly important for the future. Biologic drugs are not covered by Hatch-Waxman; but Congress established an analogous process for approving alternatives, known as biosimilars, in the Biologics Price Competition and Innovation Act of 2009, also referred to as the Biosimilars Act, which was enacted as part of the Patient Protection and Affordable Care Act. We are concerned that the same kinds of incentives and opportunities for pay-for-delay settlements are present here as with generics, and we urge this Subcommittee to keep a watchful eye in this area as well.

Conclusion

Thank you again for calling this hearing on an issue of great importance to consumers, and for giving us the opportunity to present our views.