

**H.R. 1706, THE PROTECTING CONSUMER ACCESS
TO GENERIC DRUGS ACT OF 2009**

HEARING
BEFORE THE
SUBCOMMITTEE ON COMMERCE, TRADE,
AND CONSUMER PROTECTION
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED ELEVENTH CONGRESS

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**H.R. 1706, THE PROTECTING CONSUMER
ACCESS TO GENERIC DRUGS ACT OF 2009**

TUESDAY, MARCH 31, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCE, TRADE,
AND CONSUMER PROTECTION,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 11:12 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Bobby L. Rush (chairman) presiding.

Members present: Rush, Schakowsky, Sarbanes, Sutton, Stupak, Barrow, Space, Dingell, Waxman (ex officio), Radanovich, Stearns, Whitfield, Pitts, Terry, Gingrey, Scalise, and Barton (ex officio).

Staff present: Christian Tamotsu Fjeld, Counsel; Anna Laitin, Professional Staff; Michelle Ash, Counsel; Valerie Baron, Legislative Clerk; Shannon Weinberg, Minority Counsel; Will Carty, Minority Professional Staff; and Brian McCullough, Minority Senior Professional Staff.

OPENING STATEMENT OF HON. BOBBY L. RUSH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. RUSH. Good morning, everyone. I want to thank you for coming to today's hearing. I will begin this hearing by recognizing myself for 5 minutes for the purposes of an opening statement. This hearing is on the bill H.R. 1706, Protecting Consumer Access to Generic Drug Act of 2009.

Today's legislative hearing is on a bill that Chairman Waxman and I introduced last Congress, and this subcommittee held a legislative hearing on our bill on May 2, 2007. We have introduced the bill again with the intent that it becomes law. H.R. 1706 bans what are known as exclusion payments, reverse payments or reverse consideration in patent settlements between name brand and generic drug companies. This is a practice in which the brand name company pays or provides value to the generic company, and the generic company agrees to delay the marketing of its generic drug product.

First the bill is fully supported on a bipartisan basis by the FTC. The commission believes that a legislative fix is needed because the courts have thwarted their enforcement efforts. Both Republican and Democratic chairman and commissioners have historically supported congressional action cracking down on these uncompetitive settlements. This is not a partisan issue.

Second, the bill does not ban all settlements in all patent cases. Quite the contrary. H.R. 1706 only bans exclusion payments and legal settlements. Brand name and generic companies are still free to settle their differences. In fact, before the court invalidated the FTC's enforcement efforts, drug companies were selling their patent disputes without any exclusion payments. It wasn't until the courts struck down the FTC's enforcement action in 2005 that these very unique type of settlements came back from the dead.

Third, these types of settlements were completely unique to the drug industry. They do not appear in any kind of patent dispute other than this drug industry. In all other patent disputes, the litigants settle in two ways. One, they enforce or the accused pays a patent holder a royalty to market its products. Or two, the parties agree to an early entry date.

Only in the drug industry do we see the unusual behavior of a patent holder, which is the brand name company, suing the accused infringer, the generic company, and then settle by paying the infringer to stay off the market. These unique settlements are the result of the equally unique regulatory framework of Hatch-Waxman.

I don't believe that the drug companies are acting in bad faith. I believe that they are perfectly logical under their fiduciary duty to their shareholders. They are being responsible, and they are simply responding to the incentives they face under Hatch-Waxman.

Lastly, H.R. 1706 will save taxpayers, businesses, and consumers tens of billions of dollars. That is the ultimate purpose of this bill. Congress is currently considering ways to save money in order to provide affordable health insurance to all Americans. I believe that H.R. 1706 can play an important role in reducing prescription drugs costs in our economy.

We cannot afford to do nothing on this unique uncompetitive way of doing business that costs consumers millions of dollars. I want to thank our witnesses for appearing before this committee in this first step in the legislative process.

[The prepared statement of Mr. Rush follows:]

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FOR IMMEDIATE RELEASE
March 31, 2009

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**Statement by the Honorable Bobby L. Rush, Chairman
Subcommittee on Commerce, Trade and Consumer Protection
for Legislative Hearing on
H.R. 1706, the Protecting Consumer Access to
Generic Drugs Act of 2009**

March 31, 2009

WASHINGTON, DC — “The subcommittee will come to order. Today’s legislative hearing is on H.R. 1706, the Protecting Consumer Access to Generic Drugs Act of 2009.

“Chairman Waxman and I introduced this bill in the last Congress and the subcommittee held a legislative hearing on May 2, 2007. We have introduced the bill, again, with the intent that it becomes law. H.R. 1706 bans what are known as “exclusion payments,” “reverse payments” or “reverse consideration” in patent settlements between brand-name and generic drug companies. This is a practice in which the brand-name company pays or provides value to the generic company, and the generic company agrees to delay the marketing of its generic drug product.

“The bill is opposed by both PhRMA and most generic companies. The fact that both innovator and generic companies oppose the bill is striking, because brand-name and generic companies are not supposed to agree on anything. Under the regulatory structure of Hatch-Waxman, generic companies are supposed to aggressively challenge the patents of brand-name drug companies in order to bring their products to the market. If they settle, they are supposed to settle by agreeing to an early entry date, not by agreeing to delay entry into the market. Unfortunately, the intent of Hatch-Waxman is being undermined by these uncompetitive legal settlements and consumers are losing out on the considerable savings from generic drugs.

“I want to emphasize several important points in this bill:

“First, the bill is fully supported, on a bipartisan basis, by the Federal Trade Commission. The

- more -

Commission believes a legislative fix is needed, because the courts have thwarted their enforcement efforts. Both Republican and Democratic Chairmen and Commissioners have historically supported Congressional action cracking down on these uncompetitive settlements. This is not a partisan issue.

“Second, the bill does NOT ban all settlements in drug patent cases. Quite the contrary. H.R. 1706 only bans exclusion payments in legal settlements. Brand name and generic companies are still free to settle their disputes. In fact, before the courts invalidated the FTC’s enforcement efforts, drug companies were settling their patent disputes without any exclusion payments. It wasn’t until the court struck down FTC’s enforcement actions in 2005 that these very unique types of settlements came back from the dead.

“Third, these types of settlements are completely unique to the drug industry. They do not appear in any other kind of patent dispute. In all other patent disputes, litigants settle in two ways: (1) the accused infringer pays the patent holder a royalty to market its product, or (2) the parties agree to an early entry date. Only in the drug industry do we see the unusual behavior of a patent holder (the brand name company) suing the accused infringer (the generic company) and then settling *by paying the infringer to stay off the market*. These unique settlements are the result of the equally unique regulatory framework of Hatch-Waxman. I don’t believe that drug companies are acting in bad faith. I believe they are being perfectly logical under their fiduciary duties to their shareholders, and are simply responding to the incentives they face under Hatch-Waxman.

“Lastly, H.R. 1706 will save taxpayers, businesses, and consumers tens of billions of dollars. That is the ultimate purpose of this bill. Congress is currently considering ways to save money as a means to provide affordable health insurance to all Americans. I believe H.R. 1706 can play an important role in reducing prescription drug costs in our economy. We cannot afford to do nothing on these unique, uncompetitive settlements that cost consumers billions of dollars.

“I want to thank all of our witnesses for appearing today in what is the first step of the legislative process. I look forward to an honest, civil and robust discussion and debate. We may not ultimately come to agreement, but I want to emphasize that I am committed to an open dialogue and to further discussion on how we can improve the legislation.

“I yield back the balance of my time.”

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Mr. RUSH. And I will now yield back the balance of my time, and now I want to recognize the ranking member of this subcommittee, my friend Mr. Stearns from Florida.

OPENING STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. STEARNS. Good morning, and thank you, Mr. Chairman. I am glad we are having this hearing on H.R. 1706, Protecting Consumers' Access to Generic Drugs Act. On this side of the aisle we perhaps see this bill a little differently. We see it as a solution looking for a problem. The Hatch-Waxman Act of 1984 we think is working, and we are not sure. Maybe a little bit of steering might be implied but not necessarily eliminating with a brand new bill with this H.R. 1706.

You know when you look at the history of the availability of generic drugs over the past 25 years, which have helped millions of people live healthier lives and most importantly reduce the cost of health care, in the face of ever increasing health care costs for families, I asked my staff to pull up some statistics. And since the Hatch-Waxman passage, the generic industry share of the prescription drug market has jumped from around 19 percent to over 70 percent today. So again I say let us be careful. Do no harm.

It is clear that the Hatch-Waxman Act and current practices have been successful in bringing low-cost alternatives to families and to the market. So I do have a few concerns which I will outline here. This bill addresses two facets of the generic pharmaceutical trade: reverse-payment settlement, which I am going to use the word payment settlement. I notice the chairman used the words exclusion payments and reverse payments, but I think the actual term which is payment settlements. And the other issue is the 180-day exclusivity period granted to first filers under the Hatch-Waxman Act.

This latter consideration is really there as a incentive for generic drugs who take the risk to sue. So I am not sure that it should be changed. Now, opponents of the payment settlement argue that this practice delays the introduction of generic drugs to market and permit drug innovators to continue their patent protection and market exclusivity, even if it is for a shorter period of time than the patent allows.

In reality though, the opposite is true. These settlements often bring drugs to market sooner than would otherwise be permitted by the completion of the brand drug's patents.

Critics also argue these settlements encourage patent challengers to abandon their claims in litigation when an alleged 70 to 80 percent of challenges succeed. This statistic can be misleading and does not take into account that while a challenger may win on four out of five claims, it is the invalidation of just one of those challenges that is necessary to prevent the launch of a generic drug.

Now, according to recent studies, the success rate of challenges that lead to the early introduction of a generic drug is actually closer to 45 percent, not the 70 percent that people talk about. Furthermore, patent litigation is expensive, unpredictable, and can last for many years. The emphasis in patent litigation, as in any other litigation area, is to settle. In many cases, it is a win-win situation.

The brand company wins by saving money on protecting its patent. The generic company wins by saving money on litigation expenses and gaining earlier market entry. And the consumer wins with early access to a less expensive generic product.

Now, unfortunately this legislation that we are talking about this morning would outlaw anything of value to be exchanged in a patent settlement. Therefore, an innovative drug company would have no incentive to do anything but defend its patent until expiration, inadvertently creating a chilling effect on early generic drugs introductions which the consumers would enjoy.

Given this reality, generic companies could be discouraged from investing capital in patent prosecutions until it is assured of a success, a virtual impossibility in any patent litigation scenario. If longer, drawn-out litigation was not enough of a disincentive to challenge a patent, eliminating a generic company's ability to recover its litigation costs to the 180-day exclusivity period is enough to put the final nail in the casket of generic challenges.

As a carrot to encourage patent challenges, the Hatch-Waxman Act provides the first filer 180 days of exclusivity as the only generic drug permitted on the market, simply enabling a successful generic company challenger to recoup its significant litigation costs. It is this reward that encourages the risk of challenging a patent. If this exclusivity is no longer granted, the result will be the opposite of what this bill intends. Fewer drugs patients will be challenged, and consumers will have to wait much longer until patents expire or litigation come to conclusion before cheaper generic drugs can be made available.

So I look forward to the testimony of our witnesses today, and thank you again, Mr. Chairman, for having this hearing.

Mr. RUSH. The chair thanks the gentleman. The chair now recognizes the chairman of the full committee, the gentleman from California, Mr. Waxman, for five minutes for the purposes of opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I want to thank you for holding this important hearing. This year is the 25th anniversary of the Drug Price Competition and Patent Term Restoration Act, commonly known as Hatch-Waxman or Waxman-Hatch, and that law established our generic drug approval system.

Generic drugs play a critical role in promoting public health where they are available. They promote competition, which in turn lowers prices. Lowering drug prices reduces overall health care bills. More importantly though, lower drug prices mean access to important medications for many patients who might not otherwise be able to afford them.

Today in the U.S. a remarkable 67 percent of prescriptions are filled with generic medicines, saving consumers and the federal and state governments tens of billion dollars annually. Unfortunately in recent years, we have seen that the vibrant competition we envisioned has not flourished as well as we had hoped.

The Federal Trade Commission has highlighted a significant cause of this problem. Generic and brand name drug companies have increasingly been entering into patent settlement agreements that have an anti-competitive effect. These settlement arrangements frequently involve agreements in which the generic drug makers stay out of the market in exchange for some form of compensation from the brand-name drug makers.

These settlements are beneficial to both the brand-name company and the generic challenger. The brand gets additional time to sell its drug at monopoly prices. The generic gets payments without any need to make or market the drug. Both the brand and generic firms profit, but they do so at the expense of the consumers who must continue to pay monopoly prices. This is the last thing Congress intended when we enacted Waxman-Hatch.

The law was intended to give consumers access to generics at the earliest possible opportunity, not to line the pockets of generic and brand-name drug companies. Some courts have erroneously concluded that these agreements were condoned by Hatch-Waxman. These courts are sorely mistaken. The use of our law to prevent generic competition is contrary to intent of that law.

Now Congress must act to prevent the continued erosion of these principles, the Protecting Consumer Access to Generic Drugs Act of 2009, the bill under discussion today, is a sensible solution that will help put an end to the practice of paying generic drug companies to stay out of the market. I recognize we need to proceed with care. Some patent settlement agreements can provide benefits across the board. Settlements can allow the parties involved to avoid expensive protracted litigation. Consumers can sometimes gain access to generic drugs that might otherwise have been deferred by litigation.

This legislation recognizes that reality and permits settlements in which nothing more than the date of entry is negotiated. And if FTC decides that other exceptions need to be made to enhance competition and benefit consumers, then FTC can implement those changes through rule making.

In effect, it is designed to rid us of the bad settlements and leave us with the good ones. I look forward to the testimony of the witnesses today and working with all the members of the committee to get this bill enacted into law. Thank you, Mr. Chairman.

[The prepared statement of Mr. Waxman follows:]

HENRY A. WAXMAN, CALIFORNIA
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Opening Statement of Rep. Henry A. Waxman
Chairman, Committee on Energy and Commerce
H.R. 1706, Protecting Consumer Access to
Generic Drugs Act of 2009
Subcommittee on Commerce, Trade, and Consumer Protection
March 31, 2009

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I want to thank Chairman Rush for holding this very important hearing.

This year is the 25th anniversary of the Drug Price Competition and Patent Term Restoration Act — commonly known as Hatch-Waxman, or Waxman-Hatch. That law established our generic drug approval system.

Generic drugs play a critical role in promoting public health. Where they are available, they promote competition — which in turn lowers drug prices. Lowering drug prices reduces overall health care bills. More importantly though, lower drug prices mean access to important medications for many patients who might not otherwise be able to afford them. Today in the U.S., a remarkable 67% of prescriptions are filled with generic medicines — saving consumers and the federal and state governments tens of billions of dollars annually.

Unfortunately, in recent years, we have seen that the vibrant competition we envisioned has not flourished as well as we had hoped.

The Federal Trade Commission has highlighted a significant cause of this problem: generic and brand name drug companies have increasingly been entering into patent settlement agreements that have an anti-competitive effect. These settlement arrangements frequently involve agreements in which the generic drug makers stay out of the market in exchange for some form of compensation from the brand-name drug makers.

These settlements are beneficial to both the brand name company and the generic challenger. The brand gets additional time to sell its drug at monopoly prices. The generic gets payments without any need to make or market the drug. Both the brand and generic firms profit at the expense of the consumer who must continue to pay monopoly prices.

This is the last thing Congress intended when we enacted Waxman-Hatch. The law was intended to give consumers access to generics at the earliest possible opportunity, not to line the pockets of generic and brand name drug companies.

Some courts have erroneously concluded that these agreements were condoned by Hatch-Waxman. Those courts are sorely mistaken. The use of Hatch-Waxman to prevent generic competition is contrary to the intent of the law.

Now, Congress must act to prevent the continued erosion of the principles of Hatch-Waxman.

The Protecting Consumer Access to Generic Drugs Act of 2009, the bill under discussion today, is a sensible solution that will help put an end to the practice of paying generic drug companies to stay out of the market.

I recognize that we need to proceed with care. Some patent settlement agreements can provide benefits across the board. Settlements can allow the parties involved to avoid the expense of protracted litigation. Consumers can sometimes gain access to generic drugs that might otherwise have been deferred by litigation. This legislation recognizes that reality and permits settlements in which nothing more than the date of entry is negotiated. And if FTC decides that other exceptions need to be made to enhance competition and benefit consumers, then FTC can implement those changes through rulemaking.

In effect, it is designed to rid us of the “bad” settlements and leave us with the “good” ones.

I look forward to the testimony of the witnesses today and to working with all of you to get this bill enacted into law.

Mr. RUSH. The chair thanks the chairman of the full committee. Now the chair recognizes the gentleman from Kentucky, Mr. Whitfield, for the purposes of opening statement for 2 minutes.

Mr. WHITFIELD. Mr. Chairman, thank you very much. We look forward to this hearing on H.R. 1706, Protecting Consumer Access to Generic Drugs Act. I think this legislation has the very best intents, and obviously we want to protect all sides in this debate. We want to be sure that innovative drug companies continue to spend money and research and developments come through with drugs that help curtail disease. We also want the consumer to be able to get generic drugs as soon as possible at a less cost to improve health care.

And one of the issues that I am going to be interested in today is that it was my understanding that in all the legal actions filed by the FTC about these exclusion agreements that they had lost all of the lawsuits. But then in reading the memorandum, I see that in the Sixth Circuit Court of Appeals held that such agreements are per se violations of the Federal Anti-Trust Law. But in the Second and the Eleventh Circuit Court of Appeals, they have ruled that agreements do not violate anti-trust laws and merely reflect the give and take of legal settlements.

So I hope that as we proceed with our witnesses today that we can certainly get some clarification on that issue as well as others. And I yield back the balance of my time.

Mr. RUSH. The chair thanks the gentleman. The chair now recognizes the gentleman from Maryland, Mr. Sarbanes, for 2 minutes for the purposes of opening statements.

Mr. SARBANES. Thank you, Mr. Chairman. I am looking forward to the testimony today and anxious to see this proposal move forward, which I think is a very common sense solution to the distortion in the regime that has occurred as a result of the court conclusion that the FTC didn't have authority to regulate here and tries to remedy that.

It is particularly important as we embark on looking at how to apply similar regimes to other arenas, which of course is a discussion that is going on now, we got to make sure we fix this one. Businesses and lawyers are clever in finding ways to get around impediments. That is what they have done here. And to use the vernacular, we just need to be cleverer and try to fix this. And that is what this legislation intends to do.

So I look forward to the discussion today, and I yield back my time.

Mr. RUSH. The chair thanks the gentleman from Maryland. It is my pleasure to allow Mr. Pitts from Florida—I am sorry, from Pennsylvania to allocate 2 minutes to him for the purposes of opening statement.

Mr. PITTS. Thank you, Mr. Chairman. I would like to thank you for convening a hearing on this bill. I think we all agree that our goal should be to make generic drugs available to the consumers who need them. I am somewhat concerned that the legislation will have a chilling effect on patent challenges by generic drug companies resulting in longer waiting periods for generic drugs for consumers who depend on them.

This bill would place a total ban on all patent settlements in which the company that holds the patent on the brand-name drug gives anything of value to the generic company challenging the patent except for an early entry date into the market. What will the results be? With no incentive to settle, cases will be litigated to the very end as brand drug companies fight to hold onto their authorized monopoly on the drug, the only way they have to recoup the millions of dollars they have put into developing and testing new drugs.

With millions of dollars of legal fees on the line, generic companies will only challenge a patent if they are virtually assured of a successful outcome. This goes completely against the incentives for generics to challenge patents that are built into Hatch-Waxman.

Finally, since 2003, Congress has required that litigants notify federal anti-trust authorities of their pharmaceutical patent settlements. DOJ and FTC are already notified of all patent settlements, and they can sue if they believe the outcome of a case is anti-competitive.

FTC has filed suit in a number of cases, and in the vast majority, the courts have found these settlements acceptable and refused to strike them down. So, Mr. Chairman, the system is working. These settlements should be reviewed on a case-by-case basis, and to ban these settlements will only keep generics off the market for a longer period of time, hardly a pro-consumer outcome.

I would like to thank all of our witnesses for coming to testify today, and I yield back the balance of my time.

Mr. RUSH. The chair thanks the gentleman. The chair now will recognize the chairman emeritus of the full committee, my friend from Houston, Mr. Dingell, for 5 minutes for the purpose of an opening statement.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, thank you, and I want to commend you for your leadership and for holding this hearing. At issue before the committee today is the very fundamental question of fairness. Should pharmaceutical companies be able to continue to enjoy the right to collude the legal settlements in order to stifle consumer access to generic drugs?

As the cost of health care continues to increase, mainly due to the cost of drugs, we must dispose of this question with a view towards providing consumers with a greater choice and lower prices while at the same time preserving for the industry the inviolability of intellectual property rights for manufacturers of pharmaceuticals.

At the root of this debate lie the Hatch-Waxman's amendments to the Federal Food, Drug, and Cosmetic Act, whose intent it is to promote the aggressive entry of generic drugs into the marketplace to benefit consumers. Curiously, this has not occurred. This intent has been undermined of late by the growing practices of the pharmaceutical industry in settling patent disputes by the so-called practice of "exclusion payments" in which a patent holder pays a

generic challenger in exchange for delay in the generic drug's entry into the market.

Who gets screwed here? The consumer. In my view, should a generic challenger prove its product does not infringe upon the patent held by a brand-name pharmaceutical manufacturer secretive agreements of a legal character between private parties should not prevent the generic drug's introduction into commerce.

Clearly this goes well against the intent of the committee and the Congress when we passed Hatch-Waxman. This in mind, the exclusion payments strike me as a counter to the interests of consumers and more pointedly, an unfair method of competition, which would otherwise be prohibited under section five of the Trade Commission Act.

At this juncture, I would like to note that prohibiting exclusion payments may have a beneficial effect for state budgets and indeed for the federal government because the budget of Medicare, Medicaid and S-CHIP roles are going to be stressed by both the depression that we now undergo and the awful situation we confront of the increased need of people from groups that were formerly benefited by health coverage which they had lost. So we have a very serious problem of widespread economic displacement that is increasing these costs.

By acting proscribed uncompetitive practices like exclusion payments, we could reduce the strain on the states of providing their citizens with health care, something which I believe is a fundamental right of all Americans. I look forward to working with you, Mr. Chairman, to seeing this legislation through and to make it become law. And I urge my colleagues to be of assistance in this great undertaking. Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. RUSH. The chair thanks the chairman emeritus. And now it is my pleasure to recognize the gentleman from Nebraska. I am sorry—recognize my friend—I didn't see him down there—my friend from Texas, the ranking member of the full committee, Mr. Barton, for 5 minutes for an opening statement.

**OPENING STATEMENT OF HON. JOE BARTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BARTON. Thank you, Mr. Chairman, and I look forward to the day we have a hearing on your bill and my bill to reform the BCS football championship series.

Mr. RUSH. Will the gentleman yield for a moment?

Mr. BARTON. I would be happy to yield.

Mr. RUSH. I talked about our bill this morning. I want you to know.

Mr. BARTON. Very good. Well, the Senate is beginning to steal our thunder, Mr. Chairman, so we—

Mr. RUSH. We can't let that happen.

Mr. BARTON [continuing]. Don't let that happen.

Mr. RUSH. They wouldn't know what to do with it.

Mr. BARTON. But I do want to thank you, Mr. Chairman, for this hearing on generic drugs, which is part of this committee and this subcommittee's jurisdiction. Access to lower cost drugs has not only helped Americans beat diseases, it has been a boon for health care

in a world that depends on the drugs that we, the United States, manufacture. We need to recognize that it won't be all good news if we don't weigh the pros and cons of generics competing with brand names.

Sick people depend on affordable drugs, but they also depend on innovation and research to create the drugs that they need. Without adequate reward, innovation fades, research declines, and life-saving medicine doesn't happen. The framers got it right in Article 1, Section 8 of the Constitution, and I quote "promote the progress of science by securing for a limited time the exclusive right to discoveries." We should heed Section 8. It has worked well for over 200 years.

American innovation is a cornerstone of intellectual property rights, and we need to ensure that our domestic industry continues to get the benefits of these property rights, especially in dealing with our trading partners overseas.

Pharmaceutical companies should have the opportunity to pursue constitutionally protected inventions. We should not diminish the incentive to undertake the substantial risk involved. As everybody here knows, the risk associated with new drug approvals are significant. First comes the R&D component, followed by a lengthy FDA approval process, both of which require large amounts of money, which may not be recouped if the R&D falters or the FDA approval doesn't happen. At no point does anybody guarantee any drug innovator that the competition won't invent a similar drug first and get to the market first.

I believe that when a new drug successfully makes it to market, we need to provide the innovator with intellectual property protection. It is important to get the balance right. In that spirit, Congress has always recognized the necessity of providing these protections. We have also recognized obviously the benefits of generic drug competition in the marketplace, which lowers cost and increases access.

Congress made the wise decision 20 years ago when we passed Hatch-Waxman. I started to say Waxman-Hatch. I have always supported this concept of providing a balanced incentive for both sides of the industry because it works. Inevitably, however, patent disputes arise between generic firms and brand manufacturers. Litigation can and often does take years to reach a final verdict.

However, both sides decide sometimes to settle a case when the outcome isn't certain and the parties have a negotiated settlement based on the possible benefits and the probabilities of winning the case outright. To be very clear, consumers should have the best drugs available at the cheapest possible price. But I think the best way to achieve that is to provide innovators with their strong intellectual property protection while providing a clear path for generics to enter the market.

I have a serious concern about imposing a ban on the exchange of anything of value in a private patent litigation settlement. Limiting the options of private litigants to settle out of court should be avoided if at all possible. The right to depend or challenge patents should be preserved.

Unfortunately, Mr. Chairman, I think the bill that you have introduced, H.R. 1706, would remove incentives parties have to set-

tle, could force many more cases into lengthy litigation where years may elapse before a decision is reached.

Forcing drug companies down this path probably would erode any benefit to the consumer. Since the FTC seems to me to have adequate authority to challenge these improper settlements in court, I am anxious to hear from the witnesses as to why the judicial system is not the appropriate venue to resolve these issues.

Finally, Mr. Chairman, as I said almost two years ago at our last hearing on this issue, I am very interested in the economics of the industry and whether changing the structure of incentives and rewards, including some of the changes contemplated by your bill, will ultimately benefit consumers in the long run.

I want to hear from the witnesses their views of this issue and also whether they feel that there are anti-trust concerns with these settlements, given the fact that the courts and the federal anti-trust authorities don't seem to agree on the issue.

But in any event, Mr. Chairman, this is an important hearing. I am very pleased that you are holding it, and I look forward to hearing from the witnesses and also the questions from our distinguished members of the subcommittee. And I yield back.

Mr. RUSH. The chair thanks the ranking member, and now it is my pleasure to recognize the gentleman from Michigan, Mr. Stupak, for 2 minutes for the purposes of an opening statement.

Mr. STUPAK. Mr. Chairman, I am supportive of the bill, and I will waive my 2 minutes. And I will ask that it be added on for questioning later.

Mr. RUSH. The chair thanks the gentleman. Now, the chair recognizes my friend from Ohio, Mr. Space, for 2 minutes for the purposes of an opening statement.

Mr. SPACE. Thank you, Mr. Chairman, for holding this important hearing on an issue that, at its core, is designed to provide inexpensive and effective prescriptive medications to the people that we serve.

I think in addressing this issue, like so many other issues that affect the pharmaceutical world, we have to walk a delicate line between fostering innovation and providing inexpensive access to constituents. Particularly the latter issue becomes important in light of the fact that so many people are hurting financially right now and actually making conscious decisions between purchasing prescription medication and buying food.

I hope that we will consider these issues of intellectual property and patent settlements in a very deliberate process, being very careful and mindful to maintain that balance between fostering innovation while protecting consumers. And I am hopeful that today's testimony will shed some important light on this topic. I yield back.

Mr. RUSH. The chair thanks the gentleman. Now for the second time now the chair recognizes the gentleman from Nebraska, Mr. Terry, for 2 minutes for the purposes of opening statement.

Mr. TERRY. Well, I appreciate you asking me twice.

Mr. RUSH. I am trying to get to you.

Mr. TERRY. I will waive.

Mr. RUSH. All right, the chair thanks the gentleman. Now it is my pleasure to recognize the gentleman from Louisiana, Mr. Scalise, for 2 minutes for the purposes of an opening statement.

Mr. SCALISE. Thank you, Mr. Chairman. I will waive as well and hold that time for questioning.

Mr. RUSH. Well, we thank you. Now, it is my pleasure to recognize the gentleman from Georgia, Mr. Gingrey—Dr. Gingrey for 2 minutes for the purposes of an opening statement.

Mr. GINGREY. Mr. Chairman, the third time is the charm. I want to thank you for calling this hearing today on H.R. 1706, The Protecting Consumer Access to Generic Drugs Act of 2009. I believe that it goes without saying how valuable generic drugs have been for consumers in the prescription drug market. And this hearing will pick up where the subcommittee left this issue back in 2007 when I was not a member.

As a physician for nearly 30 years and a member of this health subcommittee, I know that access to generic drugs provides proven medical remedies and improvements to the quality of life and often at a much lower cost. As this subcommittee examines such an important issue for consumers across the country, we must act in a way that preserves and bolsters access to generic drugs.

However, Mr. Chairman, despite the intent of H.R. 1706 to expedite the process by which generic drugs get to the consumer, I am concerned that this legislation may indeed have unintended consequences causing consumers to wait even longer to get access to generic versions of brand-name drugs. At the very heart of this legislation is the legitimacy of an out-of-court settlement between a drug company holding a patent on a drug and one seeking to create the generic version.

Mr. Chairman, patent law in this area is very unique. When companies are able to settle their disputes out of court, consumers are the ultimate winners. Unfortunately H.R. 1706 would prohibit the practice, thus reducing the incentive for a generic company to take on financial burden of challenging patents and potentially delaying some generics from actually coming to the market.

Mr. Chairman, for the sake of all health care consumers, I urge we use the utmost caution and care as we move forward on this legislation. I certainly look forward to hearing the thoughts of our panel this morning on such an important issue, and I yield back the remaining 30 seconds.

Mr. RUSH. The chair thanks the gentleman. Now, the chair recognizes my friend from Georgia, Mr. Barrow, for 2 minutes for the purposes of an opening statement.

Mr. BARROW. I thank the chair. In the interest of time, I will waive an opening.

Mr. RUSH. Thank you very much. Now the chair recognizes my friend from Illinois, Ms. Schakowsky, the vice chair of the subcommittee for 2 minutes for the purposes of an opening statement.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I am an original cosponsor of H.R. 1706, the Protecting Consumer Access to Generic Drugs Act of 2009, because I believe that the availability of generic drugs is a critical component to lowering health care costs for the consumer, for businesses, for the taxpayer.

The legislation would prohibit patent settlements in which a brand-name drug maker pays off a generic drug maker to prevent the generic medicine from entering the market. These payments are known as reverse or exclusion payments, and it strikes me as

incredibly disingenuous that those who would tout the importance of free markets and competition would also take exclusive action to prevent fair competition in the case of necessary and sometimes lifesaving prescription medications.

Settlements that include exclusion payments may be good for the brand-name manufacturer that gets to keep its monopoly, and it may be a good thing for the generic company that gets paid not to produce a drug, but such settlements are a bad deal for consumers.

My state of Illinois has joined others in successfully taking on anti-trust actions by brand-name drug companies. In 2003, Illinois was part of a multi-state settlement of an action against Aventis for entering into an exclusion payment settlement with a generic challenger which delayed competition with its heart drug Cardizem.

However, the Cardizem case predated recent circuit court decisions that have made it more difficult for anti-trust enforcers to challenge reverse payments. The case which garnered millions of dollars for Illinois consumers might not have been successful in the current environment.

According to a 2004 FDA analysis, the average patient taking several medications could save 14 to 16 percent on drug costs if they can replace some of their prescriptions with generics. If they were taking medications that could be completely replaced with generics, their prescription drug costs could be reduced by 52 percent.

I think that ensuring lower cost generics on the market is a key component of reigning in health care spending, and I believe that setting the bar any lower would be irresponsible on the part of this Congress. Thank you, Mr. Chairman.

Mr. RUSH. The chair thanks the gentlelady. Now, the chair wants to exercise a moment of personal privilege this morning by recognizing the chairman of the Federal Trade Commission who has come here to be with us this morning. I am not sure, Mr. Chairman, how long you will be able to stay, but you are always welcome here. We want you to know any time you want to drop in, just drop in, all right. Mr. John Lebowitz is recognized. We thank you so much for your presence.

And now we would like to welcome our expert and esteemed panel that have come. I want you to know that you are the finest panel that have ever assembled before us this morning, all right. And we recognize you so much, and we thank you so much for being here with us.

I want to recognize from my left to right, beginning with the Honorable J. Thomas Rosch, who is the commissioner of the Federal Trade Commission. And I want to recognize you, Commissioner Rosch. I think that is how you pronounce your last name. Thank you so much.

Next to him is Mr. Scott Hemphill, who is an associate professor of law at Columbia University. Welcome, Mr. Hemphill. Next to Mr. Hemphill will be Ms. Joanne Handy. She is a board member of an organization I just recently joined, AARP. Welcome, Ms. Handy.

Next to her is Ms. Diane Bieri. She is a general counsel for PhRMA. Welcome, Ms. Bieri. And next to Ms. Bieri is Dr. Barry

Sherman, who is a chief executive officer for Apotex Incorporated. Dr. Sherman, you have been here before and you are familiar. And we welcome you once again.

And next to Dr. Sherman is Mr. Ted Whitehouse of the firm Willkie Farr and Gallagher, who has been before the committee before. And he is here on behalf of Teva Pharmaceuticals. We certainly want to again welcome each and every one of you and thank you for taking out moments of your important day to be here with us.

And now we will recognize Commissioner Rosch for 5 minutes for the purposes of an opening statement.

STATEMENTS OF J. THOMAS ROSCH, COMMISSIONER, FEDERAL TRADE COMMISSION; SCOTT HEMPHILL, ASSOCIATE PROFESSOR OF LAW, COLUMBIA UNIVERSITY; JOANNE HANDY, BOARD MEMBER, AARP; DIANE BIERI, GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; BARRY SHERMAN, CHIEF EXECUTIVE OFFICER, APOTEX, INC.; AND TED WHITEHOUSE, WILLKIE FARR AND GALLAGHER, ON BEHALF OF TEVA PHARMACEUTICALS

STATEMENT OF J. THOMAS ROSCH

Mr. ROSCH. Thank you, Chairman Rosch, Congressman Stearns, and members of the subcommittee.

Mr. RUSH. Turn the mike on please. Pull it closer to you.

Mr. ROSCH. OK, I appreciate the chance to appear before you today. The written statement that we submitted represents the views of the commission as a whole. My oral testimony is my own, and it doesn't necessarily reflect the views of any other commissioner.

There are several compelling reasons why it is imperative that Congress enact legislation in this area. Reverse payment agreements strike at the heart of the special statutory framework Congress created in the Hatch-Waxman Act. That framework was designed to balance two policy goals that are critically important to the pharmaceutical industry.

Hatch-Waxman gave branded companies a longer patent life. The tradeoff was the generic companies were given a strong incentive to challenge questionable brand patents and start competing with the branded companies if they win. And that tradeoff was 180 days of generic exclusivity. In that way, generic companies were supposed to protect consumers from unwarranted patent monopoly pricing by branded companies.

But reverse payment settlements frustrate the purpose of Hatch-Waxman in two ways. First, the settlements incentivize the generic to abandon the patent challenge, leaving a suspect patent intact for the entire extended patent period.

Second, they can incentivize the generic to challenge patents that shouldn't be challenged in hopes of getting paid off for settlement. In other words, the anticompetitive settlements have ended up vesticating the incentives for generics to protect consumers and instead can result in generics feathering their own nests. By virtue of the reverse payment settlement agreement, the brand stops the

generic's challenge and so it doesn't lose its patent monopoly even if its patent is invalid or not infringed.

The generic meanwhile gets a share of the brand's monopoly profit in the form of the reverse payment, but the consumer, including the federal government as has been pointed out, ends up being a huge loser since consumers continue to pay monopoly profits until the generic starts to compete.

This is demonstrated by the pie chart on page 12 of the commission's written remarks, and a good example is our Cephalon case where the CEO of the brand boasted that his deals generated an additional \$4 billion in sales. Most of the profits from those sales will come from consumers pockets. Now, imagine if there are 10, 15 or even more of these settlements each year.

Beyond that, on their face reverse payment agreements are market division agreements between potential competitors. That is why the Sixth Circuit in the Cardizem case held that they were per se illegal, and that holding is consistent with the 1990 Supreme Court Palmer decision, which held that market division agreements between potential competitors are per se illegal. So reverse payment agreements not only violate the purpose of Hatch-Waxman but also seemingly violate the Palmer holding.

So why am I here supporting congressional legislation? Well, recent circuit court decisions have ignored Palmer and Cardizem, substituting their own judicial policy judgments. The market division agreements should be permissible to settle patent litigation.

For example, the 11th Circuit's Schering decision in which the circuit court declined to follow Palmer or Cardizem emphasized that its decision was based on "policy." But Congress is the body with the responsibility to set patent policy.

In short, the courts have disturbed the balance that Congress struck in Hatch-Waxman by permitting reverse payment settlement agreements and Congress should correct that imbalance. Congress shouldn't wait for the Supreme Court to review these erroneous judicial decisions either. There is no reason to think that the court will set things right any time soon. It has decided to review both Schering and Tamoxifen, which followed Schering. That is the Second Circuit decision and the petition currently before the case in the Cipro case, the most recent of these decisions.

In that petition, the petitioner actually suggests that the Supreme Court defer ruling on the petition until the parties file a petition in a parallel action.

More important, however, Cipro represents the extreme case. It holds that reverse payment settlements are in effect per se legal, not illegal, but per se legal. Even if the court concludes that Cipro is wrong and that reverse payment agreements are not per se legal, that still leaves open the question of whether, as Schering and Tamoxifen held, the strength of the patent is a threshold issue that has to be litigated before the public or private plaintiff can litigate the anti-trust merits.

I have said publicly, Mr. Chairman, that litigating the strength of the patent may be one way to avoid Schering and Tamoxifen, but I will be the first to admit that that may be costly and duplicative. Hatch-Waxman contemplated that the generic would litigate the strength of the patent.

Mr. RUSH. Mr. Rosch, would you please bring your comments to a close? You are a minute and 47 seconds over your time.

Mr. ROSCH. OK, can I just conclude by saying—

Mr. RUSH. Please.

Mr. ROSCH [continuing]. Mr. Chairman that at the commission at least, this is not a partisan issue. Eleven members of the commission over the years that this has been at issue, all the Republicans, all of the Democrats have joined in these cases, and all four of us, two Republicans and two Democrats who are currently on the commission, strongly support the legislation that is before the committee. Thank you.

[The prepared statement of Mr. Rosch follows:]

**PREPARED STATEMENT OF THE
FEDERAL TRADE COMMISSION**

Before the

**SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES**

on

**“HOW PAY-FOR-DELAY SETTLEMENTS MAKE CONSUMERS AND THE
FEDERAL GOVERNMENT PAY MORE FOR MUCH NEEDED DRUGS”**

March 31, 2009

**“How Pay-for-Delay Settlements Make Consumers and the Federal Government
Pay More for Much Needed Drugs”**

Chairman Rush, Ranking Member Radanovich, and members of the Subcommittee, I am Thomas Rosch, a Commissioner of the Federal Trade Commission. I appreciate the opportunity to appear before you today to testify on behalf of the Commission about the need for legislation to prevent anticompetitive agreements between branded and generic drug firms that delay consumer access to generic drugs.¹ This is an issue of great importance, not only to consumers but also to the federal and state governments who spend substantial sums on prescription drugs. Since this issue first arose in 1998, every single member of the Commission, past and present, – whether Democrat, Republican, or Independent – has supported the Commission’s challenges to anticompetitive “pay-for-delay” deals.

The threat that these agreements pose to our nation’s health care system is a matter of pressing national concern. The enormous costs that result from unwarranted delays in generic entry burden consumers, employers, state and local governments, and federal programs already struggling to contain spiraling costs. As the President and Congress turn to health care reform, these deals, by delaying generic entry, risk dramatically increasing the costs of those proposals. Over twenty years ago, Congress passed the Hatch-Waxman Act,² which has helped control the costs of prescription drugs by ensuring that weak patents do not delay lower-cost generic competition. These deals, which are unique to the pharmaceutical industry, threaten to

¹ This written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any other Commissioner.

² Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)). Prior testimony before this Subcommittee discussed the Act’s statutory background at 8-9, *available at* http://ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf.

extinguish that benefit. Therefore, congressional action to prohibit anticompetitive patent settlements that impose these costs is both appropriate and timely.

The FTC has sought to use antitrust enforcement to stop what have come to be called “pay-for-delay settlements” (or by some, “exclusion payments” or “reverse payments”). These are settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost generic product. Such settlements effectively buy more protection from competition than the assertion of the patent alone provides. And they do so at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years.

Agreements to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe, and for that reason these pay-for-delay settlements should be prohibited under the antitrust laws. But since 2005, court decisions have treated such agreements in drug patent settlements too leniently. As a result, it has become increasingly difficult to bring antitrust cases to stop pay-for-delay settlements, and such settlements have become a common industry strategy. As one investment analyst report put it, the courts’ permissive approach to exclusion payments has “opened a Pandora’s box of settlements.”³

The implications of these developments for consumers, and for others who pay for prescription drugs, are troubling. The increased costs resulting from anticompetitive agreements that delay generic competition harm all those who pay for prescription drugs: individual consumers, the federal government, state governments trying to provide access to health care

³ Stephanie Kirchgaessner & Patti Waldmeir, *Drug Patent Payoffs Bring a Scrutiny of Side-Effects*, FINANCIAL TIMES UK, Apr. 25, 2006, 2006 WLNR 6910048 (quoting S.G. Cowen & Co. analyst’s report describing the Eleventh Circuit’s opinion in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006)).

with limited public funds, and American businesses striving to compete in a global economy. In 2008, the federal government was projected to have accounted for 31 percent of the \$235 billion spent on prescription drugs, and the federal government's share is expected to rise to 40 percent by 2018.⁴

To be sure, the development of new drugs is risky and costly, and preserving incentives to undertake this task is critically important. Due regard for patent rights is thus a fundamental premise of the Act's framework. But the court decisions allowing pay-for-delay settlements grant holders of drug patents the ability to buy more protection from competition based only on an allegation of infringement. This is more protection than congressionally granted patent rights afford. These rulings disrupt the careful balance between patent protections and encouraging generic drug entry that Congress sought to achieve in the Hatch-Waxman Act.

For these reasons, the Commission strongly supports the bill introduced by Chairman Rush, Committee Chairman Waxman, and others, H.R. 1706, to prohibit these anticompetitive settlements.⁵ And we are encouraged that the list of those speaking out against pay-for-delay settlements is growing. President Obama's budget proposal expresses the Administration's opposition to these anticompetitive deals,⁶ and Assistant Attorney General nominee Christine

⁴ Centers for Medicare and Medicaid Services, Office of the Actuary, Table 11, *Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2003-2018* (2009), available at <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf>.

⁵ Legislation for this purpose has been introduced in the Senate as well as the House. See *Preserve Access to Affordable Generics Act*, S. 369, 111th Cong. (2009).

⁶ President Obama explained in his recent budget that "The Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market." OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2010 (2009) (proposed), at 28, available at http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf.

Varney testified as to her support for stopping them.⁷ In addition, this past summer, the American Medical Association House of Delegates adopted a resolution announcing its opposition to pay-for-delay settlements.⁸

As is discussed below, the Commission is continuing to bring cases challenging pay-for-delay settlements despite the difficulties created by several recent court decisions. But we believe there are compelling reasons for Congress to act to stop such anticompetitive agreements and that the approach taken in H.R. 1706 is sound.

I. The Need for a Legislative Solution

Legislation can provide a comprehensive solution to a problem that is prevalent, extremely costly, and subverts the goals of the Hatch-Waxman Act.

A. Permissive court decisions have made pay-for-delay settlements commonplace in Hatch-Waxman patent cases

The Sixth Circuit Court of Appeals held in 2003 that a branded drug firm's exclusion payments to a generic firm that had filed a patent challenge were per se unlawful, noting:

it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market.⁹

⁷ In response to a question in her recent confirmation hearing before the Senate Judiciary Committee, Ms. Varney testified that she supported opposition to "reverse payments" and would work to "align" the positions of the Department of Justice and the FTC. *Executive Nominations: Hearing Before the S. Judiciary Comm.*, 111th Cong. 38-39 (2009) (exchange between Sen. Herb Kohl, Member, S. Judiciary Comm., and Christine Anne Varney, Nominee, Assistant Att'y Gen., Antitrust Division, Department of Justice).

⁸ At their 2008 annual meeting, the House of Delegates of the American Medical Association adopted Resolution 520 concerning "'Pay for Delay' Arrangements by Pharmaceutical Companies" and resolved "that our American Medical Association support the Federal Trade Commission in its efforts to stop 'pay for delay' arrangements by pharmaceutical companies," available at <http://www.ama-assn.org/ama1/pub/upload/mm/38/a08resolutions.pdf>.

⁹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

But in 2005, two appellate courts adopted a more permissive – and, respectfully, in our view, incorrect – position on pay-for-delay settlements.¹⁰ The Eleventh Circuit reversed the Commission’s decision in the *Schering* case that a substantial exclusion payment, made to induce the generic to abandon its efforts to enter the market before expiration of the branded drug’s patent, was illegal.¹¹ In doing so, the Eleventh Circuit not only rejected the Sixth Circuit’s approach to pay-for-delay settlements, it refused to apply any antitrust analysis, either the per se rule or the rule of reason.¹² The Second Circuit in the *Tamoxifen* case likewise upheld the legality of a pay-for-delay settlement.¹³ In 2008, a third appellate court adopted a similarly lenient view of pay-for-delay settlements.¹⁴ In that case, *Cipro*, the Federal Circuit Court of Appeals held that “absent fraud before the [Patent and Trademark Office] or sham litigation,” the mere presence of a patent entitles the patent holder to purchase protection from competition

¹⁰ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S.Ct. 3001 (2007). For a detailed discussion of the *Schering* and *Tamoxifen* cases please see the FTC’s May 2, 2007 testimony before this Subcommittee at 14-19, available at http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf.

¹¹ *In the Matter of Schering-Plough Corp.*, Docket No. 9297, Federal Trade Commission, 2003 FTC LEXIS 187, Dec. 8, 2003; *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005).

¹² 402 F.3d at 1065.

¹³ *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting), *amended*, 466 F.3d 187 (2d Cir. 2006).

¹⁴ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *petition for cert. filed*, ___ U.S.L.W. ___ (U.S. Mar. 23, 2009) (No. 08-1194).

until patent expiration.¹⁵ Plaintiffs have asked the Supreme Court to review the *Cipro* decision, and we urge the Court to do so.¹⁶

The Commission believes that the courts' permissive approaches in *Cipro*, *Tamoxifen*, and *Schering* are misguided and not supported by the law. These holdings disrupt the carefully balanced patent system by overprotecting weak and narrow patents; allowing patent holders to buy protection that their patents cannot provide; and ignoring consumers' interests in competition safeguarded by the antitrust laws. The Commission is not the only advocate to voice concern about the harmful effects of these decisions. Former Solicitor General Paul Clement has criticized the standard set forth in *Tamoxifen* as "erroneous" and "insufficiently stringent . . . for scrutinizing patent settlements."¹⁷ The Solicitor General also observed that "[t]he interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate a patent holder's efforts to preserve a weak patent by dividing its monopoly profits with an alleged infringer."¹⁸ Forty-one legal scholars, economics

¹⁵ *Id.* at 1336. Bayer had settled patent litigation with the manufacturer of a generic counterpart, Barr, by making periodic payments to Barr ultimately totaling almost \$400 million in exchange for Barr's agreement to delay marketing its generic version of Cipro for almost seven years. The Commission filed an amicus brief in *Cipro* that urged the Federal Circuit to allow an antitrust challenge to the patent settlement to proceed to trial, available at <http://www.ftc.gov/os/2008/01/ciprobrief.pdf>.

¹⁶ See *Ark. Carpenters Health & Welfare Fund, et al., v. Bayer AG, et al.*, ___ U.S.L.W. ___ (U.S. Mar. 23, 2009) (No. 08-1194).

¹⁷ Brief for the United States as Amicus Curiae at 17, *Joblove v. Barr Labs., Inc.*, 127 U.S. 3001 (2007) (No. 06-830) ("U.S. Tamoxifen Br."), available at <http://www.usdoj.gov/osg/briefs/2006/2pet/6invt/2006-0830.pet.ami.inv.pdf>.

¹⁸ *Id.* at 11.

professors, and other academics likewise deemed the *Tamoxifen* standard to be “far outside the mainstream of judicial and academic analysis.”¹⁹

Because this is such an important competition issue, the Commission continues to use its antitrust enforcement authority to challenge pay-for-delay settlements in other circuits despite the permissive legal treatment afforded these settlements by three of the four circuits that have considered the issue. As the Supreme Court observed, “allowing litigation in multiple forums” by the government ensures that “legal questions of substantial public importance” are thoroughly developed.²⁰ In *Mendoza*, the Supreme Court concluded that the government is not required to accede to the first unfavorable final adjudication on a particular issue, because to do so would “deprive [the] Court of the benefit it receives from permitting several courts of appeals to explore a difficult question before [the] Court grants certiorari.”²¹

¹⁹ Brief Amici Curiae of 41 Professors of Economics, Business and Law in Support of Granting the Petition at 2, *Joblove v. Barr Labs, Inc.*, 127 S.Ct. 3001 (2007) (No. 06-830), available at [http://www.orangebookblog.com/Tamoxifen 20cert 20final 20brief.pdf](http://www.orangebookblog.com/Tamoxifen%20cert%20final%20brief.pdf).

²⁰ *United States v. Mendoza*, 464 U.S. 154, 160, 163 (1984).

²¹ *Id.* at 160.

Accordingly, the Commission has filed two cases challenging pay-for-delay settlements since the agency testified before this Subcommittee in May 2007.²² We also have a number of ongoing non-public investigations of such settlements.

The first case, filed in February 2008, challenges a course of anticompetitive conduct by Cephalon, Inc. to prevent generic competition to its leading product, Provigil, a drug used to treat excessive sleepiness caused by narcolepsy and sleep apnea, with annual sales of more than \$800 million.²³ The complaint charges that Cephalon agreed to pay in excess of \$200 million collectively to settle patent litigation with four manufacturers of generic versions of Provigil to induce them to abandon their plans to sell generic Provigil for six years, until 2012. Cephalon's CEO observed shortly after entering these agreements: "We were able to get six more years of patent protection. *That's \$4 billion in sales that no one expected.*"²⁴ Cephalon has asked the trial judge to dismiss the case based on the permissive standard adopted by appellate decisions in other circuits. The court has yet to rule on the motion to dismiss, which was fully briefed in

²² At the time the agency testified before you on May 2, 2007, the Commission had already challenged the following patent settlements: *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint available at <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint available at <http://www.ftc.gov/os/2000/05/c3946complaint.htm>; *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint available at <http://www.ftc.gov/os/2000/03/hoechstandrxc.complaint.htm>; *Bristol-Myers Squibb Co.*, Dkt. No. C-4076, (April 18, 2003), complaint available at <http://www.ftc.gov/os/caselist/c4076.htm>. The consent order in *Abbott Laboratories* is available at <http://www.ftc.gov/os/2000/03/abbot.do.htm>. The consent order in *Geneva Pharmaceuticals* is available at <http://www.ftc.gov/os/2000/03/genevad&co.htm>. The consent order in *Hoechst/Andrx* is available at <http://www.ftc.gov/os/2001/05/hoechstdo.htm>. The consent order in *Bristol-Myers Squibb* is available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>. See also *Schering-Plough Corp.*, 2003 FTC LEXIS 187 (FTC Dec. 8, 2003), vacated, 402 F.3d 1056 (11 Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Dkt. No. 9297 (Apr. 2, 2002) (consent order as to American Home Products).

²³ *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008), available at <http://www2.ftc.gov/os/caselist/0610182/080213complaint.pdf>.

²⁴ John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006 (quoting Cephalon CEO Frank Baldino) (emphasis added).

June 2008. In the meantime, Cephalon has instituted two price increases on Provigil since the Commission filed its complaint.

In the second case, the Commission has challenged patent settlement agreements in which Solvay Pharmaceuticals, Inc. agreed to pay generic drug makers Watson Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc., to delay generic competition to Solvay's branded drug AndroGel.²⁵ According to the February 2009 complaint, Solvay promised payments of hundreds of millions of dollars collectively to induce the generic companies to abandon their patent challenges and agree to forbear bringing a generic AndroGel product to market for nine years, until 2015. The case was filed in California, where one of the four defendants is headquartered. All four defendants have filed a motion seeking to transfer the case to the Northern District of Georgia. If the motion is successful, Eleventh Circuit law and the lenient *Schering* decision will govern the case.

Despite the Commission's ongoing antitrust enforcement efforts to stop pay-for-delay settlements, the appellate court decisions upholding their legality have prompted a resurgence in settlements in which the parties settle with a payment to the generic company and an agreement by the generic company not to market its product. Settlements with payments to the generic patent challenger had essentially stopped in the wake of antitrust enforcement by the FTC, state attorneys general, and private parties during 2000 through 2004. But the recent appellate court decisions have triggered a disturbing new trend.

²⁵ *FTC v. Watson Pharmaceuticals, Inc.*, No. 09-00598 (C.D. Cal. first amended complaint filed Jan. 12, 2009), available at <http://www2.ftc.gov/os/caselist/0710060/090212amendedcmpt.pdf>.

After a five-year hiatus in payments to generics following the initiation of Commission enforcement actions aimed at pay-for-delay settlements, they have become commonplace.²⁶ By the end of fiscal year 2005, the year of the Eleventh Circuit's decision in *Schering*, there were three such settlements. After the *Schering* and *Tamoxifen* rulings came out, there were significantly more. The staff's analysis of settlements filed under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 during the fiscal year ending in September 2007 found that almost half of all of the final patent settlements (14 of 33) involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for some period of time.

Moreover, the findings concerning settlements with first generic filers – that is, settlements that can serve to block FDA approval of later applicants²⁷ – are even more striking. Since 2005, 69 percent (22 of 32) of the settlements with first generic filers involved a payment to the generic challenger and a restriction on generic entry.²⁸

²⁶ Bureau of Competition Report, Federal Trade Commission, *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: A Report by the Bureau of Competition* (Apr. 2006), available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

²⁷ Further discussed, *infra*, Section IV.

²⁸ Bureau of Competition Report, Federal Trade Commission, *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: A Report by the Bureau of Competition* (May 2008), available at <http://www.ftc.gov/os/2008/05/mmaact.pdf>; Bureau of Competition Report, Federal Trade Commission, *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: A Report by the Bureau of Competition* (Apr. 2007), available at <http://www.ftc.gov/reports/mmaact/MMAreport2006.pdf>; Bureau of Competition Report, Federal Trade Commission, *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: A Report by the Bureau of Competition* (Apr. 2006), available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

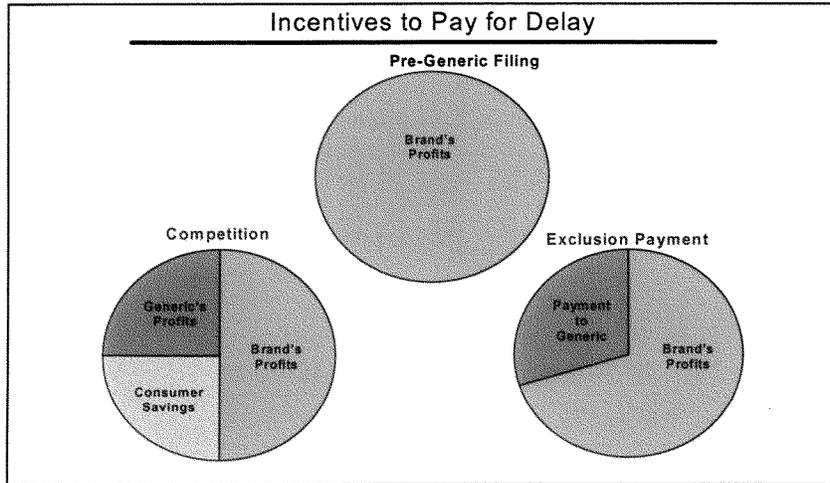
B. The profitability of delaying generic entry means that these agreements will become more prevalent

In the current legal climate, there is every reason to expect the upsurge in such settlements to continue, and early entry of generics under Hatch-Waxman to decline. Why? Because pay-for-delay settlements are highly profitable for both brand-name and generic firms. If such payments are permissible, companies have compelling incentives to use them.

Although patent challenges have the potential for substantial consumer savings, the competitive dynamic between brand-name drugs and their generic equivalents creates an incentive for brand and generic manufacturers to conspire to avoid competition and share the resulting profits. The reason is simple: in nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the amount of profit the brand-name drug company stands to lose from the same sales. This is because the generic firm sells at a significant discount off the price of the brand-name product. The difference between the brand's loss and the generic's gain is the money consumers save.

Consequently, it will typically be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer – an amount less than the brand-name manufacturer would have lost and more than the generic would have gained – to settle the patent dispute and the latter agrees to defer entry. As is illustrated below, by eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete. In other words, these settlements are harmful because the parties are resolving their dispute at the expense of consumers. Although both the brand-name companies and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry, which may occur either because (1) the generic company would have prevailed in

the lawsuit (as noted in Section I.C., *infra*, the FTC's Generic Drug Study found generic challengers enjoyed a success rate in excess of 70 percent), or (2) because the parties would have negotiated a settlement with an earlier entry date absent the payment (i.e., the payment induced the generic to delay entry longer than it otherwise would have). Instead, consumers pay higher prices because such early generic entry is delayed. By eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete.



C. Pay-for-delay settlements impose enormous costs on consumers and the health care system

Generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically-identical alternatives to brand-name drugs at a significantly reduced cost. Although it is well known that the use of generic drugs – which are priced 20 to 80 percent or more below the price of the branded drug²⁹ – provides substantial savings, what is not so well known is the important role that generic drug firms’ patent challenges play in delivering savings to consumers.

One of the key steps Congress took in the Hatch-Waxman Act to promote more rapid introduction of generics was establishing special rules and procedures to encourage firms seeking approval of generic drugs to challenge invalid or narrow patents on branded drugs. Experience has borne out the premise of the Hatch-Waxman patent challenge framework: that many patents, if challenged, will not stand in the way of generic entry,³⁰ and that successful challenges can yield enormous benefits to consumers. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the generic

²⁹ See Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (hereinafter “CBO Study”).

³⁰ See, e.g., *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280, 2008 WL 2039065 (Fed. Cir. May 14, 2008) (patents covering blood-clotting drug Lovenox held unenforceable), *petition for cert. filed*, 77 U.S.L.W. 3441 (U.S. Jan. 23, 2009) (No. 08-937); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (patent covering high blood pressure drug Altace found invalid); *Daiichi Sankyo Co., Ltd. v. Apotex Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (patent covering method of treating ear infections with ofloxacin held invalid); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) (patent covering hypertension drug Norvasc held invalid); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006) (product-by-process patent covering anti-depressant drug Paxil was invalid); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (claims of patent related to extended release urinary incontinence drug Ditropan XL held invalid and not infringed).

challengers had a success rate of 70 percent.³¹ The FTC's study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and generic applicants³² found that when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.³³ Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration.³⁴ Indeed, generic competition following successful patent challenges involving just four major brand-name drugs (Prozac, Zantac, Taxol, and Platinol) is estimated to have saved consumers more than \$9 billion.³⁵

These cost savings are lost, however, if branded drug firms are permitted to pay a generic applicant to abandon challenging the brand, thereby deferring entry. So are the savings to the federal government. In 2008, the federal government was projected to have accounted

³¹ Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006). See also John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-06 (1998) (study of all patent validity litigation from 1989-1996 found 46 percent of all patents litigated to judgment held invalid).

³² See the Commission's prior testimony before this Subcommittee at 8-9, available at http://ftc.gov/os/testimony/P859910%20Protecting_Consumers%20Access_testimony.pdf for further discussion of the Hatch-Waxman Act statutory background.

³³ Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 19-20 (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

³⁴ *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming Paxil held invalid); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom. In re Omeprazole Patent Litig.*, 84 Fed. App. 76 (Fed. Cir. 2003) (noninfringement of patents claiming Prilosec); *American Biosciences, Inc. v. Baker Norton Pharms. Inc.*, 2002 U.S. Dist. LEXIS 512 (C.D. Cal. Jan. 10, 2002) (patent claiming Taxol held invalid); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) (noninfringement of patents claiming Zantac).

³⁵ *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f90155.pdf.

for 31 percent of the \$235 billion spent on prescription drugs, and that share is expected to rise to 40 percent by 2018.³⁶ Many of the top-selling prescription drugs in the United States – including such blockbusters as the asthma/allergy drug Singulair, the deep vein thrombosis (blood clot) and pulmonary embolism treatment Lovenox, and the schizophrenia, bipolar, and depression drug Abilify – are currently the subject of patent challenges by generic firms seeking to enter the market under the provisions of the Hatch-Waxman Act. The prospective cost savings to consumers and tax-payers from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. But under much of the current case law, the parties have a strong economic incentive to enter instead into anticompetitive settlements that deprive consumers of the benefit of low-cost, non-infringing generic drugs.

Prozac provides a telling example of what will be lost if brand and generic companies can enter pay-for-delay settlements. In the course of the Prozac patent litigation, the generic challenger reportedly asked to be paid \$200 million to drop its patent challenge. The brand company rejected the idea, stating that such a settlement would violate the antitrust laws.³⁷ The generic ultimately won that patent litigation, and consumers – as well as federal and state governments – saved over two billion dollars.³⁸ Under the legal standard articulated in the *Schering*, *Tamoxifen*, and *Cipro* cases, however, the proposed settlement would have been legal and profitable for both parties. The parties would have had every reason to enter the agreement,

³⁶ Centers for Medicare and Medicaid Services, Office of the Actuary, Table 11, *Prescription Drug Expenditures: Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2003-2018* (2009), available at <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf>.

³⁷ Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 5, available at http://money.cnn.com/magazines/fortune/fortune_archive/2001/08/13/308077/index.htm.

³⁸ Kirchaessner & Waldmeir, *supra* note 3.

generic Prozac entry would not have occurred, and consumers and others would have had to pay that extra two billion dollars.

D. Permissive legal treatment of pay-for-delay settlements undermines the Hatch-Waxman Act

The problem of pay-for-delay patent settlements has arisen in – and, to the FTC’s knowledge, only in – the context of the special statutory framework that Congress created with the Hatch-Waxman Act. Congress intended that the Hatch-Waxman Act would “make available more low cost generic drugs,” while fully protecting legitimate patent claims.³⁹ The special rules that apply in this area were designed to balance the two policy goals that are of critical significance in the pharmaceutical industry: speeding generic drugs to market and maintaining incentives for new drug development. Legislative action concerning pay-for-delay settlements can be tailored to the special circumstances of pharmaceutical patent settlements and help to ensure that this unique framework works as Congress intends.

Hatch-Waxman was intended to give generic companies an incentive to challenge weak patents and to compete, not to take money in exchange for sitting on the sidelines. Because of pay-for-delay settlements, as Chairman Waxman, one of the authors of the Act, has observed, the law “has been turned on its head.”⁴⁰

The reasoning underlying these misguided appellate court rulings underscores the need for action by Congress. These decisions reflect judicial judgments about the policy choice that Congress made in Hatch-Waxman. For example, the Eleventh Circuit’s *Schering* decision –

³⁹ H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2661.

⁴⁰ Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A11 (quoting Rep. Waxman), available at <http://www.nytimes.com/2000/07/23/us/keeping-down-competition-companies-stall-generics-keep-themselves-healthy.html?sec=&spon=&pagewanted=all>.

which opined that the Hatch-Waxman framework Congress created gave generic firms “considerable leverage in patent litigation,” and could therefore “cost Schering its patent”⁴¹ — emphasized that its decision was based on “policy.”⁴² Congress, however, is the body with the responsibility to set patent policy. Striking the balance so as to promote innovation while also promoting generic entry is fundamentally a legislative choice. Accordingly, it is fitting that if courts have disturbed the balance Congress struck in Hatch-Waxman between patents and competition, Congress should address the use of exclusion payments in drug patent settlements to correct that balance.

E. Legislation is likely to be swifter and more comprehensive than litigation

While the Commission’s enforcement activities are continuing, we recognize the time and uncertainty involved in litigation challenges to anticompetitive settlements. The Commission’s *Provigil* case has been stalled at the district court level for almost a year without progress, thus illustrating the delay that can arise in litigation. Although the Commission will continue to be vigilant in this area, litigating another case to conclusion will take years, and the outcome of such litigation is uncertain given the *Schering*, *Tamoxifen*, and *Cipro* decisions. In any event, such litigation will provide little relief for those harmed in the interim by not being afforded the option of a generic alternative. The cost to consumers, employers, and government programs will be substantial. Legislation could provide a speedier and more comprehensive way to address this pressing concern.

⁴¹ 402 F.3d at 1074.

⁴² *Id.* at 1076.

II. The Arguments Against Barring Exclusion Payments Are Contradicted by Experience in the Market

In the debate over legislation to ban pay-for-delay settlements, certain arguments are routinely offered by supporters of these settlements: (1) such settlements typically allow generic entry before patent expiration and therefore benefit rather than harm consumers; (2) it is virtually impossible to settle Hatch-Waxman patent cases without payments to the generic challenger; and (3) barring such payment to generic firms will mean that fewer generic firms will undertake patent challenges. In the Commission's view, these arguments overlook market realities.

First, the suggestion that pay-for-delay patent settlements are procompetitive – by guaranteeing generic entry prior to the expiration of the disputed patent – is contrary to the Commission's experience. The *Provigil* case is a good example. The branded drug company, Cephalon, touted the “obvious benefits and efficiencies” of its settlement to the court because it “permitted the [g]enerics to enter the market three years prior to the expiration of the [] patent.”⁴³ But, in reassuring its investors that generic Provigil entry in 2012 will have little effect on Cephalon's bottom line, Cephalon has told a very different story. Most recently, in a February 13, 2009 earnings call discussing its plan to switch sales from Provigil to its follow-on product, Nuvigil, Cephalon's CEO allegedly stated, “if we do our job right . . . the Provigil number in 2012 [the date the settlement agreement permit the generics to enter the market] that

⁴³ Ceph. Mem. in Support of its Mtn. to Dismiss at 1, *FTC v. Cephalon, Inc.*, No. 08-2141 (E.D. Pa. Mem. filed May 5, 2008).

will be genericized will be very, very small.”⁴⁴ If Cephalon is successful in its plan, consumers, by any measure, will have received no benefit from the settlement.

Second, experience does not support the contention that Hatch-Waxman cases can typically only be settled by the transfer of value from the patent holder to the generic challenger. On the contrary, the settlement data that the FTC has for the period from 2000 through 2004 indicate that parties can and do find other ways to settle cases. During that period of successful Commission enforcement, pay-for-delay settlements essentially stopped. But patent settlements – using means other than exclusion payments – continued to occur. In less than five years, there were at least as many settlements as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry.⁴⁵ Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases. And patent settlements will continue if Congress enacts legislation that prohibits anticompetitive payments in settlements of Hatch-Waxman patent cases.

Third, the argument that banning pay-for-delay settlements will discourage generic drug companies from mounting patent challenges overlooks one of the fundamental purposes of the Hatch-Waxman Act: the Congressional judgment that weak patents should not create unwarranted barriers to competition from generic drugs. The Hatch-Waxman Act implements that judgment by establishing special rules and procedures when a generic firm seeks approval

⁴⁴ Cephalon Q4 2008 Earnings Call Transcript at 9 (Feb. 13, 2009), *available at* <http://seekingalpha.com/article/87859-cephalon-inc-q2-2008-earnings-call>.

⁴⁵ The agency lacks data for the approximately three year period between the end of the Generic Drug Study in 2000 and the beginning of the MMA reporting period in 2003. It is likely that there are additional settlements that occurred during this period for which the agency does not have information.

to market its product before all relevant patents have expired. Congress designed the regulatory framework to facilitate generic entry; patent challenges are not an end in themselves. The measure of success of the framework Congress devised is not the number of patent challenges filed, but the extent to which such challenges actually deliver savings to consumers. Permitting patent settlements in which the parties share monopoly profits preserved by delaying generic competition may increase the number of patent challenges that are filed, but it does not promote consumer access to generic drugs or cost savings.

III. The Provisions of H.R. 1706

The Commission believes that certain principles are important in crafting the precise form and scope of a legislative remedy to the pay-for-delay settlements. The fundamental antitrust concern underlying such settlements is the sharing of monopoly profits that are preserved by an agreement not to compete, whatever form the compensation to the generic takes. Thus, legislation must be sufficiently broad to encompass the various ways that a branded firm may share its profits with the generic, including not only the ways we have seen to date, but also those that may arise in the future. At the same time, legislation should be designed to avoid unwarranted deterrence of settlements that present no competitive problem.

H.R. 1706 embodies these principles. Section 2(a) broadly proscribes settlements in which a generic firm receives “anything of value” and agrees to refrain from selling the product. This bill also provides two mechanisms to prevent settlement avenues from being unduly limited, which might chill certain procompetitive settlements. First, Section 2(b) contains express exclusions from the general prohibition on settlements in which the generic firm receives something of value and agrees to refrain from selling its product. Second, Section 3

provides flexibility by authorizing the FTC to adopt rules to exempt other agreements from the general prohibition.

In sum, H.R. 1706 offers a straightforward means to quickly combat anticompetitive conduct that is pervasive and costly to consumers, while also providing flexibility to protect procompetitive arrangements. We would welcome the opportunity to work with the Subcommittee as it continues to consider the bill.

IV. The 180-Day Exclusivity as a Bottleneck to Generic Entry

H.R. 1706 also includes a provision that addresses the operation of the Hatch-Waxman Act's 180-day exclusivity period, which currently allows the potential for a settlement between a brand-name company and a first generic filer to generate a bottleneck that prevents *any* generic competition.⁴⁶ Hatch-Waxman rewards the first filer to challenge a branded drug patent with 180 days of market exclusivity, and bars the FDA from approving any later applicants until the period has expired or been forfeited. Hatch-Waxman was designed to provide a mechanism for a later filer to eliminate this bottleneck, by specifying that if the later filer can get a court ruling that it does not infringe, the first filer must "use or lose" its exclusivity period.⁴⁷ But, as discussed in detail in our previous testimony,⁴⁸ brand name companies have been able to use

⁴⁶ When parties enter into a settlement agreement and the generic agrees to forgo market entry until some time in the future (whether with or without an accompanying payment), that agreement does not trigger the running of the exclusivity period. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(a)(2), Pub. L. No. 108-173, 117 Stat. 2066, 2457 ("MMA") (amending 21 U.S.C. § 355(j)(5)(B)(iv)) makes settlement of patent litigation a forfeiture event only if "a court signs a settlement order or consent decree that enters a final judgment that includes a finding the patent is invalid or not infringed." If the parties request and the court enters a settlement order that does not include such a finding, as is usually the case in this context, the settlement will not constitute a forfeiture event.

⁴⁷ Under current law, the decision must be "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed." MMA, § 1102(a)(2), Pub. L. No. 108-173, 117 Stat. 2066, 2457 (amending 21 U.S.C. § 355(j)(5)(B)(iv)). That decision acts as a forfeiture event that forces the first filer to either use or lose its exclusivity period within 75 days.

⁴⁸ See http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf.

strategies to avoid the possibility that the generic company will obtain the favorable court decision it needs to relieve the bottleneck. In particular, there was a danger that a brand company could use the 180-day exclusivity to block entry by (1) choosing not to sue a later-filing generic and (2) avoiding a declaratory judgment action by that generic. Section 4 of H.R. 1706 is designed to address that problem.

Recent legal developments concerning the availability of declaratory judgment suits to later generics seeking to eliminate the 180-day bottleneck suggest that branded drug firms can no longer ensure that they will be able to avoid a declaratory judgment action merely by failing to sue the generic applicant⁴⁹ or granting a covenant not to sue.⁵⁰ But the ultimate extent and scope of this legal change is unclear. It is important that there be a clear and practical mechanism available to subsequent generic filers to seek to relieve the bottleneck created by the 180-day exclusivity when the brand-name manufacturer and first generic applicant have settled their litigation without resolving the issues of validity or infringement or are involved in

⁴⁹ The Supreme Court recently examined the availability of declaratory judgment jurisdiction in patent cases in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). The Court held that the case or controversy requirement did not require a patent licensee to breach its license agreement before seeking a declaratory judgment that the underlying patent is invalid or not infringed. In *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007), the Court of Appeals for the Federal Circuit followed the analysis in *MedImmune* and held that an ANDA applicant could bring a declaratory judgment action challenging patents listed in the Orange Book where the brand company had sued on some but not all of the listed patents. The Federal Circuit has not yet addressed the question of whether an ANDA applicant can bring a declaratory judgment action when the brand company has not sued for infringement of any listed patent.

⁵⁰ See *Caraco Pharm. v. Forest Labs.*, 527 F.3d 1278 (Fed. Cir. 2008), *cert denied*, 77 U.S.L.W. 3308 (U.S. Feb. 23, 2009) (No. 08-624) (in the context of Hatch-Waxman Act, the patentee's grant of a covenant not to sue did not eliminate the controversy between the parties). One district court has read *Caraco* to apply only to pre-MMA ANDAs. See *Ivax Pharm. v. AstraZeneca*, No. 08-2165, 2008 WL 4056518 (D.N.J. Aug. 28, 2008); *Dr. Reddy's Labs. v. AstraZeneca*, No. 08-2496, 2008 WL 4056533 (D.N.J. Aug. 28, 2008). Another district court has rejected that view and held that the Federal Circuit's *Caraco* decision applies equally ANDAs filed after enactment of the MMA. See *Dey, L.P. v. Sepracor, Inc.*, No. 08-2496, 2009 WL 230001 (D. Del. Jan. 30, 2009).

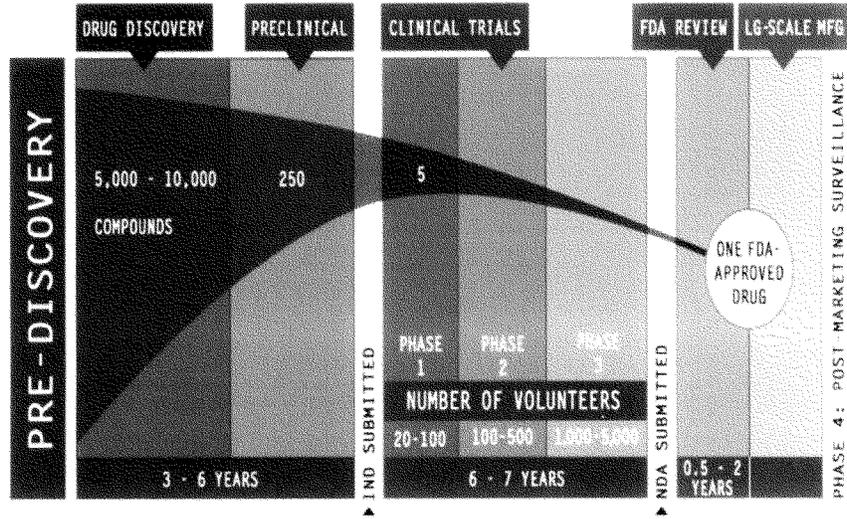
protracted litigation.⁵¹ Otherwise, even if the subsequent filer has a strong case for non-infringement, the bottleneck postpones consumer access to any lower-priced generic version of the drug. Such a result is contrary to the Hatch-Waxman Act's purposes of encouraging meritorious patent challenges and promoting generic entry.

Conclusion

Thank you for this opportunity to share the Commission's views. The Commission looks forward to working with the Subcommittee to protect consumers in this critical sector of the economy.

⁵¹ Dismissal of a declaratory judgment action, even when based on a covenant not to sue, is not a "court decision" sufficient to trigger a forfeiture event. *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006) (upholding FDA's decision to treat only an adjudicated holding on the patent merits as a "court decision" for purposes of triggering the 180-day exclusivity).

Figure 1: The Research and Development Process



Mr. RUSH. Thank you very much. Now the chair recognizes the gentleman, Mr. Scott Hemphill, for 5 minutes or thereabouts for purposes of an opening statement.

STATEMENT OF SCOTT HEMPHILL

Mr. HEMPHILL. Thank you. Chairman Rush, Congressman Stearns, and members of the subcommittee, I am Scott Hemphill, an associate professor at Columbia Law School. My scholarship and teaching focus on the balance between innovation and competition, established by anti-trust law, intellectual property and regulation.

I thank you for the opportunity to testify today about anti-competitive, pay-for-delay agreements between brand name drug makers and their generic rivals. These remarks draw upon my ongoing academic research into the economic effects of these settlements and their appropriate legal treatment. Most recently an article forthcoming in the "Columbia Law Review"—I hope these articles might be included in the hearing record.

Mr. RUSH. So ordered.

Mr. HEMPHILL. Advise the Federal Trade Commission on the anti-trust issues raised by pay-for-delay settlements, but the views I express today are mine alone.

For 25 years, the Hatch-Waxman Act has provided a way for generic drug makers to introduce a competing version of the patented brand name drug even before the relevant patent or patents expire by arguing that the patent is invalid or not infringed. The generic firm has a large incentive to do this: 180 days of exclusive sales free from generic competition when it later enters the market. Usually the brand name firm files a patent infringement suit in response. Often, the generic firm wins the suit, and when it does, drug prices fall.

But sometimes the brand name firm, instead of taking that chance, decides to settle the suit. The parties dismiss the suit and agree on a particular date when the generic firm can enter the market. That date is the result of a hard bargain between the two companies. The brand name firm pushes for as late a date as possible, arguing that it is likely to win the case at trial if put to the test. The more persuasive that argument is, the later the entry date.

Now, such a settlement which rests solely upon the inherent strength of the patent is properly permitted, but now think what happens when a brand name firm instead makes a payment to the generic firm, rather than relying solely on its prospects at trial. In that case, the payment secures a later date than is warranted by the likely validity of the patent alone. That payment to a rival made to secure additional delay in the generic entry ought to be prohibited.

This pay-for-delay settlement problem is growing. To get a better sense of the problem, I collected a data set using public information of 143 brand generic settlements between 1984 and August 2008. Of these, 60 settlements raised pay-for-delay issues. Settlements as to just 10 drugs, whose form is particularly troubling and which currently block generic entry, account for U.S. sales of about \$17 billion each year.

The problem is not just growing worse. It is also getting harder. In the early days of pay-for-delay settlements, the brand name paid cash, a couple hundred million dollars in the case of the antibiotic Cipro. These deals are, relatively speaking, easy to understand. But today firms also pay by making contemporaneous side deals that help to disguise the payment, and they can even use the 180-day period I mentioned a moment ago as a source of payment.

Let me explain. A generic firm gets 180 days if it fights the patent and wins. It loses 180 days if it fights the patent and loses. But what if it settles? In that case, it keeps the 180 days. Now, this is important because it means that a brand name firm can approach the generic and say let me keep my patent and in exchange, I will let you have the 180 days, just much later.

For a blockbuster drug such as Lipitor, such forbearance is worth hundreds of millions of dollars to a generic firm. The current approach to pay-for-delay settlement is just not working. H.R. 1706 is an important step forward in identifying and determining pay-for-delay settlement. Section 2A of the bill prohibits a settling brand name firm from providing a generic firm with "anything of value beyond a negotiated entry date" and with a few specified exceptions.

It is important that the subcommittee recognize that anything of value, properly understood, includes all forms of compensation that induce delay, including effective guarantees of exclusivity. The subcommittee might wish to make this point explicit in the bill.

To conclude, the pay-for-delay problem is getting worse as new deals are made and as deal structures become more and more complicated. Congress can help by prohibiting these anti-competitive arrangements. Thanks are due to the subcommittee for taking a leadership role on this important issue. I look forward to hearing your questions and concerns.

[The prepared statement of Mr. Hemphill follows:]

Testimony of C. Scott Hemphill
Associate Professor, Columbia Law School

House Committee on Energy and Commerce
Subcommittee on Commerce, Trade, and Consumer Protection

Hearing on H.R. 1706, Protecting Consumer Access to Generic Drugs Act of 2009

March 31, 2009

Chairman Rush, Ranking Member Radanovich, and Members of the Subcommittee, I am Scott Hemphill, an Associate Professor at Columbia Law School. My research and teaching focus upon the balance between innovation and competition established by antitrust law, intellectual property, and sector-specific regulation. I welcome the opportunity to testify today about certain anticompetitive, “pay-for-delay” agreements between brand-name drug makers and their generic rivals. These remarks draw upon my ongoing academic research into the economic effects of these settlements and their appropriate legal treatment.¹ I have advised the Federal Trade Commission on the antitrust issues raised by pay-for-delay settlements, but the views I express today are mine alone.

I wish to make three points. First, the pay-for-delay settlement problem is large and longstanding. Second, the problem is becoming more difficult, as the forms of settlement continue to evolve. And third, Congress can play a useful

¹ C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 *Columbia Law Review* (forthcoming 2009), available at <http://ssrn.com/abstract=1356530> [hereinafter *New Data*], undertakes an empirical examination of settlements, with a view toward identifying a workable policy rule. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 *New York University Law Review* 1553 (2006) [hereinafter *Paying for Delay*], analyzes the competitive effects of certain settlements and their proper treatment under antitrust law.

role in this area by passing legislation that prohibits settlements that combine payment with delay.

The pay-for-delay settlement problem

For more than twenty years, the Hatch-Waxman Act has provided a mechanism by which generic drug makers may introduce a competing version of a brand-name drug.² Frequently, the generic firm seeks to market a product prior to the expiration of a patent (or patents) claimed by the brand-name firm to cover the product. Under the Act, the generic drug maker first asserts that the brand-name firm's patent is invalid or not infringed by the generic product;³ often, the brand-name firm then files a suit in response alleging patent infringement. This form of litigation has become the norm with respect to the most important brand-name drugs. Moreover, these challenges often succeed in securing early entry by generic rivals. For example, of the ten best-selling drugs of 2000, nine attracted challenges, of which at least four led to entry prior to patent expiration.⁴

In some cases the brand-name firm, rather than take a chance that the generic firm might win the patent suit, settles the litigation. The parties dismiss the suit and agree to a particular date when the generic firm may enter the

² Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.). In 2003, Congress amended this scheme. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, subtit. A-B, 117 Stat. 2066, 2448-64 (codified at 21 U.S.C. § 355 (Supp. III 2003)).

³ Technically, the pre-expiration challenge takes the form of an Abbreviated New Drug Application ("ANDA") with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000) (also known as "Paragraph IV") that relevant patents are invalid or not infringed.

⁴ In 2000, the ten best sellers were Celebrex, Claritin, Glucophage, Lipitor, Paxil, Prevacid, Prilosec, Prozac, Zocor, and Zoloft. See Robert Pear, Spending on Prescription Drugs Increases by Almost 19 Percent, N.Y. Times, May 8, 2001, at A1. Of these, all but Glucophage attracted a pre-expiration challenge. Ctr. for Drug Evaluation & Research, FDA, Paragraph IV Patent Certifications as of April 23, 2007, <http://www.fda.gov/cder/OGD/ppiv.htm>. Of the nine challenges, those targeting Paxil, Prilosec, Prozac, and Zocor resulted in pre-expiration entry. See Paying for Delay, supra note 1, at 1567 n.57.

market. The entry date is the result of a hard-fought bargain between rivals. The brand-name firm pushes for a later entry date by arguing that, if the litigation proceeds to judgment, a court is likely to hold that the patent is valid and infringed. The likelier that judgment is, the later the entry date.

A settlement that relies solely upon the inherent strength of the patent is properly permitted. Such a settlement delays entry, to be sure, but the brand-name firm is simply using its patent protection as leverage. The brand-name firm's success in achieving a later date in this fashion defines the maximum extent of the patent right.

The situation is different when a brand name firm's makes a payment to its rival, rather than relying solely upon its prospects at trial. In that case the payment secures a later entry date than is warranted by the likely validity of the patent alone. That payment to a rival, made to secure additional delay, is a privately-arranged patent term extension that should be understood to violate antitrust law.⁵

Early generic competition benefits consumers by lowering drug prices sooner. A pay-for-delay settlement transfers wealth from consumers to drug makers, in the form of continued high pharmaceutical prices, with brand-name firms sharing a portion of that transfer with the generic firm. The higher price also alters the purchase decisions of consumers and insurance providers, introducing an additional welfare loss. If the brand-name firm paid a rival *after* patent expiration to abandon its effort to market a competing drug, that transaction would clearly be inappropriate. The same is true when the privately arranged extension postpones an entry date that is prior to patent expiration.

A payment to secure delayed entry undermines the existing balance between innovation and competition set by the Hatch-Waxman Act. The Act as

⁵ For further discussion, see *Paying for Delay*, supra note 1.

written provides brand-name firms with important special protection for their innovative efforts, including patent term extension and a variety of nonpatent regulatory delays to generic entry. For example, if the brand-name firm's approved drug contains a novel active ingredient, the Food and Drug Administration (FDA) may not accept any application to market a generic version for four years.⁶ Once the generic firm's application is accepted, and assuming that the brand-name firm files a patent suit in response, the Act blocks FDA approval of the generic firm's application for the first several years of the suit's pendency.⁷ These provisions, taken together, can provide more than seven years of protected profits even if the patent protection is very weak.⁸ A privately arranged term extension, then, is in addition to extensive protections already granted by Congress.

Pay-for-delay settlements are a frequently employed tactic for brand-name and generic firms. To examine the frequency and evolution of brand-generic settlements since 1984, I collected a novel dataset.⁹ The object was to identify and synthesize all public information about the frequency and terms of settlement. The effort drew upon press releases, trade publications, financial analyst reports and analyst calls with management, court filings of patent and antitrust litigation, SEC filings, FDA dockets, and Federal Trade Commission (FTC) reports. The search period extended from 1984, when the Hatch-Waxman

⁶ See § 355(j)(5)(F)(ii) (Supp. III 2003). The delay is five years for ANDAs that do not contain a Paragraph IV certification. *Id.*

⁷ § 355(j)(5)(B)(iii) (2000 & Supp. III 2003). The stay goes into effect provided that the brand-name firm files suit within forty-five days of receiving notice of the certification. *Id.* The "thirty-month" stay can persist for more than three years. See *Paying for Delay*, *supra* note 1, at 1566 n.50. The stay resembles a preliminary injunction, but is superior from the brand-name firm's standpoint, as there is no requirement that the brand-name firm show a likelihood of success on the merits, and no obligation to pay damages if the brand-name firm subsequently loses the patent case.

⁸ If the patent case is decided before the expiration of the automatic stay, the period is shorter.

⁹ The full results are reported in *New Data*, *supra* note 1.

Act was passed, through August 2008, and therefore ignores significant settlement activity since then.

This work yielded information for 143 settlements involving 101 brand-name drugs. Of the 143 settlements, 60 settlements include both delayed generic entry and possible contemporaneous provision of value by the brand-name firm. The 60 settlements involve 51 drugs. (For some drugs, the brand-name drug maker settled with multiple generic firms.) Most of the 51 drugs fall into two categories: monetary settlements and retained exclusivity settlements.

Monetary settlements. For 21 of the 51 drugs, the compensation was wholly or partly monetary. Sometimes the payment was an open conferral of cash. For other drugs, the possible payment was embedded within a more complicated transaction, as discussed in more detail below. The caveat “possible” is used because in some cases public information leaves it unclear whether the settlement included compensation. These 21 drugs are listed in Table 1. On average, they had annual U.S. sales, measured in the year of settlement and adjusted for inflation, of \$1.3 billion.

The 21 drugs include blockbusters such as Lipitor (more than \$7 billion in annual sales) and Nexium (more than \$3 billion). More than half are new versions of existing therapeutic agents, whose patents are generally thought to be weaker because they tend to be obvious (and hence invalid) and are easily worked around. Some of these settlements have eventually given way to generic entry, due to scheduled entry or patent expiration, while others continue to block generic competition today. Ten drugs in the latter category account for annual sales of about \$17 billion.¹⁰

¹⁰ Measured in the year of settlement and adjusted for inflation.

Table 1: Settlements with Monetary Payment

Year	Drug	Sales	Entry
1993	Nolvadex	400	9
1995	BuSpar	400	5
	Zantac	2950	2
	Sinemet CR	150	11
1997	Cipro	900	7
	K-Dur*	250	4
1999	Naprelan	50	3
2005	Lamictal	1100	3
	Niaspan	450	8
	Effexor XR	2750	5
2006	Provigil*	700	6
	Altace	700	2
	Plavix	3400	5
	Propecia	150	7
	Adderall XR*	900	3
	AndroGel*	350	9
2007	Wellbutrin XL (150 mg)	850	1
2008	Nexium	3400	6
	Lipitor and Caduet	7600	3
	Aggrenox	300	7

Drug: * indicates monetary settlements with multiple generic firms. *Sales:* Annual U.S. sales, in millions of dollars, measured in the calendar year of settlement or twelve months preceding settlement, adjusted to constant 2008 dollars using the monthly Consumer Price Index prepared by U.S. Bureau of Labor Statistics, and rounded to the nearest \$50 million increment. *Entry:* Time between settlement and scheduled entry, rounded to the nearest year, except for Altace, where no date appears to have been disclosed. Does not include immediate authorized generic sales in Nolvadex, or unexpected six-month pediatric extensions for Nolvadex and Cipro. For further details, see New Data, supra note 1.

The effect of delayed entry can be enormous. For the settlements in Table 1, a one year delay in generic entry represents, under conservative assumptions, a transfer from consumers to producers of about \$12 billion.¹¹ Whether the one-year benchmark is an overestimate or an underestimate is often difficult to assess in a particular case using public information. Part of the delay is attributable to the strength of the patent itself, rather than payment. Since the pre-expiration period covered by settlement is several years—the average period, weighted by sales, is four years—the benchmark is likely conservative.

For some drugs, public statements by management or the expectations of financial analysts help to provide a specific measure of delay. For example, in the case of Provigil, a wakefulness drug, the drug maker's CEO said that due to settlements, "We were able to get six more years of patent protection. That's \$4 billion in sales that no one expected."¹² The CEO's statement reflects the firm's pre-settlement expectation of entry in 2006,¹³ and settlements delaying entry until 2012.¹⁴ In the case of Lipitor, a blockbuster cholesterol drug, the settlement delayed anticipated entry by nearly two years.¹⁵ Overall, the \$12 billion benchmark estimate is likely to be conservative.

¹¹ Suppose generic entry achieves 75% penetration and that the generic product is priced at a two-thirds discount, relative to the brand-name drug. These figures are a simplification, because in reality, penetration and the discount (particularly during the 180-day period) are smaller at first, but quickly increase. Under these assumptions, the avoided transfer is one-half of annual sales; across 20 drugs, the total is about \$12 billion. This calculation does not include Plavix, a settlement that never took full effect because it was rejected under the terms of an earlier consent decree between Bristol-Myers Squibb and regulators, or welfare losses caused by pricing distortions.

¹² John George, *Hurdles Ahead for Cephalon*, *Phila. Bus. J.*, Mar. 20, 2006, at 1.

¹³ See, e.g., Q3 2005 Cephalon, Inc. Earnings Conference Call Transcript (Nov. 1, 2005), available at Factiva (statement of Frank Baldino, Chairman and CEO, Cephalon, Inc.) (providing earnings guidance for 2006, and assuming "generic versions of modafinil enter the market midyear").

¹⁴ See Complaint, *FTC v. Cephalon, Inc.*, No. 08-0244 (D.D.C. Feb. 13, 2008).

¹⁵ See, e.g., Merrill Lynch, *Pfizer Inc.: Settlement Good News*, June 18, 2008 ("We now expect an extra 20 months of U.S. Lipitor exclusivity (we had assumed U.S. generic competition in March 2010 and the Ranbaxy settlement delays generic launch until November 2011).").

Retained exclusivity. Money is not the only way to compensate the generic firm. For settlements involving 25 drugs, compensation took the form of retained exclusivity.¹⁶ The 180-day period is valuable to the generic firm. One hundred eighty days of duopoly is worth hundreds of millions of dollars in the case of a blockbuster. The value of this opportunity, however, is discounted by the uncertainty that the generic firm might lose the litigation, and thus never enjoy the exclusivity period. A brand-name firm's agreement to drop the patent fight—an arrangement that, under current law, does not forfeit eligibility—is valuable to the generic firm because it raises the probability of enjoying the exclusivity. In addition to the 25 drugs for which the only form of compensation is retained exclusivity, most of the settlements in Table 1 include an assured 180 days of generic sales.

Other pay-for-delay settlements. Five pay-for-delay settlements involving four drugs fit neither of these categories. Three are “interim” agreements, which restrict entry while the patent infringement suit is pending but do not resolve the suit. After such agreements were targeted for antitrust enforcement in the late 1990s,¹⁷ parties turned to the monetary and retained exclusivity settlements discussed above. The remaining two settlements are supply agreements in which the generic firm did not retain exclusivity eligibility.

The Evolution in Settlement

The settlements have occurred in two distinct waves. The first wave began in 1993 and ended in 2000 after the FTC made clear its opposition to pay-

¹⁶ For a list of these drugs, see New Data, *supra* note 1.

¹⁷ Interim settlements were reached for Cardizem CD and Hytrin (tablets and capsules), which led to FTC consent decrees.

for-delay settlements. The second wave began in 2005, after two appeals courts rejected antitrust liability for the settlements.¹⁸

The new wave of settlements is a direct response to the failure of federal courts to recognize and resolve the pay-for-delay issue.¹⁹ When private parties and the FTC have challenged the settlements on antitrust grounds, courts have failed to recognize the illegality of the settlements. That failure is likely to be compounded, moreover, by an evolution in the means by which brand name firms now pay for delay.

In the earliest settlements, such as the first five settlements in Table 1, payment was a relatively straightforward affair. In exchange for the generic firm's delayed entry, the brand-name firm paid cash. The largest naked cash payment was nearly \$400 million, which Bayer agreed to pay Barr in settling litigation over Cipro, a major antibiotic.

In the wake of increased antitrust scrutiny, naked payments have given way to more complex "side deal" arrangements. In the most common type of side deal, the generic firm contributes—in addition to delayed entry—some further value, such as an unrelated product license. The additional term provides an opportunity to overstate the value contributed by the generic firm and claim that the cash is consideration for the contributed value, rather than for delayed entry.

Side deals are now a frequent feature of entry-delaying settlements. The contributed value can include a wide range of product development,

¹⁸ In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005). The Second Circuit's ruling in *Tamoxifen* was handed down in 2005 but revised in 2006.

¹⁹ The failure has not been uniform. One appeals court recognized liability on the somewhat unusual facts of the case. In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003). A second appeals court considering the same facts reached a similar conclusion in dicta. *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809–12 (D.C. Cir. 2001).

manufacturing, and promotion services. In some of the deals listed in Table 1, the generic firm offers a product or patent license, or agrees to develop a new product.²⁰ In one variant, the generic firm develops a new formulation of the brand-name drug.²¹ In other deals, it agrees to furnish manufacturing services to the brand-name producer,²² or to provide inventory,²³ or even to provide “backup” manufacturing services.²⁴ In some cases, the generic firm provides promotional services as to the product at issue, related drugs, or unrelated products.²⁵ For some drugs, the brand-name firm reaches entry-delaying settlements with multiple generic firms, each with side deals.²⁶

Some of these arrangements are suspect on their face. It may seem clear that the brand-name firm does not need a patent license that does not clearly cover its product, new drug development that is unrelated to its current core business, a new source of raw material supply, backup manufacturing, or additional promotion. Moreover, the “value” contributed by the generic firm is often far from the firm’s actual expertise. But not all such settlements are facially absurd. In some cases, the generic firm has plausible expertise in the subject of the side deal. It can be difficult to be certain that a deal is collusive without a deep and complex inquiry into the business judgment of the two drug makers. However, outside of settlement, brand-name firms seldom contract with generic

²⁰ For example, K-Dur (two settlements), Naprelan, Provigil (four settlements), and Adderall XR (two settlements) all involved a license or product development agreement. For further details about these and other settlements discussed in this section, see New Data, *supra* note 1.

²¹ The Altace settlement had this feature.

²² The Nexium settlement and two of the Provigil settlements include such a term. In one of the Adderall XR settlements, the generic firm agreed to provide manufacturing as to products that might emerge from the development agreement. The Altace settlement included manufacturing of a new formulation by the generic firm.

²³ See, for example, Cephalon’s agreement with Barr over Provigil.

²⁴ AndroGel’s settlement as to Par has this feature, as does the Niaspan agreement.

²⁵ Examples include Niaspan, Adderall XR (one settlement), both AndroGel settlements, and Aggrenox.

²⁶ This is the case for Provigil (as to multiple first filers), Adderall XR (as to both a first filer and a later filer), AndroGel (same), and K-Dur (same).

firms for help with the activities that form the basis of side deals. That rarity provides a basis for inferring that the side deal provides a disguised means to pay for delay.

H.R. 1706

The current approach to pay-for-delay settlement is not working. Case-by-case judicial evaluation of individual settlements has failed to identify and remedy the consumer harm. And the inadequacy of judicial resolution is likely to worsen, as payment increasingly takes alternative forms.

H.R. 1706 takes an important step toward identifying and deterring pay-for-delay settlement. In particular, Section 2(a) of the bill prohibits settlements that combine a delay in generic entry with a brand name firm's provision to the generic firm of "anything of value" beyond a negotiated entry date. In defining the forms of compensation, it is crucial that this Subcommittee recognize the broad range of forms that payment can take. As noted above, generic firms are compensated not only with cash, but also with the exclusivity period itself. "Anything of value," properly understood, includes *all* forms of compensation that induce delay, including effective guarantees of exclusivity. The Subcommittee may wish to consider making this point explicit in its bill.

An alternative method to prevent pay-for-delay settlements that rely upon exclusivity is to amend the Hatch-Waxman Act, by ending eligibility for the exclusivity period for a settling generic firm. Currently, a first-filing generic firm can expect to enjoy exclusivity provided it does not lose the patent suit, even if it settles.²⁷ Ending exclusivity for settling generic firms would reduce both the

²⁷ See *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998) ("The language of the statute . . . is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation.").

amount of payment conferred in a settlement, and the extent to which a settlement delays entry.

* * *

The pay-for-delay settlement problem is getting worse. Congress has a vital role to play in establishing a broad prohibition of anticompetitive settlements, whether the brand-name firm pays with cash or with some other form of compensation. Thank you for the opportunity to discuss this important issue with the Subcommittee.

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**An Aggregate Approach to Antitrust:
Using New Data and Rulemaking to Preserve Drug Competition**

C. Scott Hemphill

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**An Aggregate Approach to Antitrust:
Using New Data and Rulemaking to Preserve Drug Competition**

C. Scott Hemphill*

Forthcoming, *Columbia Law Review* (2009)

This Article examines the “aggregation deficit” in antitrust: the pervasive lack of information, essential to choosing an optimal antitrust rule, about the frequency and costliness of anticompetitive activity. By synthesizing available information, the present analysis helps close the information gap for an important, unresolved issue in U.S. antitrust policy: patent settlements between brand-name drug makers and their generic rivals. The analysis draws upon a new dataset of 143 such settlements.

Due to the factual complexity of individual brand-generic settlements, important trends and arrangements become apparent only when multiple cases are examined collectively. This aggregate approach provides valuable information that can be used to set enforcement priorities, select a substantive liability standard, and identify the proper decisionmaker. The analysis uncovers an evolution in the means—including a variety of complex side deals—by which a brand-name firm can pay a generic firm to delay entry. The Article proposes two solutions for such anticompetitive behavior, one doctrinal and one institutional: a presumption of (illegal) payment where a side deal is reached contemporaneously with delayed entry, and an expanded role for agencies, to gather and synthesize nonpublic information regarding settlements, and potentially to promulgate substantive rules of their own. The aggregate approach also reveals the shortcomings of antitrust enforcement where, as here, firms can exploit regulatory complexity to disguise collusive activity.

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Introduction

Antitrust policymaking in the United States has a tension at its core. Antitrust law “maintain[s] certain basic rules of competition” as a way to preserve low prices, efficient production, and robust innovation.¹ In regulating a particular type of behavior, a decisionmaker may choose a rule that minimizes costly errors—false condemnations and false exonerations—even at the expense of accuracy in a particular case. Courts, as the actors charged with setting substantive antitrust policy, routinely make such choices. Unfortunately, courts lack the information needed to select optimal rules.

Consider, for example, predatory pricing. Antitrust law permits price-cutting to exclude a rival, provided that the price does not fall below cost, on the view that a more aggressive rule yields too many false condemnations.² That lenient rule increases false exonerations, but these are unlikely, the Supreme Court has concluded, because predation is “rarely tried, and even more rarely successful.”³ But how does a court come to know this? And is a court the right institution to uncover the answer?

This Article identifies and examines an “aggregation deficit” in antitrust analysis: the troubling lack of information about the frequency and costliness of anticompetitive activity. Aggregation matters for both the substance and institutional structure of antitrust policy. In setting substantive antitrust rules, courts make rough guesses, informed by economic theory and the facts of a specific case, about the distribution of real world economic conduct. What a

¹ Michael D. Whinston, Lectures on Antitrust Economics I (2006).

² *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993) (declaring that such price cuts are “beyond the practical ability of a judicial tribunal to control without courting intolerable risks of chilling legitimate price-cutting”).

³ *Id.* at 226 (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 589 (1986)).

decisionmaker actually needs is aggregate information on which to base a cost-minimizing substantive antitrust rule. In selecting an antitrust decisionmaker, moreover, we ought to favor the institution that has superior access to aggregate information.

As a vehicle for considering the substantive and institutional dimensions of an aggregate approach, this Article focuses upon a single antitrust issue: patent settlements between a brand-name drug maker and its generic rival. Settlements result from a generic drug maker's effort to market a competing version of a brand-name product. The brand-name firm responds with a patent infringement suit that claims its product is protected by one or more patents, and the generic firm counters that the patent is invalid or not infringed by the proposed generic product. The brand-name firm, rather than take a chance that the generic firm might win that argument in court, thereby ending its monopoly on the product, settles the litigation by paying the generic firm to abandon the challenge and delay entry. Does this agreement violate antitrust law?

This question is the most important unresolved issue in U.S. antitrust policy, measured by economic importance and high-level judicial attention. Recent settlements involve some of the world's most important drugs.⁴ The largest two settlements alone insulate from competition more than \$10 billion in annual brand-name sales.⁵ The importance and difficulty of the question has prompted the Supreme Court to seek the Solicitor General's views three times since 2004.⁶ As of early 2009, the Federal Trade Commission (FTC) is pursuing new litigation challenging settlements over two drugs in federal court,⁷ a new bill aiming to prohibit such settlements has been introduced in Congress,⁸ and the President has included a ban on anticompetitive settlements in his annual budget proposal.⁹

Identifying the proper scope of liability, however, is not a simple problem. Some settlements do not raise pay-for-delay concerns. For other settlements, it is difficult to tell whether a payment was made. Before an optimal antitrust rule can be developed, policymakers need accurate information regarding the scope and nature of the problem. As an initial step toward erasing this deficit, this Article assesses the problem of entry-delaying settlements by aggregating publicly available data about these settlements and considering the overall picture that emerges. This approach draws upon a new dataset of drug patent settlements, developed from a wide range of public sources. The resulting dataset provides, for the first time, a vivid

⁴ Settlements in 2008 included Lipitor (more than \$7 billion in annual U.S. sales), Pfizer Inc., Annual Report (Form 10-K) exh. 13, at 18 (Feb. 29, 2008), and Nexium (more than \$3 billion), AstraZeneca PLC, Annual Report (Form 20-F), at 55 (Mar. 12, 2008).

⁵ See *supra* note 4.

⁶ See *Joblove v. Barr Labs., Inc.*, 127 S. Ct. 1868 (2007) (order requesting Solicitor General's opinion); *FTC v. Schering-Plough Corp.*, 546 U.S. 974 (2005) (same); *Andrx Pharms., Inc. v. Kroger Co.*, 540 U.S. 1160 (2004) (same).

⁷ Complaint, *FTC v. Watson Pharms., Inc.*, No. 09-598 (C.D. Cal. Jan. 29, 2009) [hereinafter *AndroGel Complaint*]; Complaint, *FTC v. Cephalon, Inc.*, No. 08-0244 (D.D.C. Feb. 13, 2008) [hereinafter *Provigil Complaint*].

⁸ Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009).

⁹ Office of Management and Budget, *A New Era of Responsibility: Renewing America's Promise* 28 (2009) ("The Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market.").

picture of the frequency and distribution of settlement activity. Viewing the settlements collectively permits new insights about enforcement priorities, the optimal substantive rule, and the choice of decisionmaker.

The analysis reveals an evolution in the terms of settlement. Whereas early settlements simply traded cash for delay, modern settlements show sophistication in the means by which payment and delay are provided. One example is the use of side deals, consummated at the same time as settlement of the patent litigation, in which the generic firm contributes unrelated value, such as a separate patent license, ostensibly in exchange for payment. That tactic undermines reliable case-by-case characterization of settlements as collusive or not: In a particular instance, it is difficult to tell whether the brand-name firm's payment is consideration for delay, for the unrelated value, or both.¹⁰

An aggregate approach permits us to address the question in a different way. It reveals that side deals are a frequent component of settlements, but rare outside of settlement. Thus, the overall pattern suggests they provide a disguised means to confer payment. This supports the adoption of a presumption that a brand-name firm's payment to a generic firm, when contemporaneous with a generic firm's agreement to delay entry, is consideration for delay, not for the goods or services acquired in the side deal.

As an institutional matter, the aggregate approach undermines the case for courts as primary antitrust policymakers. A court is largely limited to the facts of a particular case. It lacks the capacity to collect information about the distribution of activity in the economy. To be sure, parties can supply the court with aggregate analyses based upon public information, but public disclosures contain important gaps. Moreover, courts are likely to have trouble processing this information. Agencies have a decisive advantage in collecting and synthesizing aggregate information, given their expertise and freedom to examine issues over a long period of time, outside the litigation context, and access to confidential information about the activities of regulated firms. Thus, the analysis suggests that the FTC should do more to exploit its informational advantage as a plaintiff, amicus, and rulemaker.

Finally, the aggregate perspective provides a basis for predicting the success or failure of antitrust enforcement over time. As applied to settlements, the prediction is pessimistic. Settlement has continued to evolve—even beyond side deals—in response to the enforcement emphases of particular litigants and courts. Settling parties have been able to achieve the same entry-delaying effect of the earliest settlements, while devising new disguises for the fact of payment or the very existence of agreement. As litigants respond dynamically to judicial

¹⁰ For example, in an important test case brought by the Federal Trade Commission, the case-specific approach produced divergent results at each level of review. Compare *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1070–72 (11th Cir. 2005) (concluding that Schering's payment to Upsher-Smith was for value of licenses), and *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1092, 1241 (2003) (opinion of administrative law judge) (same), with *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1019, 1051–52, 1055–56 (2003) (full Commission opinion) (concluding that payments secured delay).

scrutiny with new and complex settlement structures, existing antitrust institutions have trouble keeping up.

The Article proceeds in four parts. Part I introduces the pay-for-delay settlement problem and the aggregation deficit in antitrust. Part II draws upon the new dataset, outlining the scope and changing structure of entry-delaying settlements, and spells out how these features recommend making the settlement issue an enforcement priority. Part III examines side deals from an aggregate approach, explaining why they should be presumed to convey payment when accompanied by an agreement to delay entry. Finally, Part IV addresses the question of institutional choice. It first shows why courts make poor aggregators, and proceeds to consider how agencies can help fill the gap, by aggregating data and promulgating rules.

I. The Pay-For-Delay Settlement Problem

Part I.A describes the pay-for-delay settlement problem. Although settlements have received a great deal of attention, almost all of it has focused upon the theoretical issues raised in individual cases, at the expense of important factual questions that also arise. Part I.B describes this neglect and its connection to the larger problem of an aggregation deficit in antitrust.

A. Why Settlements Violate Antitrust Law

Pay-for-delay settlements restrict a particular kind of competition between brand-name and generic firms. The process begins when a brand-name firm launches a new drug pursuant to the Hatch-Waxman Act, the industry-specific scheme that regulates pharmaceutical competition.¹¹ Once the brand-name firm places a patented drug on the market, a generic firm may seek to launch a competing version of the same drug, asserting that any applicable patents are invalid or not infringed.¹² The assertion is contained in an Abbreviated New Drug Application, or ANDA, that is filed with the Food and Drug Administration (FDA).¹³ If the filing is successful, the generic firm can launch a competing product without repeating the costly safety and efficacy studies that the FDA requires as a condition of brand-name approval.

The first generic firm to file an ANDA is entitled, upon FDA approval, to a 180-day exclusive right to market a generic version in competition with the brand-name firm, effectively

¹¹ See 21 U.S.C. § 355(b) (2006) (providing for launch of new drug after demonstration of safety and efficacy). This account is a simplification. For more details, see C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1564–66 (2006).

¹² See § 355(j)(2)(A)(vii)(IV) (requiring certification to the FDA and notification of the rightsholder that any applicable patents are invalid or not infringed).

¹³ § 355(j)(2)(A)(vii)(IV). The ANDA contains a so-called “Paragraph IV” certification that the applicable patent protection is invalid or not infringed. Not all ANDAs contain such a certification; often, the generic firm is content to wait until patent expiration before entering. FTC, Generic Drug Entry Prior to Patent Expiration 10 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (on file with the *Columbia Law Review*) [hereinafter FTC, Generic Drug Entry] (reporting ninety-four percent of the more than 8000 ANDAs filed between 1984 and 2000 lacked a Paragraph IV certification).

creating a duopoly during that period.¹⁴ For some drugs, multiple generic firms file ANDAs on the same day, and thus share the exclusivity entitlement.¹⁵ For others, one generic firm files at least a day before the others.¹⁶ In response to the ANDA, the brand-name firm may file a patent infringement suit to establish validity and infringement. This pattern—launch, challenge, sue—is typical for major drugs.¹⁷

The two drug makers have a powerful incentive to settle. For a blockbuster drug with billions of dollars in annual sales, a brand-name firm has billions to lose from generic competition. Moreover, entry hurts the brand-name firm more than it helps the generic firm because entry lowers total producer profits by introducing price competition, particularly once other generic firms are free to enter after the 180-day period ends.¹⁸ There is therefore a large gain from trade for the two firms. A settlement in which the brand-name firm pays the generic firm, and the generic firm agrees to delay entry, is profitable for both firms. Because later filers generally have much less incentive to challenge a brand-name drug patent, including no eligibility for the 180-day period, buying off the first filer is an effective means to remove the most potent entry threat.¹⁹

Such settlements, if they include payment, reduce expected static consumer welfare. Early competition benefits consumers by lowering drug prices sooner. The consumer benefit is probabilistic, since it is not certain that entry would occur; the brand-name firm might win the suit. Settlements without payment reflect the perceived strength of the patent—for example, a generic firm’s fifty percent chance of success would yield, roughly speaking, an entry date halfway between immediate entry and patent expiration.²⁰ That result is equal to the average result of litigation, in which the consumer has a fifty percent chance of enjoying the full benefit

¹⁴ § 355(j)(5)(B)(iv). The “duopoly” characterization ignores the effect of authorized generics, discussed *infra* Part III.A.2.

¹⁵ Ctr. for Drug Evaluation & Research, FDA, Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day 3–4 (2003), available at <http://www.fda.gov/cder/guidance/5710fnl.pdf> (on file with the *Columbia Law Review*).

¹⁶ Multiple first filers may result when the brand-name drug contains no “active moiety” already approved in another NDA. In that case, the FDA must not accept an ANDA for four years after NDA approval. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b) (2006). Aside from giving the brand-name firm several years of protected sales before a generic challenge can commence, it also affords generic firms plenty of time to devise a workaround strategy. For other drugs, by contrast, the generic firms are in an immediate race to devise a plausible legal and pharmaceutical strategy, and the firms will usually differ significantly both in their assessment that the challenge is sufficiently promising to justify an investment, and in their skill and speed in developing a workaround.

¹⁷ For example, of the fourteen best-selling drugs of 2005, see Matthew Herper, *The Best-Selling Drugs In America*, *Forbes*, Feb. 27, 2006, at http://www.forbes.com/2006/02/27/pfizer-merck-genentech-cx_mh_0224topsellingdrugs.html (on file with the *Columbia Law Review*), twelve faced pre-expiration patent challenges: Lipitor, Nexium, Prevacid, Plavix, Zolof, Norvasc, Seroquel, Effexor XR, Zyprexa, Singulair, Protonix, and Risperdal. The two exceptions are Zocor and Advair Diskus. This calculation does not include biologic drugs not subject to the Hatch-Waxman regime.

¹⁸ For details and caveats, see Hemphill, *supra* note 11, at 1580–82.

¹⁹ See *id.* at 1585–86 (noting small incentive to file and vigorously pursue challenge), 1605–06 (discussing free-rider problem among later filers resulting from nonmutual issue preclusion, particularly in invalidity challenges). In some instances, the settlement also creates a bottleneck for later filers, as discussed *infra* Part II.C.2.

²⁰ This is an oversimplification, because it ignores the effect of the exclusivity period, which is a source of compensation for the generic firm. See *infra* notes 91–101 and accompanying text (describing use of exclusivity period in settlements); see also Hemphill, *supra* note 11, at 1588–94 (describing exclusivity period as source of compensation).

of immediate competition and a fifty percent chance of receiving no benefit. By contrast, bargains that reflect not only perceived patent strength but also payments from brand-name to generic manufacturers will induce the generic firm to accept a later entry date, which decreases consumer welfare. Thus, a pay-for-delay settlement transfers wealth from consumers to drug makers, in the form of continued high pharmaceutical prices, with brand-name firms sharing a portion of that transfer with the generic firm. The higher price also alters the purchase decisions of consumers and insurance providers, introducing an additional welfare loss.²¹

As I have argued elsewhere, the consumer-disregarding effect of pay-for-delay settlements requires their condemnation as a violation of antitrust law.²² Allocating markets in this fashion is a restraint on trade in violation of section 1 of the Sherman Act,²³ and may also be condemned as illegal monopolization.²⁴ It is therefore no surprise that the FTC—the agency charged with antitrust enforcement in the pharmaceutical industry—has brought numerous cases arguing that certain pay-for-delay settlements violate antitrust law,²⁵ and that private parties have done so as well.²⁶

Settling parties have offered a variety of defenses.²⁷ The most fundamental is that permitting settlement increases the brand-name firm's profit, and hence its expected reward for

²¹ Assessing this welfare loss is complex. In an ordinary market, setting a price above marginal cost produces an allocative distortion and accompanying welfare loss for consumers, because consumers who value the good above its marginal cost, but below the prevailing price, are deflected to less desired substitutes. To the extent that public and private insurance secures the purchase of a drug, this distortion is reduced, though it is not eliminated (insurance is incomplete). Moreover, the higher price produces new distortions (and hence inefficiency) in the decisionmaking process of the insurance provider, through decisions to charge higher premiums and not to reimburse drugs whose value exceeds their marginal cost. In a similar manner, the existence of incomplete insurance affects the assessment of the size of the transfer.

²² See Hemphill, *supra* note 11, at 1596.

²³ 15 U.S.C. § 1 (2006); see *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49–50 (1990) (*per curiam*) (holding that competing bar review course providers illegally restrained trade by agreeing for one to withdraw from market in exchange for payments).

²⁴ See 15 U.S.C. § 2 (prohibiting monopolization).

²⁵ The FTC has challenged brand-generic settlements over Hytrin, Cardizem CD, BuSpar, K-Dur, Provigil, and AndroGel. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058–59, 1061–62 (11th Cir. 2005) (rejecting FTC challenge to K-Dur settlement); *Bristol-Myers Squibb Co., No. C-4076*, 2003 WL 21008622 (F.T.C. Apr. 14, 2003) (describing BuSpar consent decree); *Hoechst Marion Roussel, Inc., No. 9293*, 2001 WL 333643 (F.T.C. Apr. 2, 2001) (Cardizem CD consent decree); *Abbott Labs. & Geneva Pharms., Inc., No. C-3945*, 2000 WL 681848 (F.T.C. May 22, 2000) (describing Hytrin consent decree as to Abbott); *Abbott Labs. & Geneva Pharm., Inc., No. C-3946*, 2000 WL 681849 (F.T.C. May 22, 2000) (describing Hytrin consent decree as to Geneva); *AndroGel Complaint*, *supra* note 7; *Provigil Complaint*, *supra* note 7. In addition, the FTC challenged a settlement over Ovcon that does not engage the Hatch-Waxman exclusivity provisions. See *FTC v. Warner Chilcott Holdings Co. III*, Civ. No. 05-2179, 2007 WL 158746 (D.D.C. Jan. 22, 2007) (denying motion to dismiss). The case later settled.

²⁶ Aside from private litigation running in parallel with the FTC challenges discussed in note 25, purchasers or competitors have filed antitrust suits over Cipro, Naprelan, Nolvadex, Plavix, and Procardia XL settlements that the FTC has not challenged. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (Cipro); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006) (Nolvadex); *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227, 1231 (11th Cir. 2005) (Naprelan); *Biovail Corp. v. Mylan Labs., Inc.*, No. 1:01CV66, 2002 U.S. Dist. LEXIS 6726, at *8–9 (N.D. W. Va. 2002) (Procardia XL); *Amended Complaint and Demand for Jury Trial at paras. 1–2*, *Kroger Co. v. Sanofi-Aventis*, No. 1:06-CV-163-HJW, 2006 WL 2503664 (S.D. Ohio July 31, 2006), 2006 WL 2503664 (Plavix). In addition, Sandoz, a later-filing generic firm, has alleged that the settlement between Bayer and Barr over Yasmin is part of an anticompetitive conspiracy. Sandoz alleges that Bayer and Barr agreed that Bayer would enforce a patent, which had not been asserted in litigation between Bayer and Barr, against other generic firms such as Sandoz. *Answer, Affirmative Defenses, and Counterclaims at 29–30*, *Bayer Schering Pharma AG v. Sandoz, Inc.*, No. 08-3710, 2008 WL 4486682 (S.D.N.Y. July 11, 2008).

²⁷ For a detailed account, see Hemphill, *supra* note 11, at 1573–78 (describing justifications for paying for delay).

developing innovative drugs, the marketing of which provides great benefits to consumers. Put another way, the static harm of settlement from high prices today must be weighed against the dynamic benefit of more and better drugs in the future. The potential scope of this argument is extremely broad: *Any* practice currently prohibited by antitrust law, as practiced by innovators seeking to increase their profits, could be defended upon this ground. Even simple price fixing could be excused. In general, antitrust lacks any such exemption for collusive behavior.²⁸ The case for making an exemption is particularly weak where, as here, the increase in innovative incentive from delaying competition is partially offset by the necessary payments to the generic firm.²⁹

Settling parties have offered several further objections. They assert that the suppressed competition is not cognizable because it is merely probabilistic.³⁰ That objection ignores the fact that the suppressed entry subject to antitrust regulation is almost always probabilistic.³¹ A second objection is that settlements in other industries are similarly consumer-disregarding, raising the specter of a widespread expansion of liability if these settlements are prohibited.³² It is true that market division through patent settlement is a real possibility in other industries, and to that extent, antitrust liability may be warranted there too. In addition, the Hatch-Waxman Act reflects a specific effort to promote consumer access through litigated challenges, a feature that makes the case for prohibition particularly strong in this industry.³³ A third objection—that prohibiting certain settlements increases litigation costs—is overwhelmed by the much larger adverse effect on consumer welfare.

Courts have tended to reject antitrust liability for brand-generic settlements. These courts have accepted, as a doctrinal matter, a maximalist view of the patent right. Most appellate courts that have considered the issue have adopted the view that any settlement is permissible, provided it restricts no more entry than the nominal scope of the patent if valid and infringed.³⁴ As a

²⁸ See Hemphill, *supra* note 11, at 1599–1600 (discussing why a special exception for innovators is imprudent).

²⁹ See Hemphill, *supra* note 11, at 1612–14 (making this point and arguing further that such “innovation inefficient” means of increasing brand-name drug maker incentives is unlikely interpretation of balance set by Congress between pharmaceutical innovation and competition).

³⁰ Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust*. On “Probabilistic” Patent Rights and False Positives, *Antitrust*, Spring 2003, at 68, 69.

³¹ “[I]t would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will” *United States v. Microsoft*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (per curiam).

³² See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) (expressing worry that restrictive settlement rule would spread to other industries); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 *Antitrust L.J.* 1033, 1047–49 (2004) (similar).

³³ For an elaboration, see Hemphill, *supra* note 11, at 1604–16.

³⁴ Compare *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008) (declining to impose antitrust liability), *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006) (same), and *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (same), with *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (condemning, as per se violation of Sherman Act, agreement to refrain from introducing generic drug), and *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809–12 (D.C. Cir. 2001) (reaching similar conclusion in dicta). See also *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311–13 (11th Cir. 2003) (reframing analysis for district court to apply on remand, preserving possibility of liability); cf. *Kaiser Found. Health Plan v. Abbott*, 552 F.3d 1033, 1040–41 (9th Cir. 2009) (describing the position staked out by *Valley Drug*). Courts permitting settlement add the caveat that the brand-name firm must not have

result, brand-name firms are effectively permitted to buy private term extensions to their patents. The maximalist view thus produces the absurd result that an ironclad patent and a trivial patent have the same exclusionary force. Each can support a settlement that restricts generic entry until the nominal expiration date of the patent.

The maximalist perspective also ignores the fact that the nominal scope of the patents at issue, particularly the expiration date of the last-expiring patent, is highly malleable. A sophisticated brand-name drug maker can produce a steady stream of patents, with successively later expiration dates, which in turn support a settlement date that is even later than the expiration of effective protection. A settlement involving the blockbuster drug Lipitor, Pfizer's most important product, provides an example. Pfizer sued Ranbaxy, the first-filing generic firm, over Pfizer's two strongest patents, expiring in March 2010 and June 2011,³⁵ winning as to the first patent but losing as to the second.³⁶ Analysts therefore expected entry in March 2010, or at the very latest in June 2011.³⁷ However, when the parties eventually settled, generic entry was set for November 2011, later than the expiration of either patent.³⁸ The parties defended this result on the ground that, shortly before settlement, Pfizer had also sued Ranbaxy on two minor patents that expire in 2016.³⁹ The main effect of the inclusion of these patents was to permit the parties to choose an entry date later than the expiration of the two main patents at issue.

Whether pay-for-delay settlements violate antitrust law has generated tremendous scholarly interest and a wide variety of responses.⁴⁰ The maximalist view of the patent right has

engaged in fraud upon the patent office or sham litigation. See, e.g., *Cipro*, 544 F.3d at 1336; *Tamoxifen*, 466 F.3d at 208–09, 212–13; *Schering*, 402 F.3d at 1068.

³⁵ See Duncan Blackwell, US Court of Appeal Invalidates Lipitor Patent Due to Improper Claim Dependency, *Mondaq Business Briefing*, Aug. 17, 2006 (noting expiration of U.S. Patent No. 4,681,893 patent with pediatric exclusivity in March 2010); Press Release, Pfizer, Inc., U.S. Patent and Trademark Office Accepts Pfizer's Reissue Application on Lipitor Enantiomer Patent (Jan. 6, 2009) [hereinafter *Pfizer Lipitor Press Release*] (noting June 2011 expiration for U.S. Patent No. 5,273,995).

³⁶ See *Pfizer, Inc. v. Ranbaxy Labs.*, 457 F.3d 1284 (Fed. Cir. 2006). The court ruled for Pfizer on the basic composition of matter patent, id. at 1290, and invalidated the second patent on technical grounds, id. at 1292.

³⁷ See, e.g., Merrill Lynch, Pfizer Inc.: Settlement Good News, June 18, 2008 (on file with the *Columbia Law Review*) [hereinafter *Merrill Lynch, Lipitor Settlement Report*] (prior to settlement, "we had assumed U.S. generic competition in March 2010").

³⁸ Press Release, Pfizer, Inc., Pfizer and Ranbaxy Settle Lipitor Patent Litigation Worldwide (June 18, 2008) [hereinafter *Pfizer Lipitor Press Release*]. Unless otherwise noted, this and all other press releases cited in this Article were obtained through the Factiva electronic database, as were other sources noted in the footnotes. Each can be retrieved by executing a free text search for the document's title, across all available dates. All sources obtained from Factiva are on file with the *Columbia Law Review*.

³⁹ The two patents at issue were not listed in the Orange Book, which contains listings of those patents, filed by the brand-name firm, that "count" for Hatch-Waxman purposes. *Pfizer Sues to Protect Lipitor, Caduet Process Patents*, *Drug Industry Daily*, Mar. 27, 2008, available at Factiva; see also Complaint at 1, 5–6, *Pfizer, Inc. v. Ranbaxy Labs.*, No. 08-Civ-164 (D. Del. Mar. 24, 2008) (suing for declaratory judgment of validity and infringement as to patents '511 and '740, both expiring in July 2016).

⁴⁰ At least thirty articles or book chapters, not including student notes, address the issue. See Hemphill, *supra* note 11, at 1558 n.15 (collecting nineteen articles or book chapters through 2006 by John Bigelow, Joseph Brodley, Jeremy Bulow, Thomas Cotter, Daniel Crane, Herbert Hovenkamp, Mark Janis, James Langenfeld, Crstofer Leffler, Keith Leffler, Mark Lemley, Wenqing Li, Kevin McDonald, Maureen O'Rourke, Marc Schildkraut, Joel Schrag, Carl Shapiro, and Robert Willig); see also Michael A. Carrier, *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law* ch. 15 (forthcoming 2009); Daniel A. Crane, *Patent Settlements, m Issues in Competition Policy* (Dale Collins ed., 2008); Reza Bagherian, *The Preserve Access to Affordable Generics Act: Will Congress's Response to Reverse Payment Patent Settlements*

been rejected by the FTC, senior officials of the Department of Justice Antitrust Division,⁴¹ and the Solicitor General,⁴² but they, like commentators, have a variety of views on the subject. Some take the view that all settlements that combine payment with delayed entry are per se violations of antitrust law.⁴³ Others would impose a presumption of illegality.⁴⁴ Still others say that the matter should be judged through a more detailed examination of the strength of the patent, compared to the details of the settlement.⁴⁵ The stronger the patent, the less troubling a long delay in entry would be.

Antitrust law is not the only way to address the pay-for-delay settlement problem. For example, Congress could modify or eliminate the 180-day exclusivity period, particularly for settling parties, or provide a means and incentive for drug purchasers, including the government, to challenge pharmaceutical patents. Such changes could address the incentives that give rise to the pay-for-delay settlement problem in the first place. As an alternative, settlements could be challenged at the moment they are reached, by requiring the court conducting the patent infringement case to approve the settlement using procedures akin to those employed in class actions to prevent collusive settlements. Private “objectors” or the FTC could be recruited to try to persuade the court that the settlement ought to be rejected.

Putting aside the question of political feasibility, however, such changes would not determine the legal status of the many settlements that have already been reached. Thus, antitrust law is a necessary component of any complete resolution of the pay-for-delay issue.

Enhance Competition in the Pharmaceutical Market?, 7 J. Marshall Rev. Intell. Prop. L. 150 (2007); Pamela J. Clements, The Hatch-Waxman Act and the Conflict Between Antitrust Law & Patent Law, 48 IDEA 381 (2008); Ronald W. Davis, Reverse Payment Patent Settlements: A View into the Abyss, and a Modest Proposal, 21 Antitrust Mag., Fall 2006, at 26; Lucy Grace Dearce, Deconstructing and Recalibrating the *Valley Drug* Analysis of Reverse Payments, 47 IDEA 587 (2007); Christopher Fasel, Patent Term Limits, Anti-Trust Law, and the Hatch-Waxman Act: Why Defense of a Legally Granted Patent Monopoly Does Not Violate Anti-Trust Laws, 17 Kan. J.L. & Pub. Pol’y 109 (2007); A. Paul Heeringa, Dodging Antitrust Bullets in Patent Settlement Agreements: Lessons Learned from the “Reverse Payment” Dilemma, 5 DePaul Bus. & Comm. L.J. 265 (2007); Christopher M. Holman, Symposium Review, Do Reverse Payment Settlements Violate the Antitrust Laws?, 23 Santa Clara Computer & High Tech. L.J. 489 (2007); Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III, 30 Seattle U. L. Rev. 377 (2007); James F. Ponsoldt & W. Hennen Ehrenclou, The Antitrust Legality of Pharmaceutical Patent Litigation Settlements, 2006 U. Ill. J.L. Tech. & Pol’y 37 (2006).

⁴¹ David L. Meyer, Deputy Assistant Attorney Gen., DOJ Antitrust Div., Speech at the George Mason University Law Review Symposium on Antitrust: We Should Not Let the Ongoing Rationalization of Antitrust Lead to the Marginalization of Antitrust 18 (Oct. 31, 2007) (prepared remarks available at <http://www.usdoj.gov/atr/public/speeches/227399.pdf>) (on file with the *Columbia Law Review*) (concluding that courts have gone too far in granting “carte blanche” to patentholders, and noting agreement of Solicitor General in *Joblove* and *Schering*).

⁴² Brief for the United States as Amicus Curiae at 9–12, *Joblove v. Barr Labs., Inc.*, 127 S. Ct. 3001 (2007), denying cert. to 466 F.3d 187 (2d Cir. 2006) (No. 06-830), 2007 WL 1511527 [hereinafter Brief for the United States, *Joblove*].

⁴³ See, e.g., Cristofer Leffler & Keith Leffler, Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal, 21 Res. L. & Econ. 475 (2004).

⁴⁴ The FTC, for instance, has held that:

=xIf there has been a payment from the patent holder to the generic challenger . . . [then] [a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.=ft

Schering-Plough Corp., 136 F.T.C. 956, 988 (2003) (citations omitted).

⁴⁵ See Brief for the United States, *Joblove*, supra note 42, at 12–15; see also *Tamoxifen*, 466 F.3d at 228 (Pooler, J., dissenting) (favoring similar test).

B. Neglected “Fact” Questions

Beyond this theoretical question—do pay-for-delay settlements violate antitrust law?—there is a set of factual questions that must be answered. For example, how frequently do pay-for-delay settlements occur? Knowing the answer is necessary to assess whether to make the settlement issue an enforcement priority. A second factual question arises in many modern settlements. If settlement and delay occur as part of a larger set of transactions between the two firms, how do we know that the payment was made in exchange for delay, rather than for some other valuable consideration? Often, this is a difficult question. In the only case involving a side deal that has been fully litigated so far, attempts to determine whether the particular settlement was anticompetitive produced divergent results at each level of review.⁴⁶ These factual questions have been neglected by scholars so far.

This gap in our understanding of modern settlement practice exemplifies a general problem in antitrust enforcement. Given a theoretical model of anticompetitive behavior, true under specific factual circumstances, how do we establish with confidence that those circumstances are present in a particular case? If that determination is imperfect, how do we identify a cost-minimizing rule—that predation claims should be treated leniently because predation is “rarely tried, and even more rarely successful,”⁴⁷ or that resale price maintenance ought to be accorded rule of reason treatment because its procompetitive uses are not merely “infrequent or hypothetical”?⁴⁸

Because a court lacks the independent capacity to collect the information necessary to develop an optimal rule, it relies upon others, including academics and other governmental institutions. In considering predation, for example, the Supreme Court has explicitly relied upon a “consensus among commentators” that the practice is rarely tried or successful.⁴⁹ If the external consensus changes, the Court suggests, so too may the substantive rule.⁵⁰ Agencies and Congress play a similar role. For example, Justice Breyer, dissenting from the Court’s recent decision to end a longstanding per se ban on resale price maintenance, thought any change should await solid information about “how often are harms or benefits [from the practice] likely to occur,” and questioned how easily the two can be distinguished, or “[h]ow easy [it is] to separate the beneficial sheep from the antitrust goats?”⁵¹ Such information must be supplied by

⁴⁶ See supra note 10 (describing litigation over agreement between Schering-Plough and Upsher-Smith).

⁴⁷ See supra notes 2–3 and accompanying text.

⁴⁸ *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705, 2717 (2007).

⁴⁹ *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 589 (1986) (“[T]here is a consensus among commentators that predatory pricing schemes are rarely tried, and even more rarely successful.”); see also *State Oil v. Khan*, 522 U.S. 3, 20 (1997) (noting importance of “recognizing and adapting to changed circumstances and the lessons of accumulated experience”).

⁵⁰ Lower courts have taken that instruction seriously. See, e.g., *United States v. AMR Corp.*, 335 F.3d 1109, 1114–15 (10th Cir. 2003) (“Recent scholarship has challenged the notion that predatory pricing schemes are implausible and irrational.”). In later predation cases, however, the Court has repeated the “rarely tried . . . rarely successful” language of *Matsushita*, without repeating the “consensus among commentators” qualifier. E.g., *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312, 323 (2007); *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 226 (1993).

⁵¹ *Leegin*, 127 S. Ct. at 2729 (Breyer, J., dissenting).

others, if it is to be collected at all, since “both Congress and the FTC, unlike courts, are well-equipped to gather empirical evidence outside the context of a single case.”⁵²

Real world evidence about the frequency and distribution of anticompetitive activity helps to build the requisite consensus among commentators. Such work has furthered our understanding of predation,⁵³ vertical contracting,⁵⁴ and other competitive practices. Industry-specific analyses have been important too.⁵⁵ In addition to measuring the aggregate costs of a class of antitrust violation, this study adds a distinctive dimension, the effort to understand the evolution of a practice over time. Understanding this evolution provides evidence about how well existing antitrust instruments can be expected to cope. Frequent or rapid mutations in the practices of regulated firms raise doubts about whether common law processes can effectively regulate those practices.

Whether by legislative reform or judicial decisions, “economic policy must be contrived with a view to the typical rather than the exceptional,”⁵⁶ to use George Stigler’s apt phrase. Both legislators and judges would benefit from a clear idea of how often and in what form settlements occur, and how effective we can expect judicial management to be. This is a fitting moment to examine real world evidence of settlements, before the Supreme Court or Congress establishes a new rule. The Supreme Court has not weighed in on the settlement question, but if and when it does, its rule will be difficult to undo, thanks to the infrequency of antitrust review, a cautious approach to *stare decisis*, and a fear of upsetting reliance interests.⁵⁷ The next Part begins the examination necessary to formulate an optimal rule for pay-for-delay settlements.

An agency such as the FTC is well positioned to fill these informational gaps. The agency has a statutory mandate to collect, study, and publish information about particular industries. It has general authority to require firms to divulge confidential information relevant

⁵² *Id.* at 2737.

⁵³ E.g., Patrick Bolton, Joseph F. Brodley & Michael H. Riordan, *Predatory Pricing: Strategic Theory and Legal Policy*, 88 *Geo. L.J.* 2239, 2244–49 (2000) (presenting evidence that casts doubt on traditional assumption that predatory pricing is rare).

⁵⁴ E.g., James C. Cooper et al., *FTC, Vertical Antitrust Policy as a Problem of Inference 17–23* (2005), available at <http://www.ftc.gov/speeches/froeb/050218verticalecon.pdf> (on file with the *Columbia Law Review*) (describing interplay of evidence and theory to update prior beliefs over time which, in vertical context, places heavy burden on plaintiffs).

⁵⁵ E.g., Peter Davis, *The Effect of Local Competition on Admission Prices in the U.S. Motion Picture Exhibition Market*, 48 *J.L. & Econ.* 677, 700–01 (2005) (identifying small price reduction from local competition in motion picture exhibition, but no evidence that horizontal mergers between exhibitors led to ticket price increases); see also Howard A. Shelanski, *Competition and Deployment of New Technology in U.S. Telecommunications*, 2000 *U. Chi. Legal F.* 85, 114–18 (identifying correlation between competition and innovation in sample of new technology deployments in U.S. telecommunications networks and suggesting strict enforcement of merger policy is unlikely to reduce welfare). And empirical methods are common in the analysis of particular cases. See, e.g., Jonathan B. Baker & Daniel L. Rubinfeld, *Empirical Methods in Antitrust Litigation: Review and Critique*, 1 *Am. L. & Econ. Rev.* 386, 386–91 (1999) (noting and offering explanations for increased use of empirical methods in merger cases); Timothy F. Bresnahan, *Empirical Studies of Industries with Market Power*, in *2 Handbook of Industrial Organization* 1011, 1012–13 (Richard Schmalensee & Robert D. Willig eds., 1989) (assessing “new empirical industrial organization” model in which single or related industries are analyzed independently).

⁵⁶ George J. Stigler, *The Case Against Big Business*, *Fortune*, May 1952, at 123, 158.

⁵⁷ See Transcript of Oral Argument at 11, *Leegin*, 127 S. Ct. 2705 (No. 06-480) (reporting Chief Justice Roberts’s concern that discount stores had developed in reliance upon *per se* prohibition of resale price maintenance).

to antitrust policymaking.⁵⁸ In the particular context of settlement, the FTC's position is even stronger: It has unique access to the details of every brand-generic settlement since December 2003, due to drug makers' special statutory obligation to file all such settlements with the agency.⁵⁹ This aggregate information complements other sources of FTC expertise developed and used in litigation, congressional testimony, and public hearings.⁶⁰

The FTC sometimes uses this advantage to good effect. In 2002, the agency published an important survey of brand-generic drug competition, drawing upon information supplied by drug makers under FTC compulsion as well as information collected independently by the FDA.⁶¹ That study indicated the importance of the pay-for-delay settlement problem and made a variety of policy recommendations. But there has been no follow-up to the 2002 study; more generally, industry studies—once a staple product of the FTC—have become less frequent.⁶²

The FTC's conclusions, based on its aggregate information, can be deployed in a variety of policymaking settings. In the case of the 2002 study, the conclusions were used in amicus briefs, legislative advocacy, and litigation brought by the agency.⁶³ But in each of these settings, the agency is essentially supplying its information to an external decisionmaker.⁶⁴ The agency has available to it a more aggressive option, however, which emphasizes the FTC's role as a decisionmaker in its own right: antitrust rulemaking.

The FTC possesses the power to promulgate rules with the force of law that are subject to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,⁶⁵ which imposes upon courts a “duty to defer to reasonable agency interpretations . . . [of an ambiguous] statute that an agency is charged with administering.”⁶⁶ At first, this assertion may seem

⁵⁸ FTC Act, 15 U.S.C. §§ 46(b), 49, 57b-1(c) (2006).

⁵⁹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63. The Antitrust Division also receives a copy. Id. § 1112(c).

⁶⁰ See More than Law Enforcement: The FTC's Many Tools—A Conversation with Tim Muris and Bob Pitofsky, 72 Antitrust L.J. 773, 777–78 (2005) (using recent FTC action in health care industry to illustrate tools available to FTC); see also Health Care Servs. & Prods. Div., Bureau of Competition, FTC, Overview of FTC Antitrust Actions in Pharmaceutical Services and Products (2008), available at <http://www.ftc.gov/bc/0809rxupdate.pdf> (on file with the *Columbia Law Review*) (describing various enforcement actions taken by FTC in pharmaceutical industry).

⁶¹ FTC, Generic Drug Entry, supra note 12.

⁶² F.M. Scherer, Sunlight and Sunset at the Federal Trade Commission, 42 Admin. L. Rev. 461, 467–68, 470–79 (1990), describes a wide range of industry studies conducted by the FTC up until about 1980. Scherer attributes the falloff after that point to budget cuts and disinterest by FTC Bureau of Economics directors and staff, in part because “[i]ndustry case studies have fallen out of favor” in economics graduate programs. Id. at 484–85. See also Appendix I: Investigations by the Commission, 1915–39, 8 Geo. Wash. L. Rev. 708 (1940) (collecting wide variety of industry studies during early years of FTC).

⁶³ All these routes were used after the issuance of the 2002 study. See, e.g., Petition for Writ of Certiorari at 5–6, 17, 21, 24, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2005) (No. 05-273); Brief for Federal Trade Commission as Amicus Curiae Supporting Appellant at 7, 20, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097); Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary, 108th Cong. 41–42 (2003) (prepared statement of Timothy J. Muris, Chairman, Federal Trade Commission).

⁶⁴ I say “essentially,” because in the case of adjudication, the FTC makes an initial determination, which is then reviewed by an appeals court.

⁶⁵ 467 U.S. 837 (1984). For a discussion of the FTC's authority, see *infra* Part IV.

⁶⁶ Thomas W. Merrill & Kristen E. Hickman, *Chevron's Domain*, 89 Geo. L.J. 833, 833 (2001).

startling, because its power is seldom used. The agency has promulgated just one such antitrust rule, and that was more than forty years ago.⁶⁷ Since then, the Commission has considered promulgating antitrust rules from time to time, but has never followed through.⁶⁸

In Part IV, I argue that the FTC's aggregation advantage is a reason to favor antitrust rulemaking, and that pay-for-delay settlement is an attractive candidate for a rule. But first, I will lay out what an aggregate approach can tell us about drug patent settlements.

II. Filling the Gap: Introducing an Aggregate Approach

This Part introduces an aggregate perspective to the issue of settlements between brand-name and generic drugmakers. Part II.A outlines the data collection effort. Part II.B shows the magnitude and continuing importance of settlements with delayed entry. It proceeds to describe three sources of evolution in the form of settlement, and the effects of each. Part II.C elaborates an initial payoff from the aggregate approach: a clear sense that settlements ought to be considered a top priority for antitrust enforcement.

A. Data Collection

To examine the frequency and evolution of brand-generic settlements since 1984, I collected a novel dataset. The object was to identify and synthesize all public information about the frequency and terms of settlement. The effort drew upon press releases, trade publications, financial analyst reports and analyst calls with management, court filings of patent and antitrust litigation, SEC filings, FDA dockets, and FTC reports.⁶⁹ For ten settlements, the actual settlement agreement was available.⁷⁰ In addition to the terms of settlement, I recorded the

⁶⁷ Discriminatory Practices in Men's and Boys' Tailored Clothing Industry, 16 C.F.R. pt. 412 (1968).

⁶⁸ See, e.g., FTC Staff Narrows Rulemaking Possibilities to Three Areas, 1978 Antitrust & Trade Reg. Rep. (BNA) No. 884, at A-13 (Oct. 12, 1978) (noting FTC staff's search for suitable rulemaking subject).

⁶⁹ The broadest search was a review of all articles in the Factiva database mentioning "settlement" and a "new drug application." The database includes newspapers, magazines, trade journals, press releases, company presentations at analyst conferences, and transcripts of calls between company executives and equity analysts. The search included linguistic variants of "settlement" and the abbreviations "NDA" and "ANDA." The Factiva search found a number of settlements that were not present in other forms, such as analyst reports. In many cases, articles in Factiva filled in important settlement details.

The FTC's 2002 report provided a detailed accounting of terms for the earliest settlements, with the drug name disguised. FTC, Generic Drug Entry, supra note 12. In December 2003, a new law required drug makers to file brand-generic agreements with the FTC. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, § 1112, 117 Stat. 2066, 2461-63 (2003). The FTC has presented summary information, with few details, in annual updates. FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005 (2006); FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006 (2007); FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007 (2008).

⁷⁰ See Defendants' Notice of Submission of Zenith Settlement Agreement, Kaiser Found. v. Abbott Labs., No. 02 Civ. 2443 (C.D. Cal. Mar. 14, 2006) [hereinafter Hytrin Abbott-Zenith Agreement]; Stipulation of Filing of Redacted Settlement Agreement, Pfizer, Inc. v. Zenith Goldline Pharms., Nos. 00-CV-0408 (JAP), 01-CV-6007 (JAP) (D.N.J. June 14, 2002) [hereinafter Zolofl Agreement]; Adams Respiratory Therapeutics, Inc., Quarterly Report (Form 10-Q) ex. 10-1 (May 15, 2007) [hereinafter Mucinex Agreement]; Andrx Pharm. Corp., Annual Report (Form 10-K) ex. 10.109 (Mar. 16, 2006) [hereinafter

annual sales figures at the time of settlement and noted whether the generic firm was eligible for the exclusivity period.⁷¹ I also determined whether a major provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) applied to the settlement.⁷² To be included in the set, the agreement must pertain to patent litigation resulting from an ANDA filing by a generic firm.⁷³ The search period extended from 1984, when the Hatch-Waxman Act was passed, through August 2008, and therefore ignores subsequent settlement activity.⁷⁴

This work yielded information for 143 settlements involving 101 brand-name drugs. For 28 drugs, the brand-name drug maker settled with multiple generic firms. Multiple settlements can be the result of settlements with multiple first filers sharing the exclusivity entitlement,⁷⁵ or settlements with later filers who lack eligibility for the exclusivity period. Although the focus of the subsequent analysis is settlements with first filers, in some cases settlements with later filers can raise pay-for-delay issues as well.⁷⁶

Several checks confirm that the dataset contains nearly all significant settlements that delay entry.⁷⁷ The dataset oversamples settlements that restrict entry for important drugs.

Glucotrol XL Agreement]; Barr Pharms., Quarterly Report (Form 10-Q) exhs. 10.1, 10.2, 10.3 (Nov. 9, 2006) [hereinafter Adderall XR Shire-Barr Agreement]; Bristol-Myers Squibb, Quarterly Report (Form 10-Q) exhs. 99.1, 99.2 (Aug. 8, 2006) [hereinafter Plavix Agreement]; Cephalon, Inc., Quarterly Report (Form 10-Q) exh. 10.1 (Nov. 8, 2006) [hereinafter Provigil Carlsbad Agreement]; King Pharms., Inc., Current Report (Form 8-K) exhs. 10.1, 10.2 (Jan. 8, 2008); King Pharms., Quarterly Report (Form 10-Q) exhs. 10.1, 10.2, 10.3, 10.4, 10.5 (May 9, 2006) [hereinafter Altace Agreement]; Kos Pharms., Quarterly Report (Form 10-Q) exhs. 10.2, 10.3, 10.4 (Aug. 9, 2005) [hereinafter Niaspan Agreement].

⁷¹ To determine eligibility, I assessed whether the drug was subject to the exclusivity period, whether the settling generic firm was a first filer, whether any exclusivity eligibility had already been triggered at the time of settlement, and whether the settlement itself included a forfeiture of retained exclusivity. The second determination is the most difficult, because the FDA considers the identity of the first filer to be confidential information, and because there are often multiple first filers. I based the determination on FDA letters granting ANDA approval with exclusivity (which are not confidential), generic-firm press releases reporting presumed first filer status, and a comparison of complaints in patent suits with FDA reports of the *date* of a first ANDA filing, which is not confidential.

⁷² Pub. L. No. 108-173, 117 Stat. 2066 (2006). The relevance of this fact is discussed *infra* Part III.C.

⁷³ This criteria rules out, for example, an agreement over Ovcon 35, which was not a patent dispute but did feature an agreement that was challenged as anticompetitive by the FTC. See Complaint at 7, *FTC v. Warner Chilcott Holdings Co.*, No. 1:05-cv-02179-CKK, 2005 WL 3439585 (D.D.C. Nov. 7, 2005). See *supra* note 25. It also omits drugs, such as Advicor, where a settlement as to another drug discouraged the filing of an ANDA in the first place. See, e.g., Niaspan Agreement, *supra* note 70 (providing eventual entry as to Advicor, a drug on which the generic firm had not yet filed an ANDA).

⁷⁴ E.g., Associated Press, *Teva, Barr Settle Patent Dispute with Sanofi*, Int'l Bus. Times, Nov. 19, 2008, available at <http://www.ibtimes.com/articles/20081119/teva-barr-settle-patent-dispute-with-sanofi.htm> (on file with the *Columbia Law Review*) (reporting settlement of Allegra, Allegra-D, and Nasacort AQ litigation); Press Release, AstraZeneca, AstraZeneca Settles US Pulmicort Respules Patent Litigation with Teva (Nov. 25, 2008); Press Release, Medicis Pharm. Corp., Medicis and IMPAX Announce R&D Collaboration and Settlement (Dec. 1, 2008) (reporting settlement of Solodyn litigation); Press Release, Watson Pharms., Inc., Warner Chilcott and Watson Pharmaceuticals Announce Agreements on Loestrin 24 and Femcon Fe Patent Litigation (Jan. 12, 2009) (reporting settlement of Loestrin 24 and Femcon Fe litigation, as well as co-promotion, license, and supply agreements as to other Warner Chilcott products); Press Release, Medicis Pharmaceutical Corp., Medicis and IMPAX Announce R&D Collaboration and Settlement (Dec. 1, 2008) (reporting settlement of Solodyn litigation).

⁷⁵ See note 16 *supra*.

⁷⁶ This applies, for example, to the settlements involving K-Dur, AndroGel, and Hytrin discussed *infra* note 104. In these cases, a later filer received an entry-delaying settlement in addition to the first filer.

⁷⁷ For example, the FTC catalogued 14 troubling settlements in 2002, but did not name names: 8 cash or side deal settlements, 2 "supply agreements," and 4 retained exclusivity settlements. FTC, *Generic Drug Entry*, *supra* note 12, at 34. Of these, I can match 7, 2, and zero settlements, respectively, to my dataset. Of the 11 settlements in the 2005 update, I can account for 8, as well as 26 of 28 in the 2006 update and 20 of 33 in the 2007 update. See *supra* note 69. Barr has stated that it reached settlements as to 14 drugs. *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?*

Omitted settlements are likely to be for minor drugs, or settlements that had no effect on entry. For those settlements in the dataset, publicly available information contains significant gaps. In particular, price terms are normally omitted, and detailed settlement terms are sometimes missing. Even with these limitations, the new dataset is a useful tool for examining the extent and evolution of settlement; indeed, it may be the most comprehensive examination of brand-generic settlements until and unless the FTC uses its power of compulsion to produce a complete dataset.

B. A Typology of Settlements

Of the 143 settlements in the dataset, 60 settlements include both delayed generic entry and possible contemporaneous provision of value by the brand-name firm. The 60 settlements involve 51 out of the 101 drugs in the dataset. For an additional two drugs, the Hatch-Waxman dispute was resolved through acquisition: the generic firm bought out the brand-name firm, thus ending the possibility of competition between the two.⁷⁸ (Neither merger was challenged, however, suggesting that the firms lacked market power in the first place.) As to the remaining 48 drugs, settlement either raises no pay-for-delay issue, or else my data collection effort was unable to identify any.⁷⁹ Some such settlements include an agreement on the generic entry date, without any payment. These negotiated outcomes likely reflect the perceived strength of the relevant patents. Their existence demonstrates that settlement without payment is feasible.⁸⁰ Table 1 summarizes the three categories of agreement.

For the 51 drugs raising pay-for-delay issues, payment and delay take a variety of forms. For 21 of the 51, the compensation was wholly or partly monetary.⁸¹ Sometimes the payment was an open conferral of cash. For other drugs, the possible payment was embedded within a more complicated transaction. The caveat “possible” is used because in some cases public

Hearing Before the S. Comm. on the Judiciary, 110th Cong. 23 (2007) (statement of Bruce L. Downey, Chairman and CEO, Barr Pharmaceuticals, Inc.). My data likewise contain 14 settlements as of the time of Barr’s statement. Similarly, the data contain 10 Teva settlements by early 2007, which is identical to Teva’s own statement. See Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 110th Cong. 7 (2007) (prepared statement of Theodore C. Whitehouse, Partner, Wilkie Farr & Gallagher LLP), available at http://energycommerce.house.gov/cmtc_mtgs/110-ctcp-hrg.050207.Whitehouse-Testimony.pdf (on file with the *Columbia Law Review*).

⁷⁸ The two drugs are Prefest and Mircette. Lewis Krauskopf & Martha McKay, N.J. Briefs: Barr Paying King \$15M for Rights to Prefest, *The Record* (Bergen County, N.J.), Nov. 23, 2004, at L11; Press Release, Barr Pharms., Inc., Barr, Organon and Savient Finalize Mircette Settlement and Acquisition (Dec. 2, 2005).

⁷⁹ Of the 81 settlements in this category, 67 pertain to 48 drugs whose settlements appear to raise no pay-for-delay issue. The remaining 14 settlements pertain to drugs in which the brand-name firm reached at least one other settlement that does raise a pay-for-delay issue. To avoid double-counting, these latter settlements are not included in the number of drugs in this category.

⁸⁰ See, e.g., Jon Leibowitz, Op-Ed., *This Pill Not to Be Taken with Competition: How Collusion Is Keeping Generic Drugs off the Shelves*, *Wash. Post*, Feb. 25, 2008, at A15 (pointing to feasibility of no-delay settlements as supporting conclusion that pay-for-delay settlements should be prohibited). Even if no-delay settlements were infeasible, however, the main reasons to condemn pay-for-delay settlements would still hold.

⁸¹ This category includes “underpayment” settlements discussed in Part III.A.2 *infra*.

information leaves it unclear whether the settlement included compensation.⁸² These 21 drugs are listed in Table 2, together with details about the various forms of payment, which are explained later in this Article. On average, they had annual U.S. sales, measured in the year of settlement and adjusted for inflation, of \$1.3 billion.

Table 1: Typology of Agreements

Type	Drugs	Settlements
Payment and Delay	51	60
Acquisition	2	2
Other settlements	48	81
	101	143

The 21 drugs include blockbusters such as Lipitor (more than \$7 billion in annual sales) and Nexium (more than \$3 billion). Five drugs with annual sales exceeding \$2 billion account for more than two-thirds of the total, measured by annual sales. More than half are new versions of existing therapeutic agents, whose patents are generally thought to be weaker because they tend to be obvious (and hence invalid) and are easily worked around.⁸³

The effect of delayed entry can be enormous. For the questionable settlements in Table 2, a one year delay in generic entry represents, under conservative assumptions, a transfer from consumers to producers of about \$14 billion.⁸⁴ One of the 21 settlements, Plavix, never took full effect;⁸⁵ with Plavix removed, the transfer from a one-year delay is \$12 billion. Whether the one-year benchmark is an overestimate or an underestimate is often difficult to assess in a particular case using public information. Part of the delay is attributable to the strength of the patent itself, rather than payment. Since the pre-expiration period covered by settlement is several years—the average period, weighted by sales (and excluding Plavix), is 4.1 years—the benchmark is likely conservative.

⁸² This issue is explored in more detail in Part III *infra*.

⁸³ This group consists of Sinemet CR, K-Dur, Naprelan, Niaspan, Effexor XR, Propecia, Adderall XR, AndroGel, Wellbutrin XL, Nexium, and Aggrenox. Even for those drugs that are not new versions, some of the relevant patents are noticeably weak. For example, Altace was protected by a patent not on the basic compound, but an enantiomer, and was subsequently invalidated. *Aventis Pharma Deutschland, GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1295, 1303 (Fed. Cir. 2007). Provigil is protected not by a compound patent, which expired, but by a particle-size patent. *Provigil Complaint*, *supra* note 7, at 2.

⁸⁴ Suppose generic entry achieves 75% penetration and that the generic product is priced at a two-thirds discount, relative to the brand-name drug. These figures are a simplification, because in reality, penetration and the discount (particularly during the 180-day period) are smaller at first, but quickly increase. Under these assumptions, the avoided transfer is one-half of annual sales, or \$661 million per drug. Across 21 drugs, the total is about \$14 billion. This figure does not include welfare losses caused by pricing distortions. See *supra* note 21.

⁸⁵ See *Bristol-Myers Squibb Co.*, Annual Report (Form 10-K), at 31 (Feb. 26, 2007) (estimating negative effects from Apotex launch of \$1.2 to \$1.4 billion in 2006).

Table 2: Settlements with Monetary Payment

Year	Drug	Sales	Payment		Entry	
1993	Nolvadex	400	\$	U	U: Authorized generic (AG) sales	9
1995	BuSpar	400	\$			5
	Zantac	2950	\$			2
	Sinemet CR	150	\$			11
1997	Cipro	900	\$			7
	K-Dur*	250		O	O: product licenses	4
1999	Naprelan	50		O	O: intellectual property (IP)	3
2005	Lamictal	1100		U	U: Lamictal CD (different form)	3
	Niaspan	450		O U	O: manufacturing, promotion U: Advicor (combination version)	8
	Effexor XR	2750		U	U: immediate release version	5
2006	Provigil*	700		O U	O: IP, development, manufacturing, inventory; U: Actiq	6
	Altace	700		O	O: development, supply of new form	2
	Plavix	3400		O P	O: Inventory P: deal sweeteners if settlement failed	5
	Propecia	150		U	U: Zocor, Proscar (same ingredient)	7
	Adderall XR*	900		O U	O: development, manufacturing, promotion U: immediate release version	3
	AndroGel*	350		O	O: manufacturing, promotion	9
2007	Wellbutrin XL (150 mg)	850		P	P: waived damages for 300-mg strength	1
2008	Nexium	3400		O U	O: manufacturing U: Prilosec, Plendil	6
	Lipitor & Caduet	7600		U P	U: AG sales in Canada P: waived damages, Accupril	3
	Aggrenox	300		O U	O: promotion	7

Year: Year of settlement; for Provigil, year of last settlement among four first-filers. *Drug:* * indicates monetary settlements with multiple first filers (Provigil) or with both first filer and later filer (K-Dur, Adderall XR, AndroGel). *Sales:* Annual U.S. sales, in millions of dollars, measured in the calendar year of settlement or twelve months preceding settlement, adjusted to constant 2008 dollars using the monthly Consumer Price Index prepared by U.S. Bureau of Labor Statistics, and rounded to the nearest \$50 million increment. *Payment:* "\$" is cash. "O" is overpayment by the brand-name firm; see *infra* Part III.A.1. "U" is underpayment by the generic firm; see *infra* Part III.A.2. "P" is a probabilistic payment, such as waived damages or probabilistic deal sweeteners; see *infra* Part IV.C. *Entry:* Time between settlement and scheduled entry, rounded to the nearest year, except for Altace, where no date appears to have been disclosed. Does not include immediate authorized generic sales in Nolvadex, or unexpected six-month pediatric extensions for Nolvadex and Cipro. The details of each settlement are cited *infra*. For annual sales, the sources are on file with the *Columbia Law Review*.

A more nuanced figure might be developed by offering a specific prediction about what would have happened in each case absent the settlement. The particular circumstances of a settlement can provide important indications of the likely alternative outcome. A weak patent, and likely early entry, might be identified by an analysis of the patent's validity and scope, or inferentially by a large payment. Another basis for inference is preparations by a generic firm to launch "at risk"—that is, to enter even before a court has ruled on invalidity or noninfringement. Launches at risk suggest that the patent protection is weak, because the generic firm does not fear the prospect of damages, which would exceed the generic firm's profits if imposed, or a preliminary injunction, which would spoil the expensive preparations for a generic launch.

For some drugs, public statements by management or the expectations of financial analysts help to provide a specific measure of delay. In the case of Provigil, for example, the drug maker's CEO said that due to settlements, "We were able to get six more years of patent protection. That's \$4 billion in sales that no one expected."⁸⁶ The CEO's statement reflects the firm's pre-settlement expectation of entry in 2006,⁸⁷ and settlements delaying entry until 2012.⁸⁸ In the case of Lipitor, the settlement delayed anticipated entry by nearly two years.⁸⁹ Overall, the \$12 billion benchmark estimate is likely to be conservative.

For settlements involving 25 drugs, the brand-name firm compensated the generic firm as part of an entry-delaying agreement, but the compensation was not monetary. Instead, compensation took the form of retained exclusivity. As explained in Part I, the 180-day period is valuable to the generic firm. One hundred eighty days of duopoly is worth hundreds of millions of dollars in the case of a blockbuster.⁹⁰ The entitlement can also be sold to another generic firm.⁹¹ The value of this opportunity, however, is discounted by the uncertainty that the generic

⁸⁶ John George, *Hurdles Ahead for Cephalon*, *Phila. Bus. J.*, Mar. 20, 2006, at 36.

⁸⁷ See, e.g., Q3 2005 Cephalon, Inc. Earnings Conference Call Transcript (Nov. 1, 2005), available at Factiva (statement of Frank Baldino, Chairman and CEO, Cephalon, Inc.) (providing earnings guidance for 2006, and assuming "generic versions of modafinil enter the market midyear").

⁸⁸ Press Release, Cephalon, Inc., Cephalon, Inc. Announces Agreement with Teva Pharmaceutical Industries Ltd. Regarding Settlement of Provigil Patent Litigation (Dec. 9, 2005); Press Release, Cephalon, Inc., Cephalon Announces Agreement with Ranbaxy Laboratories Ltd. Limited Regarding Settlement of Provigil Patent Litigation (Dec. 22, 2005); Press Release, Cephalon, Inc., Cephalon Announces Agreement with Mylan Pharmaceuticals, Inc. Regarding Settlement of Provigil Patent Litigation (Jan. 10, 2006); Press Release, Cephalon, Inc., Cephalon Announces Agreement with Barr Laboratories, Inc. Regarding Settlement of Provigil and Actq Patent Litigations (Feb. 1, 2006) [hereinafter *Provigil Barr Press Release*].

⁸⁹ See, e.g., Merrill Lynch, *Lipitor Settlement Report*, supra note 37 ("We now expect an extra 20 months of U.S. Lipitor exclusivity (we had assumed U.S. generic competition in March 2010 and the Ranbaxy settlement delays generic launch until November 2011)."). Later, Pfizer succeeded in having the invalidated patent reissued. See Pfizer Lipitor Press Release, supra note 38 (announcing U.S. Patent and Trademark Office's acceptance of Pfizer's correction of patent's technical defect). Under the settlement, the generic firm will enter in November 2011. Pfizer Lipitor Press Release, supra note 38.

⁹⁰ See supra note 84.

⁹¹ A generic firm can either selectively waive its entitlement to a particular later filer, or relinquish it entirely. This is a profitable strategy where the firm with the entitlement has been unable to secure FDA approval—for example, due to difficulties in formulating or manufacturing the product—and a later filer is ready to go to market, but for the fact that it is "bottled up" behind the first filer. For a fuller explanation of this bottleneck, see infra notes 117–119 and accompanying text. Selective waiver has been permitted for numerous drugs, including Zantac, Zolofit, and Wellbutrin XL. See *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 1–2 (D.D.C. 1997) (Zantac); *Complaint at 5, Teva v. Invagen*, No. 07-315 (S.D.N.Y. Jan. 12, 2007) (Zolofit); Press Release, Teva Pharms., Teva Announces Launch of Generic Wellbutrin XL Tablets, 300 mg Under Agreement with Anchen and IMPAX (Dec. 18, 2006) (Wellbutrin XL). The FDA has insisted that selective waiver, as opposed to

firm might lose the litigation, and thus never enjoy the exclusivity period.⁹² A brand-name firm's agreement to drop the patent fight—an arrangement that does not forfeit eligibility⁹³—is valuable to the generic firm because it raises the probability of enjoying the exclusivity. The 25 drugs are listed in Table 3.⁹⁴

The ability to settle with retained exclusivity disrupts the alignment of interests between the generic firm and consumers. Ordinarily, late entry dates are bad for consumers, but also bad for the alleged infringer, whose profits are a function of the amount of time on the market, and who therefore can be expected to fight for an earlier entry date. Here, by contrast, the generic firm cares more about protecting its 180-day duopoly entitlement, and less about *when* exactly that entry occurs. It is therefore willing to trade a later entry date for the better chance to enjoy the 180 days.⁹⁵ Meanwhile, consumers and taxpayers finance the continued sale of drugs at the higher, brand-name price.

This argument has an important limit. If the generic firm's pre-expiration entry lasts for less than 180 days, then its profits are, roughly speaking, linearly increasing as it pushes for an earlier entry date. In that case, the alignment between the generic firm and consumers is more nearly maintained. Of the 25 drugs listed in Table 3, 7 have entry dates so late that they have less than 180 days of exclusive sales.⁹⁶ For the remaining 18 drugs, the misalignment critique applies.

The 25 drugs have average annual sales of \$580 million. Of these, the 18 drugs with "full" exclusivity have average sales of \$442 million. If guaranteed exclusivity induces a delay of one year for each of these drugs, the transfer, using the same calculus described above, would be about \$4 billion.

relinquishment, can occur only once the exclusivity has been triggered through a favorable court ruling or commercial marketing. See FDA, Response to Citizen Petition of Pfizer, Inc., No. 2004P-0227 at 4–5 & n. 5 (July 2, 2004); see also Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 42 (D.D.C. 2000) ("[E]xclusivity periods are a transferable commodity which can be waived in favor of another generic manufacturer for a substantial price.") (citing *Granotec, Inc. v. Shalala*, 46 U.S.P.Q.2d (BNA) 1398, 1405 (4th Cir. 1998) (per curiam)); *Boehringer Ingelheim Corp.*, 993 F. Supp. at 2 (approving FDA interpretation allowing selective transfer); 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,881 (Aug. 6, 1999) (codified at 21 C.F.R. § 314.107) (explaining FDA position that "applicant may selectively waive its exclusivity only after the 180-day exclusivity period has begun to run with the occurrence" of favorable court ruling or commercial marketing).

⁹² Other risks include the possibility that a later-filing generic firm wins a patent suit, triggering the first filer's exclusivity period before the generic firm secures approval, or that the patent expires before the generic firm wins the suit.

⁹³ Settlement does not remove entitlement to the exclusivity period. See *infra* Part II.C.2 (discussing factors influencing settlements).

⁹⁴ The list omits settlements where retained exclusivity did not seem to play a role, where there was no delayed entry, or where there the available data was ambiguous about continued entitlement to the exclusivity period. Entry as to one drug on the list, Exelon, was not disclosed, but was assumed to be at least 180 days prior to patent expiration.

This list is an underestimate. For example, my data collection identified none of the four early retained exclusivity settlements discussed in the FTC report. See *supra* note 77 (comparing this Article's dataset with that of the FTC report).

⁹⁵ For a detailed analysis, see Hemphill, *supra* note 11, at 1588–94.

⁹⁶ Frequently, this occurs when a brand-name firm secures a six-month pediatric extension that is tacked onto the end of the patent term. 21 U.S.C. § 355a(b), (c) (2006). See, e.g., Press Release, Dr. Reddy's Labs., Dr. Reddy's Laboratories Announces Settlement of Imitrex Litigation with GlaxoSmithKline (Oct. 10, 2006) (noting expected launch of generic Imitrex under settlement in fourth quarter of 2008, prior to expiration of pediatric exclusivity on February 6, 2009).

Table 3: Settlements with Retained Exclusivity

Year	Drug	Sales	Full?
2002	Zoloft	3000	*
2004	Femhrt	50	*
	Estrostep	50	*
2005	Lamictal CD	50	*
2006	Duoneb	250	*
	Imitrex tablets	900	
	Imitrex injection	200	
2007	Mucinex	150	*
	Diastat	100	*
	Valtrex	1350	*
	Adenoscan	350	*
	Avandia	1200	
	Avandamet	300	
	Avandaryl	100	
	Keppra	900	
	Paxil CR	350	*
	Flomax	1200	
	Cardizem LA	100	*
	Exelon	201	*
2008	Astelir	200	*
	Optivar	50	*
	Xopenex	500	*
	Miacalcin	150	*
	Depakote ER (500 mg)	700	*
	Mirapex	400	*

Year and Sales: As in Table 2. *Full:* Indicates whether the entry date was early enough to permit 180 days of sales prior to patent expiration. For annual sales, the sources are on file with the *Columbia Law Review*.

The preservation of exclusivity can take a second form. In some cases, a generic firm wins a patent challenge, but is blocked from approval by a second patent that the generic firm either did not challenge at all, or challenged unsuccessfully. In such a case, the generic firm “wastes” the exclusivity resulting from that partial victory, which is triggered and expires while the generic firm is blocked from entering by the second patent.⁹⁷ Once the second patent expires, the generic firm enters, but without exclusivity. A generic firm can avoid wasting its exclusivity by abandoning its challenge, and agreeing to enter with exclusivity upon the expiration of the second patent.⁹⁸ This benefits the brand-name firm, and harms consumers, for the same reason:

⁹⁷ See Donald O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements* § 4.02[H], at 4–43 (7th ed. 2008) (discussing situation where exclusivity is “effectively useless because a second patent, as to which [the generic firm had declined to challenge validity or infringement], had not yet expired when the 180-day exclusivity began to run”).

⁹⁸ The Zoloft settlement between Pfizer and Zenith is an apt example. Pfizer had two patents on Zoloft: a strong patent expiring in 2006, and a weak patent expiring in 2013. In 1999, Zenith challenged the 2013 patent but not the 2006 patent. Winning as to the 2013 patent would have wasted the exclusivity, unless that happened after the expiration of the 2006 patent.

Prices are higher during the (preserved) duopoly exclusivity period than with full competition from other generic firms.

In addition to the drugs for which the only form of compensation is retained exclusivity, all of the drugs in Table 2, except for the first five, have secured an assured 180 days of generic sales.⁹⁹ Other settlements explicitly trigger exclusivity,¹⁰⁰ or involve generic firms that are ineligible for exclusivity in the first place.¹⁰¹

(Patent suits are slow, but not that slow.) Instead, Zenith agreed to enter with exclusivity upon the expiration of the basic patent. See Zolofit Agreement, *supra* note 70.

Barr's challenge to Prozac raised a similar possibility. See Barr Labs., Inc., Amendment to a Previously Filed 10-K405 (Form 10-K405/A), at 10–11 (May 15, 2001) (noting that 180-day period could be wasted if challenge to one patent succeeded, triggering exclusivity as to it, while a second patent blocked FDA approval of the generic drug). As it turned out, the patent had expired by the time exclusivity was triggered, and only six days remained of the associated pediatric exclusivity period. The premature triggering question was limited to the six-day overlap: Was the 180-day period truncated by the overlap with pediatric exclusivity? Congress passed a statute providing for the full benefit of exclusivity in such circumstances, and generic entry was protected for the six days. Best Pharmaceuticals for Children Act (BPCA) § 10, 21 U.S.C. § 355a(k) (2006); Press Release, Barr Labs., Inc., Barr Confirms Prozac Exclusivity Runs Until January 29 (Jan. 9, 2002) (announcing letter from FDA stating that BPCA “extends” exclusivity by the amount of the overlap, in this case to January 29, 2002).

The Lipitor settlement appears to contain another variant. When Ranbaxy won its challenge to one patent in the Federal Circuit, this triggered exclusivity, but prematurely, since the other valid and infringed patent prevented FDA approval. Pfizer, Inc. v. Ranbaxy Labs., 457 F.3d 1284, 1290–92 (Fed. Cir. 2006). The combined result would have been to permit entry without exclusivity in March 2010. (The patents expiring in 2016 were never listed in the Orange Book, and did not affect that result.) However, Pfizer had three more Orange Book-listed patents in reserve, on which Ranbaxy was likely the first ANDA filer but Pfizer did not sue. Under pre-MMA law, each patent provided a fresh opportunity for exclusivity. See Apotex Inc. v. FDA, 414 F. Supp. 2d 61, 72–74 (D.D.C. 2006), *aff'd per curiam*, 226 F. App'x 4 (D.C. Cir. 2007) (granting *Chevron* deference to FDA's interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) (2000), to provide separate exclusivity for separate patents). By declining to sue Ranbaxy on these patents, Pfizer preserved Ranbaxy's exclusivity despite the initial trigger, a preferable result for both parties. The MMA replaced this “patent-by-patent” approach to exclusivity with a single opportunity for each product. 21 U.S.C. § 355(j)(5)(B)(iv)(f) (2006) (making exclusivity available only to “first applicant”); *id.* (j)(5)(B)(iv)(II)(bb) (defining “first applicant” by reference to drug, not patent); see also John. R. Thomas, *Pharmaceutical Patent Law 367* (2005) (explaining post-MMA scheme).

⁹⁹ The first five settlements included no pre-expiration entry, for reasons discussed *infra*. In the case of Lamictal and AndroGel, the preserved exclusive sales is a synthetic construct achieved by contract. For Lamictal, the 180-day period expires when the relevant patent expires, and the generic firm is granted a license during the pediatric exclusivity. Teva Launches Generic Lamictal Tablets in US, *Pharmaceutical Bus. Rev.* Online, July 23, 2008, at http://www.pharmaceutical-business-review.com/article_news.asp?guid=3B55AC72-6DFA-4112-8CAA-A81234A9C2C3 (on file with the *Columbia Law Review*) [hereinafter *Lamictal Press Release*] (noting settlement provision that Teva has exclusive right to enter during pediatric exclusivity, which expires on January 22, 2009). In the case of AndroGel, the first-filing generic firm disclaimed exclusivity. Watson and Unimed Pharmaceuticals, Inc. Settle Lawsuit over AndroGel Testosterone Gel, *PR Newswire*, Sept. 13, 2006. The reason is presumably to avoid antitrust attention, since retained exclusivity helps effectuate delay, as discussed in the next section. However, the settlement is structured to preserve exclusive sales in practice: First filer Watson's negotiated entry date, August 31, 2015, is 180 days earlier than later filer Par's entry date of February 26, 2016. See *Solvay Settles Dispute with Par*, *Watson*, *Associated Press*, Sept. 13, 2006, available at Factiva (reporting entry dates for both filers).

¹⁰⁰ For example, Yasmin sales commenced by June 2008, see Bayer AG, *Stockholders' Newsletter 43* (July 30, 2008), which sufficed to trigger exclusivity under either Bayer's NDA or Barr's ANDA. See § 355(j)(5)(B)(iv) (triggering exclusivity for post-MMA drugs upon “first commercial marketing,” “including the commercial marketing of the listed drug”); Press Release, Barr Pharms, Inc., Barr and Bayer Sign Supply and Licensing Agreements for Launch of Generic Yasmin and Yaz Oral Contraceptives (June 24, 2008) [hereinafter *Yasmin Press Release*].

For some settlements, such as Yasmin, retained exclusivity (and the accompanying bottleneck) is not necessary because exclusivity can be secured by other means. In the case of Yasmin, the brand-name firm sued the later filer on different patents. *Answer, Affirmative Defenses, and Counterclaims at 29–30*, *Bayer Schering Pharma AG v. Sandoz, Inc.*, No. 08-3710 (S.D.N.Y. July 11, 2008) (alleging, *inter alia*, that Bayer's refusal to assert patent asserted against Sandoz—the Barr litigation concerned a different patent—is part of conspiracy that violates antitrust law).

¹⁰¹ This is the case when the generic firm is not a first filer, or when the brand-name drug does not give rise to exclusivity eligibility.

Five pay-for-delay settlements fit neither of these categories. Three are “interim” agreements, which restrict entry while the patent infringement suit is pending but do not resolve the suit. After such agreements were targeted for antitrust enforcement in the late 1990s,¹⁰² parties turned to the monetary and retained exclusivity settlements discussed above. The remaining two settlements are supply agreements in which the generic firm did not retain exclusivity eligibility.¹⁰³ A summary of the four categories of pay-for-delay settlements appears in Table 4. Again, the number of settlements is larger than the number of drugs, because—for a few drugs—the brand-name firm entered multiple settlements.¹⁰⁴

Table 4. Pay-for-Delay Settlements Summarized

Type	Drugs	Settlements
Monetary	21	28
Retained exclusivity only	25	27
Interim agreement	3	3
Supply agreement	2	2
	51	60

The firms that have entered settlements with both payment and delay are quite diverse: 28 brand-name firms and 25 generic firms in all.¹⁰⁵ The most frequent brand-name settler is Glaxo, with 2 settlements in Table 2 and 8 in Table 3.¹⁰⁶ Teva and Barr are the most frequent

¹⁰² Interim settlements were reached for Cardizem CD and Hytrin (tablets and capsules), which led to the FTC consent decrees cited in note 25 supra.

¹⁰³ The drugs are Procardia XL and Wellbutrin SR. In the case of Procardia XL, the generic firm received an immediate license not only on the 30-milligram strength for which it was the first filer, but two other strengths as well. Defendant Pfizer, Inc.’s Motion to Dismiss the Complaint at 4–6, *Great Lakes Health Plan, Inc. v. Pfizer, Inc.*, No. 1:01-CV-106 (N.D. W. Va. July 30, 2001). In the case of Wellbutrin SR, the generic firm relinquished any eligibility for the 180 days, and received a license to sell not only the 100-milligram strength for which it was first filer, but another strength as well. See FDA Memorandum in Opposition to Motion for Preliminary Injunction at 11, *Andrx v. Thompson*, No. 1:03-cv-23171-JEM (S.D. Fl. Dec. 11, 2003) (referring to “Company X,” which filed a substantially complete ANDA after Andrx’s incomplete ANDA of June 18, 1999, but before Andrx’s sufficiently complete ANDA on August 12, 1999); Complaint at 10–12, *Andrx v. Thompson*, No. 03-23171 (S.D. Fl. Nov. 26, 2003) (discussing Andrx’s understanding that first filer, in FDA’s view, was Watson).

¹⁰⁴ Provigil entered monetary settlements with four first filers. See supra note 88 (identifying settlements). In addition, the drugs K-Dur, Adderall XR, AndroGel, and Hytrin had monetary settlements with generic firms that filed ANDAs with Paragraph IV certifications, but were not first filers. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1060–61 (11th Cir. 2005) (K-Dur); *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1346 (S.D. Fla. 2000), rev’d on other grounds, 344 F.3d 1294 (11th Cir. 2003) (Hytrin); Press Release, Shire PLC, Shire and Impax Settle All Pending Litigation Concerning Adderall XR (Jan. 19, 2006) (Adderall XR) [hereinafter Adderall XR Shire-Impax Press Release]; Press Release, Unimed Pharms., Inc., Unimed Pharmaceuticals, Inc. Settles AndroGel Litigation with Watson Pharmaceuticals, Inc. and Paddock Laboratories/Par Pharmaceutical Companies, Inc. (Sept. 13, 2006) [hereinafter AndroGel Press Release]. In Table 4, to avoid double counting, Hytrin is included in the count for interim settlement drugs, but not monetary settlement drugs. Exelon had retained exclusivity settlements with three first-filing generic firms. Press Release, Watson Pharms., Inc., Watson and Novartis Settle Lawsuit Over Exelon Patent Litigation (Dec. 6, 2007); Press Release, Dr. Reddy’s Labs., Dr. Reddy’s Announces Settlement of Exelon ANDA Litigation with Novartis (Jan. 22, 2008); Press Release, Sun Pharm. Indus., Sun Pharma Announces Settlement of Litigation over Generic Exelon (Dec. 6, 2007).

¹⁰⁵ Accounting for mergers, the set of generic firms falls to 20. Teva and Barr are considered separately, though they merged in December 2008. Press Release, Teva Pharm. Indus. Ltd., Teva Completes Acquisition of Barr (Dec. 23, 2008).

¹⁰⁶ In Table 2, Zantac and Lamictal. In Table 3, Lamictal CD, Imitrex (both tablets and injection), Valtrex, Avandia, Avandamet, Avandaryl, and Paxil CR.

generic settlers, with 11 and 9 settlements, respectively. Barr has been more aggressive than Teva: 6 of its settlements, compared to 4 of Teva's, appear in Table 2.¹⁰⁷ One generic firm, Ranbaxy, has played a role disproportionate to its settlement count, reaching settlements involving the blockbusters Lipitor¹⁰⁸ and Nexium¹⁰⁹ in the span of a few months in 2008. Although many individual drug makers enter into multiple brand-generic settlements, repeat negotiations between brand-generic pairs are rare.¹¹⁰

C. The Evolution in Settlement

Three factors have shaped a continuing evolution in the structure and content of brand-generic settlements: 1) the waxing and waning of antitrust enforcement, 2) a change in judicial interpretation of the Hatch-Waxman Act, and 3) major statutory amendments to the Act in 2003. This evolution poses challenges when choosing an optimal substantive antitrust rule and antitrust decisionmaker, topics taken up in Parts III and IV, respectively.

1. *Antitrust Challenges.* — The form of settlement varies significantly with the level of perceived antitrust risk, particularly as to monetary settlements. Table 2 depicts this pattern. Monetary settlements occurred at a rate of about one per year from 1993 through 1999. In 2000, the FTC initiated antitrust actions against several settlements,¹¹¹ and monetary settlements subsided. In 2005, the government and private purchaser plaintiffs lost antitrust suits in the Eleventh and Second Circuits, respectively.¹¹² That year saw monetary settlements as to three drugs, and in 2006, six more. Moreover, some settlements may be timed to correspond to a

¹⁰⁷ For Barr, Nolvadex, Cipro, Niaspan, Provigil, Adderall XR, and Aggrenox. For Teva, Lamictal, Effexor XR, Provigil, and Wellbutrin XL. In addition, Barr has three settlements in Table 3 (Estrostep, Femhrt, and Mirapex), and Teva has six (Zolofit, Adenoscan, Avandamet, Avandaryl, Avandia, and Lamictal CD). The Zolofit settlement was reached with Ivax, which Teva later acquired.

¹⁰⁸ See Pfizer Lipitor Press Release, supra note 38.

¹⁰⁹ See Press Release, Ranbaxy Pharms., Inc., Ranbaxy and AstraZeneca Reach Agreement in Eesomeprazole Patent Litigation (Apr. 15, 2008) [hereinafter Nexium Press Release].

¹¹⁰ Of the settlements in Tables 2 and 3, Glaxo negotiated with Teva over Lamictal, then Avandia, Avandaryl, and Avandamet. GlaxoSmithKline PLC, Annual Report 2007 (Form 20-F), at 152–53 (Feb. 29, 2008) (Avandia, Avandaryl, and Avandamet); Lamictal Press Release, supra note 99. Glaxo settled with Genpharm over Zantac, then settled with Genpharm's successor, Mylan, over Paxil CR. See, e.g., Eric Reguly, Shares in Glaxo Rise as Lawsuit Is Settled—Glaxo Wellcome, Times (London), Oct. 24, 1995, available at Factiva (Zantac), Press Release, Mylan, Inc., Mylan Announces Settlement of Paroxetine Hydrochloride Extended-Release Tablets with GlaxoSmithKline (Oct. 23, 2007) (Paxil CR); Press Release, Glaxo Wellcome PLC, Glaxo Wellcome PLC Re Genpharm Litigation (Oct. 23, 1995) (same).

Looking beyond the tables, Bayer negotiated with Barr over Cipro, then later reached settlements over Yasmin and Yaz, settlements in the dataset but not part of either table. In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1328 (Fed. Cir. 2008) (Cipro); Yasmin Press Release, supra note 100 (Yasmin and Yaz). Barr negotiated with Ortho-McNeil over Ortho-Novum 7/7/7, which may be a retained exclusivity agreement, then Ortho Tri-Cyclen. Consent Judgment and Order, Ortho-McNeil Pharm., Inc. v. Barr Labs., No. 00-CV-2805 (D.N.J. July 23, 2003) (Ortho Tri-Cyclen); Press Release, Barr Labs., Inc., Barr Laboratories Announces Agreement in Ortho-Novum 7/7/7 Patent Litigation (Oct. 29, 2001) (Ortho-Novum 7/7/7).

¹¹¹ The first private suit I am aware of was filed in 1998. See In re Cardizem CD Antitrust Litig., 332 F.3d 896, 903 (6th Cir. 2003) (noting that complaint was filed in August 1998).

¹¹² In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005), amended and superseded by 466 F.3d 187 (2d Cir. 2006) (upholding agreement between Zeneca and Barr); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1070–72 (11th Cir. 2005) (upholding Schering's agreements with Upsher-Smith and ESI Lederle).

depletion in FTC enforcement capacity. In 2008, shortly after the FTC challenged one monetary settlement, there was a renewed flurry of monetary settlements, including Lipitor and Nexium.

The intensity of antitrust enforcement affects not only the fact, but also the form, of monetary settlements. The first monetary settlements—including the first five listed in Table 2—blocked entry until patent expiration, and the brand-name firm paid cash.¹¹³ Starting in 1997 and frequently after 2000, that basic form changed in two ways, both of them likely a response, in part, to increased pressure from antitrust enforcers.¹¹⁴ First, settlements began to include some pre-expiration entry. That shift provides drug makers with the rhetorical opportunity to argue that the settlement guarantees some competition. Some entry looks better than no entry. From this perspective, the law has shifted in the drug makers' favor even further than they may have anticipated, given the prevailing view of appellate courts that it is fine to pay for settlements with no pre-expiration entry.¹¹⁵

Second, starting in 1997, settlements frequently included not only payment and delay, but also additional contractual terms that tend to obscure whether payment has occurred. The forms of these disguises, and their importance for case-by-case litigation, are discussed in Part III.

2. *Judicial Interpretation.* — The shift toward settlements with pre-expiration entry has a second cause. Prior to 1998, the FDA had insisted that, in order to enjoy the 180-day exclusivity period, a generic firm must successfully defend its pre-expiration challenge. In 1998, that view was defeated in the courts, on the ground that it was contrary to the text of the Hatch-Waxman Act.¹¹⁶ After that, a first-filing generic firm could expect to enjoy exclusivity provided it did not lose the patent suit, even if it settled. That made it possible to compensate using retained exclusivity, provided that entry occurred before patent expiration.

The end of the successful defense requirement also created a new form of delay with respect to nonsettling firms. This is due to a statutory quirk in the 180-day exclusivity provision:

¹¹³ These include Nolvadex (\$66 million), BuSpar (\$73 million), Zantac (\$133 million), Sinemet CR (unknown), and Cipro (\$398 million). See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1328–29 (Fed. Cir. 2008) (Cipro); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193–94 (2d Cir. 2006) (Nolvadex); *Bristol-Myers Squibb Co.*, 135 F.T.C. 444 (2003) (FTC Analysis to Aid Public Comment), available at 2003 WL 1092114 (BuSpar); Hemphill, *supra* note 11, at 1570 n.69 (inferring size of BuSpar settlement from FTC, *Generic Drug Entry*, *supra* note 12, at 32 tbl.3-3); *id.* at 1569 & n.63 (inferring same for Zantac); *Faulding Inc.*, Annual Report (Form 10-K), at 9 (Sept. 27, 1996) (Sinemet CR). In addition, “interim” agreements involving two drugs, *Cardizem CD* and *Hytrin*, included naked cash payments. See *Cardizem*, 332 F.3d at 902–03 (*Cardizem CD*); *Abbott Labs. & Geneva Pharms., Inc.*, No. C-3945, 2000 WL 681848, ¶¶ 25–27 (F.T.C. May 22, 2000) (*Hytrin*).

¹¹⁴ The first such settlement, *K-Dur*, was negotiated in 1997, and predated increased antitrust pressure. See *Schering-Plough*, 402 F.3d at 1059–61.

¹¹⁵ See cases cited *supra* note 34.

¹¹⁶ See *Granutec, Inc. v. Shalala*, 46 U.S.P.Q.2d (BNA) 1398, 1401 (4th Cir. 1998) (discussing clarity of statute’s language); *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff’d*, 140 F.3d 1060 (D.C. Cir. 1998) (“The language of the statute . . . is plain and unambiguous. It does not include a ‘successful defense’ requirement, and indeed it does not even require the institution of patent litigation.”); *Ctr. for Drug Evaluation & Research, FDA, Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act 4* (1998), available at <http://www.fda.gov/cder/guidance/2576fnl.pdf> (on file with the *Columbia Law Review*) (stating that “FDA will not enforce the ‘successful defense’ provisions” and “intends to formally remove” them from Code of Federal Regulations).

A later-filed ANDA may not be approved until 180 days after either the first filer's initiation of commercial marketing or a court determination of invalidity or noninfringement. A settlement with the first filer eliminates the possibility of commercial marketing or a court ruling. The 180 days is never triggered, and the later ANDA filer is stuck, for the FDA lacks authority to approve the application, blocking subsequent entry.¹¹⁷

This resulting "bottleneck," however, is defeasible. If a second generic firm files an ANDA, is sued by the brand-name firm, and wins the patent suit, that decision triggers the first filer's exclusivity period. The second ANDA filer can enter 180 days later.¹¹⁸ To avoid that outcome, the brand-name firm may decline to sue the second generic firm, in which case the generic firm must bring a declaratory judgment suit challenging the patents,¹¹⁹ win that suit, and then wait 180 days.

3. *Statutory Change.* — Statutory change represents a third possible source of evolution, but here, the actual change has been unexpectedly small. In 2003, as noted above, Congress amended the Hatch-Waxman regime as part of the MMA.¹²⁰ These provisions were designed, in part, to curb anticompetitive settlements. The most important change was a new forfeiture procedure, which causes a generic firm to lose its entitlement to the exclusivity period under certain circumstances described below.¹²¹ The MMA's passage led some to conclude that the settlement problem had been resolved.¹²²

¹¹⁷ Of the 21 monetary settlements described in Table 2, at least 11 appear to create a bottleneck. As for the others, the first 5 settlements predated the demise of the successful defense requirement, and so their effect, at least as of the date of settlement, is debatable. Four recent settlements—Wellbutrin XL, Nexium, Caduet, and Aggrenox—are governed by the new rules, considered below. In the remaining settlement, AndroGel, the first filer abandoned any claim to the bottleneck. Of the 25 drugs described in Table 3, 9 appear to create a bottleneck under the old rules. The remaining 16 are subject to the new rules discussed *infra*.

¹¹⁸ In several early settlements, the generic firm disavowed exclusivity eligibility by changing its certification from paragraph IV to paragraph III. See *Ciprofloxacin*, 544 F.3d at 1328–29 (Cipro); *Tamoxifen*, 466 F.3d at 193–94 (Nolvadex); *Bristol-Myers*, 135 F.T.C. at 453–54 (FTC Analysis to Aid Public Comment) (BuSpar). In the case of Nolvadex, however, the generic firm reasserted its continued entitlement to exclusivity, after other potential generic entrants emerged and the successful defense requirement was held invalid. *Tamoxifen*, 466 F.3d at 195–96; see also *Cipro*, 544 F.3d at 1340 n.14 (considering and dismissing plaintiffs' contention that later filers were discouraged by belief that first filer retained exclusivity).

¹¹⁹ For some settlements, this route was blocked by the Federal Circuit's view that the generic firm lacked standing to bring suit, a roadblock that was later cleared by judicial interpretation. See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 132 n.11 (2007) (identifying problems with Federal Circuit's "reasonable anticipation of suit" test); *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1288 (Fed. Cir. 2008) (noting Court's rejection of reasonable anticipation of suit test); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1334 (Fed. Cir. 2007) ("In light of the Supreme Court's recent decision . . . we reverse.")

¹²⁰ Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in scattered sections of U.S. Code, including 21 U.S.C.).

¹²¹ 21 U.S.C. § 355(j)(5)(D) (2006).

¹²² See, e.g., Kent S. Bernard, *The 2008 EC Sector Inquiry Regarding Pharmaceuticals: What Does It Mean from a Research-Based Company Perspective?*, GCP: The Online Magazine for Global Competition Policy, Nov. 2008, at 8, available at <http://www.globalcompetitionpolicy.org/index.php?id=1466&action=907> (on file with the *Columbia Law Review*) ("In the U.S., the evil of paying the first challenger was that he could block any others, so that a single settlement could block all generic competition on a compound. The law has since changed on this point, and the bottleneck is no longer an issue."); see also Brief for the United States as Amicus Curiae at 18, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779), 2004 WL 1562075 [hereinafter Brief for the United States, *Andrx*] (concluding that MMA's passage lessened need for Supreme Court review).

Five years after the MMA's passage, however, there is little evidence that settlements featuring both payment and delayed entry have become less popular. As noted above in Figure 2, monetary settlements have been a common occurrence after 2003; if anything, they appear to have increased in frequency. And the incidence of monetary settlements for blockbuster drugs has increased. The most important settlements, preserving brand-name profits on blockbusters such as Lipitor, Nexium, and Plavix, occurred after the statutory change. The only blockbuster settlement that predates the MMA is Zantac. That 1995 settlement also preceded significant antitrust enforcement efforts and avoided antitrust scrutiny.

One reason for the limited effect is that the new forfeiture regime only applies prospectively. It is limited to drugs for which the first ANDA was filed after December 2003.¹²³ Most drugs, therefore, are governed by the old regime. Patent litigation frequently takes four or five years to reach settlement. In the Lipitor litigation, for example, a generic firm first filed an ANDA in 2003, but the firms did not settle until 2008. All but 4 of the 21 monetary settlements depicted in Table 2, and 9 of the 25 retained exclusivity settlements in Table 3, were reached under the pre-MMA rules. In short, even if the pre-MMA regime is only transitional, it remains important.

Moreover, even when fully applicable, the new forfeiture rules do little to curb pay-for-delay settlement. Like the old rules, they permit a brand-name firm to neutralize the first filer's challenge through settlement. That first filer still has the largest incentive to challenge the patent because only it is eligible to receive the 180-day reward. And the new rules still contain a bottleneck.¹²⁴ Forfeiture applies only upon the satisfaction of two statutory conditions.¹²⁵ The first condition is relatively easy to satisfy.¹²⁶ The second condition is triggered only if an appeals court rules that the relevant patents are invalid or not infringed, or if a settlement reaches a

¹²³ To be more precise, December 8, 2003. MMA § 1102(b)(1), 117 Stat. at 2460. An exception is that one basis for forfeiture, an unappealed or unappealable determination that the agreement violates antitrust law, 21 U.S.C. § 355(j)(5)(D)(i)(V), applies also to "old" ANDAs, MMA § 1102(b)(2), 117 Stat. at 2460.

¹²⁴ The FDA recently reached the same conclusion:

=xtInherent in the structure of the "failure to market" forfeiture provisions is the possibility that a first applicant would be able to enter into a settlement agreement . . . in which a court does not enter a final judgment of invalidity or non-infringement (i.e., without a forfeiture event under subpart (bb) occurring), and that subsequent applicants would be unable to initiate a forfeiture with a declaratory judgment action. This inability . . . could result in [approval delays of other ANDAs]. This potential scenario is not one for which the statute currently provides a remedy.=ft

Letter from Gary J. Buehler, Dir., Office of Generic Drugs, FDA, to Marc A. Goshko, Executive Dir., Teva N. Am. 5 n.6 (Jan. 17, 2008), available at <http://www.fda.gov/ohrms/DOCKETS/dockets/07n0389/07n-0389-let0003.pdf> (on file with the *Columbia Law Review*).

This is not the only possible interpretation, since a court might conclude instead that the certification asserting patent invalidity or noninfringement was not "lawfully maintained." § 355(j)(5)(D)(i)(I)(bb).

¹²⁵ See § 355(j)(5)(D)(i)(I) (setting condition of "later of" (aa) and (bb)). Aside from forfeiture for failure to market, there is also a provision for forfeiture in the case of certain illegal agreements, but that condition requires a successful government antitrust suit against the settling parties. § 355(j)(5)(D)(i)(V).

¹²⁶ See § 355(j)(5)(D)(i)(I)(aa) (requiring satisfaction by "the earlier of" 75 days after the first filer's effective date, and 30 months after application filing).

similar result.¹²⁷ The new bottleneck, like the old one, is defeasible. A later-filing generic firm can break the logjam by winning its challenge and waiting 180 days. The post-MMA rules make the relevant condition for defeasement an appeals court win, rather than a district court win—a condition now applicable to both post-MMA and pre-MMA drugs.¹²⁸ This change delays further the moment of generic entry.

D. Setting Enforcement Priorities

The foregoing survey has several implications for antitrust enforcement. First, it demonstrates that the settlement issue is a first-order enforcement question. The size of the buyer overcharge from pay-for-delay settlements likely exceeds \$16 billion.¹²⁹ The large implications for consumer welfare justify vigorous FTC and private enforcement efforts, continued scholarly investigation of the evolution and effect of settlements, and a concerted effort by the FTC and Antitrust Division to reach a full convergence of their historically divergent views of settlements.¹³⁰

The survey also underscores the importance of prompt Supreme Court review.¹³¹ In terms of their practical importance, drug patent settlements have an at least comparable impact to other antitrust issues on which the Supreme Court has granted certiorari. By way of comparison, resale price maintenance, the subject of a recent major Supreme Court case, has long been avoidable for most well-counseled firms.¹³²

Moreover, settlement has become a patent issue, not only an antitrust issue. Although framed as an antitrust case by plaintiffs, the Federal Circuit has embraced the view that

¹²⁷ See § 355(j)(5)(D)(i)(bb). There is also a third possibility, that the brand-name firm withdraws the relevant patent information from the Orange Book. § 355(j)(5)(D)(i)(l)(bb)(CC).

¹²⁸ Prior to the MMA, a generic firm's district court win triggered the running of the exclusivity period. Court Decisions, ANDA Approvals, and 180-Day Exclusivity, 65 Fed. Reg. 43,233, 43,234 (July 13, 2000) (codified at 21 C.F.R. § 314.107); Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 47 (D.D.C. 2000). The FDA had previously taken the view that the generic firm could wait until an appeals court ruling without triggering exclusivity, in order to avoid the choice between launching at risk and losing exclusivity. 21 C.F.R. § 314.107(e)(1) (1999), repealed by 65 Fed. Reg. 43,233 (July 13, 2000). The MMA restores the appeals court trigger for pre-MMA ANDAs. Pub. L. No. 108-173, § 1102(b)(3), 117 Stat. 2066, 2460 (2003) (codified at 21 U.S.C. § 355). For new ANDAs, the rule is analogous. Forfeiture (rather than triggering) of exclusivity occurs 75 days after a generic firm's appeals court win, § 355(j)(5)(D)(i)(l)(bb)(AA) (setting failure to market trigger), and provided that the "easy-to-satisfy" condition discussed supra note 126 is also satisfied.

¹²⁹ The one-year benchmark measures discussed in Part II, \$12 billion for monetary settlements and \$4 billion for retained exclusivity settlements, imply a total \$16 billion transfer from buyers to sellers. Again, that figure leaves out any effect from increased utilization due to competitive prices.

¹³⁰ Compare Petition for Writ of Certiorari at 3, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2005) (No. 05-273), 2005 WL 2105243 (arguing that pay-for-delay settlements violate antitrust law), with Brief for the United States as Amicus Curiae at 11–12, *Schering-Plough*, 548 U.S. 919 (No. 05-273), 2006 WL 1358441 (raising doubts about FTC position). For evidence of convergence, see Meyer, supra note 41, at 18 (expressing agreement of DOJ Antitrust Division official with FTC position that courts are too lenient toward settlements).

¹³¹ The courts of appeals have varied in their treatment of settlements, see supra note 34 (collecting and comparing cases). The Solicitor General, assessing the cases prior to the most recent *Cipro* decision of the Federal Circuit, took the view that these cases do not create a true circuit split. Brief for the United States, *Joblove*, supra note 42, at 15–16.

¹³² See *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705, 2722 (2007) (describing practice of avoiding discussions of pricing policy on advice of "counsel knowledgeable of the intricacies of the law").

settlement is essentially a patent issue, governed by patent law—indeed, governed by Federal Circuit law¹³³—and that patent law trumps antitrust doctrine within the nominal scope of the patent. The settlement issue fits well with other patent cases on which the Court has taken certiorari in recent years, and is of a piece with the Court’s effort to combat perceived hypertrophy in the claimed extent of patent protection.¹³⁴

The MMA provisions targeting anticompetitive settlements provide no basis for postponing review. The “transitional” pre-MMA rules continue to have a significant impact. One of the first pay-for-delay settlements concerned an ANDA filed in 1985; the certiorari petition in the resulting antitrust suit was filed 21 years later.¹³⁵ Antitrust challenges regarding ANDAs filed in 2003 or earlier are likely to remain pending for quite some time. And because post-MMA ANDAs are governed by similar rules, a Court decision about a pre-MMA case largely controls the analysis for post-MMA cases as well.

This aggregate survey reveals a final advantage of prompt review. Antitrust challenges to early settlements are still making their way to the Court.¹³⁶ These contain payment and delay, but not much else. Later settlements, however, add contractual complexity. They add difficult factual layers—Was there payment? Was there delay?—atop the legal question of whether payment in exchange for delay violates antitrust law. For a Court that dislikes wading into factual complexity, the early cases provide a more attractive vehicle for setting a clear rule.

III. Developing Substantive Policy from Aggregate Data

This Part examines how an aggregate approach affects the choice of a substantive antitrust rule. Part III.A highlights one particularly troubling element of the evolution in settlements: the rise of side deals that disguise the fact of payment in a pay-for-delay settlement. Part III.B demonstrates that the exchanges seen in these side deals, though common in settlements, are uncommon otherwise. Part III.C argues that the absence of similar deals outside the settlement context provides a basis for presuming that side deals are disguised payments for delay, not for value.

¹³³ See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332–34 (Fed. Cir. 2008) (concluding that settlement did not violate antitrust law, apparently as matter of Federal Circuit law, not Second Circuit law).

¹³⁴ See, e.g., *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741–43 (2007) (rejecting, as too low a bar, Federal Circuit test for patent nonobviousness); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393–94 (2006) (rejecting Federal Circuit rule that permanent injunctions must be issued against patent infringement, absent exceptional circumstances).

¹³⁵ *Petition for a Writ of Certiorari, Joblove v. Barr Labs., Inc.*, 127 S. Ct. 3001 (2007) (No. 06-830), 2006 WL 3694387.

¹³⁶ For example, *Cipro*, which could yield petitions from both the Federal Circuit and the Second Circuit. See *supra* notes 26, 110, 113, 133 (describing *Cipro* litigation).

A. The Rise of Side Deals

As explained in Part II.B, the earliest settlements were straightforward affairs. The brand-name firm paid cash in exchange for the generic firm's delayed entry. The largest naked cash payment was nearly \$400 million, which Bayer agreed to pay Barr in settling litigation over Cipro, a major antibiotic.¹³⁷

In the wake of increased antitrust scrutiny, naked payments have given way to more complex arrangements. Today, side deals take two complementary forms: overpayment by the brand-name firm for value contributed by the generic firm, and underpayment by the generic firm for value provided by the brand-name firm.

1. *Overpayment by the Brand-Name Firm.* — In the most common type of side deal, the generic firm contributes—in addition to delayed entry—some further value, such as an unrelated product license. The additional term provides an opportunity to overstate the value contributed by the generic firm and claim that the cash is consideration for the contributed value, rather than for delayed entry. In reviewing K-Dur, the earliest settlement with this type of side deal, the Eleventh Circuit accepted such a factual assertion, which provided a basis for rejecting antitrust liability.¹³⁸

Side deals are now a regular feature of entry-delaying settlements. The contributed value can include a wide range of product development, manufacturing, and promotion services. In some deals, the generic firm offers a product or patent license, or agrees to develop a new product.¹³⁹ In one variant, the generic firm develops a new formulation of the brand-name drug.¹⁴⁰ In other deals, it agrees to furnish manufacturing services to the brand-name producer,¹⁴¹ or to provide inventory,¹⁴² or even to provide “backup” manufacturing services.¹⁴³ In some cases, the generic firm provides promotional services as to the product at issue, related

¹³⁷ See supra note 113 and accompanying text.

¹³⁸ Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1070–71 (11th Cir. 2005).

¹³⁹ For example, K-Dur (two settlements), Naprelan, Provigil (four settlements), and Adderall XR (two settlements) all involved a license or product development agreement. See In re Schering-Plough Corp., 136 F.T.C. 956, [TAN 8-10] (2003) (K-Dur settlements as to Upsher-Smith and ESI Lederle); Andrx Pharm., Inc. v. Elan Corp., No. 00-3481, slip op. at 6 (S.D. Fl. Apr. 24, 2003) (order granting motion for judgment on the pleadings) (Naprelan); Provigil Complaint, supra note 7, at 16–20 (patent licenses as to Teva, Ranbaxy, and Barr, and product development as to Mylan and Barr); Adderall XR Shire-Barr Agreement, supra note 70, ex. 10.1; Adderall XR Shire-Impax Press Release, supra note 104.

¹⁴⁰ See King Pharm., Quarterly Report (Form 10-Q), at 10 (Aug. 7, 2007) (noting that generic firm has responsibility for providing new formulations).

¹⁴¹ The Nexium settlement and two of the Provigil settlements include such a term. Nexium Press Release, supra note 109; Provigil Complaint, supra note 7, at 16–18 (describing supply terms included in agreements with Teva and Ranbaxy). In one of the Adderall XR settlements, the generic firm agreed to provide manufacturing as to products that might emerge from the development agreement. Adderall XR Shire-Barr Agreement, supra note 70, ex. 10.2. The Altace settlement included manufacturing of a new formulation by the generic firm. Altace Agreement, supra note 70.

¹⁴² E.g., Provigil Complaint, supra note 7, at 19–20 (describing Cephalon's agreement with Barr); Plavix Agreement, supra note 70, ex. 99-1.

¹⁴³ AndroGel's settlement as to Par has this feature. AndroGel Press Release, supra note 104 (noting back-up manufacturing agreement as to Par). So does the Niaspan agreement. See Niaspan Agreement, supra note 70, ex. 10.4, at 1.

drugs, or unrelated products.¹⁴⁴ For some drugs, the brand-name firm reaches entry-delaying settlements with multiple generic firms, each with side deals.¹⁴⁵

Some of these arrangements are suspect on their face. It may seem clear that the brand-name firm does not need a patent license that does not clearly cover its product, new drug development that is unrelated to its current core business, a new source of raw material supply, backup manufacturing, or additional promotion.¹⁴⁶ However, not all such settlements are facially absurd. In some cases, the generic firm has plausible expertise in the subject of the side deal.¹⁴⁷ It is very difficult to be certain that a deal is collusive without a deep and complex inquiry into the business judgment of the two drug makers.

2. *Underpayment by the Generic Firm.* — The brand-name firm, rather than paying too much, can charge too little. One mechanism involves “authorized generic” sales. These are sales made by a generic firm under the brand-name firm’s product approval. The brand-name firm supplies the product to the generic firm at a discount, which the generic firm then resells under its own label at a profitable price. The compensation is buried in the discounted price offered by the brand-name firm.

In several early settlements, the authorized generic product was launched at the time of settlement.¹⁴⁸ This practice fell out of favor after a court concluded that the authorized generic sales triggered the 180-day period.¹⁴⁹ Some modern settlements avoid the trigger problem by

¹⁴⁴ Examples include Niaspan, Adderall XR (one settlement), both AndroGel settlements, and Aggrenox. See Niaspan Agreement, supra note 70, ex. 10.2, at 1 (promotion of Advicor, a drug protected by same patents as Niaspan); Adderall XR Shire-Barr Agreement, supra note 70, ex. 10-1 (promotion of unrelated drug); AndroGel Press Release, supra note 104 (promotion of AndroGel); News Release, Barr Pharmaceuticals, Inc., Barr Announces Agreements to Settle Mirapex and Aggrenox Patent Challenges (Aug. 12, 2008).

¹⁴⁵ This is the case for four of the drugs discussed supra 104: Provigil (as to multiple first filers), Adderall XR (as to both a first filer and a later filer), AndroGel (same), and K-Dur (same). See supra notes 139–144.

¹⁴⁶ For example, in the case of a settlement involving the wakefulness drug Provigil, the brand-name firm, Cephalon, apparently was aware of one generic firm’s intellectual property for three years before showing any interest in seeking a license. Provigil Complaint, supra note 7, at 16.

¹⁴⁷ See, e.g., Adderall XR Shire-Barr Agreement, supra note 70 (describing Barr investments in drug delivery technology, to be exploited in new product development by brand-name firm as part of settlement). The agreement was later terminated, with substantial payments to Barr. Shire LLC, Current Report (Form 8-K), at 1.01 (Mar. 2, 2009) (reporting reimbursement of \$30 million in expenses, one-time payment of \$10 million, and \$25 million in foregone revenue from license for authorized generic supply).

¹⁴⁸ For example, Nolvadex and Procardia XL involved authorized generic sales. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193–94 (2d Cir. 2006) (Nolvadex); Defendant Pfizer Inc.’s Motion to Dismiss the Complaint at 5, No. 01-106 (N.D. W. Va. July 30, 2001) (Procardia XL).

¹⁴⁹ This conclusion was reached as to Procardia XL, one of the two supply agreements discussed supra. See Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Evaluation and Research, FDA, to Deborah A. Jaskor, Senior Dir., Teva Pharms. Regarding Docket No. 00P-1446/CP1, at 1 (Feb. 6, 2001) (on file with the *Columbia Law Review*) (concluding, in response to Teva’s citizen petition, that private-label sales triggered running of exclusivity period); see also *Mylan Pharms., Inc. v. Thompson*, 207 F. Supp. 2d 476, 488 (N.D. W. Va. 2001) (concluding that Teva was likely to prevail on that contention).

providing for authorized generic sales only after another generic firm enters,¹⁵⁰ or on a drug other than the subject of the generic firm's ANDA filing,¹⁵¹ or in another country.¹⁵²

In a related form of discounted sale, which avoids the trigger issue, the brand-name firm sells an entire product line to the generic firm. One settlement involving an extended-release version of a drug, for example, transferred (for a possibly discounted price) the immediate-release version to the generic firm.¹⁵³ In a more complicated set of deals, a brand-name firm may have sold a generic firm rights to one product, and the generic firm delayed entry in two other products.¹⁵⁴ (A further variant of this strategy, simultaneous settlement of multiple drugs with uneven entry terms, is considered in Part IV.C.) Once again, it is very difficult as a practical matter for a decisionmaker to know whether the transfer price provides compensation from the brand-name firm to the generic firm, and if so, how much.

B. Infrequency Outside of Settlement

Outside of settlement, brand-name firms seldom contract with generic firms for help with the activities that form the basis of side deals. Indeed, as a general matter, brand-name and generic firms seldom execute major deals outside the settlement context, with the exception of authorized generic arrangements, which necessarily are reached between a brand-name firm and a generic firm.

A review of the annual securities filings of settling drug makers supports this proposition. To examine the extent of business dealings outside of settlement, five major brand-name firms¹⁵⁵

¹⁵⁰ See *infra* Part IV.C.

¹⁵¹ For example, in settling Nexium litigation, AstraZeneca made Ranbaxy an authorized generic distributor of Prilosec and Plendil. Press Release, Ranbaxy Pharms., Inc., Ranbaxy and AstraZeneca Reach Agreement in Esomeprazole Patent Litigation (Apr. 15, 2008). The Effexor XR settlement granted the generic firm an early license to sell an immediate-release of Effexor. Wyeth Pharmaceuticals, Current Report (Form 8-K) (Jan. 13, 2006). The Niaspan settlement provided a license as to Advicor. Niaspan Agreement, *supra* note 70, ex. 10.3. The Propecia settlement appears to be a fourth example. There, Merck made Dr. Reddy's an authorized generic distributor of Proscar and Zocor around the same time that the parties settled litigation over Propecia. See Press Release, Dr. Reddy's, Dr. Reddy's Launches Authorized Generic Versions of Proscar and Zocor (June 23, 2006) (noting January 2006 agreement to make Dr. Reddy's authorized generic distributor); Letter from Mary Graham to Judge Gregory M. Sleet, Regarding Merck & Co. v. Dr. Reddy's Labs., No. 04-1313 (D. Del.) (Mar. 1, 2006) (reporting to judge that parties had reached settlement as to Propecia).

¹⁵² For example, in settling Lipitor litigation, Pfizer made Ranbaxy an authorized generic distributor of Lipitor in Canada. Q2 2008 Ranbaxy Laboratories LTD Earnings Conference Call, Voxant FD Wire (July 29, 2008), available at Factiva (noting particularly significant authorized generic opportunity for Ranbaxy in Canada, triggered by another firm's entry at to Lipitor).

¹⁵³ See Adderall XR Shire-Barr Agreement, *supra* note 70, at ex. B.

¹⁵⁴ Galen sold Barr rights to Loestrin, and Barr delayed entry as to two other products, Estrostep and Femhrt. Brian Lavery, Galen and Barr Make Deal on Drug Rights and Patents, N.Y. Times, Sept. 12, 2003, at W1. This transaction is not included in Table 2 because the Loestrin sale was completed first. Compare Barr Acquires Galen's Loestrin Under Final Agreement, Drug Industry Daily, Mar. 26, 2004, available at Factiva, with Press Release, Barr Pharms., Inc., Barr Announces Agreement with Galen Resolving Outstanding Patent Challenges on Estrostep and Femhrt (Apr. 27, 2004). That ordering limited the degree to which a Loestrin sale could confer compensation upon Barr, in exchange for delayed entry on Estrostep and Femhrt, because Barr could simply walk away with its Loestrin "quid" without providing an Estrostep/Femhrt "quo."

¹⁵⁵ Abbott, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, and Pfizer were selected as brand-name firms.

and five major generic firms¹⁵⁶ were chosen based upon their frequency of settlement activity and economic importance. For each brand-name firm, annual filings between 2000 and 2007 were searched for the names of the five generic firms.¹⁵⁷ Each resulting “hit” led to further examination, to see whether the discussion indicated a business relationship between the two firms, as opposed to, say, a description of litigation or competition. The business transactions were examined further using articles in the trade press and other materials. The same exercise was performed for each of the generic firms, as to each of the five brand-name firms.¹⁵⁸

The resulting inquiry into twenty-five total brand-generic business dealings—each of five brand-name firms, with each of five generic firms—produced just two responsive business arrangements, both of them involving Ranbaxy: an unusual drug development deal with one brand-name firm,¹⁵⁹ and a purchase of rights to a set of minor dermatology drugs from another brand-name firm.¹⁶⁰ Several other business arrangements do not match the terms of the side deals discussed above.¹⁶¹ This evidence is not decisive; such non-settlement deals could exist, yet be too insignificant to report in an annual filing. If so, however, they are apparently not of first-rank importance to the operations of the firm.

Further evidence about the firms’ limited business dealings, outside of settlement, is revealed by one specific type of side deal known as co-promotion. Brand-name firms frequently enter co-promotion arrangements to augment their promotion efforts—for example, to reach physicians that their own detailing team does not visit. In a second search, the same annual filings were reviewed for mentions of promotion, and those mentions which pertained to product promotion were examined further. That search produced many examples in which a brand-name firm recruited other brand-name firms to help promote a drug, but no significant examples, outside the settlement context, in which the brand-name firm recruited a generic firm to promote

¹⁵⁶ Barr, Mylan, Ranbaxy, Teva, and Watson were the selected generic firms.

¹⁵⁷ Form 10-K, in the case of Abbott, Bristol, and Pfizer; Form 20-F, in the case of AstraZeneca and GlaxoSmithKline.

¹⁵⁸ Form 10-K, in the case of Barr, Mylan, and Watson; Form 20-F, in the case of Teva; and detailed annual reports filed under Indian securities law, in the case of Ranbaxy.

¹⁵⁹ Glaxo and Ranbaxy have an unusual drug development initiative, in which Ranbaxy takes “hit” molecules from Glaxo that show initial promise, and helps develop and winnow them into “candidates” for further development by Glaxo. Ranbaxy Labs. Ltd., Annual Report 2003, at 30; Ranbaxy, GSK in R&D Pact, *Hindustan Times*, Oct. 23, 2003, available at Factiva. In 2006, the agreement was expanded to permit Ranbaxy to participate in development beyond the candidate stage, to the point of a new investigational new drug application in India. Ranbaxy Labs. Ltd., Annual Report 2006, at 16; see also Ranbaxy Seeks Nod for Human Clinical Trials, *Fin. Express*, Oct. 14, 2008, available at Factiva.

¹⁶⁰ See Ranbaxy Labs. Ltd., Annual Report 2007, at 13 (describing purchase from Bristol-Myers Squibb); *Alicia Ault, Ranbaxy Buys BMS Derm Brands*, *Skin & Allergy News*, July 1, 2007 (listing the products).

¹⁶¹ For example, Bristol agreed to commercialize EmSam, a patch treatment for depression, after it was already developed by a Mylan-Watson joint venture, and ready for FDA approval. B-MS and Somerset in Emsam Distribution Deal, *Pharma Marketletter*, Jan. 3, 2005, available at Factiva. Bristol and Barr have had complex marketing arrangements on several products, but this is the accidental result of an antitrust settlement between DuPont and Barr, inherited by Bristol when it bought DuPont’s drug business. Rick Mullin, *Bristol-Myers Untangles Barr-DuPont Agreements*, *Chemical Week*, May 8, 2002, at 27, available at Factiva. Ranbaxy bought Glaxo’s generic drug operations in Spain and Italy. Ranbaxy Labs. Ltd., Annual Report 2006, at 5. In 1999, Watson paid Glaxo to acquire the rights to Androderm, a testosterone patch, but this was a reacquisition of rights to a product developed by a company later acquired by Watson. Taren Grom, *Generics: Best Years to Come*, *Med Ad News*, Oct. 1, 1999, available at Factiva (describing Watson’s acquisition of TheraTech); *Watson Rights*, *Chain Drug Review*, June 28, 1999, available at Factiva (announcing reacquisition of Androderm rights).

a brand-name drug.¹⁶² On the other hand, generic firms do occasionally have significant branded drugs, and the search did reveal instances when they have hired brand-name firms to help market the drug.¹⁶³

This result is not surprising, considering the business of generic firms. Generally, they do not have substantial promotion teams, for they seldom have major branded drugs to promote. The absence of generic provision of other services, outside the settlement context, is equally unsurprising. Although some generic firms have made efforts to develop a brand-name drug business,¹⁶⁴ as a general matter, their research and development capacity is limited; this is not their core business. Nor do they have powerful manufacturing capabilities such that they would be the obvious and efficient alternative supplier for a brand-name firm.¹⁶⁵ The contrast is less severe in side deals featuring transferred assets. It is quite common for a brand-name firm to set up an authorized generic arrangement with some generic firm. Transfers of product lines to other drug makers are common as well.

C. Adopting a Presumption of Payment

Viewed in isolation, it is difficult to tell whether a side deal represents payment for value or disguised payment for delayed generic entry. A broader comparison of side deals in conjunction with settlements, versus brand-generic deals outside this context, tells a different story. At least with respect to overpayment side deals, the absence of brand-generic deals outside of settlement is a strong reason to suspect that the deals are used to pay for delay.

In such cases, it is appropriate to impose a presumption that the side deal provides disguised payment to the generic firm. Under this pay-for-delay presumption, drug makers would be free to come forward with evidence that their unusual deal was for value and therefore raises no anticompetitive issues. That burden is most appropriately placed upon them, as the least-cost providers of the necessary information. An alternative approach, also supportable by the evidence from aggregation, would make this presumption conclusive.

¹⁶² A minor exception is promotion efforts outside the United States. In particular, Ranbaxy promotes a Sanofi vaccine in India. See Ranbaxy to Market Aventis Vaccines, Bus. Line, Oct. 6, 2002, available at Factiva (describing agreement to market six vaccines); Aventis Arm in Vaccine Tie-Up with India's Ranbaxy, Reuters News, Oct. 4, 2002 (describing marketing agreement).

¹⁶³ For example, Teva recruited a predecessor of Sanofi-Aventis to help sell its multiple sclerosis drug Copaxone. Teva Pharmaceutical Industries Ltd., Annual Report (Form 20-F), at 20 (Mar. 31, 2001); Sanofi-Aventis, Annual Report (Form 20-F), at 61 (Mar. 7, 2008) (explaining the deal). Another example is the EmSam deal discussed supra note 161.

¹⁶⁴ See, e.g., Teva Pharms. Inc., Innovative Research & Development, at <http://www.tevapharm.com/research> (on file with the *Columbia Law Review*) (describing efforts to develop innovative drugs that have yielded two products, Copaxone and Azilect).

¹⁶⁵ For example, Cephalon agreed to buy Provigil's active ingredient from a third generic firm, even though the firm had not manufactured the product and Cephalon already had an adequate source of supply. Provigil Complaint, supra note 7.

That conclusion is not, by itself, enough to impose liability. It resolves the “factual” question of whether a settlement containing a side deal constitutes payment for delay, but not the “theoretical” question of whether pay-for-delay settlements violate antitrust law.¹⁶⁶

This proposal, like any aggressive antitrust rule, is potentially overinclusive. It raises the probability of false condemnation. But here, the rarity of such arrangements outside of settlement lowers the likelihood of false positives. The error cost analysis has a further component: How costly are false positives when they occur? Not very costly, as it turns out, because the generic firm is seldom a distinctive source of the particular value in question.

The rule comports with the comparative rigor with which we treat collusive activity generally. Antitrust’s lenient approach to exclusionary conduct reflects an error cost calculation focused upon false positives.¹⁶⁷ As noted in the introduction, decisionmakers think that true positives are rare and difficult to distinguish, and also that false positives are particularly costly, because they amount to condemnation of the “very conduct” (competitive price cuts) that antitrust is supposed to protect.¹⁶⁸ As other commentators have noted, false negatives are an important countervailing problem.¹⁶⁹ For collusion, by contrast, avoiding false negatives is the important goal, particularly where false positives are rare and low-cost, and where no significant equilibrating factors tend to restore competition. That relatively aggressive approach is shared even by “Chicago School” analysts, who support an enforcement emphasis upon collusion.¹⁷⁰

What about underpayment side deals? The likelihood of false positives is higher, compared to overpayment deals, because authorized generic arrangements and product transfers frequently occur outside the context of settlement. The cost of false positives remains low, however, due to the absence of distinctive value arising from dealing with this particular generic firm, which happens to be locked in a patent suit with the brand-name firm, as the counterparty in a transaction with this particular brand-name firm.

¹⁶⁶ See *supra* Part I.A.

¹⁶⁷ See, e.g., *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004) (justifying lenient rule for refusals to deal as response to costliness of false condemnations); *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993) (justifying lenient rule for predatory pricing as response to “intolerable risks of chilling legitimate price-cutting”).

¹⁶⁸ See, e.g., *Trinko*, 540 U.S. at 414 (“Mistaken inferences and the resulting false condemnations ‘are especially costly, because they chill the very conduct the antitrust laws are designed to protect.’” (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986))).

¹⁶⁹ See, e.g., Andrew I. Gavil, *Exclusionary Distribution Strategies by Dominant Firms: Striking a Better Balance*, 72 *Antitrust L.J.* 3, 5 (2004) (arguing that lenient rule toward exclusion creates substantial false negative risk); Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 *Antitrust L.J.* 311, 346 (2006) (arguing that “profit-sacrifice test” for exclusionary conduct creates substantial false negative risk); see also Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 *Minn. L. Rev.* 101, 179 (2006) (arguing that passive possession of invalid patents serves to exclude competitors which, if permitted, creates false-negative costs).

¹⁷⁰ See, e.g., *Premier Elec. Constr. Co. v. Nat’l Elec. Contractors Ass’n*, 814 F.2d 358, 369 (7th Cir. 1987) (Easterbrook, J.) (noting heightened risk where “[n]o automatic mechanism corrects blunders”); Richard A. Posner, *Antitrust Law* 48 (2d ed. 2001) (noting that Reagan-era Antitrust Division, led by Bill Baxter, shifted enforcement focus from exclusionary to collusive practices); Richard A. Posner, *Oligopoly and the Antitrust Laws: A Suggested Approach*, 21 *Stan. L. Rev.* 1562, 1562 (1969) (suggesting that section 1 of Sherman Act reaches both explicit and tacit collusion in oligopoly).

The high cost of false negatives and low cost of false positives support a presumption in the underpayment context, just as in the overpayment context. A more conservative alternative would be to make the presumption applicable only to future settlements. That way, parties have ample notice that they must not reach underpayment deals with parties with which they are settling. Given the absence of distinctive value offered by the settling firm, that route places at most a minimal burden upon parties that wish to reach authorized generic or asset transfer arrangements.

This policy suggestion could be implemented by several routes. For example, it could be adopted by a court considering a particular case, using the federal courts' common lawmaking authority under the Sherman Act. Alternatively, it could be instituted through new congressional legislation, or promulgated as an agency rule by the FTC. The next Part considers the strengths and weaknesses of these alternative routes.

IV. Expanding the FTC's Role as Aggregator

This Part turns to the institutional question of who should employ this aggregate approach to antitrust questions. Part IV.A explains why an agency—here, the FTC—is better positioned to collect and synthesize aggregate information, relative to courts. Part IV.B argues that this advantage in wielding aggregate information favors a shift in substantive policymaking authority from courts to agencies.

A. Information Gathering and Synthesis

A court establishing antitrust policy faces the fundamental problem that it has little capacity to collect aggregate data. The disadvantage of courts as a fact-finder is a familiar idea from the literature on institutional choice.¹⁷¹ The problem is particularly acute here. At best, a single court needs many years to develop a sense of the overall distribution of cases, as antitrust cases appear only rarely on its generalist docket. The Supreme Court is in a slightly better position, since it is exposed to appeals from all over the country. But many instances of anticompetitive behavior are never litigated, and courts have particularly limited ability to observe nonpublic data about settlements outside the case at bar.

¹⁷¹ For an excellent review of this literature, see Margaret H. Lemos, *The Commerce Power and Criminal Punishment: Presumption of Constitutionality or Presumption of Innocence?*, 84 *Tex. L. Rev.* 1203, 1251–57 (2006) (reviewing the argument that courts are weak fact-finders, limited by the single case in front of them, absence of expertise, and absence of fact-finding capacity). Among the many sources cited there, see, e.g., Benjamin Cardozo, *The Growth of the Law* 116–17 (1924) (“Some of the errors of courts have their origin in imperfect knowledge of the economic and social consequences of a decision, or of the economic and social needs to which a decision will respond.”); Cass Sunstein, *The Partial Constitution* 147 (1993) (“Courts are rarely experts in the area at hand. Moreover, the focus on the litigated case makes it hard for judges to understand the complex, often unpredictable effects of legal intervention. Knowledge of these effects is crucial but sometimes inaccessible.”); William W. Buzbee & Robert A. Schapiro, *Legislative Record Review*, 54 *Stan. L. Rev.* 87, 143 (2001) (“The courts . . . are not well-suited to gather the evidence necessary to assess the magnitude of complex social practices . . .”).

Private parties cannot entirely fill the gap. These plaintiffs struggle to learn the content of settlements. Some early agreements escaped notice entirely.¹⁷² Later settlements have been shielded from scrutiny due to the difficulty of discerning, from public information, the extent of pay-for-delay deals. This information gap partially explains why so few of the most recent settlements have been challenged.

This Article helps fill the gap, but it is not a complete solution. My data does not include nonpublic details that would help build confidence about whether a side deal conveys payment. For example, how much did the brand-name firm agree to pay for a co-promotion agreement? How much did a generic firm pay for a product transfer? Is payment conditioned on successful performance by the other party? Was a particular product development deal a long-felt need of the firm, which shopped for alternate sources? How was the service provided valued internally by the payor? Public data for most settlements lack these details.

Outside the context of side deals, two other issues are important. First, do the parties intend for the generic firm to retain exclusivity when it enters the market? In some cases, one or both parties divulge their view publically, but in other cases they do not. Second, how often does the brand-name firm contract with this counterparty and other generic firms outside the context of settlement? Reciprocally, what is each generic firm's experience with brand-name firms outside the context of settlement? Public information of the type collected in Part II paints only an incomplete picture of the frequency of particular arrangements outside the settlement context. With details such as these, an inference of payment for each case could be strengthened, and more importantly the inference of payment across cases could be strengthened as well.

The FTC already has in place all the tools it needs to perform this task. As noted in Part I.B, it receives information about each settlement and has statutory authority to require firms to produce additional information of the types discussed above.¹⁷³ That authority ought to be used to collect two types of information. First, the agency should seek full details about each settlement—at least to answer the questions listed above. Some of these questions may be answerable by examination of the agreement itself. To the extent they are not, the gaps could be filled using voluntary questionnaires or, if necessary, compulsory process. Second, the agency should collect from each brand-name firm a detailed catalogue of its dealings with generic firms, and vice versa for generic firms.

This information would be the key input in a comprehensive study of side deals. It would provide a firm basis for the agency to endorse or reject the conclusion offered in Part II, based upon public information, that contemporaneous side deals should possess a presumption of payment. If the information is sufficiently lopsided, error cost minimization might suggest the more aggressive rule should be instituted, making the presumption of illegality conclusive and effectively banning contemporaneous side deals.

¹⁷² See, e.g., Reguly, *supra* note 110, at 25 (reporting Zantac settlement).

¹⁷³ See *supra* notes 58–59 and accompanying text.

In this respect, the analysis in Part II provides a rough draft for a more comprehensive, future agency report. The public data presents a *prima facie* case that something is amiss regarding the increasing utilization of side deals. For skeptical readers of this Article, who may think that the survey results reported in Part II are too weak to justify a presumption of payment through side deals, the case for deploying the agency as an aggregator should be even stronger; agency action is necessary to fill these informational gaps and better explain whether and when compensation is conferred for delay.

The FTC has not fully exploited its information gathering advantage. Of the drugs with monetary settlements in Table 2, two-thirds occurred after the end of the FTC's last major study in 2002. Moreover, all of the retained exclusivity settlements in Table 3 post-date the study. To be sure, the FTC evaluates each individual agreement to determine whether further investigation is appropriate, and no doubt it asks some of the questions detailed above in considering its response. But it does not synthesize the resulting information, aside from very general annual summaries of settlement activity. As this Article reveals, only through such an aggregate approach can we expect to generate a useful picture of—and rule for—brand-generic settlement.

B. Antitrust Rulemaking

The previous section advocates a focused increase in the FTC's "competition policy research and development."¹⁷⁴ If the FTC accepted the suggestion, it would eventually reach a firm, empirically grounded conclusion about the optimal policy for side deals, and thus either confirm or reject the conclusion reached in Part II. That conclusion could be deployed in a variety of policymaking settings, including litigation brought by the agency, *amicus* practice, and advocacy for congressional legislation. This section considers a further possibility, that a comprehensive aggregate study of settlement practice could form the basis for substantive policymaking by the agency in the form of rulemaking.

There is of course an enormous literature on the choice of courts versus agencies, adjudication versus rulemaking, and rules versus standards, and this Article does not engage the full complexity of those debates. My goal here is simply to suggest how the virtues of an aggregate perspective on settlement practice shift the balance in a way that favors agency rulemaking. In other words, the settlement issue highlights certain advantages of moving away from a court-centered model.

Why bother with rulemaking? Even if the expert agency is better than a court at arriving at a correct policy conclusion, thanks to its superior capacity for aggregation, it does not necessarily follow that the agency ought to set policy. It could instead simply furnish the information to a court or Congress, which might then implement the same conclusion, with some

¹⁷⁴ Timothy J. Muris, *Looking Forward: The Federal Trade Commission and the Future Development of U.S. Competition Policy*, 2003 *Colum. Bus. L. Rev.* 359, 403–04.

of the same benefits—for example, efficiency compared to case-by-case adjudication, and certainty for businesses about the range of acceptable practices.

Put another way, why would we care whether the agency itself makes policy in the first instance, rather than acting as an input to a court? The question suggests a bureaucratic version of the Coase Theorem. If there is no friction in communicating an expert policy conclusion from the agency to the court, then it does not matter which of the two has policymaking authority. If, on the other hand, the agency’s message arrives garbled or is ignored by the court, that provides reason to prefer that the agency reach a substantive policy judgment of its own, rather than merely furnishing advice to the court.

One reason to expect the court to do a less effective job is that courts have trouble correctly identifying anticompetitive strategic behavior,¹⁷⁵ particularly in a setting as complex as the Hatch-Waxman Act. That view is borne out by a recent appeals court opinion about settlement. For example, the court relied, as a reason to deny antitrust liability, upon the mistaken idea that a settlement with one generic firm would spur other generic firms to action, and that these firms would have the large incentive provided by the exclusivity period.¹⁷⁶ In fact, later filers are ineligible for the exclusivity period. This error was unforced; the point does not appear to have been argued below. The same court took comfort in the view that often there is more than one generic challenger, and the court concluded that multiple challengers are difficult to buy off.¹⁷⁷ In fact, however, multiple settlements do happen.

Courts have also had trouble evaluating the facts of particular cases. For example, in the case discussed above, the plaintiff had argued that the brand-name firm compensated the generic firm not only with cash, but also through authorized generic sales.¹⁷⁸ The court ignored this idea entirely.¹⁷⁹ In a second case focused on side deals, the appeals court essentially ignored the extensive evidence that the payment was for delay, rather than the separate value offered by the generic firm.¹⁸⁰ This pattern is likely to continue, given the evidence of complexity discussed in Part III.A.

An expert agency, essentially by definition, is less likely to make mistakes identifying the strategic behavior of parties. To be sure, this information could be communicated to a court. But as a practical matter, courts have not welcomed the information about settlements supplied by the FTC. In a key case brought by the FTC, the appeals court largely ignored the analysis

¹⁷⁵ See Herbert Hovenkamp, *The Antitrust Enterprise* 47 (2005) (“[T]here is relatively little disagreement about the basic proposition that often our general judicial system is not competent to apply the economic theory necessary for identifying strategic behavior as anticompetitive.”).

¹⁷⁶ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 214 (2d Cir. 2006).

¹⁷⁷ See *id.* at 211–12 (noting “possibility” of settlements with multiple challengers but dismissing it: “We doubt, however, that this scenario is realistic”); see also Brief for the United States, *Andrx*, *supra* note 122, at 18 (concluding that shared exclusivity would cause settlements to subside).

¹⁷⁸ Brief for Plaintiffs Appellants at 7, 28, *Tamoxifen*, 466 F.3d 187 (No. 03-7641), 2004 WL 5261441.

¹⁷⁹ *Tamoxifen*, 466 F.3d at 215–16.

¹⁸⁰ See generally *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

employed by the agency, granted essentially no deference to its findings of fact, and indeed berated the agency for failing to follow the appeals court's earlier rule.¹⁸¹ For the most part, courts have also ignored the results of the FTC's extensive 2002 study and its subsequent annual summary updates, as well as its amicus recommendations.¹⁸²

A second reason to expect courts to be less effective than the FTC is that antitrust courts are obliged to impose treble damages when they condemn behavior as a violation of the Sherman Act. The large measure of damages may strike a court as excessive, particularly where the conduct seems ambiguous or complicated, such that the parties might not be expected to know that their behavior violated antitrust law.¹⁸³ That impression may be reinforced where the conduct is out in the open, rather than hidden, so that a usual justification for a damages multiple—the difficulty of detection—is missing. The combined effect is to make a court gun shy, and to cause it to select a deliberately underinclusive antitrust rule.¹⁸⁴ And indeed, courts rejecting antitrust liability for settlements have repeatedly adverted to treble damages in their analysis.¹⁸⁵

The FTC is less constrained. Its substantive conclusions would be made under the Federal Trade Commission Act's prohibition of "unfair methods of competition,"¹⁸⁶ rather than under the Sherman Act. The Supreme Court has stated repeatedly that the FTC Act's prohibitions are broader than the Sherman Act.¹⁸⁷ Thus, behavior that constitutes unfair

¹⁸¹ See *Schering-Plough*, 402 F.3d at 1068 n.18, 1075 n.26, 1076 (11th Cir. 2005); Daniel A. Crane, *Technocracy and Antitrust*, 86 Tex. L. Rev. 1159, 1201 (2008) (describing *Schering-Plough*).

¹⁸² See Brief of Federal Trade Commission in Support of Appellants, In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097), 2008 WL 644394 (favoring antitrust liability for brand-generic settlement, a position rejected by the appeals court); Brief of Federal Trade Commission in Support of Plaintiffs-Appellants, *Tamoxifen*, 466 F.3d 187 (No. 03-7641), 2005 WL 3332374 (same); see also Brief of Federal Trade Commission in Support of Appellant, Teva Pharms. USA, Inc. v. Pfizer, Inc., 405 F.3d 990 (Fed. Cir. 2004) (No. 04-1186), available at <http://www.ftc.gov/os/2004/04/040331amicusbrieftevaupfizer.pdf> (on file with the *Columbia Law Review*) (arguing that generic firm has Article III standing to challenge brand-name firm's patent in a declaratory judgment action, in part because that result would improve industry competition, a position rejected by appeals court).

¹⁸³ In other contexts, courts are thought to narrow substantive rights when the consequence of their violation is believed to be too severe. See, e.g., Akhil Reed Amar, *Fourth Amendment First Principles*, 107 Harv. L. Rev. 757, 799 (1994) ("The exclusionary rule renders the Fourth Amendment contemptible in the eyes of judges and citizens. Judges do not like excluding bloody knives, so they distort doctrine, claiming the Fourth Amendment was not really violated.")

¹⁸⁴ See Margaret H. Lemos, *The Other Delegate: Judicially Administered Statutes and the Nondelegation Doctrine*, 81 S. Cal. L. Rev. 405, 464-68 (2008) (describing factors that might lead courts to adopt underinclusive antitrust liability rules). This argument embraces both substantive rules, as discussed in the text, and procedural rules. See *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1964-66 (2007) (interpreting pleading standard for antitrust suits); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585-88 (1986) (describing summary judgment standard for antitrust suits).

¹⁸⁵ See *Tamoxifen*, 466 F.3d at 204 (citing *Ciprofloxacin*, 363 F. Supp. 2d at 529) (asserting that treble damages might chill settlements); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (stating that treble damages would discourage settlements).

¹⁸⁶ FTC Act § 5(a)(1), 15 U.S.C. § 45(a)(1) (2006).

¹⁸⁷ See, e.g., *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986) (holding that section 5 covers "not only practices that violate the Sherman Act and other antitrust laws, but also practices that the Commission determines are against public policy for other reasons") (citations omitted); *FTC v. Brown Shoe Co.*, 384 U.S. 316, 321 (1966) (holding that section 5 reaches "practices which conflict with the basic policies" underlying antitrust law, as well as incipient violations of antitrust law); *FTC v. R.F. Keppel & Bros., Inc.*, 291 U.S. 304, 310 (1934) ("It would not have been a difficult feat of draftsmanship to have restricted the operation of the Trade Commission Act to those methods of competition in interstate commerce which are forbidden at common law or which are likely to grow into violations of the Sherman Act, if that had been the purpose of the legislation."); see

competition does not necessarily also violate the Sherman Act's prohibitions of unreasonable restraints of trade or monopolization.

This conclusion is resisted by some observers, who think it is "no longer tenable" to treat the FTC Act as broader than the Sherman Act.¹⁸⁸ However, the Supreme Court's rejection of strict equivalence can be justified on an eminently pragmatic ground. The argument for equivalence rests upon the proposition that, as Richard Posner puts it, "the Sherman and Clayton Acts have been interpreted so broadly that they no longer contain gaps that a broad interpretation of Section 5 of the FTC Act might be needed to fill."¹⁸⁹ But to the extent that the Sherman Act as actually interpreted by courts contains important gaps, as exemplified by the lack of liability for pay-for-delay settlements, the quoted statement does not hold. Where, as here, courts are reaching incorrect conclusions about liability, an understanding that the two statutes are different is useful, because it allows the FTC to enjoin settlements without being automatically reversed by a court equipped with the (erroneous) view that antitrust law does not extend so far.

Moreover, nonequivalence is particularly useful where, as here, treble damages leads courts to constrict the scope of liability. Even if it is appropriate for courts to constrict liability to compensate for the heightened false-positive risk created by treble damages, it does not follow that the FTC must follow the same path. The FTC imposes injunctive relief, not treble damages. That difference reduces concerns about false positives and overdeterrence. Put another way, the FTC's optimal scope of liability may well be broader than the courts'. Nonequivalence allows the FTC to take advantage of that difference, compared to the Sherman Act, which applies a harsher penalty to a narrower class of activity.¹⁹⁰

A third advantage of the FTC is that it is less subject to the constraint of stare decisis. Lower courts are bound by their own or Supreme Court precedent.¹⁹¹ The Supreme Court, for its part, is not quick to revisit antitrust doctrine,¹⁹² and frequently feels constrained to follow its own

also *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972) (noting that FTC must "consider[] public values beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws").

¹⁸⁸ Richard A. Posner, *The Federal Trade Commission: A Retrospective*, 72 *Antitrust L.J.* 761, 766 (2005).

¹⁸⁹ *Id.*

¹⁹⁰ For an argument along similar lines, see Thomas C. Arthur, *A Workable Rule of Reason: A Less Ambitious Antitrust Role for the Federal Courts*, 68 *Antitrust L.J.* 337, 384–85 n.285 (2000). The nonequivalence provides an answer to the valid concern, raised by Daniel Crane, that the shared authority of the Antitrust Division and FTC over antitrust matters might undermine the FTC's claim to *Chevron* deference. Crane, *supra* note 181, at 1209. Crane points out that the FTC has characterized its powers as being co-extensive "for the most part" with the FTC Act, *id.* at 1209 n.269 (quoting the FTC's opinion in *Schering-Plough*, see *supra* note 10), and suggests that it might be necessary to combine the two enforcers before granting *Chevron* deference. But the quoted language also underscores the non-identity of the two statutes, consistent with the Supreme Court's long-held view.

¹⁹¹ See, e.g., *Khan v. State Oil Co.*, 93 F.3d 1358, 1363 (7th Cir. 1996) ("[T]he Supreme Court has told the lower federal courts, in increasingly emphatic, even strident, terms, not to anticipate an overruling of a decision by the Court; we are to leave the overruling to the Court itself."), vacated 522 U.S. 3, 20 (1997) ("The Court of Appeals was correct in applying that principle despite disagreement with *Albrecht*, for it is this Court's prerogative alone to overrule one of its precedents.").

¹⁹² Compare *Dr. Miles Medical Co. v. John D. Park & Sons Co.*, 220 U.S. 373 (1911), with *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705 (2007).

previous views.¹⁹³ The FTC is freer to change course, provided that the new interpretation is a reasonable understanding of the FTC Act.¹⁹⁴

One way for the FTC to implement these advantages is to promulgate a legislative rule—that is, a rule having the force of law and entitled to *Chevron* deference by a court.¹⁹⁵ FTC rulemaking has been suggested periodically by commentators as a way to shift decisionmaking authority to the FTC and fill gaps in the coverage of other antitrust statutes.¹⁹⁶ The rulemaking route, though not without controversy, is an attractive and feasible means to take full advantage of the aggregate approach to settlement.

The FTC possesses the power to promulgate rules with the force of law and subject to *Chevron* deference. As noted in Part I.B, the FTC has already promulgated one such antitrust rule,¹⁹⁷ which was issued and eventually rescinded after notice and comment.¹⁹⁸ The FTC's rules and operating procedures do not deny the agency's possession of this authority, to be administered under ordinary notice-and-comment procedures, but neither do they fully spell it out.¹⁹⁹

The FTC's rulemaking power arises from its general rulemaking authority,²⁰⁰ which the D.C. Circuit interpreted in *National Petroleum Refiners Ass'n v. FTC* as a grant to make rules

¹⁹³ See, e.g., *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 9 (1984) (“It is far too late in the history of our antitrust jurisprudence to question the proposition that certain tying arrangements pose an unacceptable risk of stifling competition and therefore are unreasonable ‘per se.’”).

¹⁹⁴ See, e.g., Jerry L. Mashaw, Norms, Practices, and the Paradox of Deference: A Preliminary Inquiry into Agency Statutory Interpretation, 57 *Admin. L. Rev.* 501, 505–14 (2005) (discussing this aspect of agency flexibility).

¹⁹⁵ Some commentators use the term “substantive rules” instead of “legislative rules” for the rules I have in mind, but the choice of terminology is unimportant for my purposes. See, e.g., Jacob E. Gersen, *Legislative Rules Revisited*, 74 *U. Chi. L. Rev.* 1705, 1710 (2007) (“[I]t has become commonplace to use the terms legislative rules and substantive rules interchangeably.”).

¹⁹⁶ See, e.g., Jonathan B. Baker, Two Sherman Act Section 1 Dilemmas: Parallel Pricing, the Oligopoly Problem, and Contemporary Economic Theory, 38 *Antitrust Bull.* 143, 207–19 (1993); David Balto, Returning to the Elman Vision of the Federal Trade Commission: Reassessing the Approach to FTC Remedies, 72 *Antitrust L.J.* 1113, 1117–19 (2005); Philip Elman, Comment, Rulemaking Procedures in the FTC's Enforcement of the Merger Law, 78 *Harv. L. Rev.* 385 (1964); William E. Kovacic, Antitrust Policy and Horizontal Collusion in the 21st Century, 9 *Loy. Consumer L. Rep.* 97, 107–08 (1997); see also Crane, *supra* note 181, at 1206–09 (raising possibility of FTC rulemaking, but also raising doubts about its use).

¹⁹⁷ *Discriminatory Practices in Men's and Boys' Tailored Clothing Industry*, 16 C.F.R. pt. 412 (1968). The rule was promulgated pursuant to sections 2(d) and 2(e) of the Clayton Act, 15 U.S.C. § 13(d), (e) (2006).

¹⁹⁸ *Trade Regulation Rule: Discriminatory Practices in Men's and Boys' Tailored Clothing Industry*, 58 *Fed. Reg.* 35907 (1993) (providing notice of proposed rulemaking to rescind rule). The rule appears never to have been used by the agency in law enforcement. *Notice of Repeal of Rule*, 59 *Fed. Reg.* 8527–28 (1994) (providing notice of repeal of rule).

¹⁹⁹ According to the FTC's Operating Manual, “the Commission has statutory authority under FTCA § 6(g) to promulgate rules respecting unfair methods of competition.” *FTC, Operating Manual* ch. 7, at 33, available at <http://www.ftc.gov/foia/ch07rulemaking.pdf> (on file with the *Columbia Law Review*). The Rules of Procedure accommodate antitrust rulemaking too. See 16 C.F.R. § 1.22(a) (2008) (“For the purpose of carrying out the provisions of the statutes administered by it, the Commission is empowered to promulgate rules and regulations applicable to unlawful trade practices.”). The closest they come to acknowledging legislative rulemaking authority is to note that *Petroleum Refiners*, discussed *infra* note 201, gives the FTC “authority to promulgate rules with substantive effect.” *FTC, Operating Manual*, *supra*, at 2–3. On the applicability of ordinary notice-and-comment procedures, see *id.* at 33 (describing rulemaking under 5 U.S.C. § 553 (2006), and spelling out that “[w]hether to provide an opportunity for oral presentation of data, views, and arguments remains discretionary with the agency”).

²⁰⁰ 15 U.S.C. § 46(g) (granting FTC authority to “make rules and regulations for the purpose of carrying out the provisions of this subchapter”).

with the force of law.²⁰¹ Although the *Petroleum Refiners* result is doubtful as an original matter,²⁰² it is currently relatively settled that an ambiguous statute, such as the FTC Act, suffices to confer that authority. Similar rulings have been made for other statutes,²⁰³ and overruling *Petroleum Refiners* today would jeopardize rulemaking in these other contexts, including the grant analyzed in *Chevron* itself.²⁰⁴ These prudential considerations, and a later congressional enactment,²⁰⁵ tend to confirm the viability of rulemaking authority. Although the FTC reportedly sought candidates for antitrust rulemaking after *Petroleum Refiners*,²⁰⁶ it has not yet found any. A rulemaking focused on settlements is an attractive candidate if this procedural route is pursued again.

Rulemaking is not the only way to shift substantive policymaking authority from courts to the FTC. The FTC can bring individual cases through agency adjudication,²⁰⁷ reviewed in a court of appeals of a respondent's choosing,²⁰⁸ or directly in an action in district court. The FTC has taken both routes in attacking settlements. The agency adjudication route resulted in an appeals court loss; two cases in district court are pending.

Rulemaking has significant, familiar advantages over the adjudicatory route. Rulemaking permits affected parties to test aggregate data in an open way, with ample opportunity for rebuttal.²⁰⁹ The opportunity for input and testing tends to produce superior policy.²¹⁰ The

²⁰¹ 482 F.2d 672, 698 (D.C. Cir. 1973) (upholding rule requiring posting of octane ratings on gas pumps). The FTC has two distinct missions, consumer protection and antitrust, and *Petroleum Refiners* specifically dealt with a consumer protection rule, not an antitrust rule. But the relevant statutory language covers both consumer protection and antitrust rules, and the applicability of the court's ruling to both types of rules is fairly implied in its opinion. See, e.g., *id.* at 684–85, 693, 694.

²⁰² See Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 Harv. L. Rev. 467, 493–509 (2002) (arguing that when Congress passed FTC Act and other statutes, its intent to deny legislative rulemaking authority was evidenced by lack of sanction for rule violation).

²⁰³ See, e.g., *In re Permanent Surface Mining Regulation Litig.*, 653 F.2d 514, 523–25 (D.C. Cir. 1981) (*en banc*) (holding that general language in Surface Mining Control and Reclamation Act suffices to grant legislative rulemaking powers); *Nat'l Ass'n of Pharm. Mfrs. v. FDA*, 637 F.2d 877, 887 (2d Cir. 1981) (reaching similar conclusion as to § 701 of Food, Drug, and Cosmetic Act); *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 873–74 (D.C. Cir. 1979) (reaching similar conclusion as to Clean Air Act); see also Merrill & Watts, *supra* note 202, at 557 n.484, 563–65 (discussing these cases).

²⁰⁴ See Merrill & Watts, *supra* note 202, at 587–90 (describing this “*Chevron* paradox”).

²⁰⁵ After *Petroleum Refiners*, Congress authorized legislative rulemaking in the consumer protection sphere, while preserving whatever antitrust rulemaking authority already existed. See 15 U.S.C. § 57a (2006) (authorizing rulemaking regarding “unfair or deceptive acts or practices in or affecting commerce”). This legislative action took place against the backdrop of both *Petroleum Refiners* and the previously promulgated antitrust rule. The decision not to disturb explicit preservation of antitrust rulemaking authority, while altering the contours of consumer protection rulemaking authority, is arguably a ratification of the FTC and D.C. Circuit's views. On the other hand, an examination of the legislative history paints a more skeptical view. See Einer Elhauge & Damien Gerardin, *Global Antitrust Law and Economics* 5 n.11 (2007) (concluding, based upon legislative history, that Congress came to no considered view about existence or absence of antitrust rulemaking authority when it passed Magnusson-Moss Act).

²⁰⁶ FTC Staff Narrows Rulemaking Possibilities to Three Areas, *supra* note 68, at A-13 (noting FTC staff's interest in rulemaking about “delivered pricing in the cement industry, physician influence over health insurance payments, and mergers”).

²⁰⁷ FTC Act § 5(b), 15 U.S.C. § 45(b) (2006).

²⁰⁸ *Id.* § 5(c). The chosen court of appeals must be one in which the condemned practice was used, or in which the respondent does business. In the settlement context, that means as a practical matter that the administrative ruling will be reviewed in a court of appeals already known to be hostile to liability.

²⁰⁹ See, e.g., Arthur Selwyn Miller & Jerome A. Barron, *The Supreme Court, the Adversary System, and the Flow of Information to the Justices: A Preliminary Inquiry*, 61 Va. L. Rev. 1187, 1211–18 (1975) (assessing problems that result when judges use data “not subject to test or challenge by the losing party”).

resulting rule thus has a superior claim to judicial deference, compared to judicial review of a single case: The rule has been thoroughly vetted under notice and comment, after a broad, deep review of the full terrain of behavior by regulated parties. It is this superior breadth and greater vetting, rather than the doctrinal force of *Chevron* itself,²¹¹ that presents the strongest reason to think that a rule might succeed where adjudication has failed.

Rulemaking helps in another way. The FTC Act is broader than the Sherman Act, as noted above, but the degree of its additional breadth has been a subject of controversy. Some lower courts have regarded with skepticism the FTC's efforts to regulate behavior not already governed by the Sherman Act.²¹² A powerful way for the FTC to overcome this skepticism would be to support its claim to authority with aggregation, buttressed by notice-and-comment rulemaking. In this way, the FTC could combine, in a mutually reinforcing manner, the two ways in which its authority is special, compared to ordinary, judicial antitrust policymaking: In having a statute with broader reach than the Sherman Act, and in possessing the power to collect information beyond the reach of the judiciary.

Rulemaking has a further effect: It attracts congressional attention to an important policy issue where adjudication may not. The FTC's first controversial foray into rulemaking was the Cigarette Rule,²¹³ a consumer protection rule promulgated in 1964 that governed the advertising and labeling of cigarettes. One powerful effect of the rule was to attract congressional attention to the issue, in part because the industry argued that the FTC had usurped congressional prerogatives. The rule was withdrawn the following year, replaced by a watered-down statute.²¹⁴

A modern antitrust rule might be expected to create a similar provocation. Whether that is an argument in favor of rulemaking is less certain. In the case of cigarette regulation, congressional action preempted the FTC's rule in key respects.²¹⁵ However, the FTC stayed deeply engaged in congressional debates on the issue, and played an important role in promoting

²¹⁰ See, e.g., Richard J. Pierce, Jr., Two Problems in Administrative Law: Political Polarity on the District of Columbia Circuit and Judicial Deterrence of Agency Rulemaking, 1988 Duke L.J. 300, 308 ("Rulemaking yields higher-quality policy decisions than adjudication because it invites broad participation in the policymaking process by all affected entities and groups, and because it encourages the agency to focus on the broad effects of its policy rather than the often idiosyncratic adjudicative facts of a specific dispute.").

²¹¹ William N. Eskridge, Jr. & Lauren E. Baer, The Continuum of Deference: Supreme Court Treatment of Agency Interpretations from *Chevron* to *Hamdan*, 96 Geo. L.J. 1083, 1120-36 (2008) (presenting evidence that *Chevron* is less important than commonly thought).

²¹² See, e.g., *Ethyl Corp. v. FTC*, 729 F.2d 128, 136 (2d Cir. 1984) (interpreting FTC Act's scope as similar to Sherman Act); *Boise Cascade Corp. v. FTC*, 637 F.2d 573, 577 (9th Cir. 1980) (similar).

²¹³ Trade Regulation Rule on Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, Statement of Basis and Purpose, 29 Fed. Reg. 8324 (1964), withdrawn, 30 Fed. Reg. 9485 (1965).

²¹⁴ Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. 89-92 (1965), 79 Stat. 282 (codified at 15 U.S.C. § 1331 et seq.).

²¹⁵ See § 5 (preempting FTC authority as to "statement[s] relating to smoking and health" on packaging and advertising, and otherwise leaving its authority unchanged).

further statutory change.²¹⁶ Increased congressional attention might therefore be regarded as a modest positive overall, or at least not a negative.

At the same time, some of agencies' distinctive disadvantages seem less pronounced here. A shift from courts to agencies raises concerns about an agency's comparatively greater vulnerability to capture by regulated parties.²¹⁷ As applied to the FTC, this concern finds some support in the early history of the agency, where a protectionist attitude toward small businesses in certain industries can be plausibly attributed to capture.²¹⁸ Moreover, the settlement issue is currently of concentrated interest only to the pharmaceutical industry, making the capture concern particularly salient, although one could imagine insurers and other drug purchasers providing a counterweight.

On the other hand, the modern FTC is a much more effective organization today than the agency that received so much criticism several decades ago, and has erased the taint of the earlier capture critique.²¹⁹ Its newfound success can be attributed in part to a bipartisan consensus about the role of economic analysis in modern antitrust law. That consensus has had a further effect, which is to help neutralize a second attribute of agencies, namely their sensitivity to political changes over time.²²⁰ In any event, whatever the general merits of this characterization, it seems inapplicable to the settlement issue, where FTC commissioners across the political spectrum have been unanimous in their view that settlements raise serious competitive concerns.

C. Responding to Novel Forms of Regulatory Avoidance

Settlement practice continues to evolve to exploit regulatory complexity. The usual assumptions about settlement are that it entails an agreement, by which the cash or its equivalent is exchanged for entry, for an entry date that is constrained to be no later than patent expiration. In fact, the forms of payment and even the fact of agreement are manipulable. The following examples from recent settlement practice bear this out.

1. *Multiple Settlement with Uneven Entry.* — In some instances, the brand-name and generic drug makers settle several disputes at the same time, affording the brand-name firm an

²¹⁶ For an account of these changes, see Sidney M. Milkis, *The Federal Trade Commission and Consumer Protection: Regulatory Change and Administrative Pragmatism*, 72 *Antitrust L.J.* 911, 918–19 (2005) (“eight years after Congress rejected the FTC’s regulation of cigarette advertising the agency’s policies were adopted in their entirety”).

²¹⁷ Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 *Colum. L. Rev.* 1, 12–25, 34–56 (1998) (reviewing literature applying public choice theory to agencies). Some observers of agency behavior doubt the explanatory power of capture arguments. See, e.g., *id.* at 52–56 (noting that “empirical evidence [supporting public choice theory] is far from overwhelming”); Mark Kelman, *On Democracy-Bashing: A Skeptical Look at the Theoretical and “Empirical” Practice of the Public Choice Movement*, 74 *Va. L. Rev.* 199, 238–68 (1988) (offering a skeptical review of claimed examples of capture).

²¹⁸ Richard A. Posner, *The Federal Trade Commission*, 27 *U. Chi. L. Rev.* 47, 83 (1969) (offering capture-based explanation for poor FTC performance).

²¹⁹ See Posner, *supra* note 188, at 765 (revising earlier negative views).

²²⁰ Cf. Matthew C. Stephenson, *Legislative Allocation of Delegated Power: Uncertainty, Risk, and the Choice Between Agencies and Courts*, 119 *Harv. L. Rev.* 1035, 1038 (2006) (depicting choice of agency versus court as providing relative stability across issues and instability over time).

opportunity to pay the generic firm for delayed entry on one drug by granting early generic entry on a second drug. Consider, for example, Lamictal, a blockbuster epilepsy treatment that is offered in both chewable and nonchewable forms. A generic firm launched a pre-expiration challenge to each form; both centered upon the same patent.²²¹ In the joint settlement of both disputes, the generic firm received a license to the chewable version that permitted entry three years before entry on the nonchewable version.²²²

Uneven entry does not automatically raise pay-for-delay concerns. For example, a one-year delay as to one drug might exactly offset a one-year acceleration of entry on a second drug of equal importance. More generally, if a generic firm's interests are aligned with consumer interests, there is little to worry about, because a generic firm will insist upon early enough entry (and increased consumer welfare) on one drug to compensate for the reduced generic entry (and consumer welfare) on the other drug. Of course, in such a situation, it is difficult to see why the parties would bother with uneven entry. The explanation is that the drug with early entry is one on which the parties expect comparatively little incremental entry from other generic firms. In the case of Lamictal, the nonchewable version is far more important than the chewable version; in fact, the chewable version had low enough sales as to be unlikely to attract additional generic challengers.²²³

2. *Probabilistic Payment.* — A special case of the strategy arises when entry as to one of the drugs has already occurred, and there are accrued damages—probabilistic, as the patent suit has not yet been resolved—that the brand-name firm can forgive as part of the settlement. Lipitor is again exemplary. Pfizer and Ranbaxy had done battle on a second significant drug, Accupril. Ranbaxy had launched a generic version of the drug at risk, without waiting for a district court to rule whether Pfizer's patent was valid and infringed.²²⁴ Pfizer secured a preliminary injunction, which was affirmed by the Federal Circuit.²²⁵ At this point, Pfizer's

²²¹ Letter from Gary Buehler, Dir. of Office of Generic Drugs, FDA, to Philip Erickson, Teva Pharms. USA (Aug. 30, 2006) (on file with the *Columbia Law Review*) (describing patent dispute over Lamictal); Letter from Gary Buehler, Dir. of Office of Generic Drugs, FDA, to Philip Erickson, Teva Pharms. USA (June 21, 2006) (on file with the *Columbia Law Review*) (describing patent dispute over Lamictal CD).

²²² Press Release, Teva Pharms. USA, Teva Announces Settlement of Lamictal Litigation with GlaxoSmithKline (Feb. 17, 2005) (describing entry for Lamictal CD in 2005, and for Lamictal in 2008).

²²³ U.S. sales of Lamictal and Lamictal CD were \$825 million and \$47 million, respectively, in 2004. *Id.* A second example is Barr's settlement of Provigil litigation, wherein Cephalon granted a slightly earlier license to another drug, Actiq, on which Barr already had a license. See Press Release, Barr Pharms., Inc., Barr Granted Rights to Generic of Cephalon's ACTIQ Cancer Pain Treatments (Aug. 10, 2004), available at <http://www.medicalnewstoday.com/articles/12020.php> (on file with the *Columbia Law Review*) (describing initial Barr license); Provigil Barr Press Release, *supra* note 88 (describing earlier Actiq license). A third possible example is Optivar and Astelin, which had first filer challenges that pertain to the same patent. Meda AB, Interim Report, at 6 (May 6, 2008). The settlement as to both drugs permits entry as to Optivar, the less important drug, three months earlier than Astelin. *Id.* at 6–7 (noting settlement terms); Meda AB, 2007 Annual Report, at 19 (Feb. 26, 2008) (reporting that Astelin and Optivar had U.S. sales of \$188 million and \$37 million, respectively, in 2007).

²²⁴ See *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1371 (Fed. Cir. 2005); see also Press Release, Teva Pharms. Indus., Teva Launches Quinapril HCl Tablets; Pursuant to Agreement with Ranbaxy (Dec. 16, 2004) (announcing partnership by which Teva would distribute quinapril manufactured by Ranbaxy pursuant to its ANDA). Ranbaxy indemnified Teva as part of this launch. See Teva Pharms. Indus., Report of Foreign Private Issuer (Form 6-K), at 10 (May 10, 2007).

²²⁵ *Pfizer*, 429 F.3d at 1371, 1383 (noting and affirming preliminary injunction entered March 29, 2005).

damages claim against Ranbaxy, although probabilistic, was large in expected value.²²⁶ The Lipitor settlement also “resolved” the Accupril dispute, likely by forgiving the accumulated expected damages.

The forgiveness strategy can be applied not only across several drugs, but also across several strengths of a single drug. For example, in Wellbutrin XL, the generic firm had challenged the patent applicable to two different strengths of the drug. It launched at risk as to only one strength. The subsequent settlement forgave accumulated damages on the first strength, and delayed entry on the second.²²⁷

3. *“No Authorized Generic” Provisions.* — As previously explained, retained exclusivity is a source of compensation to a generic drug maker.²²⁸ That compensation is reduced, however, if a brand-name drug maker launches an authorized generic product to compete with the generic entrant, in addition to the brand-name firm’s existing branded product. The brand-name firm can increase the generic entrant’s profits from exclusivity by agreeing not to launch an authorized generic product. Numerous recent agreements include a “no authorized generic” term.²²⁹

4. *Avoiding Agreement.* — Through careful design, settling parties can arrange for delayed entry without any formal agreement as to timing. The parties can condition periodic payment upon nonentry, and make payment a function of brand-name profits that depend upon nonentry—for example, a royalty paid on brand-name sales.²³⁰ One settlement, involving the drug Altace, appears to have used a variant of this strategy. There, the brand-name firm acquired

²²⁶ The rulings indicated a high likelihood that Pfizer would win on the merits. Accupril has annual sales of about \$400 million, so the expected damages were likely at least tens of millions of dollars. Press Release, Par Pharm. Cos., Par Pharmaceutical Companies, Inc. Receives Final Approval to Market Generic Accupril Tablets (Dec. 22, 2004).

²²⁷ Press Release, Biovail Corp., Biovail Announces Comprehensive Settlement Related to Wellbutrin XL (Mar. 5, 2007). The agreement was actually reached in February. Biovail Corp., Annual Report (Form 20-F), at 4 (Mar. 22, 2007).

²²⁸ See supra text accompanying notes 91–95.

²²⁹ Examples include Adderall XR, Plavix, and Effexor XR, and appear to include Lamictal and Nexium as well. See Adderall XR Shire-Barr Agreement, supra note 70, ex. 10.1, cl. 3.7 (“Shire has not granted and shall not grant a license . . . or other arrangement that allows any Third Party to market a Generic Equivalent before: (i) the License Effective Date or (ii) the expiration of 180 days following Barr’s launch of a Generic Product”); Q4 2006 Barr Pharms., Inc. Earnings Conference Call (Aug. 15, 2006), available at Factiva (noting “no authorized generic” provision); Plavix Agreement, supra note 70, ex. 99.1 (permitting generic manufacturer “to sell its Plavix brand product, but not to launch an authorized generic”); Wyeth, Current Report (Form 8-K), at 1.01 (Jan. 13, 2006) (noting that Teva’s patent license for Effexor XR is exclusive at first). See Lamictal Press Release, supra note 99 (describing Lamictal generic entry as “exclusive”); GlaxoSmithKline, PLC, 2006 Annual Report (Form 20-F), at 157 (Mar. 2, 2006) (describing grant as to Lamictal as “exclusive”); Nexium Press Release, supra note 109 (describing Nexium generic entry as “exclusive”).

This source of payment to induce delay has attracted some attention of antitrust enforcement. The clause was reportedly one reason why antitrust enforcers rejected the Plavix agreement. See John Carreyrou et al., FBI Raids Offices at Bristol-Myers Over Plavix Deal, Wall St. J., July 28, 2006, at A3 (reporting that FTC opposition to “no authorized generic” clause caused rejection of initial agreement); see also Declaration of Bernard Sherman at 10–12, Sanofi-Synthelabo v. Apotex, Inc., 492 F. Supp. 2d 353 (S.D.N.Y. 2006) (No. 02-CV-2255) (declaring that Sanofi orally offered to secretly include “no authorized generic” term in revised deal, after initial agreement containing that term was rejected by regulators). Logically, if a “no authorized generic” provision raises an antitrust problem, then so does retained exclusivity itself, for the effect of the provision is to raise the value of retained exclusivity.

²³⁰ Naprelan adopted this strategy. See Andrx Pharms., Inc. v. Elan Corp., No. 00-3481, slip op. at 6 (S.D. Fl. Apr. 24, 2003) (order granting motion for judgment on the pleadings) (describing royalty on brand-name sales, but finding allegation insufficient to survive dismissal on the pleadings). A promotion deal could be structured this way too.

a new tablet formulation of the drug and agreed to pay a royalty on its sales.²³¹ This gave the generic firm an incentive not to enter precipitously, as early entry might jeopardize the orderly transition to a new and more profitable formulation. In addition, periodic cash payments, purportedly in exchange for developing the new formulation, were made contingent on unspecified events. This may have been directly for nonentry or indirectly for a successful transition; it is impossible to tell based on the limited data available.

* * *

These examples demonstrate that drug makers are adept at achieving a particular substantive outcome—brand-name compensation of generic firms, combined with delayed generic entry—while altering the form of settlement to evade the most obvious risks of antitrust liability. The continuing shift in strategy here resembles the economics of tax shelters. As a regulatory prohibition becomes more stringent, the cost of noncompliance rises. Some regulated parties will give up and simply comply, resulting in a welfare gain. Others will continue to avoid regulation, and instead shift to new strategies. These strategies are more costly to the firm, for otherwise they would have been chosen in the first place; this shift represents a social loss.²³² Thus, whether an increase in enforcement is warranted depends upon the amount of residual noncompliance and the increase in social costliness of the new behavior.²³³

The review of settlement behavior in this Article paints a mixed picture. To be sure, this process of continuing evolution threatens the ability of existing antitrust institutions to keep pace, particularly courts. Courts are increasingly unlikely to be an effective check on settlement. In part, this is because they are poor aggregators. In addition, courts must be fed cases by either a government agency or a private plaintiff. The FTC has limited case-by-case enforcement capacity; practically speaking, it can bring at most a few pharmaceutical antitrust cases at a time, and they are likely to last for five years or more. That capacity is small, compared to the frequency of pay-for-delay settlements. Private plaintiffs, meanwhile, are reluctant to bring cases. Having lost the simplest cash-for-delay agreements, why should they take a chance challenging more complex settlements?

Continuing evolution makes the crisis in case-by-case adjudication more acute for another reason. A single appellate or Supreme Court opinion imposing liability does not fully

²³¹ King Pharm., Quarterly Report (Form 10-Q), at 10 (Aug. 7, 2007) (describing King's exercise of previously secured option to buy Cobalt's tablet NDA, and to pay Cobalt to manufacture and supply the tablet form). A royalty on sales for the acquired tablet product does not appear in the parties' disclosure of the agreements, but it is mentioned in the FTC's 2006 update describing a "complex set of transactions" that fit the Altace transactions. FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006, at 6 (2007).

²³² See Louis Kaplow, Optimal Taxation with Costly Enforcement and Evasion, 43 J. Pub. Econ. 221, 230–33 (1990) (providing model of costly evasion in response to increased enforcement); David A. Weisbach, An Economic Analysis of Anti-Tax-Avoidance Doctrines, 4 Am. L. & Econ. Rev. 88, 99–101 (2002) (assessing shift by taxpayers, in response to increased enforcement, to more costly shelters).

²³³ The statement in text is an incomplete account. Also important are the cost of administering the system itself and costs resulting from overinclusion—for example, restricting some value-increasing side deals. For a discussion of why the latter cost is likely small, see Part III.C.

resolve liability for the newest settlements. A win on a simple case is a very helpful start, but only sets the stage in making sense of the more complicated cases. Thus, even if it were settled as a theoretical matter that paying for delayed entry is prohibited, and settled as a factual matter that side deals provide a disguised means to pay for delay, it does not necessarily follow that the newest settlements also violate antitrust law. Given the malleability of side deals, even an on-point judicial decision imposing liability would not preclude firms from arguing that their arrangements were conceptually or factually distinct. On the other hand, if a court is forced to start with one of the most complex cases, without the benefit of affirmative precedent on the simpler cases, correctly identifying liability seems unlikely.

Here, too, FTC rulemaking can help. As to new forms of payment, for example, the FTC could set a rule stating that *any* conferral of value by a brand-name firm, if made contemporaneously with a generic firm's agreement to delay entry, will be considered to exchange payment for delay. Probabilistic damages would clearly fit within that definition. Agreements to preserve exclusivity, whether simply by agreeing not to contest ANDA approval or by an affirmative agreement not to launch an authorized generic product, would also be included, as just another form of payment. In these examples, the aggregation approach helps to identify and respond to emergent settlement practices before they become more prevalent. For settlements without formal agreement, moreover, FTC rulemaking does even better, because the FTC Act, unlike section 1 of the Sherman Act, does not require an agreement to be effective.²³⁴

Agency rulemaking is not the only possible route for implementing a broadly applicable rule. If a court can be persuaded to think broadly about the implications of settlement, it may implement a similarly broad ruling, though the considerations above tend to make that less likely. Legislative action is also a possibility. The MMA closed some loopholes, though it preserved others, including the bottleneck and retained exclusivity. Its requirement that an appeals court trigger exclusivity also worsened the delays in an important respect, through a provision buried seven steps deep in the statutory structure: 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

Thus, although Congress could directly implement any of the presumptions or rules discussed above, its ability to do so quickly and correctly is open to significant doubt. These difficulties also suggest a reframing of the legislative project. Rather than closing identified loopholes with another new layer of complexity, it would be better to remove existing complexity—in particular, by ending retained exclusivity. Simply put, if a generic firm ends its litigation against a brand-name firm, it should no longer be eligible for the exclusivity period.

In a sense, this provision would offer a partial return to the FDA's original view that a generic firm must earn exclusivity by winning a patent suit.²³⁵ It would reduce both the amount

²³⁴ Compare 15 U.S.C. § 1 (2006) (prohibiting certain "contract[s], combination[s] . . . [and] conspirac[ies], in restraint of trade"), with 15 U.S.C. § 45(a)(1) (declaring that "[u]nfair methods of competition in or affecting commerce . . . are hereby . . . unlawful").

²³⁵ See *supra* note 116 and accompanying text.

of payment conferred in a settlement, and the extent to which a settlement delays entry. The provision should apply to both new and existing settlements, like other statutory provisions that have been given retrospective effect. Finally, the political economy of such a statutory change is attractive. If, as some observers might argue, retained exclusivity is not a valuable form of compensation for delay, then its omission from the settlement equation will not be missed, and there is little reason for drug makers to resist this statutory change.

A rule directed to all contemporaneous conferrals of value by a brand-name firm would appear to resolve the pay-for-delay issue, closing the avenue for escape to yet further forms of regulatory avoidance. This appears to be true even as to informal contemporaneous understandings reached between parties, as in the Altace example above. In tax planning, informal alternatives to contract greatly expand the opportunity for avoidance.²³⁶ That problem is much less severe for drug patent settlements, where repeat interactions are much less frequent,²³⁷ and the negative consequence of curtailing brand-generic interactions—of tolerating an overinclusive ban on the content of side deals—is small. Eliminating continued entitlement to the exclusivity period, despite settlement, would also simplify consideration of any arrangement reached by the brand-name and generic firms. Thus, it seems unlikely that effective avoidance would survive the promulgation of a strong rule. If that judgment is incorrect, the agency's ability to respond flexibly, without being subject to *stare decisis*, may prove to be a significant advantage.

Conclusion

Examining in detail the terms and effects of drug patent settlements reveals several important points. Drug patent settlements that restrict generic competition are an increasingly important, unresolved problem in antitrust enforcement. The evolution in settlement structure makes it less likely that courts will correctly identify and condemn them. There is therefore much reason to fear a continuation and intensification of false negatives if the current policy persists. Case-by-case evaluation is a failure and is likely to remain so, at least absent intervention by the Supreme Court. One partial response is to impose a presumption of payment where side deals accompany delayed entry. This would force firms to explain their increasingly questionable side deals, and would potentially discourage such complex dealmaking in the future.

²³⁶ See, e.g., Alex Raskolnikov, *Relational Tax Planning Under Risk-Based Rules*, 156 U. Pa. L. Rev. 1181, 1205–13 (2008) (describing avoidance strategies by which tax planners enter implicit agreements); Alex Raskolnikov, *The Cost of Norms: Tax Effects of Tacit Understandings*, 74 U. Chi. L. Rev. 601, 613–30 (2007) (describing contractual norms relevant to tax planning).

²³⁷ See *supra* note 110 and accompanying text. One ground for caution is a trend of continuing industry consolidation. See, e.g., Andrew Ross Sorkin & Duff Wilson, *In Tight Market, \$68 Billion Deal Is Reported for Pfizer and Wyeth*, N.Y. Times, Jan. 26, 2009, at A1; Press Release, Teva Pharms. Indus. Ltd., *Teva Completes Acquisition of Barr* (Dec. 23, 2008). Further consolidation, as it reduces the number of industry players, could increase the frequency of repeat play, and hence the opportunity for informal arrangements. It would also raise the cost of overinclusion, by reducing the number of available alternative counterparties with which to conduct business arrangements for non-settlement purposes.

The analysis supports several further measures. This study reveals persistent gaps in public knowledge about settlements, both in their existence and their terms. These are gaps that the FTC is uniquely positioned to fill. The agency should step in to collate the extensive information it already has, supplement it with additional factfinding, and disseminate authoritative information of the type offered here. In that respect, this study represents a prima facie case that additional information gathering is necessary, and can serve as a first draft for the FTC's future work. So long as settlements and their terms remain hidden, it will be difficult to do integrative work of the kind suggested here, and difficult to develop the "consensus among commentators" that is a key step in discerning appropriate antitrust policy. The additional insight will help academics and policymakers in revising, if necessary, the initial conclusion presented here that pay-for-delay settlements are frequently tried and frequently successful.

ARTICLES

PAYING FOR DELAY: PHARMACEUTICAL PATENT SETTLEMENT AS A REGULATORY DESIGN PROBLEM

C. SCOTT HEMPHILL*

Over the past decade, drug makers have settled patent litigation by making large payments to potential rivals who, in turn, abandon suits that (if successful) would increase competition. Because such "pay-for-delay" settlements postpone the possibility of competitive entry, they have attracted the attention of antitrust enforcement authorities, courts, and commentators. Pay-for-delay settlements not only constitute a problem of immense practical importance in antitrust enforcement, but also pose a general dilemma about the proper balance between innovation and consumer access.

This Article examines the pay-for-delay dilemma as a problem in regulatory design. A full analysis of the relevant industry-specific regulatory statute, the Hatch-Waxman Act, yields two conclusions. First, certain features of the Act widen, often by subtle means, the potential for anticompetitive harm from pay-for-delay settlements. Second, the Act reflects a congressional judgment favoring litigated challenges, contrary to arguments employed to justify these settlements. These results support the further conclusion that pay-for-delay settlements are properly condemned as unreasonable restraints of trade. This analysis illustrates two mechanisms by which an industry-specific regulatory regime shapes the scope of antitrust liability: by creating (or limiting) opportunities for anticompetitive conduct as a

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practical economic matter, and by guiding as a legal matter the vigor of antitrust enforcement in addressing that conduct.

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“[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.”

—Verizon Communications Inc. v.
Law Offices of Curtis V. Trinko, LLP¹

INTRODUCTION

To what extent do legislative enactments shape the scope of anti-trust liability? The answer is not purely a matter of antitrust law. Antitrust’s basic law, the Sherman Act, takes a famously broad approach in its two major liability-setting provisions. Section 1 purports to condemn “[e]very contract, combination . . . , or conspiracy, in restraint of trade”;² section 2 forbids a firm to “monopolize.”³ These provisions do not much constrain antitrust enforcement agencies or courts. Subsequent interpretation has narrowed the scope of section 1 to *unreasonable* restraints⁴ and given content to the ill-defined concept of “monopolization.” A law referred to as “the Magna Carta of free enterprise”⁵ can hardly be expected to determine the results of particular cases. Instead, enacted antitrust law is generally understood to grant agencies and courts a broad license to develop policy in an incremental fashion.⁶

¹ 540 U.S. 398, 411–12 (2004) (quoting *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (citation and internal quotation marks omitted)). Justice Scalia wrote the opinion of the Court in *Trinko*; then-Chief Justice Breyer authored *Town of Concord*.

² 15 U.S.C. § 1 (2000) (emphasis added).

³ *Id.* § 2.

⁴ The claimed statutory hook for this result is that “restraint of trade” imported the common-law understanding of trade restraint law as it existed in 1890, “along with its dynamic potential.” *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 732 (1988).

⁵ *United States v. Topco Assocs.*, 405 U.S. 596, 610 (1972); see also *Appalachian Coals, Inc. v. United States*, 288 U.S. 344, 359–60 (1933) (“As a charter of freedom, the Act has a generality and adaptability comparable to that found to be desirable in constitutional provisions.”).

⁶ See, e.g., *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 688 (1978) (explaining that Sherman Act authorizes “the courts to give shape to the statute’s broad mandate by drawing on common-law tradition”). Academics share this understanding. See, e.g., Einer Elhauge, *Preference-Estimating Statutory Default Rules*, 102 COLUM. L. REV. 2027, 2044 (2002) (acknowledging that statutes delegate to courts “ongoing judicial resolution” of antitrust matters); William N. Eskridge, Jr. & John Ferejohn, *Super-Statutes*, 50 DUKE L.J. 1215, 1231–37 (2001) (using Sherman Act as classic example of “broadly enabling” statute); John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387, 2444–45 n.212 (2003) (noting “independent policymaking discretion” provided to agencies and courts under statutes such as Sherman Act); Thomas W. Merrill, *The Common Law Powers of Federal Courts*, 52 U. CHI. L. REV. 1, 44–46 (1985) (commenting that section 1 of Sherman Act represents implied delegated lawmaking). For a critique of this view, see Daniel A. Farber & Brett H. McDonnell, “Is There a Text in This Class?” *The Conflict Between Textualism and Antitrust*, 14 J. CONTEMP. LEGAL ISSUES 619 (2005).

That license has limits, for two other kinds of regulatory law address firm conduct within the ambit of antitrust. One important and familiar source is intellectual property law, particularly patent law. Accounts of the intersection between antitrust and patent law emphasize the conflict in means between the two.⁷ The usual account of antitrust law emphasizes allocative efficiency: avoidance of the distortion that results when consumers' unwillingness to pay high prices diverts them to less desirable substitutes.⁸ The instrumental case for patent law, by contrast, depends upon high prices as a means to reward and thereby encourage innovation, a source of "dynamic" efficiency.⁹ Because many competitive practices both distort allocation and provide a dynamic benefit, the conflict in means between antitrust and intellectual property can be stark. A substantial literature seeks an optimal reconciliation between these competing values by encouraging innovation without sacrificing too much consumer access.¹⁰

Intellectual property law, however, is not the only kind of regulatory enactment that affects antitrust decisionmaking. This Article isolates and examines a second overlap between antitrust and regulatory law, the ways in which an *industry-specific regulatory regime* alters the

Also relevant here is section 5 of the Federal Trade Commission (FTC) Act, 15 U.S.C. § 45(a)(2) (2000), which grants the FTC power to prevent "unfair methods of competition," understood by the FTC in this context to be "for the most part[] co-extensive with the Sherman Act." *In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651, Part VI, n.107 (F.T.C. Dec. 8, 2003).

⁷ See, e.g., 1 HERBERT HOVENKAMP, MARK D. JANIS & MARK A. LEMLEY, *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 1.3 (2002 & Supp. 2005), and sources cited therein (discussing interaction of intellectual property and antitrust law).

⁸ See, e.g., RICHARD A. POSNER, *ANTITRUST LAW* 9–32 (2d ed. 2001) (describing centrality of allocative efficiency to antitrust analysis and considering objections). A policy that promoted prices *below* marginal cost would also harm allocative efficiency.

⁹ See, e.g., Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 *HARV. L. REV.* 1813, 1822 (1984) ("[W]hen patent policy is . . . implicated, profit plays a central role, because it serves as a reward—and, in turn, an incentive—for the inventive activity that produces the benefits of the patent system.").

¹⁰ See, e.g., John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 *ANTITRUST L.J.* 449 (1997) (emphasizing importance of cumulative innovation for optimal balance between patent and antitrust, and advocating greater protection of follow-on innovators); William F. Baxter, *Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis*, 76 *YALE L.J.* 267 (1966) (characterizing balance between competition and innovation as problem of optimal subsidy to innovators); Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 *U. PA. L. REV.* 761 (2002) (proposing industry-specific adjustments to antitrust-patent balance that vary depending upon technology of innovation); Kaplow, *supra* note 9 (analyzing optimal balance by assessing ratio between reward to innovator and deadweight loss resulting from patentee's practice); Stephen M. Maurer & Suzanne Scotchmer, *Profit Neutrality in Licensing: The Boundary Between Antitrust Law and Patent Law*, 8 *AM. L. & ECON. REV.* (forthcoming 2006) (arguing that certain profit-preserving practices by patentees are permissible under antitrust law).

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contours of antitrust enforcement. A particular regulatory regime sets the boundaries of feasible anticompetitive conduct. At the same time, it embodies a specific congressional judgment about the proper balance between competition and innovation in an industry. Both effects shape antitrust enforcement in often subtle ways. Identifying the impact of an industry-specific regulatory regime in a particular context requires careful, sustained attention to the principal features of the relevant regulatory scheme. That general project, though difficult, is also necessary to identify the boundaries of permissible competitive conduct in regulated industries as diverse as telecommunications, financial services, and—the primary focus of the present analysis—pharmaceuticals.

“Pay-for-delay” settlements in the U.S. pharmaceutical industry pose a puzzle of great current importance in antitrust enforcement. Such settlements emerge as an alternative to patent litigation between the manufacturer of a patented drug—call it the “innovator”—and its would-be rival, a so-called “generic” drug maker seeking to market a competing version of the same drug prior to the patent’s scheduled expiration. If the generic firm wins in litigation, either by establishing that the patent is invalid or not infringed by the generic firm’s competing product, the generic firm wins the means to enter the market prior to scheduled expiration. Successful pre-expiration challenges reallocate billions of dollars from producers to consumers.¹¹

The antitrust issue arises when the two drug makers settle the patent suit prior to its litigated conclusion. In some settlements, the innovator pays the generic firm a large sum, the generic firm agrees to abstain from entry, and the parties agree to dismiss the patent suit. The effect of such pay-for-delay agreements is to remove the possibility of early competition in the drug, and to deny consumers the allocative benefit of low prices, which would have followed with some probability had the litigation proceeded to conclusion.

The Federal Trade Commission (FTC), the U.S. antitrust enforcement agency charged with supervising the pharmaceutical industry, has insisted that pay-for-delay agreements violate antitrust law and has challenged numerous agreements as unreasonable restraints of trade.¹² By contrast, some, though not all, federal appellate courts have permitted the settlements.¹³ The difference of opinion is not limited to the courts: The Solicitor General not only declined to support an FTC petition seeking Supreme Court review of one pay-for-delay

¹¹ See *infra* Part I.A.2 for further discussion of pre-expiration patent suits.

¹² See *infra* Part I.B for further discussion of these antitrust suits.

¹³ See *infra* notes 83–85 and accompanying text for a discussion of the conflicting case law.

case, but filed an unusual, contrary brief expressly disagreeing with the FTC approach.¹⁴

Economists and legal scholars have devoted substantial attention to these cases, in light of their economic importance and deepening doctrinal confusion about their resolution.¹⁵ Commentators have

¹⁴ Compare Petition for Writ of Certiorari, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. Aug. 29, 2005), 2005 WL 2105243, with Brief of the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. May 17, 2006), 2006 WL 1358441. After offering the Solicitor General an opportunity to participate in its petition for certiorari, see 15 U.S.C. § 56(a)(3)(A), (C) (2000), the FTC had proceeded alone under its independent litigation authority; the Court then invited the Solicitor General to express the views of the United States.

¹⁵ For technical economic analyses considering liability, compare Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in 4 INNOVATION POLICY AND THE ECONOMY 145, 159–73 (Adam B. Jaffe et al. eds., 2004) (advocating liability for certain settlements and noting where law affords players opportunities to manipulate system), Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, 21 RES. L. & ECON. 475 (2004) (similar), and Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 407–08 (2003) [hereinafter Shapiro 2003a] (similar), with Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements That Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 660–62 (2004) (arguing that under certain conditions, settlements are efficient and should be permitted). See also Joel Schrag, *The Value of a Second Bite at the Apple: The Effect of Patent Dispute Settlements on Entry and Consumer Welfare* 3–4 (FTC, Working Paper No. 281, 2006) (arguing that settlement undermines subsequent entrants' incentive to challenge patent, thereby harming consumers).

Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003) [hereinafter Hovenkamp et al. 2003], provides a road map for courts considering the antitrust treatment of a broad range of intellectual property settlements and is inclined toward imposing liability for pay-for-delay settlements. Additional articles favoring liability include Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 18–19, 22–31 (2004) [hereinafter Hovenkamp, *Sensible Rules*] (advocating rebuttable presumption of liability), Herbert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 MINN. L. REV. 712, 712 (2004) [hereinafter Hovenkamp et al. 2004] (arguing that presumption of liability is less costly than case-specific analysis); Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33, 54 (2004) (arguing in favor of per se rule of liability); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1767, 1787 (2003) (arguing in favor of rule of presumptive liability). See also Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, ANTITRUST, Summer 2002, at 53, 53 [hereinafter Brodley & O'Rourke 2002] (advocating statutory changes to facilitate detection of anticompetitive agreements); Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, ANTITRUST, Summer 2003, at 70, 71–72 [hereinafter Shapiro 2003b] (arguing in favor of liability when settlements deprive consumers of litigation's expected benefits).

For analyses generally opposing liability, see, for example, Daniel A. Crane, *Ease over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 710–11 (2004) [hereinafter Crane 2004] (arguing that presumption of liability leads to costly error); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Applications*, 54 FLA. L. REV. 747, 753 (2002) [hereinafter Crane 2002] (similar); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent*

framed the cases as part of the wider debate about the intersection of patent and antitrust, and frequently seek to resolve these cases at that level of generality. For example, one prominent economic analysis, in advocating liability for pay-for-delay settlements, relies upon the proposition that, as a general matter of patent and antitrust, consumers have an entitlement “to the level of competition that would have prevailed, on average, had the two parties litigated.”¹⁶ Opponents of liability frequently pitch their arguments in similarly broad terms.¹⁷ Focusing upon the importance of patent law for resolving this antitrust problem is both enlightening and readily comprehensible: Pharmaceutical innovators rely to an unusual degree upon patents to protect their profits, and drug profits are a major part of what patents protect.¹⁸

However, this perspective is incomplete. Existing analyses, though attentive to the antitrust-patent intersection, have overlooked the importance of the antitrust–regulated industry intersection. A major objective of this Article is to fill that gap by examining in detail the industry-specific regulatory scheme that governs competition in the pharmaceutical industry, the Drug Price Competition and Patent Term Restoration Act of 1984,¹⁹ commonly known as the Hatch-Waxman Act, and related regulations of the Food and Drug Administration (FDA).

Rights and False Positives, ANTITRUST, Spring 2003, at 68, 69 (arguing that presumption of liability circumvents question of patent validity); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1034–35 (2004) (arguing that imposing presumption of liability indulges in undesirable probabilistic analysis). One analysis, 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, 778–79 (2003), opposes liability in the narrow context of “partial” or “interim” agreements that do not resolve the litigation but merely block entry pending its resolution. Thomas Cotter’s approach offers qualified support for some pay-for-delay settlements. 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, 1090–93 (2004); Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1816 (2003) [hereinafter Cotter 2003].

¹⁶ Shapiro 2003a, *supra* note 15, at 396; *see also* Shapiro 2003b, *supra* note 15, at 70.

¹⁷ *See, e.g.*, Schildkraut, *supra* note 15, at 1046–49 (offering general settlement-oriented defense of pay-for-delay agreements).

¹⁸ *See infra* Part I.A.1 for a discussion of the close connection between patents and pharmaceuticals.

¹⁹ Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.). In 2003, Congress amended this scheme in Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, subtit. A–B, 117 Stat. 2066, 2448–64 (codified at 21 U.S.C. § 355 (Supp. III 2003)), an Act better known for providing a new prescription drug benefit.

The regulatory design perspective advanced here has two payoffs. First, the analysis provides a sound basis for resolving the antitrust treatment of pay-for-delay settlements in the pharmaceutical industry. Second, in the course of resolving this particular antitrust question, the analysis offers a road map for resolving antitrust problems in other regulated industries, by giving shape and structure to the judicial command quoted at the outset of this Article: “[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.”²⁰

In particular, antitrust analysis should recognize and reflect a regulated industry setting in two important respects. First, the industry-specific regulatory regime serves as an economic input in antitrust analysis by setting the boundaries of feasible anticompetitive conduct by regulated parties. Second, the regime is a legal input, for the regime embodies a specific congressional judgment about the balance between competition and innovation. That judgment is *in pari materia* with the open-ended analysis of antitrust law and constrains its operation. Careful engagement with regulatory facts and economic theory within an industry is necessary to identify these two inputs as part of an adequate antitrust analysis.

The Hatch-Waxman regime affects, through both economic and legal mechanisms, the contours of antitrust law as applied to pharmaceutical competition. First, as an economic matter, the Act alters the prospect for anticompetitive conduct by regulated parties. An important feature of the regime is a large incentive to litigate the validity and scope of an innovator’s patents, a “bounty” worth hundreds of millions of dollars for a major drug. The bounty has an unusual form: In the case of a determination of invalidity or noninfringement, the generic firm enjoys a 180-day exclusive right to market a generic version of the drug in competition with the innovator, effectively a duopoly during that period, before other generic firms are permitted to enter the market.²¹

But *only the first generic firm* to challenge an innovator’s patents has any prospect of earning the bounty.²² Because no other firm has a similar opportunity, buying off the first challenger is an effective means to head off the most potent threat to entry. Previous accounts have neglected this effect, ascribing the feasibility of agreement

²⁰ *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411–12 (2004) (quoting *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (citation and internal quotation marks omitted)).

²¹ 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003).

²² 21 U.S.C. § 355(j)(5)(D)(iii) (Supp. III 2003); 21 C.F.R. § 314.107(c)(1)–(2) (2006). See *infra* Part II.A.2 for further discussion.

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instead to a different feature—an “approval bottleneck” that denies later generic firms the opportunity to receive FDA approval—that is present in some, but not all, pay-for-delay agreements. Courts have misperceived the availability of the bounty, resulting upon occasion in serious error.²³ In addition, the bounty can provide a means, generally overlooked, for the innovator to compensate a generic firm. A settlement that guarantees the bounty to a generic firm can provide a disguised payment for delay, making possible an allocative harm even where little or no cash changes hands.

Second, as a legal matter, the Act reflects a congressional judgment, unexplored in the literature, about the balance between competition and innovation. This judgment is important, given one set of arguments made against liability for pay-for-delay settlements—that they should be allowed because patent policy reflects an inclination toward settlement and a preference for innovation even at the expense of immediate consumer access. But whatever the general norms of patent policy, an industry-specific scheme alters that norm within its domain. The Hatch-Waxman Act imposes upon certain pharmaceutical innovators an effective tax on innovation. The incidence of taxation, however, is highly uneven. For some innovators, a different set of industry-specific features comes to the fore—a series of distinctive protections for innovators that serve to delay entry by a generic firm. These features effectively subsidize certain pharmaceutical innovations. Congress’s use of decentralized litigation to implement the resulting tax-and-subsidy scheme is an instrument present in pharmaceutical regulation, but missing from the patent system generally. This industry-specific feature undermines and displaces the general norms thought to favor settlement.

This Article concludes that a settlement should be accorded a presumption of illegality as an unreasonable restraint of trade if the settlement both restricts the generic firm’s ability to market a competing drug and includes compensation from the innovator to the generic firm. This view differs sharply from the result reached by most courts that these settlements should be permitted.²⁴ This view also differs from the pro-liability position of the FTC and some com-

²³ For a vivid example, see *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641, 2006 WL 2401244 (2d Cir. Aug. 10, 2006), in which the court relied, as a reason to deny antitrust liability, upon the mistaken notion that the innovator’s settlement agreement with the first filer would “open[] the [relevant] patent to immediate challenge” by other firms, “spurred” in part by the supposed availability of the 180-day exclusivity period. *Id.* at *22. See *infra* Part II.A.2 for further discussion of this case.

²⁴ See, e.g., *Tamoxifen*, 2006 WL 2401244, at *1; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005).

mentators by applying the presumption not only to settlements with an “approval bottleneck” or with large cash payments, but also to settlements without a bottleneck and with little or no cash payment.

The Article proceeds in three Parts. Part I describes the pay-for-delay settlement problem and disagreement about its resolution among enforcement agencies, courts, and commentators. Part II explains the means by which the industry-specific regulation of pharmaceuticals alters the scope of anticompetitive activity by regulated parties. Part III assesses the congressional judgment about competition and innovation offered by the Hatch-Waxman Act, and shows how this judgment undermines certain arguments against antitrust liability. The Conclusion discusses the utility gained by understanding other antitrust problems through the lens of regulatory design.

I

THE PAY-FOR-DELAY DILEMMA

A. *Pharmaceutical Innovation and Competition*

1. *Innovation and Patent Policy*

There is generally thought to be a close fit between pharmaceuticals and patent policy. Drug makers rely heavily upon patent protection: New drugs are developed in anticipation of the profits that patents secure. Almost uniquely, in this industry a patent is considered necessary to recoup an initial investment.²⁵ A new drug is essentially an information good—once its formula is understood, it is relatively straightforward and cheap for others to manufacture it

²⁵ For example, large-scale surveys of research and development employees have indicated that patents are unimportant for appropriating returns from research and development in most industries, with pharmaceuticals providing an important exception. See Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECON. ACTIVITY (SPECIAL ISSUE) 783, 795–96, 819 (discussing survey commenced in 1981 that shows that pharmaceutical and other chemical manufacturers valued patents particularly highly as means of appropriation); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)* 23–25 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000) (reporting, among results of 1994 survey, that pharmaceutical industry is rare sector in which patents are used to appropriate rents); *id.* at tbl.1 (reporting that patents are considered effective basis for protection in fifty percent of surveyed product innovations in drug industry; most other industries had lower rates).

The present analysis has two significant limitations. First, not only patents, but also government and university research efforts, are important to the development of pharmaceuticals. Second, although this Article focuses upon the appropriation basis for and profit-protecting effect of patents, other motivations and effects may be important as well. See, e.g., Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625 (2002) (analyzing patents' role in credibly conveying to outside observers information held by patentees); Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1 (2005) (emphasizing distinctive role of aggregations of patents in patent system's functions).

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without incurring similar research and development costs.²⁶ Drug companies, compared to innovators in other industries, cannot as easily rely upon a head start, complementary assets, and scale of production as means to preserve profits.²⁷ Nor can a drug maker easily keep the chemical formula secret. For blockbuster drugs as with blockbuster films, the ability to legally exclude rivals from offering a copy preserves the return from a massive initial investment. Economic theory predicts that the expectation of profits from new discoveries will induce investment in research, development, and testing.²⁸ The available empirical evidence suggests that higher drug profits are indeed correlated with greater research and development efforts.²⁹

Pharmaceuticals are thought to possess an unusually simple technology of innovation. In other industries, the technology of innovation is cumulative and incremental, with the set of potential innovators widely dispersed. When an innovation developed elsewhere is itself the raw material for further invention, strong, multiple rights of exclusion can lead to underuse.³⁰ Cumulative innovation is an important complication for intellectual property policy,³¹ but it is

²⁶ This is not always so. For example, so-called “biologics” derived from living sources are relatively difficult to make and replicate, providing their manufacturers with an additional source of protection. See, e.g., Val Brickates Kennedy, *Amgen CEO Assesses Generic Threat*, MARKETWATCH, Mar. 1, 2006, <http://www.marketwatch.com> (search for “Amgen CEO”) (reporting Amgen CEO’s comment that generic biologics are relatively difficult to manufacture).

²⁷ Such factors are not unimportant to drug companies, but they are neither necessary nor sufficient for commercial success.

²⁸ F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 NEW ENG. J. MED. 927, 927, 929 (2004) (explicating prediction of economic theory that prospective profits induce expenditures for research, development, and testing).

²⁹ Carmelo Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 195 (2005) (reporting positive correlation between profit and research spending).

³⁰ For careful discussions of this problem, see Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 667–79 (1998); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119, 122–26 (Adam Jaffe et al. eds., 2001).

³¹ For discussions of these complications, see generally LAWRENCE LESSIG, *THE FUTURE OF IDEAS: THE FATE OF THE COMMONS IN A CONNECTED WORLD* 205–15 (2001), which discusses the difficulties in achieving innovation through patent policy when innovation is cumulative, and SUZANNE SCOTCHMER, *INNOVATION AND INCENTIVES* 127–96 (2004), which discusses the roles of cumulative innovation and licensing in innovation policy.

less important for pharmaceuticals.³² Partly as a result, pharmaceuticals have been associated with the case for strong patents.³³

2. *Competitive Entry Prior to Patent Expiration*

The reality of pharmaceutical innovation and competition is more complicated than this initial account suggests, for the law provides not only a right of exclusion, but also an elaborate regulatory scheme to test the validity and scope of a pharmaceutical patent. As explained in some detail below, if an innovator's patent is found invalid or not infringed, a generic rival may enter the market prior to the scheduled expiration of the patent. Early generic entry is an important source of allocative benefit to consumers.

Under the Federal Food, Drug, and Cosmetic Act, an innovator must demonstrate that a drug is safe and effective before the FDA will approve it for marketing.³⁴ Making that demonstration as part of a so-called New Drug Application (NDA)³⁵ is a lengthy, expensive process, consuming years and many millions of dollars to conduct the necessary clinical trials.³⁶

³² Cumulative innovation is not entirely unimportant. In the overlapping field of biotechnology, patented research tools are an "upstream" input into the development of new therapies, raising a potential "downstream" underuse problem, which is discussed in Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCI.* 698 (1998). For an empirical analysis suggesting that patented research tools have not hampered innovation in practice, see John P. Walsh et al., *Working Through the Patent Problem*, 299 *SCI.* 1021 (2003). See generally Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 *BERKELEY TECH. L.J.* 813 (2001) (arguing that biopharmaceutical patents on upstream invention pose potential threat to competition and cumulative innovation, and that both patent law and antitrust enforcement must check this threat).

³³ See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 *V.A. L. REV.* 1575, 1615–17 (2003) (matching pharmaceutical industry with normative case for patents that are "broad, stand alone, and confer almost total control over subsequent uses of the product").

³⁴ 21 U.S.C. § 355(d) (2000).

³⁵ For the statutorily required application process, see 21 U.S.C. § 355(b) (2000 & Supp. III 2003); JOHN R. THOMAS, *PHARMACEUTICAL PATENT LAW* 306–07 (2005).

³⁶ See Joseph A. DiMasi et al., *The Price of Innovation. New Estimates of Drug Development Costs*, 22 *J. HEALTH ECON.* 151 (2003), which reports the results of a confidential survey of drug companies with respect to a random sample of approved compounds. The mean out-of-pocket cost for clinical tests of the sampled compounds is \$130 million (all figures in 2000 dollars). *Id.* at 162 tbl.1 (summing items in "mean cost" column). Not all investigational compounds reach the end of all three phases of human testing and animal tests; if an estimate of the cost of failure is attributed to the successes, the cost per approved new drug rises to \$282 million. *Id.* at 165. Applying an eleven percent annual discount rate to the later outlays, the capitalized cost is \$467 million. *Id.* In the authors' estimation, the costs of clinical tests constitute more than half the total cost of drug development. See *id.* at 166 (separately estimating out-of-pocket and capitalized preclinical costs to be \$121 million and \$355 million respectively).

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Once an NDA has been approved, a generic firm can market a competing version of the drug without repeating that process provided it adheres to the strictures of the Hatch-Waxman Act. The basic regime, established by the Act in 1984, has remained unchanged in its main features, even after substantial statutory revisions in 2003. The generic firm files an application called an Abbreviated NDA (ANDA) demonstrating, among other things, the bioequivalence of its product and the brand-name product.³⁷ Establishing bioequivalence is not trivial but is much less expensive than NDA clinical trials, requiring an outlay on the order of \$1 million.³⁸

An ANDA may seek pre- or post-expiration marketing of a generic drug. ANDAs for post-expiration marketing seek to secure entry once the relevant patents have expired. An ANDA directed to *pre-expiration* marketing of a generic drug, by contrast, contains a “Paragraph IV” certification asserting that the innovator’s patents are either invalid or not infringed by the generic product.³⁹ A generic firm might argue that the patent is invalid because it was procured inequitably,⁴⁰ or inherently anticipated by the prior art,⁴¹ or because the drug’s initial testing violates the public use bar.⁴² Alternatively, the firm might contend that it has devised a noninfringing bioequivalent form of the drug—for example, a different crystalline

³⁷ 21 U.S.C. § 355(j)(2)(A), (8)(B) (2000) (listing requirements and defining bioequivalence). The requirements include, aside from bioequivalence, demonstrations that the generic drug contains the same active ingredient, conditions of use, route of administration, dosage form, strength, and labeling. § 355(j)(2)(A).

³⁸ See Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61,640, 61,645 (Oct. 29, 2003) (reporting estimates of ANDA preparation and filing costs between \$300,000 and \$1 million).

³⁹ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). There are three alternative certifications, called “Paragraphs” (although they are actually subclauses) I, II, and III. § 355(j)(2)(A)(vii)(I)–(III). The first two permit immediate approval on the grounds, respectively, that the required information has not been filed by the innovator or that the relevant patents have expired. § 355(j)(2)(A)(vii)(I), (II). A Paragraph III certification concedes that one or more patents have not expired, and that approval is not sought until expiration. § 355(j)(2)(A)(vii)(III).

⁴⁰ See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 530 (E.D.N.Y. 2005) (noting first ANDA filer’s inequitable conduct argument).

⁴¹ See, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1334 (Fed. Cir. 2005) (invalidating patent on grounds of inherent anticipation by prior patent).

⁴² See, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1308 (Fed. Cir. 2004) (invalidating patent for violating public use bar of 35 U.S.C. § 102(b) during clinical trials), *vacated on reh’g en banc*, 403 F.3d 1328 (Fed. Cir. 2005), *aff’d on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

structure of the same active ingredient,⁴³ or a different way to accomplish some desirable time-release feature of the innovator's drug.⁴⁴

Submitting an ANDA containing such a certification—call it an ANDA-IV—is an act of infringement⁴⁵ that often prompts the innovator to file a patent suit. If the court determines that the relevant patents are invalid or not infringed, the generic manufacturer, if it was the first firm to file an ANDA-IV (an important qualification discussed in Part II), enjoys a 180-day exclusive right to market a generic version of the drug in competition with the innovator, effectively creating a duopoly for that period.⁴⁶

Several other features of the regulatory regime delay the moment at which a generic firm can begin enjoying the 180-day period. For example, if the innovator's drug contains a novel active ingredient,⁴⁷ the FDA must not accept an ANDA-IV in the first four years after NDA approval.⁴⁸ Moreover, once the ANDA-IV is filed, and provided that the innovator files a patent suit in response, a statutory stay operates to block FDA approval for the first several years of the suit's pendency.⁴⁹ That "thirty-month" stay, as it is often but inaccurately called, can last for more than three years.⁵⁰

⁴³ See, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1023 (N.D. Ill. 2003) (describing defendant's noninfringement claim), *aff'd*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated on reh'g en banc*, 403 F.3d 1328 (Fed. Cir. 2005), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

⁴⁴ See, e.g., Complaint Counsel's Trial Brief at 17–18, *In re Schering-Plough Corp.*, No. 9297 (F.T.C. Jan. 23, 2002), 2002 WL 1488085 [hereinafter Schering Trial Brief], available at <http://www.ftc.gov/os/adjpro/d9297/020123cctb.pdf> (describing generic firm's contention that its product had composition and viscosity different from that specified in innovator's patent).

⁴⁵ 35 U.S.C. § 271(e)(2)(A) (2000).

⁴⁶ 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003). The 2003 amendments altered the operation of the exclusivity period in important respects. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(1), 117 Stat. 2066, 2457–58 (2003). One major effect was to remove a statutory bottleneck that resulted when a first-filing generic firm neither marketed its product nor secured a judicial determination of invalidity or noninfringement; in that event, the FDA was powerless to approve the ANDA-IVs of subsequent filers. For further discussion, see *infra* Part II.A.3.

⁴⁷ More precisely, a drug containing no "active moiety" already approved in another NDA. 21 C.F.R. § 314.108(a) (2006).

⁴⁸ See 21 U.S.C. § 355(j)(5)(F)(ii) (Supp. III 2003). The delay is five years for ANDAs with Paragraph I, II, or III certifications. *Id.*

⁴⁹ § 355(j)(5)(B)(iii) (2000 & Supp. III 2003). The stay goes into effect provided that the innovator files suit within forty-five days of receiving notice of the certification. *Id.*

⁵⁰ The default maximum duration of the stay is thirty months, measured from the innovator's receipt of notice, provided that notice is received by the innovator no earlier than the point five years after the innovator's marketing approval. § 355(j)(5)(B)(iii). If the generic firm files an ANDA-IV during the first year of its eligibility to do so—that is, between four years and five years after NDA approval—then the stay is lengthened so that it ends five years plus thirty months after the marketing approval date. § 355(j)(5)(F)(ii). The maximum increase is less than a year, because the innovator's receipt of notice is

Pre-expiration challenges are a frequently deployed mechanism for the early introduction of generic competition. Since 1984, generic firms have filed pre-expiration challenges involving more than 200 drugs, apparently at an increasing rate.⁵¹ Of the ten best-selling drugs of 2000, nine attracted challenges.⁵² With respect to the most important new drugs, pre-expiration litigation is the norm, not the exception.⁵³

These challenges often secure early entry by generic rivals. The FTC studied challenges initiated between 1992 and 2000 involving 104 drugs.⁵⁴ Of the fifty-nine drugs whose challenges were neither pending nor settled at the end of the study period, the innovator declined to sue with respect to twenty-nine,⁵⁵ effectively permitting rapid generic entry. The generic firm won in another twenty-two cases.⁵⁶ ANDA challenges have led to pre-expiration competition for many major drugs.⁵⁷

necessarily later than the four-year point. The district court can also lengthen or shorten the stay in response to uncooperative behavior by either party. § 355(j)(5)(B)(iii).

⁵¹ See FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* 10 (2002) [hereinafter *FTC STUDY*] (reporting challenges involving 130 drugs between 1984 and 2000, including challenges involving 104 drugs between 1992 and 2000); *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act" Before the S. Comm. on the Judiciary*, 108th Cong. 117 (2003) (statement of Timothy Muris, Chairman, FTC) (noting challenges involving more than eighty drugs between January 2001 and June 2003).

⁵² See Robert Pear, *Spending on Prescription Drugs Increases by Almost 19 Percent*, N.Y. TIMES, May 8, 2001, at A1 (listing, as top ten sellers, Celebrex, Claritin, Glucophage, Lipitor, Paxil, Prevacid, Prilosec, Prozac, Zocor, and Zolofit); CTR. FOR DRUG EVALUATION & RESEARCH, FDA, PARAGRAPH IV PATENT CERTIFICATIONS AS OF SEPTEMBER 14, 2006, <http://www.fda.gov/cder/OGD/ppiv.htm> (including all but Glucophage in list of drugs that have attracted Paragraph IV challenges). Although Glucophage appears to have attracted no challenge, an extended-release variant, Glucophage XR, has attracted a challenge. *Id.*

⁵³ *But cf.* Richard A. Epstein & Bruce N. Kuhlik, *Is There a Biomedical Anticommons?*, REGULATION, Summer 2004, at 54, 57 ("[W]hatever the dramatic tales in individual cases, litigation is the exception and not the norm. In the vast majority of cases—approximately 95 percent of the time—generics are content to wait until patent expiration to begin commercial sales (although recent trends point toward more patent challenges).") The source and nature of the ninety-five percent figure is left unstated but is probably a reference to the FTC's determination that ninety-four percent of the more than 8000 ANDAs filed between 1984 and 2000 lacked a Paragraph IV certification. *FTC STUDY*, *supra* note 51, at 10.

⁵⁴ *FTC STUDY*, *supra* note 51, at 10.

⁵⁵ *Id.* at 15 fig.2-1.

⁵⁶ *Id.* The innovator won in the remaining eight cases. *Id.* These figures ignore two cases in which the patent expired before the litigation was resolved, and one in which an NDA was withdrawn before the litigation was resolved. *Id.*

⁵⁷ Of the ten best sellers from 2000, at least four—Paxil, Prilosec, Prozac, and Zocor—have seen pre-expiration competition. See, e.g., Jenna Greene, *Big Pharma's Big Leap*, IP L. & BUS., Jan. 1, 2006, at 40, 42 (noting August 2001 launch of generic Prozac and September 2003 launch of generic Paxil, each with 180-day exclusivity); *KUDCO's*

B. *The Competitive Harm of Paying for Delay*

Innovators faced with generic competition have shown considerable ingenuity in maximizing the returns from a successful drug. Some strategies, such as an improved variant of an existing drug or a discount to price-sensitive customers, arguably provide immediate benefit to consumers. That is not true, however, of a pay-for-delay settlement of a pre-expiration patent challenge. The basic settlement structure is simple, though individual settlements offer many variations on the theme. The generic firm abstains from entry, the innovator agrees to pay the generic firm a large sum, typically in the tens or hundreds of millions of dollars,⁵⁸ and the parties agree to dismiss the patent suit. The agreement may also provide for limited pre-expiration entry.

Consider, for example, a pre-expiration challenge involving the anti-ulcer medication Zantac, which settled on the eve of trial.⁵⁹ Under the terms of the settlement, the generic firm conceded the validity of the patents at issue and agreed not to market a competing

Omeprazole Generic Launched in the US, MDIS PUBLICATIONS, Dec. 11, 2002, available at 2002 WLNR 220240 (reporting launch of generic Prilosec by subsequent filer following first-filer agreement to relinquish exclusivity); *FDA, Court Clear Way for Teva's, Ranbaxy's Generic Zocor*, GENERIC LINE, June 23, 2006 (on file with the *New York University Law Review*) (noting approval of generic Zocor, with exclusivity for different dosages granted to different firms). Other major drugs that have seen early competition include Allegra, Glucophage XR, Macrobid, Neurontin, OxyContin, and Wellbutrin SR. Press Release, Barr Pharmaceuticals, Inc., Barr Says Court Denies Preliminary Injunction to Halt Generic Allegra Sales (Jan. 27, 2006), <http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=809655> (noting generic Allegra launch with exclusivity in September 2005); *Alpharma, Ivax Share Generic Metformin ER Exclusivity*, GENERIC LINE, Dec. 3, 2003 (on file with the *New York University Law Review*) (describing pre-expiration competition from generic Glucophage XR); *Mylan Pharm., Inc. v. FDA*, No. Civ. A. 104CV242, 2005 WL 2411674, at *2 (N.D. W. Va. Sept. 29, 2005) (noting launch of generic Macrobid with exclusivity); Leila Abboud, *Diminutive Alpharma Takes a Risky Slap at Drug Titan Pfizer*, WALL ST. J., Oct. 11, 2004, at C1 (describing pre-expiration competition from generic Neurontin); *Generic OxyContin Gives Purdue Pain*, MED AD NEWS, Aug. 1, 2005, at 8, 8, available at 2005 WLNR 13598257 (reporting launch of generic OxyContin with exclusivity); *Generic Wellbutrin SR Shipped After Andrx 180-Day Deal*, GENERIC LINE, Apr. 7, 2004 (on file with the *New York University Law Review*) (reporting pre-expiration launch of generic version of 150-milligram Wellbutrin SR after first filer agreed to relinquish exclusivity eligibility).

⁵⁸ See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519 (E.D.N.Y. 2005) (reporting payment of \$398 million over six years), *notice of appeal filed*, Nos. 05-2851, -2852 (2d Cir. June 7, 2005); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005) (reporting payment of \$60 million).

⁵⁹ Eric Reguly, *Shares in Glaxo Rise as Lawsuit Is Settled—Glaxo Wellcome*, TIMES (London), Oct. 24, 1995, at 25.

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drug.⁶⁰ In exchange, Glaxo, Zantac's manufacturer, paid the generic firm in cash⁶¹—the size of the payments, though not disclosed,⁶² probably exceeded \$100 million⁶³—and other consideration.⁶⁴ The settlement was quite valuable for Glaxo as well. At the time of the settlement, Zantac was the world's best-selling prescription medicine, with annual U.S. sales of about \$2 billion,⁶⁵ and removing the risk of early generic entry appears to have conferred upon Glaxo a multibillion-dollar benefit.⁶⁶

⁶⁰ Press Release, Glaxo Wellcome PLC, Glaxo Wellcome PLC Re Genpharm Litigation (Oct. 23, 1995) [hereinafter Zantac 1995 Press Release] (on file with the *New York University Law Review*) (announcing settlement).

⁶¹ *Id.*

⁶² *Id.* (noting merely that total was "not considered as material" to Glaxo Wellcome's overall results).

⁶³ Zantac was one of the drugs included in the FTC's study of pay-for-delay settlements. See FTC STUDY, *supra* note 51, app. C at A-16. The Zantac settlement was reached within the study period, and therefore should appear as part of a table listing settlements that entailed a cash payment in exchange for a delayed entry date. See *id.* at 32 tbl.3-3.

The table describes the major details of each such settlement but disguises the identity of the drug products involved. However, for some settlements discussed in the FTC study, the identity of the drug products can be inferred by matching the FTC-provided details to publicly available information. One of the settlements, involving "Drug Product I," featured a payment of \$132.5 million, made in part to settle additional patent litigation; a delay of one year, nine months between agreement and expiration; and innovator sales exceeding \$1 billion. *Id.*

Several factors support the conclusion that Drug Product I is Zantac. First, Drug Product I is the only drug listed on the FTC's table whose sales (like Zantac's) exceeded \$1 billion in the year of agreement. *Id.* Second, Product I's delay of one year, nine months matches the delay between the Zantac agreement and the expiration of the first patent in issue. See Zantac 1995 Press Release, *supra* note 60 (noting agreement in late October 1995); Press Release, Glaxo Wellcome PLC Re Zantac Patent Litigation (Apr. 7, 1997) (on file with the *New York University Law Review*) (noting July 1997 expiration of basic patent). Third, Product I's settlement of additional patent litigation, an unusual feature of the agreement, fits the Glaxo-Genpharm pact, which also settled parallel Zantac litigation outside the United States. Zantac 1995 Press Release, *supra* note 60. Fourth, Drug Product I fits none of the cases, described in notes 67-68 *infra* and accompanying text, that have received antitrust attention from the FTC or private parties.

⁶⁴ Genpharm and related companies also received licenses and supply agreements to sell a generic version of Zantac in several other countries. Zantac 1995 Press Release, *supra* note 60. In addition, Genpharm retained entitlement to the exclusivity period, for which it appears to have received consideration when it later waived exclusivity in favor of a subsequent filer. See *Granutec Inc. v. Shalala*, 46 U.S.P.Q.2d 1398, 1403, 1405 (4th Cir. 1998) (characterizing Genpharm's waiver of exclusivity as "quite lucrative"). See *infra* Part II.B.1 for a discussion of retained exclusivity.

⁶⁵ *Annual Report: Top 100 Drugs: Histamine H(2) Receptor Antagonists*, MED AD NEWS, May 1, 1996, at 1, 36, available at 1996 WLNR 4446118 (reporting that in 1995, Zantac was world's best-selling prescription medicine, with U.S. sales of \$2.15 billion).

⁶⁶ See Reguly, *supra* note 59 (noting almost £2 billion increase in Glaxo market valuation immediately following settlement); see also *Soothing Glaxo's Ulcers*, FIN. TIMES (London), Oct. 24, 1995, at 20 ("With so much at stake, the fact that Glaxo is having to pay Genpharm to turn it from a competitor into a distributor [in certain non-U.S. markets] is

Pay-for-delay agreements in the pharmaceutical industry have been an important focus of FTC enforcement efforts and private litigation. The FTC has challenged settlements involving four drugs.⁶⁷ Private antitrust suits have challenged settlements involving at least nine drugs, including the four challenged by the FTC.⁶⁸ Not every settlement has attracted an antitrust challenge. Of the settlements identified in the FTC study, about half of them may have escaped antitrust challenge, including Zantac.⁶⁹

money well spent.”); Zantac 1995 Press Release, *supra* note 60 (quoting Glaxo CEO’s statement that “[t]his settlement is a business decision which eliminates the risk of the Genpharm challenge”).

⁶⁷ Challenges involving three of the drugs—Hytrin, Cardizem CD, and BuSpar—resulted in consent decrees. See *In re Abbott Labs. & Geneva Pharm., Inc.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000) (Hytrin consent decree); *In re Abbott Labs. & Geneva Pharm., Inc.*, No. C-3946, 2000 WL 681849 (F.T.C. May 22, 2000) (same); *In re Hoechst Marion Roussel, Inc.*, No. 9293, 2001 WL 333643 (F.T.C. Apr. 2, 2001) (Cardizem CD consent decree); *In re Bristol-Myers Squibb Co.*, No. C-4076, 2003 WL 21008622 (F.T.C. Apr. 14, 2003) (describing BuSpar consent decree). With respect to the fourth drug, K-Dur, the innovator and first-filing generic firm chose to litigate rather than settle with the FTC. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058–59, 1061–62 (11th Cir. 2005).

⁶⁸ For the four drugs where private litigation has run in parallel with FTC challenges, see *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 899–900 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1295–96 (11th Cir. 2003) (Hytrin); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 365–66 (S.D.N.Y. 2002); *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 521–22 (D.N.J. 2004).

The five additional drugs are Nolvadex, Cipro, Naprelan, Procardia XL, and—most recently—Plavix. See *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641, 2006 WL 2401244, at *1, *3 (2d Cir. Aug. 10, 2006) (Nolvadex); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 516–17 (E.D.N.Y. 2005) (Cipro); *Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3d 1227, 1231 (11th Cir. 2005) (Naprelan); *Biovail Corp. v. Mylan Labs., Inc.*, No. 1:01CV66, 2002 U.S. Dist. LEXIS 6726, at *8–9 (N.D. W. Va. 2002) (Procardia XL); Amended Complaint and Demand for Jury Trial at 1–2, *Kroger Co. v. Sanofi-Aventis*, No. 1:06-cv-00163-HJW (S.D. Ohio July 31, 2006), 2006 WL 2503664 (Plavix).

⁶⁹ The FTC study raises antitrust concerns about final settlements involving fourteen drug products. FTC STUDY, *supra* note 51, at 26 (noting that fourteen settlements corresponding to fourteen drug products had potential to delay FDA approval of subsequent applicants). Six final settlements from this period prompted antitrust challenges: BuSpar, Nolvadex, K-Dur, Cipro, Procardia XL, and Naprelan.

Five of the six drugs can be matched to the disguised information in the FTC report, by means of a matching process analogous to that described in note 63 *supra*. The first four are likely Drug Products J, K, L, and M, respectively, listed in the FTC study, *supra* note 51, at 32 tbl.3-3, and Procardia XL is likely the second of two supply agreements discussed *id.* at 30. The remaining drug, Naprelan, is difficult to identify based upon publicly available information.

That leaves eight final settlements among those identified by the FTC which appear to have attracted no antitrust challenge. One of these is likely the Zantac settlement, see *supra* text accompanying notes 59–66; the other seven are unknown.

In addition to these final settlements, the FTC reports interim settlements (interim in the sense discussed in note 15 *supra*) involving three drugs. See FTC STUDY, *supra* note 51, at 34 & n.11 (reporting four settlements, two of which address capsule and tablet forms of the same drug). Hytrin and Cardizem CD account for two of these, see *Valley Drug Co.*,

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For a while the threat of antitrust condemnation stemmed the tide of new pay-for-delay settlements, or at least those with a large cash component.⁷⁰ More recently, however, innovators and generic firms have reversed course, reaching a spate of new agreements in 2005 and 2006.⁷¹ One prominent settlement involving Plavix, a blockbuster blood thinner, did not achieve its full effect, due in part to a unique regulatory setting that effectively required the parties to secure pre-approval of the agreement.⁷² Federal antitrust enforcers

344 F.3d at 1300–01; *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 902–03, and the third settlement is unknown.

⁷⁰ The blockbuster Prozac provides an illuminating example. The CEO of first-filing generic firm Barr “stated publicly that he was open to a \$200 million settlement—plus a guarantee that Barr would be able to sell Prozac before [innovator] Lilly’s patent expired.” Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 118. Lilly’s CEO rejected that overture; as he put it, “we felt that settling violated antitrust laws, and it isn’t morally right.” *Id.*

For a more systematic assessment, the FTC data is a useful source. The FTC’s study period covers ANDA-IVs for which innovator notification occurred between 1992 and 2000, and covers the subsequent progress of those applications only through mid-2002. Since the December 2003 amendments to the statutory scheme—that is, following a gap in the data of more than a year—drug companies have been required to file settlements with the FTC. Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003). A brief report issued by the FTC states that no settlement entered into in the first nine months of 2004 included a cash payment in exchange for delay. See BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2004, at 4–5 (2005), available at <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf> [hereinafter FTC STUDY UPDATE]. Moreover, the FTC was aware at that point of no settlement after 1999, when the FTC commenced investigation of these settlements, that included a cash payment in exchange for a generic firm’s agreement not to market a product. *Id.* at 4.

⁷¹ See BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2005, at 3–4 (2006), available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf> (reporting that, among agreements received during period of October 2004 through September 2005, three agreements covering five products included both compensation to generic firm and restriction upon generic marketing); Jon Leibowitz, Comm’r, FTC, Remarks at Second Annual In-House Counsel’s Forum on Pharmaceutical Antitrust: Exclusion Payments to Settle Pharmaceutical Patent Cases: They’re B-a-a-a-ck! 5–6 & n.12 (Apr. 24, 2006), available at <http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf> (reporting that between October 2005 and April 2006, “more than two thirds of approximately ten agreements” included payment); Leila Abboud, *Branded Drugs Settling More Generic Suits*, WALL ST. J., Jan. 17, 2006, at B1 (reporting settlements of patent litigation reached in 2005 for major drugs, including Provigil, Niaspan, Effexor, and Ditropan XL).

⁷² To take full effect, the settlement agreement required approval by the FTC and state attorneys-general, under the terms of an earlier consent decree meant to address prior alleged anticompetitive activity by a settling innovator firm. See *In re Bristol-Myers Squibb Co.*, No. C-4076, 2003 WL 21008622 (F.T.C. Apr. 14, 2003) (describing consent decree); John Carreyrou & Joann S. Lublin, *Emergency Room: How Bristol-Myers Fumbled Defense of \$4 Billion Drug*, WALL ST. J., Sept. 2, 2006, at A1. The states denied approval, whereupon the settling generic firm launched its product, despite the absence of

have commenced a close examination of this and other recent settlements.⁷³

The FTC's concern is straightforward. Privately optimal agreements that impose large negative effects upon nonparties frequently raise antitrust concerns.⁷⁴ In an agreement between competitors, consumers are the relevant nonparties. Despite consumers' aggregate economic interest—for the short-run consumer gain from lower prices exceeds producers' reduced profits—collective action problems present an obstacle to paying off producers who (unless legally constrained) will act at the consumers' expense.⁷⁵ A rival's effort to remove a patent-based barrier to entry, like a price cut, provides an indirect allocative benefit in the course of a private pursuit of profit. An agreement that reduces this benefit⁷⁶ constitutes a "treat[y] with [a] competitio[r]"⁷⁷ that is the classic object of section 1 of the Sherman Act. Indeed, the arrangement here bears a strong resemblance to the facts of *Palmer v. BRG of Georgia, Inc.*,⁷⁸ in which the Supreme Court considered an agreement reached between competing bar review course providers, pursuant to which one provider withdrew from the market in exchange for payments.⁷⁹ There, the Court had little trouble identifying the agreement as an illegal restraint of trade.⁸⁰

A substantial economic literature reaches a similar conclusion. Economic modeling has shown formally that settlements that include a cash payment from the patentee to the infringer provide consumers with less welfare, on average, than seeing the litigation to comple-

a district court adjudication of the infringement suit. Carreyrou & Lublin, *supra*. For further discussion of the agreement and early launch, see *infra* notes 118 and 210.

⁷³ See, e.g., Carreyrou & Lublin, *supra* note 72; Kristina Henderson, *Cephalon: FTC Seeks Info on Provigil Settlement*, DOW JONES CORP. FILINGS ALERT, July 13, 2006 (on file with the *New York University Law Review*) (reporting FTC request for additional information in connection with settlement involving drug Provigil).

⁷⁴ For a powerful, general economic account of contracting at the expense of nonparties, see generally Ilya Segal, *Contracting with Externalities*, 114 Q.J. ECON. 337 (1999).

⁷⁵ If transaction costs were low enough, consumers could band together and make a large fixed payment in exchange for marginal-cost pricing, either by contracting with or owning the producer. See generally HENRY HANSMANN, *THE OWNERSHIP OF ENTERPRISE* 149–223 (1996) (discussing examples of consumer-owned enterprises).

⁷⁶ An important complication for calculations of consumer welfare in the pharmaceutical context is that often, purchases are made not directly by the consumers, but by insurance companies or government on the consumers' behalf.

⁷⁷ *United States v. Citizens & S. Nat'l Bank*, 422 U.S. 86, 116 (1975).

⁷⁸ 498 U.S. 46 (1990) (per curiam).

⁷⁹ *Id.* at 46–47.

⁸⁰ *Id.* at 49–50; see also *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972) (holding that competitor agreements allocating territories to minimize competition are illegal).

tion.⁸¹ The conclusion that this loss gives rise to an antitrust violation depends upon acceptance of the view, on which these models are premised, that consumers are entitled as a matter of antitrust law to the average benefits of litigation.⁸²

C. Justifying Payment for Delay

Paying for delay works an allocative harm. Yet courts have adopted a relatively sympathetic, albeit highly uneven, stance toward pay-for-delay settlements. Two circuits have rejected antitrust condemnation of pay-for-delay settlements, at least absent direct evidence of invalidity or noninfringement.⁸³ Another circuit has fashioned a rule of per se illegality.⁸⁴ Other circuits may weigh in soon.⁸⁵

Four overlapping justifications have supported the courts' willingness to overlook the allocative harm.

⁸¹ *E.g.*, Bulow, *supra* note 15, at 165–68; Shapiro 2003a, *supra* note 15, at 407–08. For a critique, see McDonald, *supra* note 15, at 69; for a rebuttal, see Shapiro 2003b, *supra* note 15, at 73–75.

⁸² See Shapiro 2003a, *supra* note 15, at 396.

⁸³ See *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641, 2006 WL 2401244, at *1 (2d Cir. Aug. 10, 2006) (declining to impose antitrust liability where generic firm accepted cash payment from innovator and agreed to delay entry); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (same); see also *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1304, 1312–13 (11th Cir. 2003) (rejecting per se condemnation of interim settlement involving drug Hytrin as “premature,” and remanding for further proceedings).

The state of the law in the Eleventh Circuit is not entirely clear. One panel considering a settlement denied dismissal with a brief analysis relatively sympathetic to antitrust liability. *Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3d 1227, 1235–36 (11th Cir. 2005) (concluding that facts pled were sufficient to state Sherman Act claim). In addition, on remand from the court of appeals decision in *Valley Drug*, a district court found antitrust liability on the particular facts of that case. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1286 (S.D. Fla. 2005) (condemning Hytrin settlement as per se violation of Sherman Act).

⁸⁴ See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (condemning, as per se violation of Sherman Act, agreement to refrain from introducing generic drug). See also *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809–12 (D.C. Cir. 2001), which considered the same settlement later condemned by the Sixth Circuit in *Cardizem*, and in dicta reached a similar conclusion.

⁸⁵ The Ninth Circuit may soon weigh in on the same settlement (involving the drug Hytrin) considered in the Eleventh Circuit's *Valley Drug* opinion. One case that had been part of the multidistrict litigation considered in *Valley Drug* was released to its original court, the Central District of California. After a trial, the jury returned a verdict for defendants. See *Jury Verdict, Kaiser Found. v. Abbott Labs.*, No. 2:02cv2443 (C.D. Cal. Apr. 4, 2006). Both parties have appealed to the Ninth Circuit (docketed as Nos. 06-55687 and 06-55748).

The Third Circuit may eventually consider the same settlement (involving the drug K-Dur) considered in the Eleventh Circuit's *Schering* opinion. See *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 530–33 (D.N.J. 2004) (concluding that plaintiffs' allegations stated claim of anticompetitive conduct using similar analysis as FTC in *Schering*).

1. *The Judicial Reflex Favoring Settlement*

First, these agreements settle litigation, and settlements are in certain respects desirable, because they conserve litigation expense and benefit parties who are in the best position to arrange their own affairs. Judicial opinions permitting pay-for-delay settlements frequently rely upon the view that the benefits of settlement weigh against antitrust liability,⁸⁶ echoing the Supreme Court's view, expressed more than a century ago, that settling patent litigation is "a legitimate and desirable result in itself."⁸⁷ Or, as one appellate court has put the general proposition, "sound judicial policy . . . requires that settlements be encouraged, not discouraged."⁸⁸

Partly this result simply reflects a judicial reflex in favor of settlement. This reflex may be unusually acute due to the highly technical nature of pharmaceutical patent cases, which many federal judges prefer to avoid. Settlement also saves litigation costs, which can be quite substantial—millions of dollars per side for a major pharmaceutical patent case.⁸⁹ Saved litigation expense arguably offsets the allocative loss.

2. *The Effect on the Parties' Incentives*

Second, the litigation settled is patent litigation, and patent policy provides reason to favor innovation over competition, and to permit practices that might ordinarily be condemned as antitrust violations. Permitting a wide range of settlements benefits both patentees and infringers—benefits that underpin what we might call the innovator's

⁸⁶ See, e.g., *Schering*, 402 F.3d at 1076 (emphasizing "costs of lawsuits to the parties," "public problems associated with overcrowded court dockets," and "correlative public and private benefits of settlements"); *Valley Drug Co.*, 344 F.3d at 1308 n.20 ("The cost and complexity of most patent litigation is a familiar problem to the court system. The cost savings of settlement . . . are equally widely-recognized" (internal citations omitted).); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) (expressing concern that restrictive settlement rule would chill desirable settlements); see also *In re Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, ¶ 384 (F.T.C. June 27, 2002) (relying upon Professor Robert Mnookin's testimony that settlement is beneficial by economizing on litigation expense, including distraction and time spent on litigation).

⁸⁷ *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 93 (1902) (discussing license agreement that settled "a large amount of litigation regarding the validity of many patents").

⁸⁸ *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1221 (4th Cir. 1976); see also *Speed Shore Corp. v. Denda*, 605 F.2d 469, 473 (9th Cir. 1979) (noting "deeply-instilled policy of settlement," which must be balanced against unreasonable restraint claim); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) ("Settlement is of particular value in patent litigation . . .").

⁸⁹ AM. INTELLECTUAL PROP. LAW ASS'N, REPORT OF THE ECONOMIC SURVEY 2005, at 22 (2005) (reporting median expense of \$4.5 million for patent litigation with more than \$25 million at risk). The innovator is likely to spend more, as it has more at stake in the case.

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and infringer's arguments for patent exceptionalism. These arguments are introduced here and discussed further in Part III.

The innovator's argument is that a lenient policy toward settlement increases patentee profits, which preserves and improves the incentive to innovate. The cases⁹⁰ and commentary⁹¹ note this advantage of permitting settlement. This view has a statutory hook—the Patent Act, which provides a potential legal basis for an authoritative, highly innovation-protective stance regarding the proper tradeoff between innovation and consumer access, to which antitrust law should conform.

The infringer's interests normally assume a secondary role in discussions of the interaction between patent policy and antitrust law. But as Judge Richard Posner noted in a case concerning the antitrust treatment of certain pharmaceutical agreements, restrictions on an infringer's opportunity to settle affect its incentives: "A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement . . ."⁹² That case was not about a pay-for-delay settlement, but the quoted dictum, and its conclusion that *limiting* such settlements "might well be thought anticompetitive,"⁹³ has proved influential among some courts that have considered pay-for-delay settlements.⁹⁴

⁹⁰ See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641, 2006 WL 2401244, at *13 (2d Cir. Aug. 10, 2006) (arguing that restrictive settlement rule "would heighten the uncertainty surrounding patents and might delay innovation"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) (arguing that restrictive settlement rule would undermine innovator's incentives for research, thereby harming consumers); *Valley Drug Co.*, 344 F.3d at 1308–09 (expressing concern that restrictive rule would "undermine . . . patent incentives," "impair . . . incentives for disclosure and innovation," and "decreas[e] the value of patent protection").

⁹¹ For commentary making this point, see, for example, Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 525 (2002); Cotter 2003, *supra* note 15, at 1809; Crane 2004, *supra* note 15, at 705; Crane 2002, *supra* note 15, at 749; Langenfeld & Li, *supra* note 15, at 778, 797–805.

⁹² *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

⁹³ *Id.*

⁹⁴ See *Tamoxifen*, 2006 WL 2401244, at *15 (repeating with approval quoted statement from *Asahi*); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (same); see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 527 (E.D.N.Y. 2005) (describing *Asahi* approach); David Balto, *Bringing Clarity to the Patent Settlement Debate: Judge Posner's Asahi Decision*, 23 BIOTECHNOLOGY L. REP. 168, 170 (2004) (approving *Asahi* approach).

3. *The Generality of Pay-for-Delay Settlement*

Third, the underlying economic structure of a pay-for-delay settlement generalizes beyond the particular cases under consideration. The pharmaceutical industry settlements that have received so much attention are merely the most visible and dramatic examples of this economic structure. Suppose, for example, that a patentee sues an alleged infringer who has entered the market, and the alleged infringer later agrees to exit the market, in exchange for which the patentee waives a claim to accrued damages. This agreement matches the basic pay-for-delay structure: a conferral of value that heads off litigation that, if the alleged infringer won, would increase consumer access. Although there is no cash payment, the alleged infringer's prior entry makes forgiveness of accrued damages a source of compensation by the incumbent.⁹⁵ Nor is the waiver a necessary component of the deal; the essential problem is unchanged if the alleged infringer exits and pays the patentee a sum less than the value of the patentee's infringement claim.⁹⁶ In this case, too, the settlement likely brings less expected consumer benefit than taking litigation to conclusion.

It is far from clear that, *as a general matter*, consumers are entitled to the expected outcome of the avoided litigation. Courts and commentators have revealed difficulties in claiming such a general right on behalf of consumers, if that right undermines the availability of settlement in other industries.⁹⁷ A satisfactory account of the circumstances under which a private party may be pressed into service as an "unwilling private attorney[] general"⁹⁸ has proved elusive.

⁹⁵ Prior entry and accrued damages distinguish waiver-for-exit settlements from the term-division settlements discussed in Part II.B.1.

⁹⁶ For example, take a setting for which a damage-plus-waiver agreement is the settlement outcome, and increase the amount of damages accrued, so that the alleged infringer must now make a payment to satisfy the patentee.

⁹⁷ See, e.g., *Tamoxifen*, 2006 WL 2401244, at *16 n.20 ("[A]ny settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements") (quoting *Asahi*, 289 F. Supp. 2d at 994 (emphasis and alteration in original)); *Cipro*, 363 F. Supp. 2d at 529 (expressing concern that restrictive settlement rule "could not logically be limited to drug patents, and would work a revolution in patent law"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (noting that even in "traditional" settlements, "implicit consideration" flows from patentee to infringer, implying that restrictive rule for pharmaceutical settlements would apply to other industries as well); Schildkraut, *supra* note 15, at 1047-49 (arguing that restrictive rule with respect to pharmaceutical patent settlements jeopardizes settlements of patent litigation in other industries as well).

⁹⁸ *Nestle Co. v. Chester's Mkt., Inc.*, 756 F.2d 280, 284 (2d Cir. 1985) (discussing, in trademark context, problem of enlisting private parties as attorneys general); see also

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Imposing liability for pharmaceutical pay-for-delay settlements introduces the specter of antitrust liability in a wide range of cases in which settlement imposes negative externalities upon consumers.

4. Payments as a “Natural By-Product” of Regulation

A final reason given to resist antitrust liability for pay-for-delay settlements relies upon the role of pharmaceutical regulation in altering the incentives of the parties, compared to the usual incentives of patentees and infringers. In particular, courts have seized upon the fact that a generic firm has a strong incentive to challenge an innovator but faces little risk. The generic firm’s infringement is by certification rather than entry—indeed, entry is barred by the automatic stay—so the generic firm is not subject to large damages if it loses the suit.⁹⁹ Whereas a settlement of litigation in which entry had already occurred might include a payment from the infringer to the patentee, a settlement in the present context, if settlement is to occur at all, must necessarily include a payment from the patentee to the infringer. From this, some courts, echoed by the Solicitor General, have concluded that “[r]everse payments are a natural by-product of the Hatch-Waxman process.”¹⁰⁰

These courts are right to recognize the importance of the regulatory regime, but judicial treatments reflect deep confusion about the implications of that regime. True, paying for delay is “natural,” in the sense that the result is not unexpected given the incentives of the parties; the parties, if not legally constrained, will prefer pay-for-delay settlement to litigation. But that fact in no way *justifies* payments for delay.¹⁰¹ No doubt many government actions—activities that effectively narrow the set of suppliers from whom the government can purchase, for example¹⁰²—make price-fixing easier. But such an

Cipro, 363 F. Supp. 2d at 531 (“This concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation . . .”).

⁹⁹ That is not to say that the generic firm has *nothing* at risk, for if it loses the suit, its investment in proving bioequivalence and in litigation will have been wasted.

¹⁰⁰ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005) (alteration in original) (quoting *Cipro*, 261 F. Supp. 2d at 250–51) (internal quotation marks omitted); see also *Tamoxifen*, 2006 WL 2401244, at *15 (quoting language approvingly). The Solicitor General quoted this language approvingly in a brief to the Supreme Court. Brief of the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, *supra* note 14, at 7.

¹⁰¹ See, e.g., Hovenkamp et al. 2003, *supra* note 15, at 1758 (noting that it does not follow from rationality of exclusion payments that payments cannot be anticompetitive).

¹⁰² Calvin Biesecker, *Federal Contract Bundling, Driven by DoD, Reaches 10-Year High*, *Report Says*, DEF DAILY, Oct. 11, 2002 (reporting Defense Department’s increasing inclination to consolidate contracts in larger bundles, which only large companies are equipped to fulfill, with possible consequence of higher prices due to less competition among bidders).

action provides no necessary protective coloration to oligopolists who subsequently choose to collude. To understand the effects of the regulatory regime requires a deeper examination of the incentives it creates.

II

REGULATORY DESIGN AND ALLOCATIVE HARM

As noted in the previous Part, the pharmaceutical industry is most commonly associated with the simplest model of the patent system. But in fact, in defining the incentives of pharmaceutical innovators, the regulatory scheme reflects a number of idiosyncratic choices. The differences start with the most basic, the term length of protection. Pharmaceutical innovations enjoy longer-lasting protection than innovations in other industries, which partly offsets the time consumed by clinical trials.¹⁰³ The effective term is extended by another six months if the drug maker performs tests to evaluate the drug's pediatric health benefits.¹⁰⁴ And certain drugs treating "rare diseases or conditions" are outside even this highly modified scheme; they receive *sui generis* seven-year exclusivity.¹⁰⁵

The Hatch-Waxman bounty—the 180-day duopoly granted to a generic firm that wins a pre-expiration challenge—is another major difference. This Part explains how that feature of the regulatory arrangement widens the prospect for allocative distortion, relative to the usual patent regime. It does so, first, by ensuring that a pay-for-delay settlement is (if legal) an attractive and feasible proposition for the innovator and generic firm. Second, the ability of an innovator to *guarantee* a bounty to a generic firm, an opportunity unavailable under litigation, is a significant noncash means to pay for delay.

Recall the form that this bounty takes: The first generic firm to file an ANDA-IV enjoys the exclusive right to market a generic version of the drug for 180 days. The legal form of the exclusivity is a delay in FDA approval of any other firm's ANDA-IV.¹⁰⁶ Winning a patent suit is one route to exclusivity. For example, if an innovator's generic rival secures a judgment that the relevant patents are invalid or not infringed, the FDA may approve the generic firm's ANDA,

¹⁰³ In particular, a one-year extension for every two years spent in clinical trials, plus the time spent in post-trial FDA approval, subject to the limitations that the extension may not exceed five years or leave a remainder exceeding fourteen years. See 35 U.S.C. § 156(c), (g)(1)(B), (g)(6) (2000).

¹⁰⁴ 21 U.S.C. § 355a (2000 & Supp. III 2003).

¹⁰⁵ Orphan Drug Act, 21 U.S.C. §§ 360aa–dd (2000); see Geeta Anand, *Lucrative Niches: How Drugs for Rare Diseases Became Lifeline for Companies*, WALL ST. J., Nov. 15, 2005, at A1 (discussing drug companies' use of Orphan Drug Act exclusivity).

¹⁰⁶ 21 U.S.C. § 355(j)(5)(B)(iv).

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freeing the firm to market its competing generic version, protected initially by the exclusivity period.

Winning a suit is not the only route to exclusivity. Exclusivity merely requires FDA approval of the first filer, which can be secured without litigation if the innovator declines to sue the first filer, as may occur if the innovator's patent is very likely invalid or not infringed.¹⁰⁷ For a time, the FDA resisted this straightforward understanding of the statutory text, insisting instead upon a "successful defense" before granting exclusivity¹⁰⁸ but abandoned the interpretation after its judicial rejection.¹⁰⁹

The reward provided by the bounty is valuable, worth several hundred million dollars to a generic firm that successfully challenges the patents on a major drug.¹¹⁰ The bounty thus provides a substantial inducement to challenge drug patents. A bounty-hunting generic firm will go on the attack if the drug is very valuable or the innovator's patents very weak (likely invalid or not infringed), or both. With

¹⁰⁷ With respect to those challenges discussed in the FTC study, *supra* note 51, in which the innovator declined to sue the first filer within the required forty-five days, *see supra* note 55, the study does not reveal how many of the twenty occurred after the demise of the successful defense requirement or enjoyed exclusivity.

Declining to sue might reflect the view that a good-faith basis is absent, or the view that the benefits do not justify the expense. FDA approval normally requires a year or more, even without a suit, and so litigation of an easy case might not outlast the FDA process. Moreover, initiating a suit resolves uncertainty about the validity and scope of the patents, and there may be strategic benefits to retaining uncertainty, both in moderating the pricing of the first generic entrant and in deterring additional, subsequent entrants.

¹⁰⁸ *See* 21 C.F.R. § 314.107(c)(1) (1995) (amended in 1998 to remove "successful defense" requirement).

¹⁰⁹ This interpretation was rejected by several federal courts, then repudiated by the FDA. *See* *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (holding that plain language of § 355 "does not include a 'successful defense' requirement"); *CTR. FOR DRUG EVALUATION & RESEARCH, FDA, GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 4* (1998), *available at* <http://www.fda.gov/cder/guidance/2576fml.pdf> (stating that "FDA will not enforce the 'successful defense' provisions" and "intends to formally remove" them from Code of Federal Regulations). The demise of the interpretation was strongly foreshadowed in an early district court opinion authored by Judge Harold Greene, of AT&T consent decree fame, which made clear the inadequacy of the FDA's initial argument as a textual matter. *See Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1526 (D.D.C. 1989) (finding no textual basis for requiring successful suit to trigger exclusivity), *appeal dismissed*, 43 F.3d 712 (D.C. Cir. 1989).

¹¹⁰ For example, Apotex reportedly earned between \$150 million and \$200 million from the exclusivity period on Paxil, a blockbuster antidepressant. Comment of Apotex Corp. in Support of Citizen Petition of Mylan Pharmaceuticals, Inc. at 4, No. 2004P-0075/CP1 (F.D.A. Mar. 24, 2004), *available at* <http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf> [hereinafter Comment of Apotex Corp.]. That large reward, moreover, came despite competition from an additional generic firm licensed by GlaxoSmithKline, Paxil's manufacturer. *Id.* See the Conclusion for further discussion.

respect to very valuable drugs, the challenge is justified even if the ex ante likelihood of success is low. The more valuable the drug, the lower the threshold probability of success necessary to justify a challenge. A generic firm can justify a challenge with just a one-in-five chance of success, provided that the innovator's sales range in the hundreds of millions of dollars; the level of sales for a best-selling drug likely justifies a challenge with a prospect of success of just one percent.¹¹¹ It is therefore no surprise that so many of the best-selling drugs have attracted challenges.

A. *The Feasibility of Payment for Delay*

1. *General Conditions*

A pay-for-delay agreement must satisfy two conditions to make practical sense for the parties. The first condition is a *gain from trade*: The patentee loses more under early entry than the alleged infringer gains. This condition is likely to be satisfied where the new entrant serves exactly the same market as the incumbent, for total duopoly profits are normally less than monopoly profits.¹¹² In some settings, however, entry rather than deferral may lead to higher total producer profits, as when the entrant has superior access to a market, a unique means to price discriminate, or lower costs.¹¹³

Competition between innovators and generic drug makers satisfies the gain-from-trade condition.¹¹⁴ Consider, for example, a generic firm's challenge with respect to Plavix. Without entry, Plavix's manufacturer might expect to earn, say, \$10 billion in profits from U.S. sales during the drug's remaining patent life.¹¹⁵ If it loses a patent chal-

¹¹¹ For a back-of-the-envelope calculation, suppose that a generic firm can expect fifty percent market penetration during a half of a year of protected duopoly, with a profit margin of two-thirds, and no profits otherwise. If entry has a probability p of success, the innovator's annual sales are S , and the generic firm's entry expense is \$10 million, then its expected profits are $pS/6$ —\$10 million. The generic firm breaks even provided that $pS > \$60$ million. Thus a drug with \$300 million in sales supports a challenge that is twenty percent likely to succeed. A drug with \$6 billion in sales supports a challenge that is one percent likely to succeed.

¹¹² In the limiting case, duopolists jointly achieve the same profit-maximizing price and quantity of a monopolist.

¹¹³ Where entry increases total profits, the entrant can pay the incumbent for permission to enter (if it lacks an entitlement to do so) or, if licensing is unavailable, simply enter and then pay damages, provided they are not too high.

¹¹⁴ See, e.g., Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements*, in *ECONOMIC APPROACHES TO INTELLECTUAL PROPERTY POLICY, LITIGATION, AND MANAGEMENT* 251, 255–60 (Gregory K. Leonard & Lauren J. Stiroh eds., 2005) (contrasting cases in which entrant's gains are less or more than patentee's losses).

¹¹⁵ Assuming, for example, five years of remaining patent protection, \$2 billion in U.S. profits per year, and a discount rate offset by profit growth.

lenge, then it and the successful generic firm would share duopoly profits for 180 days, with small profits thereafter once additional firms entered the market. In that event, \$1 billion might be a plausible estimate of each firm's profits.¹¹⁶

If the parties reach a settlement ending the dispute and no other generic firm initiates a challenge, the joint gain from an entry-preventing agreement is \$8 billion—the innovator's \$10 billion no-entry profit, less the \$2 billion jointly earned under entry. If the two share the joint gain equally and invalidation is certain, the innovator would pay the rival \$5 billion to induce the rival to abandon its suit.¹¹⁷ Purchasers would lose the \$8 billion that is transferred to producers instead, plus billions more in deadweight loss from the resulting allocative distortion. If invalidation is uncertain, the stakes are lowered accordingly; a twenty-five percent chance of invalidation makes the expected gain from trade \$2 billion, implying an equal-sharing payment of \$1.25 billion.

Not only does an agreement benefit the generic firm compared to its expected return from litigation (otherwise the generic firm would not agree), but in fact the generic firm does even better than it would have, had it won the suit. Nor is a cash payment the only way for an innovator to confer value upon a generic firm. Indeed, the actual Plavix settlement lacked a large cash payment.¹¹⁸ Part II.B.1 explains

¹¹⁶ Typically, the innovator retains price-insensitive customers and may even raise prices somewhat, while the generic firm sells at a roughly thirty percent discount. See, e.g., MORGAN STANLEY EQUITY RESEARCH, QUANTIFYING THE IMPACT FROM AUTHORIZED GENERICS 4 (2004) [hereinafter QUANTIFYING THE IMPACT]; see also Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 335–36 (1992) (noting initial price rise by innovator upon introduction of generic competition). A rough measure employed by industry analysts is to assume that volume drops by one-half during the interim period. See QUANTIFYING THE IMPACT, *supra*, at 8.

¹¹⁷ After paying the settlement fee, the innovator would retain \$5 billion in profits, a \$4 billion improvement upon entry. The rival would enjoy a \$5 billion profit, once again a \$4 billion (\$5 billion–\$1 billion) improvement upon entry.

An equal-sharing approach is customary for these analyses. For a theoretical justification of this approach, see Ariel Rubinstein, *Perfect Equilibrium in a Bargaining Model*, 50 ECONOMETRICA 97 (1982). It can be doubted, however, whether the generic firm's \$1 billion gain under competition ought to be considered as part of the alternative to settlement (the "threat point") within an alternating-offers game such as Rubinstein's. See generally John Sutton, *Non-Cooperative Bargaining Theory: An Introduction*, 53 REV. ECON. STUD. 709, 712–17 (1986) (evaluating how "outside option" available to one party affects Rubinstein's model). If the \$1 billion is treated instead as an outside option, the relevant gain is \$9 billion, and the payment \$4.5 billion.

¹¹⁸ Two versions of the agreement were proposed to regulators, both reprinted in Bristol-Myers Squibb Co., Quarterly Report (Form 10-Q), Exhibits 99.1, 99.2 (Aug. 8, 2006). Both versions include a payment described as compensation for the generic firm's inventory. *Id.* Exhibit 99.1, ¶¶ 13, 18(i); Exhibit 99.2, ¶¶ 10, 14(i). The initial version also included a breakup fee, payable to the generic firm if the agreement failed to receive regu-

how an innovator can confer value upon the generic firm without cash. But for now, it is enough to note that some conferral is necessary in order for the parties to take joint advantage of the gain from trade.

The second general condition is that the settlement must offer an *effective means to delay entry*. If there are many potential challengers, and paying one merely attracts others, a payoff does little good. Even a cursory review of the mechanisms for generic competition, however, suggests that this condition will be satisfied in the pharmaceutical context. A firm must file an ANDA-IV to be eligible for a settlement. The ANDA-IV contains a demonstration by the generic firm that its proposed product is bioequivalent to the innovator's drug, and that the firm is capable of making the proposed product.¹¹⁹ The challenge process requires a detailed description of the basis for belief of invalidity or noninfringement for each relevant patent of the innovator.¹²⁰ To be a credible threat to the innovator, a generic firm must undertake these expenses (one generic firm cannot free-ride on another's showing of bioequivalence) and be prepared to see the suit to conclusion.¹²¹ The number of firms capable of such action is limited.

Moreover, the generic firms are not identically situated. The firms have differing views about their prospect of success in a partic-

latory approval, which increased with the length of delay in receiving a response from regulators. *Id.* Exhibit 99.1, ¶ 18. The revised agreement omits mention of a breakup fee, but the generic firm has alleged that the fee remained an unwritten term of the deal that its bargaining partner failed to report to regulators. Carreyrou & Lublin, *supra* note 72. That discrepancy, together with a second unwritten term (a commitment not to launch an authorized generic), is reportedly the basis for a criminal referral to the Justice Department. *Id.*

Paying a generic firm to delay its launch, purportedly in order to seek regulatory approval, raises serious antitrust concerns, particularly if the likelihood of approval is low. Even without the breakup fee, there are other ways the innovator might compensate the generic firm for its agreement to accept delay—for example, by agreeing to reduce the generic firm's exposure to damages should it launch its product prior to a district court adjudication. Such a term was included in the Plavix settlement. *See id.* (reporting that agreement provides for reduced damages); Bristol-Myers Squibb Co., *supra*, Exhibit 99.1, ¶ 18(iii); Exhibit 99.2, ¶ 14(ii).

¹¹⁹ *See* 21 C.F.R. § 314.94(a)(9) (2006) (requiring ANDA filers to provide materially identical information to that required for NDAs); § 314.50(d)(1) (describing NDA requirements).

¹²⁰ *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II) (Supp. III 2003). Prior to the 2003 amendments, the requirement was codified at 21 U.S.C. § 355(j)(2)(B)(ii) (2000).

¹²¹ It might appear that a large number of well-funded entities could credibly threaten to initiate challenges in order to extract payoffs, but multiple factors limit this possibility in practice. First, their very number would make it pointless to pay off just one of them. Second, the credibility of such a threat is undermined by the technical requirements involved in actually filing an ANDA-IV, though this difficulty might be contracted around. Third, without the filing of a challenge, it is more difficult to establish that the resulting agreement is in settlement of litigation.

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ular challenge, different information about the infirmities of an innovator's patents, differing abilities to make a bioequivalent version of the drug, and different speeds in developing a noninfringing alternative, as well as different estimates of the drug's future profitability. As a result, firms will have different incentives to bring a challenge. As evidence for this, it was not until 2003 (nineteen years after the establishment of the regulatory regime) that the FDA issued guidelines to deal with multiple filings on the same day.¹²²

2. *The First Filer's Unique Eligibility for the Statutory Bounty*

Once the first generic firm files an ANDA-IV, a sharp difference in incentives emerges between that ANDA-IV filer and all other generic firms, because *only the first filer is eligible for the exclusivity period*. Even if the first filer loses, withdraws, or settles, a subsequent filer does not become eligible for the bounty. (Whether a subsequent filer becomes eligible for FDA approval, a distinct issue, is discussed in the next section.) FDA regulations issued in 1994 make clear that only the first-filed ANDA potentially delays the approval of subsequently filed ANDAs by operation of the 180-day exclusivity period,¹²³ an interpretation revisited and endorsed once again in 1999.¹²⁴ This is not the only plausible interpretation of the relevant statutory provision,¹²⁵ but it is a defensible one.¹²⁶ Amendments to

¹²² CTR. FOR DRUG EVALUATION & RESEARCH, FDA, GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAs ARE SUBMITTED ON THE SAME DAY 3, 4 (2003), available at <http://www.fda.gov/cder/guidance/5710fnl.pdf>. By July 2003, the issue had arisen twice, once in 1999 and again in 2002. See Citizen Petition of Zenith Goldline Pharmaceuticals, Inc. (F.D.A. Aug. 8, 2000), <http://www.fda.gov/ohrms/dockets/dailys/00/Aug00/081100/cp00001.pdf> (alendronate sodium); Citizen Petition of Ranbaxy Laboratories Limited (F.D.A. May 13, 2003), <http://www.fda.gov/ohrms/dockets/dailys/03/May03/052703/03P-0217-cp00001-01-vol1.pdf> (modafinil sodium). An earlier response from the FDA to these petitions had apparently been unnecessary because ANDAs had not been approved for either drug prior to the FDA's response.

¹²³ See 21 C.F.R. § 314.107(c)(1)-(2) (1995) (identifying delay only with respect to "first application" and defining "first application"); see also 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,874 (proposed Aug. 6, 1999) (noting this aspect of 1994 regulation).

¹²⁴ 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. at 42,874.

¹²⁵ Section 355(j)(5)(B)(iv) provides that if "a previous application has been submitted," a subsequent filer must wait until 180 days after the "first commercial marketing of the drug under the previous application" or a favorable court decision, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). In essence, the FDA concluded that the only "previous" application that triggers the delay is a *first* application. The alternative interpretation is that *any* previous application can be a source of delay, not just the first.

¹²⁶ The FDA considered and rejected the alternative interpretation; though it did not explain its reasoning in detail, it did state that in the case where the first filer withdrew its application, its preferred interpretation was consistent with a goal of "encouraging prompt challenges." 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications,

the Hatch-Waxman scheme made in 2003 codified the FDA's interpretation.¹²⁷

The singular availability of the bounty is underappreciated.¹²⁸ Most cases and commentary ignore or blur the difference between a successful first filer, which receives exclusivity, and a filer that is first to win a challenge, which may not receive exclusivity.¹²⁹ A recent federal appellate case, which rejected antitrust liability for a pay-for-delay settlement, provides a useful illustration.¹³⁰ There, the panel majority relied upon the erroneous view that bounty eligibility *does* cede to other filers. According to the majority, the innovator's settlement agreement with the first filer, by neutralizing the competitive threat of the first filer, "opened the [relevant] patent to immediate challenge by other potential generic manufacturers, which did indeed follow—spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory

64 Fed. Reg. at 42,875. A related policy justification is that having the first filer as a single "champion" encourages a potential challenger to file an ANDA as early as possible. Moreover, the reference in § 355(j)(5)(B)(iv) to "*the* previous application," *id.* (emphasis added), suggests contemplation of only a single previous filer, which supports the FDA view.

Likely the FDA also recognized that the alternative reading can produce anomalous results. If not only a first filer but also a second filer can be a "previous applicant," then the 180-day period, as enjoyed by a second filer, would not restrict the approval of a *first* filer (from the first filer's point of view, the second filer is not a "previous applicant" under any interpretation), making the subsequent filer's exclusivity into an entitlement of an oddly truncated sort.

It is possible that innovators and generic firms had doubts about the correctness of the FDA's interpretation, but provided that they attached at least some probability to its correctness, the analytical point in the text holds.

¹²⁷ See 21 U.S.C. § 355(j)(5)(D)(iii) (Supp. III 2003) (stating that upon first applicant's forfeiture, no applicants are eligible for exclusivity period).

¹²⁸ Though the point appears to have been ignored in the antitrust literature, several discussions of the Hatch-Waxman Act in academic journals provide passing mention. See Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 417 (1999) (noting that even if later filer wins its suit, it "would be compelled to wait 180 days before enjoying the fruits of its victory and would not receive any exclusivity of its own" because "under the language of the statute, the 180 days of exclusivity belong solely to the first challenger and not to the first winner"); see also Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, HEALTH AFF., Sept.–Oct. 2001, at 119, 123 (noting briefly that "[s]ubsequent challengers are ineligible for exclusivity").

¹²⁹ Typical is this statement, contained in the Senate report accompanying a predecessor bill to the 2003 amendments: "The law as it stands gives temporary protection from competition to the first manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires, giving the generic firm a 180-day head start on other companies making generic versions of the drug." S. REP. NO. 107-167, at 4 (2002). From this ambiguous statement it is a short step to the erroneous statement that a second filer, if first in receiving FDA approval, could enjoy the exclusivity.

¹³⁰ *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641, 2006 WL 2401244, at *22 (2d Cir. Aug. 10, 2006).

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in a subsequent infringement lawsuit.”¹³¹ The majority apparently believed that, at least during the period of the FDA’s successful defense interpretation (that is what the panel means by “at the time”), exclusivity eligibility ceded to a later filer.

How the Second Circuit panel reached this conclusion is not clear. No party or amicus brief argued that later ANDA filers might be eligible for the exclusivity. Other courts in similar circumstances have not reached this conclusion.¹³² In support, the majority cited the district court opinion in another settlement case, but that opinion does not demonstrate the proposition.¹³³ Moreover, at another point the panel stated the correct rule.¹³⁴ The likeliest explanation is that the court simply repeated an incorrect assertion made by the district court below.¹³⁵

As a result, the court mistakenly attributed a nonexistent incentive to subsequent filers. That this error was apparently not challenged when first made in the district court, briefed or corrected during the appeals process, or noted by the panel’s dissenting opinion, demonstrates that the singular availability of the bounty, and its significance for antitrust analysis, is poorly understood. The mistake is not merely technical, for a correct understanding of the exclusivity period is necessary to a proper understanding of generic firm incentives.

¹³¹ *Id.*

¹³² For example, a district court opinion considering the same settlement reflected the court’s and parties’ understanding that later filers were fighting to secure FDA approval, not exclusivity. See generally *Mylan Pharm. Inc. v. Henney*, 94 F. Supp. 2d 36 (D.D.C. 2000), vacated as moot sub nom. *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627 (D.C. Cir. 2002). Another case involving the same settling generic firm (Barr), settlement structure (a conversion upon settlement from Paragraph IV to Paragraph III), and timing (during the FDA’s transition away from the authorized generic interpretation), also makes clear that subsequent filers sought access to FDA approval, not the exclusivity period. See generally *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005).

¹³³ See *Tamoxifen*, 2006 WL 2401244, at *22 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 242–43 (E.D.N.Y. 2003)). The cited discussion in *Cipro* merely notes the significance of the absence of a statutory bottleneck preventing FDA approval, an issue discussed in the next section.

¹³⁴ See *Tamoxifen*, 2006 WL 2401244, at *2 (noting that during relevant period, exclusivity was available, provided successful defense was satisfied, “to the first ANDA filer to elect a paragraph IV certification” (emphasis added)).

¹³⁵ The district court asserted that under the successful defense doctrine, “the ANDA filer which first successfully defended” would receive the bounty. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 134 (E.D.N.Y. 2003). That statement is incomplete, since it omits the requirement that the filer be a first filer. From this statement, the court concluded that “[i]n other words,” during the heyday of the successful defense requirement, “if [later-filing generic firms] had successfully defended against [the innovator’s] patent infringement suit, the first one to do so would receive the 180-day exclusivity period pursuant to then-existing FDA regulations.” *Id.* This latter statement flatly contradicts the consistent FDA view.

Generic firms other than the first filer will lag behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue a challenge. The subsequent filers' return on a challenge, aside from being smaller, depends upon the outcome of the first filer's suit (and possible settlement), providing a strategic motivation to slow down until that uncertainty is reduced.¹³⁶ It is therefore inaccurate to assert, as some cases have, that "[i]n a reverse-payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market."¹³⁷ The settlement does secure an important change in the competitive situation; it removes from consideration the most motivated challenger, and the one closest to introducing competition. Similarly, although it may be correct in a literal sense that a settlement "clear[s] the field,"¹³⁸ the implication is very different from that drawn by the Second Circuit: The most vigorous challenger has been removed from the field, thereby removing an important source of early competition.

3. *The Approval Bottleneck*

Settling with the firm that is closest to introducing competition and has the greatest incentive to do so is a highly profitable opportunity, even if subsequent filers remain free to secure FDA approval. But in addition, the entry of subsequent filers can be blocked entirely in some instances, due to a statutory bottleneck created by the Hatch-Waxman regime.

As already noted, the 180-day exclusivity period operates by delaying FDA approval of a later-filing generic firm's ANDA-IV. In particular, the statute requires that a later-filed ANDA-IV not be approved until 180 days after the first filer's initiation of commercial marketing or a court determination of invalidity or noninfringement,

¹³⁶ Another possible difference among generic firms is that one filer may have a claim that it is uniquely able to exploit. The private plaintiffs challenging the settlement in *Cipro* have made an assertion of this sort. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 530 (E.D.N.Y. 2005). The subsequent filer retains *some* incentive even without the exclusivity period, particularly as winning may provide a head start in marketing. However, each filer benefits from favorable judgments in the others' suits, reducing the benefits from aggressive pursuit. A further complication is that a subsequent filer sometimes has an incentive for speed that the first filer lacks. The first filer receives the exclusivity whether it proceeds quickly or slowly (although the value of the exclusivity may decline over time); a subsequent filer receives a proportionately larger fraction of the rewards of normal generic entry by securing entry earlier.

¹³⁷ *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003); see also *Tamoxifen*, 2006 WL 2401244, at *23 n.28 (citing with approval quoted statement).

¹³⁸ *Tamoxifen*, 2006 WL 2401244, at *8, *22 (quoting *Tamoxifen*, 277 F. Supp. 2d at 133, and noting that agreement "opened the [relevant] patent to immediate challenge").

whichever comes first.¹³⁹ A settlement between the first ANDA-IV filer and the innovator removes an opportunity for commercial marketing or a court determination. Without the occurrence of either triggering event, the later ANDA-IV filer is stuck, for the FDA lacks authority to approve the application.

The resulting delay is frequently emphasized in discussions of the pharmaceutical regime.¹⁴⁰ The degree of delay should not be overstated, however, since the block is incomplete. If a later ANDA filer wins a favorable court decision, that decision triggers the exclusivity period—that is, the *first* filer's exclusivity period. The subsequent ANDA filer could enter 180 days later.¹⁴¹

Nor is the bottleneck a pervasive feature of pay-for-delay settlements, for two reasons. First, the bottleneck applies only to settlements reached during a limited time period. The bottleneck did not arise until the demise of the successful defense requirement, for under that interpretation a *pending* suit between an innovator and first ANDA-IV filer, not yet having been successfully defended, was considered insufficient to block approval of a subsequent ANDA-IV filer.¹⁴² Moreover, the bottleneck does not apply to filings made after December 2003. Due to a statutory change, to simplify greatly a complicated scheme, FDA approval of those later-filed ANDA-IVs generally cannot be long delayed on account of a settlement between the innovator and a first-filing generic firm.¹⁴³ Second, some settlements

¹³⁹ See 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003).

¹⁴⁰ For analyses emphasizing the statutory bottleneck, see, for example, HOVENKAMP ET AL., *supra* note 7, § 7.4e, at 7-31 (Supp. 2005); *id.* at 7-35, -37 (Supp. 2006); Brodley & O'Rourke 2002, *supra* note 15, at 54; Hovenkamp et al. 2003, *supra* note 15, at 1757; Hovenkamp et al. 2004, *supra* note 15, at 717 & n.23. The Hovenkamp et al. treatise does note that the removal by amendment of the statutory bottleneck, discussed *infra* note 143 and accompanying text, "reduces, but certainly does not eliminate, the gains from anticompetitive settlements." HOVENKAMP ET AL., *supra* note 7, § 7.4e, at 7-36 (Supp. 2006). This apparent recognition that the bottleneck is not strictly necessary is not explicated.

¹⁴¹ However, if the innovator declined to sue the later filer, as often happens, it would be difficult to secure the necessary victory in court.

A further possibility is that there are no subsequent filers to be blocked. That, however, does not necessarily imply that there is no harm, since would-be filers may have been deterred by the futility of filing in light of the fact or likelihood of a blocking settlement.

¹⁴² During the heyday of the successful defense interpretation, however, doubts about its validity might have affected decisionmaking to some degree, in anticipation of its invalidity once tested. See *supra* note 126.

¹⁴³ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(2)-(b), 117 Stat. 2066, 2458-60 (2003) (codified at 21 U.S.C. § 355(j)(5)(D) (Supp. III 2003)) (providing for forfeiture of entitlement to 180-day exclusivity period if parties settle).

do not take advantage of the bottleneck—for example, because the generic firm alters its filing in a way that removes the block.¹⁴⁴

The approval bottleneck is sufficient but not necessary to demonstrate the feasibility of pay-for-delay settlement or the presence of allocative harm. And there is a downside to overreliance upon the bottleneck as the primary means to demonstrate the feasibility of a settlement that produces an allocative harm. The absence of an approval bottleneck can give the erroneous impression that there is no activity of competitive concern. Some courts have been distracted in just this manner.¹⁴⁵ Attention to limits on exclusivity eligibility, not just FDA approval, better identifies the extent of the allocative harm.

B. *The Exclusivity Period as a Source of Compensation*

1. *The Value of a Guaranteed Bounty*

The specific form of the bounty's implementation expands the potential for allocative harm in a second way. To see this effect, consider an ordinary patent validity suit with some probability of a judgment of invalidity.¹⁴⁶ To be concrete, suppose that the probability of a judgment of invalidity is fifty percent. If the parties see the litigation to conclusion, then consumers have a fifty percent chance of receiving the incremental benefits of competition, rather than facing a monopolist for the remainder of the patent term.

Two different kinds of settlement are just as good as litigation from a consumer's point of view. One settlement solution is simply to agree to decide by some random means, such as a coin flip, whether entry occurs. Another of equal effect is for the parties to divide up the remaining term in accordance with the probability of success. If the chance of success is fifty percent, then the patentee might agree to

¹⁴⁴ For example, one component of the settlements of patent suits involving Cipro, Nolvadex, and BuSpar was that the settling generic firm changed its certification from Paragraph IV to Paragraph III. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519 (E.D.N.Y. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641, 2006 WL 2401244, at *4 (2d Cir. Aug. 10, 2006); Complaint ¶ 32, *In re Bristol-Myers Squibb Co.*, No. C-4076 (F.T.C. Apr. 14, 2003), 2003 WL 21008622. One complication that has occasionally arisen is lingering doubt about whether the conversion entirely removed the block. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 244 (E.D.N.Y. 2003) (discussing first filer's efforts, post-settlement, to continue to assert entitlement to exclusivity period); *Tamoxifen*, 2006 WL 2401244, at *4 (similar).

¹⁴⁵ See, e.g., *Tamoxifen*, 2006 WL 2401244, at *19 (focusing upon proposition that although *this* competitor is excluded, settlement "would have no effect on other challengers" (quoting *Cipro*, 363 F. Supp. 2d at 534)); *Cipro*, 261 F. Supp. 2d at 242–43 (similar).

¹⁴⁶ Assume for now that launching a product "at risk"—that is, prior to a favorable judgment, but after the eventual expiration of the automatic stay—is not a significant factor. For a discussion of launching at risk, see *infra* Part III.B.2.

permit competition halfway into the remaining term. Consumers receive the full benefit of competition, but for one half of the period; that is equivalent to a fifty percent chance of enjoying the benefits of competition for the entire period, ignoring litigation costs and changes in market conditions. In this setting, each outcome—a lawsuit with a probabilistic outcome, a randomized settlement, and a settlement splitting entry in accordance with the probabilities—has the same effect upon expected patentee profits, entrant profits, and consumer welfare.

An agreement that divides up the remaining term into monopoly and competition periods fits the widely accepted rule that an agreement on entry dates raises no anticompetitive concern. The FTC, for example, has provided a safe harbor for agreements that set an entry date but include no cash payment from the innovator to the generic firm.¹⁴⁷ A term division solution has also been endorsed in commentary.¹⁴⁸ Economic modeling of pharmaceutical competition commonly accepts the same underlying view.¹⁴⁹

¹⁴⁷ This view has been expressed in a major opinion of the Commission. See *In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651, Part VII (F.T.C. Dec. 8, 2003) (“[W]e do not challenge agreements on entry dates, standing alone.”); see also *id.* Part II(B)(4) (“A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer’s patent.”). It has been referred to in a subsequent advisory opinion declining to challenge a settlement. See *In re Bristol-Myers Squibb Co.* (Teva Pharmaceuticals USA, Inc.), No. C-4076, FTC, at 2–3 (May 24, 2004), available at <http://www.ftc.gov/os/caselist/c4076/040525advisoryc4076.pdf> (advisory opinion under 2002 BMS consent, with respect to Carboplatin, explaining that absence of payment resolved antitrust concerns). The view is reflected in other settlement activity as well. For example, the consent decrees permit no-payment settlements, and the 2004 update to the FTC study noted with satisfaction that no settlement included a payment from the innovator to the generic firm. FTC STUDY UPDATE, *supra* note 70, at 4. Finally, the safe harbor was advocated in the FTC’s briefing to the Supreme Court in *Schering*. See Petition for Writ of Certiorari, *FTC v. Schering-Plough Corp.*, *supra* note 14, at 18 (“[S]ettlements that are beneficial or neutral to consumers are certainly possible. For example, if the parties simply compromise on an entry date prior to the patent’s expiration, without cash payments, the resulting settlement presumably would reflect the parties’ own assessment of the strength of the patent.”); see also Supplemental Brief for Petitioner at 6 n.5, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. June 12, 2006), 2006 WL 1647529 (settlement with compromise entry date but no cash payment does not “normally” raise antitrust concerns).

¹⁴⁸ See, e.g., HOVENKAMP ET AL., *supra* note 7, § 7.4e, at 7-45 (Supp. 2005); Brodley & O’Rourke 2002, *supra* note 15, at 55–56; Hovenkamp et al. 2003, *supra* note 15, at 1762; Schildkraut, *supra* note 15, at 1043–44.

¹⁴⁹ For models that address pharmaceutical settlements without modeling the effect of the exclusivity period, see, for example, Leonard & Mortimer, *supra* note 114; Shapiro 2003a, *supra* note 15. See also Joseph Farrell & Carl Shapiro, How Strong Are Weak Patents? (Oct. 2005) (unpublished manuscript, available at <http://faculty.haas.berkeley.edu/shapiro/weak.pdf>), which offers a model explaining how a patentee can control the conduct of downstream oligopolists; though the model takes its motivation from the pharmaceutical settlement cases, it omits consideration of industry-specific features.

The model, however, fits pharmaceutical regulation poorly. In suits involving an ANDA-IV filer, a division-of-term settlement and a probabilistic lawsuit are not equivalent. Providing a generic firm with fifty percent of the remaining patent term is not the same thing as a fifty percent chance of winning the suit—not for the generic firm, innovator, or consumers. The key source of profits for a generic firm is the exclusivity period. Rather than monopoly followed by general entry, there is an intermediate stage of duopoly between the two. This feature is not reflected in the standard model.

Key to the difference is an important feature of the Hatch-Waxman regulatory arrangement: If the parties agree to a negotiated entry date, the generic firm enjoys the exclusivity period when it finally enters the market. This result follows directly from the approval bottleneck discussed in Part II.A.3. That section demonstrated how a first-filing generic firm could retain its exclusivity eligibility, despite settlement. One effect discussed there is that so long as the settling generic firm stays out of the market, later filers are denied FDA approval. In addition, once the generic firm *does* enter, it makes good on that eligibility, and enjoys the 180 days of exclusivity. This effect of the statute holds true in the same set of important though limited situations in which the approval bottleneck can delay FDA approval of later ANDA-IV filers.¹⁵⁰

By making the bounty a certainty rather than a probability, the innovator confers value upon the generic firm. That opportunity to confer value disrupts the equivalence between litigation and a term-dividing settlement.¹⁵¹ The disruption is most easily seen by considering two distinct aspects of the settlement negotiation.

First, it is costly to the innovator to allow the generic firm to enjoy the bounty with certainty rather than merely a probability. The innovator will accept a settlement only if the entry date is set late enough to compensate the innovator for the value thereby transferred to the generic firm. On average, that date leaves consumers with less benefit than they would receive through litigation.

To see this, it is helpful to consider a stylized model of the dynamics of negotiation. Consider a market served by an innovator,

¹⁵⁰ That is, those reached after the demise of the successful defense requirement, where the relevant ANDA was filed prior to the rule change of December 2003. See *supra* notes 142–43 and accompanying text. For settlements reached during the successful defense period, moreover, this feature might still be potentially relevant, if the anticipated demise of the successful defense requirement affected the terms of settlement. Cf. *supra* note 142.

¹⁵¹ For a brief analysis along similar lines, see Bulow, *supra* note 15, at 146–47. For an account of the potential harm from settlement that does not rely upon the particular role of an intermediate duopoly period, see generally Schrag, *supra* note 15.

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who is equipped with a single patent granting ten years of exclusivity, and by generic firms, exactly one of which initiates a challenge to the patent. The innovator and the generic firm litigate or negotiate to determine the division of profits for the remainder of the patent term. If the parties litigate, there is a trial, and the patent is found valid and infringed with some probability—say, to continue with our maintained assumption, fifty percent. If the patent is found valid and infringed, the generic firm is barred from entry, and the monopolist enjoys monopoly profits for the remainder of the term. Otherwise the generic firm enters immediately, leading to two stages of competition: an exclusivity period set by statute, during which the innovator and generic firm each earn duopoly profits; and a residual period during which other firms can enter as well, and the two firms earn much lower profits.

The parties can choose to settle rather than litigate by agreeing upon the date of entry by the generic firm. Entry after negotiation resembles entry after litigation: There is a duopoly period followed by a residual period of competition. Entry after negotiation is certain, rather than probabilistic. Moreover, if the negotiated entry date is late enough, there is no final competition period, but instead monopoly followed by a truncated duopoly period. Suppose further that the parties decide whether to litigate or settle at the beginning of the ten-year period, and any agreement or trial is concluded instantaneously.

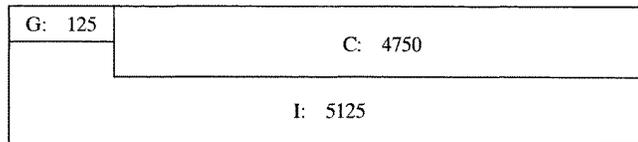
A few numerical assumptions ease the exposition. Suppose that under monopoly, the innovator receives 1000 each year, the generic firm and consumers nothing; that under duopoly, the innovator and generic firm each receive 500 per year, and consumers again nothing; and that under competition, consumers receive 1000 per year, and the innovator and generic firm each receive nothing. Think of each unit as a million dollars—\$1 billion per year for the innovator under monopoly, and so forth—and the example roughly matches the magnitudes for a blockbuster drug.¹⁵²

¹⁵² These assumptions are unrealistic in two respects. First, the model assumes that total duopoly profits equal monopoly profits. By contrast, under most models of competition, producer surplus drops under duopoly compared to monopoly, and consumer surplus rises. This is a variation on the point made in Part II.A.1, that duopoly profits are lower than monopoly profits. Pharmaceutical duopoly does tend to approximate monopoly profits, but the more important point is that the polar assumption serves to elucidate the effect presented in the text. Second, the model assumes that firms earn no profits once full entry commences. But as acknowledged in Part I, firms often enjoy some profits once the duopoly period has ended. These profits, if large enough, undercut the effect discussed in the text.

Under litigation, the innovator has a fifty percent chance of receiving 10,000 in monopoly profits and a fifty percent chance of receiving 250 in duopoly profits, an expected value of 5125. The generic firm has a fifty percent chance of receiving 250 and a fifty percent chance of receiving nothing, an expected value of 125. Consumers have a fifty percent chance of receiving 9500 (1000 per year for nine-and-a-half years; the first half-year is the duopoly period) and a fifty percent chance of receiving nothing, an expected value of 4750.

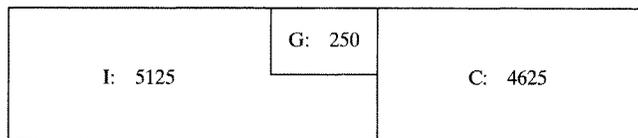
This can be depicted graphically. The length of the rectangle is ten years, and its height shows the division of expected benefits within a period:

LITIGATION



Now consider settlement. Under settlement, the generic firm receives 250 with certainty, because the bounty is now guaranteed. The additional 125 to the generic firm, compared to litigation, must come from somewhere. The innovator also receives 250 during the duopoly period. To be indifferent between settlement and litigation, the innovator must earn at least 4875 during the monopoly period. That level of profit can be earned provided that entry begins 4.875 years into the remaining patent term or later. Again depicting the result graphically:

SETTLEMENT: MINIMUM ACCEPTED BY INCUMBENT



Consumers, in order to equal their benefit from litigation of 4750, require that the entry date be no later than 4.75 years; assuming that entry date, consumers begin to receive 1000 per year six months after entry, or beginning at year 5.25. If the entry date is 4.875 years, the level insisted upon by the innovator, consumers are worse off by 125 under settlement compared to litigation.

Moreover, the actual negotiated date of entry is likely to be substantially later than the threshold date that leaves the innovator indifferent between litigation and settlement. The innovator will bargain with the generic firm over the gains conferred by making the bounty a certainty. Securing a later entry date is very important to the innovator. For the generic firm, an earlier entry date is better, given the higher present value of earlier payment, but only modestly so. Enjoying the exclusivity period with certainty is more important to a generic firm than its timing. In fact, if future market demand is anticipated to increase, a generic firm might *prefer* the later entry date, so long as the increase in projected profits exceeds the discount from the delay in their receipt.

The innovator is likely to bargain not for a settlement that perfectly matches its profits under litigation, but for a more profitable settlement—that is, one with a later entry date. The generic firm is likely to agree, so long as it secures the duopoly period with certainty rather than having to take its chances in litigation. Suppose, for example, that the innovator and generic firm agree to an entry date nine years into the remaining patent term—that is, a year before expiration. Now the innovator earns with certainty nine years of monopoly profits (9000) plus 250 from the duopoly period; the generic firm earns 250 with certainty; and consumers see competition only in the last six months, for a total benefit of 500. Again depicted graphically:

SETTLEMENT: RESULT OF BARGAINING

I: 9250	G: 250	C: 500
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Indeed, this is not even the latest entry date to which the parties might agree.

The assumptions of the stylized model are unrealistic, particularly with respect to the generic firm, which normally earns some profit during the competition period, and hence has some reason to prefer earlier rather than later entry dates.¹⁵³ Yet the simple depiction here is sufficient to show the problem for consumers from no-payment settlements—an innovator will be unwilling to accept any entry date that would leave consumers at least as well-off, and the date the innovator

¹⁵³ A formal, general model of the settlement game is the subject of work in progress.

actually chooses is even worse for consumers. Delayed entry can thereby align the incentives of the innovator and generic firm, a point generally overlooked.¹⁵⁴

2. *The Complication of Litigation Expense*

Considering litigation expense does not eliminate these allocative harms, and may, in fact, exacerbate them. To see why, it is useful to consider two respects in which saved litigation expense is thought to count in favor of settlement.

First, and as noted in Part I, saved litigation expense is thought to offset the allocative harm from the settlement. But although litigation expense is large in absolute terms, perhaps tens of millions of dollars, its size is dwarfed by the hundreds of millions or billions of dollars reallocated when parties enter a pay-for-delay settlement. The savings are insignificant except in the least important cases. Aside from its small role in any realistic assessment of the welfare effects of a settlement, saved expense is also an unlikely explanation of the parties' motivation for entering the settlement.

Second, even those who favor antitrust liability for pay-for-delay settlements make an exception for settlements with payments keyed to the size of litigation expense. In particular, as a matter of current practice the FTC effectively grants safe harbor to settlements in which the innovator makes a payment equal to or less than saved litigation expense.¹⁵⁵ This position has been endorsed by commentators.¹⁵⁶

By differentiating pay-for-delay settlements that include large cash payments from those with payments that are equal to or less than saved litigation expense, the safe harbor usefully distinguishes those settlements likely to inflict the largest allocative harm. But the policy nevertheless permits some settlements that inflict allocative harm. That is true for two reasons. The first reason is an extension of the zero-payment settlement analysis of the previous section. Suppose, for example, that the innovator saves no litigation expense by settling.

¹⁵⁴ For a contrasting view, see Hovenkamp et al. 2003, *supra* note 15, at 1762, which argues that delayed entry "does not align the incentives of pioneer and generic litigants: Generics will want the delay to be as short as possible, and patentees to make the delay as long as possible."

¹⁵⁵ See *In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651, Part II (F.T.C. Dec. 8, 2003). Earlier orders had the same structure. See consent decrees cited *supra* note 67.

¹⁵⁶ See, e.g., HOVENKAMP ET AL., *supra* note 7, at § 7.4e, 7-39 (Supp. 2006) (allowing that settlements should be permitted where payment is "no more than the expected value of litigation and collateral costs attending the lawsuit," and provided that patentee's "ex ante likelihood of prevailing in its infringement lawsuit is significant"); see also Hovenkamp et al. 2003, *supra* note 15, at 1758-59 (same); Shapiro 2003b, *supra* note 15, at 76 n.10 ("[C]ash payments should be calculated net of the patent holder's avoided litigation costs.").

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In that case an entry-splitting settlement that includes no cash payment is identical to the settlement discussed in the previous section. It fits within the safe harbor, yet entails an allocative harm.

Now suppose that the innovator saves some litigation expense by settling, but that the generic firm's bargaining power is such that it is able to extract all of the benefit from the innovator's saved expense. In that case, nothing has changed; a settlement that includes a payment equal to that saved expense is equivalent to the zero-payment settlement where there are no litigation savings.

If the innovator has some bargaining power, however, the safe harbor permits additional allocative harm. For in that case, the innovator will be able not only to retain part of the gain from saved litigation expense, but also to bargain for part of the generic firm's litigation savings. If the innovator has at least equal bargaining power, it should need to pay no more than *half* of the *difference* between the parties' saved litigation costs in order to secure a settlement. Allowing a larger payment, as the safe harbor does, permits the innovator to confer additional value upon the generic firm in exchange for additional delay, leading to additional allocative loss. Indeed, if the innovator has most of the bargaining power and the generic firm's saved expense is large enough (it need not be as large as the innovator's savings), the litigation savings component of the deal, considered alone, requires a net conferral of value from the generic firm to the innovator. In that case, the generic firm will not pay the innovator; instead, the parties will simply agree to a later entry date, thereby imposing a greater allocative harm.¹⁵⁷

C. Assessing the Allocative Harm from Settlement

The foregoing analysis establishes that the allocative harm of settlement extends to a wider range of settlements than commonly supposed. Problematic settlements are feasible even where there is no formal bottleneck to FDA approval, because buying off the single firm with bounty eligibility carries a strong prospect of allocative harm. Settlements with small cash payments, moreover, can nevertheless entail payment for delay. Even where there is no cash payment, a term-dividing settlement provides the opportunity for an innovator to provide noncash compensation—the guarantee of the bounty itself—in exchange for delay.

¹⁵⁷ The problem is compounded by the potential for manipulation, as the innovator could inflate its cost estimate in order to permit a larger payment insulated from antitrust scrutiny.

Recognizing the true breadth of allocative harm from pharmaceutical settlements has implications for the choice of antitrust decision rule. It is further reason to think that the rule of effective per se legality fashioned by some courts is inappropriate. On the other hand, a rule of per se illegality is also too extreme: Particularly where the anticompetitive effect is modest or subtle, as when the settlement lacks an approval bottleneck or large cash payment, it may be important to provide defendants with an opportunity to offer a procompetitive justification for the settlement.

A better, middle route is the version of a rule-of-reason analysis applied by the FTC in a recent case and endorsed by commentators,¹⁵⁸ expanded in scope to cover settlements with any cash payment or retention of exclusivity eligibility. A settlement that contains a cash payment or permits the retention of exclusivity eligibility raises a “red flag,” and an accompanying presumption of illegality.¹⁵⁹ That presumption can be rebutted, however, by demonstrating that the settlement’s provisions “are justified by procompetitive benefits that are both cognizable and plausible.”¹⁶⁰ That procedure gives proper weight to the high likelihood of allocative harm arising from these settlements, while leaving space for defendants, the parties best positioned to come forward with justifications, to explain why the settlement is necessary to achieve some procompetitive end.

III

REGULATORY DESIGN AND CONGRESSIONAL JUDGMENT

Part II demonstrated how an industry-specific regulatory arrangement, here the Hatch-Waxman Act, alters the opportunity for collusive conduct. That analysis showed the various means by which the regulatory structure expands the opportunity for allocative harm from settlement. We must still contend with the important objections described in Part I—that the expected allocative losses from a pay-for-delay settlement ought to be tolerated. After all, these agreements settle litigation—and normally settlements are thought desirable, because they conserve litigation expense and benefit parties who are in the best position to arrange their own affairs. Moreover, the litiga-

¹⁵⁸ See, e.g., *Schering*, 2003 WL 22989651, Parts I.C & II.B.1; Hovenkamp, *Sensible Rules*, *supra* note 15, at 26–31 (“[T]he Federal Trade Commission’s approach in [*Schering*] seems about right.”); see also Hovenkamp et al. 2003, *supra* note 15, at 1759–60 (suggesting burden-shifting approach).

¹⁵⁹ See *Schering*, 2003 WL 22989651, Part II.B.4; Hovenkamp, *Sensible Rules*, *supra* note 15, at 30.

¹⁶⁰ See *Schering*, 2003 WL 22989651, Part I.C; Hovenkamp, *Sensible Rules*, *supra* note 15, at 30.

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tion settled is *patent* litigation, and patent policy favors innovation over consumer access; the interaction of patent policy with antitrust might be thought to permit allocatively harmful practices ordinarily condemned under antitrust law alone.

Here we come to the second effect of industry-specific regulation, its role as a congressional judgment about the proper balance between innovation and competition. This judgment, like the judgment about innovation policy reflected in the Patent Act, influences the scope and vigor of antitrust enforcement. For example, patent policy may contain a norm favoring innovation and favoring settlement that alters the antitrust treatment of practices involving patented goods. But even if patent policy *generally* contains such a norm, an industry-specific regulatory arrangement supplants that norm within its domain. To understand the alteration, it is necessary to understand in some detail how the regulatory regime differs in its effects from the usual effects of patent law.

This Part explains those differences and their relevance for antitrust enforcement. Part III.A presents the case for identifying, as a general matter of patent law and antitrust law, certain exceptions to the ordinary operation of antitrust law. Part III.B describes a key alteration, compared to patent law generally, wrought by the industry-specific regulatory regime in pharmaceuticals, which provides an effective tax for some drug development projects and a subsidy to others. Part III.C explains how Congress's industry-specific congressional judgment about the balance between innovation and competition undermines certain arguments against antitrust liability.

A. *An Uneasy Case for Patent Exceptionalism*

If patent policy depends upon above-cost pricing, and antitrust policy is suspicious of firm practices that defend and extend above-cost pricing, then there is a case to be made for a reconciliation of means in which antitrust gives way, and the patentee is allowed to employ certain practices that would otherwise be prohibited. To make headway, it is useful to consider first whether antitrust law of its own accord provides a special accommodation to the makers of innovative goods, and then to assess whether the Patent Act alters the baseline of enforcement for patented goods.

1. *Innovation as an Internal Norm of Antitrust*

A norm favoring innovation may at first seem foreign to antitrust law. After all, low prices are an important goal of antitrust enforce-

ment—even, some have claimed, the primary goal.¹⁶¹ And there are important areas of antitrust doctrine in which low consumer prices trump other efficiency-promoting values.¹⁶²

However, allocative efficiency does not exhaust the concerns of antitrust analysis.¹⁶³ Promoting innovation matters, too. Some innovation-promoting antitrust rules may have only a minimal conflict with allocative efficiency—for example, when an antitrust enforcement agency insists upon the maintenance of rivalrous research and development efforts as a condition of merger.¹⁶⁴ A greater conflict is posed by a policy that advocates market concentration as an inducement or (more controversially) a platform for innovation.¹⁶⁵

Basic structures of antitrust doctrine reflect the need to provide a reward for “skill, foresight and industry”¹⁶⁶ in order to induce innovation, even at some expense of allocation. As a general matter, monopolies are subject neither to dissolution by government decree nor to a duty to provide access to rivals at a discounted rate.¹⁶⁷ Nor are product design decisions normally subject to disclosure to rivals, though disclosure would improve the rivals’ ability to compete in the

¹⁶¹ See, e.g., Aaron S. Edlin, *Stopping Above-Cost Predatory Pricing*, 111 *YALE L.J.* 941, 948 n.25 (2002) (“Despite the wish of economists and their fellow travelers that the goal of antitrust be to promote overall efficiency, neither case law nor legislative history stands for the proposition that overall economic welfare or wealth maximization trumps low prices.”).

¹⁶² For example, under current U.S. doctrine, cost savings achieved through a merger are generally not cognizable unless they are “sufficient to reverse the merger’s potential to harm consumers in the relevant market, e.g., by preventing price increases in that market.” U.S. Dep’t of Justice & FTC, *Horizontal Merger Guidelines* § 4, 4 *Trade Reg. Rep. (CCH)* ¶ 13,104 (amended Apr. 8, 1997); see also *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1088–90 (D.D.C. 1997) (applying Guidelines section 4). In addition, the Supreme Court has repeatedly invoked “consumer welfare” as the touchstone of antitrust analysis. See, e.g., *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 221, 224 (1993); *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 107 (1984) (quoting *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (citation omitted)).

¹⁶³ See, e.g., *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (describing goals of both antitrust and regulation as “low and economically efficient prices, innovation, and efficient production methods”).

¹⁶⁴ See, e.g., Michael L. Katz & Howard A. Shelanski, *Merger Policy and Innovation: Must Enforcement Change to Account for Technological Change?*, in 5 *INNOVATION POLICY AND THE ECONOMY* 109, 147–48 (Adam B. Jaffe et al. eds., 2005) (discussing conditions placed upon merger between Ciba-Geigy and Sandoz designed to preserve rivalrous research and development).

¹⁶⁵ The canonical statement of concentration as an attractive platform for innovation is JOSEPH A. SCHUMPETER, *CAPITALISM, SOCIALISM & DEMOCRACY* 87–106 (3d ed. 1950). As Katz & Shelanski explains, *supra* note 164, at 131–34, it remains an open question whether competition or concentration better promotes innovation.

¹⁶⁶ *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945) (L. Hand, J.).

¹⁶⁷ See, e.g., *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trnko, LLP*, 540 U.S. 398, 415 (2004) (so holding, in context of telecommunications regulation).

provision of complementary goods.¹⁶⁸ A contrary policy would lower prices in the short run but reduce the prospective incentive to invest in new and improved products and processes, an important engine of economic growth. This dynamic benefit of policies that preserve monopoly profits offsets their static allocative cost. As the Supreme Court recently explained, in rejecting a refusal-to-deal claim in the regulatory context of telecommunications law:

The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts “business acumen” in the first place; it induces risk taking that produces innovation and economic growth.¹⁶⁹

Not all of the Court’s opinions have gone this far, to be sure;¹⁷⁰ but it is fair to say that as an ordinary element of antitrust law consumer access is balanced against the incentive to create.

The difficult question is how far to push the argument for dynamic efficiency. The higher the producer profits allowed, the larger the dynamic benefits. An agreement with a rival to divide markets normally attracts condemnation under section 1 of the Sherman Act. But an innovator might argue that the additional profits induce enough incremental innovation to make the practice beneficial overall. The argument is fundamentally similar for patented and unpatented (though costly-to-create) goods. An innovator who builds a telecommunications network and one who designs a new drug are similarly positioned to argue that a certain profit-improving practice should be permitted, despite its adverse allocative consequences, in light of its salutary effect upon the incentive to innovate. The tradeoff inherent in providing incentives for creation while tolerating allocative distortion affects intellectual property and other assets alike.¹⁷¹

An argument favoring exemptions for innovative goods, however, likely fails as a matter of general antitrust law. It is difficult to establish convincingly that an exemption carries large benefits for future

¹⁶⁸ See, e.g., *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 281 (2d Cir. 1979) (holding that camera manufacturer had no obligation to predisclose information about new product design to competitors).

¹⁶⁹ *Trinko*, 540 U.S. at 407. The reference to “business acumen” comes from *United States v. Grunnell Corp.*, 384 U.S. 563, 571 (1966).

¹⁷⁰ See, e.g., *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 483–86 (1992) (entertaining antitrust liability for manufacturer’s refusal to sell parts to competitors in servicing).

¹⁷¹ This is a point recognized in Einer Elhauge, *Defining Better Monopolization Standards*, 56 STAN. L. REV. 253, 301–05 (2003) (noting that tradeoff between innovation and competition is not limited to intellectual property context).

innovation.¹⁷² Nor is a generalist court equipped to make the necessary fine-grained determinations of industrial policy, relaxing antitrust here and tightening it there, in accordance with its views about desirable innovation and acceptable deadweight loss. Certainly such case-by-case determinations of incremental innovation and incremental, deadweight loss are projects ill-suited to the capacities of a generalist court. There is, therefore, often good reason to limit attention to allocative efficiency in practice, even if one is committed to a full range of efficiency arguments—including dynamic efficiency—in theory.¹⁷³

2. *The Patent Act as a Statutory Basis for Exceptionalism*

The Patent Act provides a statutory foothold, external to antitrust law, for a patentee to insist upon a more innovation-protective antitrust policy than that available to innovators generally. There will not, of course, always be a conflict between antitrust law and patent policy. To the extent that the Sherman Act already reflects an acceptance of dynamic arguments, there may be no conflict in means. But often there *will* be a conflict, and in those cases the Patent Act provides a basis for seeking an exception to the ordinary operation of antitrust.

The high-water mark in judicial recognition of patent exceptionalism is the Supreme Court's holding in *United States v. General Electric* that a patentee may agree to a price-restricted license with its competitor.¹⁷⁴ The extent of or rationale for exceptionalism is often left undeveloped. This is a problem in *General Electric* and other old cases,¹⁷⁵ but the modern pay-for-delay cases fare little better. They

¹⁷² Moreover, as Aaron Edlin has noted, "once one widens the scope of antitrust concerns beyond prices in order to evaluate overall social welfare, one confronts an impossible tangle of how to evaluate social welfare or societal wealth in a world rife with market failures." Edlin, *supra* note 161, at 948 n.25.

¹⁷³ Resistance to recognizing cost savings as a basis for permitting a merger reflects similar concerns. See, e.g., POSNER, *supra* note 8, at 29 ("Efficiency is the ultimate goal of antitrust, but competition a mediate goal that will often be close enough . . ."); *id.* at 133–36 (discussing merger efficiencies).

¹⁷⁴ 272 U.S. 476, 488, 494 (1926) (holding that licensor patentholder may "impose the condition that [licensee] sales should be at prices fixed by the licensor and subject to change according to [the licensor's] discretion").

¹⁷⁵ Typical is this statement from the Court's opinion in *United States v. United Shoe Machinery Co.*:

Of course, there is restraint in a patent. Its strength is in the restraint, the right to exclude others from the use of the invention, absolutely or on the terms the patentee chooses to impose. This strength is the compensation which the law grants for the exercise of invention. Its exertion within the field covered by the patent law is not an offense against the Anti-Trust Act.

247 U.S. 32, 57 (1918). The statement leaves unexplained what counts as "within the field" of the Patent Act.

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are sprinkled with statements that, for example, antitrust liability should be withheld for “a rather simple reason: one of the parties owned a patent,”¹⁷⁶ and that “[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition.”¹⁷⁷ Such ipse dixit, if taken seriously, might justify a kind of naïve exceptionalism in which a court simply notes the conflict between antitrust and patent and concludes against antitrust liability without further analysis.

A more sophisticated version of exceptionalism ties the contemplated exception to a specific provision of the Patent Act or to a policy closely related to its provisions. Such statute-oriented specificity emerges from the Supreme Court’s instruction in *Simpson v. Union Oil Co.*, explaining the rule of *General Electric*, that “[t]he patent laws which give a . . . monopoly on ‘making, using, or selling the invention’ are *in pari materia* with the antitrust laws and modify them *pro tanto*.”¹⁷⁸ This version of *in pari materia* emphasizes that when two statutes govern the same activity, they must be reconciled by some means. In making that reconciliation, the Patent Act has a claim to primacy, as Congress’s more specific take upon how best to balance innovation and consumer access with respect to patented goods.

Simpson refers to the *specific* rights provided by the Patent Act—the exclusion with respect to making, using, and selling, and a related right to license—not a general policy favoring patentee profit-taking.¹⁷⁹ The necessity of specific statutory support also is indicated by the Court’s insistence elsewhere that exceptions created by the Patent Act must be “strictly construed.”¹⁸⁰ Such constraints have prompted the recognition, for example, that a patentee enjoys no

¹⁷⁶ Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1064 (11th Cir. 2005).

¹⁷⁷ *Id.* at 1065–66.

¹⁷⁸ *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964). *Simpson*, though not a case involving a patentee, is often cited as a statement of patent’s relationship to antitrust. See, e.g., *Schering*, 402 F.3d at 1067; *Miller Insituform, Inc. v. Insituform of N. Am., Inc.*, 830 F.2d 606, 608 (6th Cir. 1987); *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 646–47 (9th Cir. 1981); *In re Indep. Serv. Orgs. Antitrust Litig.*, 989 F. Supp. 1131, 1142 (D. Kan. 1997).

¹⁷⁹ The *Simpson* Court continues in a skeptical tone after the quotation: “That was the *ratio decidendi* of the *General Electric* case. We decline the invitation to extend it.” *Simpson*, 377 U.S. at 24 (citation omitted). The continuation of the quotation suggests that the cases cited *supra* note 178 likely overstate the degree to which *Simpson* can be said truly to endorse an exceptionalist position.

¹⁸⁰ *United States v. Masonite Corp.*, 316 U.S. 265, 280 (1942) (“Since patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed . . .”); see also *Lear, Inc. v. Adkins*, 395 U.S. 653, 663 (1969) (noting, in course of rejecting licensee estoppel, that “the Sherman Act ma[kes] it clear that the grant of monopoly power to a patent owner constituted a limited exception to the general federal policy favoring free competition”).

exception for restrictive practices that cover products not within the scope of the patent or that extend beyond its duration.¹⁸¹

Without an explicit statutory provision to rely upon, a patentee claiming an exception may instead seek refuge in the innovation-protective policy of the Act. Yet *every* profit-enhancing practice of a monopolist, however damaging to allocation because of its effect on prices, might be defended on the ground that it increases innovation. As a way to cabin such an argument, it is helpful to consider what we might call the innovation efficiency of the practice, the ratio of incremental innovation to incremental deadweight loss produced by the practice. Such a ratio has proved useful in commentary,¹⁸² and gives

¹⁸¹ See, e.g., *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.26 (11th Cir. 2003) (distinguishing *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907–08 (6th Cir. 2003), on ground that agreement contained restrictions broader than patent at issue); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1297 n.16, 1317 (S.D. Fla. 2005) (concluding that agreement contained restrictions broader than patent at issue, and indicating antitrust significance of that fact).

It is not always clear what to make of specific Patent Act provisions. For example, the Patent Act provides that “a patent shall be presumed valid.” 35 U.S.C. § 282 (2000). This provision has been interpreted by the Federal Circuit to require that an invalidity defense to patent infringement must be established by clear and convincing evidence, rather than a mere preponderance. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983); see 2 DONALD S. CHISUM, *CHISUM ON PATENTS* § 5.06(2)(d)(iii), at 5-793 n.103 (2003 & Supp. 2005) (collecting cases reciting standard). Some courts inclined against antitrust liability for pay-for-delay settlements have derived from this requirement an innocent-until-proven-guilty principle for antitrust: So long as invalidity has not been established by an authoritative adjudication, a patentee is free to act in ways that achieve the same degree of exclusion as a hypothetical patentee with a certainly valid patent. E.g., *Schering*, 402 F.3d at 1066 (discussing presumption of patent validity as basis for exclusion of rivals, including exclusion by settlement); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 533 (E.D.N.Y. 2005) (rejecting probabilistic view of consumer entitlement to competition as contrary to statutory presumption of validity).

This interpretation of the validity presumption is doubtful, since the probability of losing the suit—the prospect that motivates a patentee to agree to make the payment in the first place—already takes into account the allocation of proof. Calculations about settlement thus already reflect the probability that a generic rival would have been able to secure victory despite the heightened burden. See Shapiro 2003b, *supra* note 15, at 74. In addition, the presumption is probably best understood narrowly; it does not apply, for example, to the showing required to establish the likelihood of success necessary to secure a preliminary injunction. See *New Eng. Braiding Co. v. A.W. Chesteron Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992) (presumption is “procedural device” for allocating burdens of production and persuasion at trial, not “evidence which can be ‘weighed’ in determining likelihood of success” at preliminary injunction stage).

¹⁸² See Kaplow, *supra* note 9, at 1829–34 (describing and applying ratio test); SCOTCHMER, *supra* note 31, at 109–12, 119–20 (similar); William W. Fisher III, *Reconstructing the Fair Use Doctrine*, 101 HARV. L. REV. 1659, 1707–19 (1988) (applying ratio test to copyright doctrine of fair use); Paul Klemperer, *How Broad Should the Scope of Patent Protection Be?*, 21 RAND J. ECON. 113 (1990) (deriving optimal patent term and breadth, judged by ability to deliver fixed profit with minimum deadweight loss); Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. ECON. 106 (1990) (similar).

shape to the Supreme Court's declaration that "we would not expect that any market arrangements *reasonably necessary to effectuate the rights that are granted* would be deemed a *per se* violation of the Sherman Act."¹⁸³ Where a practice produces a large deadweight loss without much benefit for innovation, it will be more difficult to understand the arrangement as reasonably necessary to effectuate the Patent Act's innovation policy, and the practice will be more vulnerable to antitrust condemnation.

The innovation interest is not limited to the patentee. An alleged infringer may be an entrant also engaged in innovative activity. Identifying and negotiating with every patentee that holds rights that are possibly relevant to the entrant's product is costly for the entrant, particularly in industries where innovation is cumulative.¹⁸⁴ Identifying relevant patents is discouraged in practice, moreover, by the specter of enhanced damages for willful infringement, an outcome thought to be made more likely by prior awareness of relevant patents.¹⁸⁵ The likely outcome is that an entrant will frequently stumble into patent infringement suits in which it finds itself a defendant.

Seeing the litigation to conclusion is unlikely to be an attractive option for the defendant. Often, winning the litigation will be unrewarding for the entrant, due in part to a free-riding problem discussed in the next section. Yet a rule that prohibits all settlements that work an allocative harm will render some settlements unavailable. If all of the resulting confrontations must lead to a full adjudication of the patent, the result might be to reduce the supply of innovative entrants.¹⁸⁶ There is reason, therefore, to accept a certain amount of settlement, even settlement that works an allocative harm, in order to maintain incentives for a potential infringer's innovative entry.¹⁸⁷

¹⁸³ *Broad. Music, Inc. v. CBS, Inc.*, 441 U.S. 1, 19 (1979) (first emphasis added). This statement was made in the course of considering BMI's management of blanket copyright licenses.

¹⁸⁴ For further discussion of cumulative innovation, see *supra* notes 30–33 and accompanying text.

¹⁸⁵ See Mark A. Lemley & Ragesh K. Tangri, *Ending Patent Law's Willfulness Game*, 18 *BERKELEY TECH. L.J.* 1085, 1100 (2003) ("[T]he willfulness game creates a strong incentive not to read patents."); *id.* at 1101 n.43 (collecting sources noting that employees are advised not to read patents if they can avoid it).

¹⁸⁶ *Cf.* David Rosenberg & Steven Shavell, *A Solution to the Problem of Nuisance Suits: The Option to Have the Court Bar Settlement 1* (John M. Olin Ctr. for Law, Econ. & Bus., Harvard Law Sch., Discussion Paper No. 489, 2004), available at <http://ssrn.com/abstract=623285> (noting, in context of nuisance suits, that removing option to settle would reduce supply of plaintiffs).

¹⁸⁷ Even when the resolution of the suit forces the alleged infringer to exit the market, the limited period prior to exit is a source of some consumer benefit.

Patent exceptionalism has sharp critics. The concept runs contrary to the enforcement agencies' expressed view that "for the purpose of antitrust analysis, the Agencies regard intellectual property as being essentially comparable to any other form of property,"¹⁸⁸ and to the government's longstanding opposition to *General Electric*.¹⁸⁹ A forceful argument can be made, too, that patent law at most confers rights of exclusion and enjoyment that match but do not exceed those enjoyed by owners of tangible property, and if so, exceptionalism is unwarranted.¹⁹⁰ The present purpose is not to argue patent exceptionalism's merits, but merely to note its possible basis in statute and precedent. Provided that paying for delay effectively supports a Patent Act policy, patent exceptionalism provides a potential, and to some courts a persuasive, basis for insulating the practice from antitrust attack.

B. A Tax-and-Subsidy Scheme for Pharmaceutical Innovation

The previous section identifies some statutory basis for treating patentees differently under antitrust law. But patent law and antitrust law are not the only means by which innovative monopolists are regulated. Antitrust is *in pari materia* not only with patent law, but with industry-specific regulation as well. A reconsideration of the applicability of patent exceptionalism to pay-for-delay settlements in the pharmaceutical industry begins with an examination of the innovation and competition policy embodied in the Hatch-Waxman Act, compared to the treatment of patented goods generally.

That examination requires an investigation of the economic effects of the Act's principal components. That investigation receives no assistance from legislative history, which is too scant to provide

¹⁸⁸ U.S. DEP'T OF JUSTICE & FTC, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 2.0(a) (1995), available at <http://www.usdoj.gov/atr/public/guidelines/0558.htm> (making quoted statement one of three general principles guiding antitrust treatment of intellectual property licensing).

¹⁸⁹ See PTCJ Interview with Richard H. Stern, Chief, Intellectual Property Section, Antitrust Division, U.S. Department of Justice, 377 PAT. TRADEMARK & COPYRIGHT J. (BNA) E-1, E-2 (May 4, 1978) (interview with antitrust official describing government's efforts to overturn or narrow *General Electric*). The United States has also opposed the idea, arguably advanced in the Federal Circuit's *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1327-28 (Fed. Cir. 2000), that refusals to license intellectual property are immune in nearly all circumstances from antitrust scrutiny. See Brief for the United States as Amicus Curiae at 10, CSU, L.L.C. v. Xerox Corp., No. 00-62 (U.S. Feb. 20, 2001), 2001 WL 34135314 (noting that if holding of that case were so understood, "we would have serious concerns . . . and would not be prepared to endorse it").

¹⁹⁰ See A. Douglas Melamed & Ali M. Stoeppelwerth, *The CSU Case: Facts, Formalism and the Intersection of Antitrust and Intellectual Property Law*, 10 GEO. MASON L. REV. 407, 410-13 (2002) (making this argument and collecting evidence).

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even arguable use here. The main source of such history is a House report accompanying an early version of the Act, but the key 180-day exclusivity period became law without informative discussion in that report and without debate.¹⁹¹ Moreover, it was apparently not contemplated at the time of passage that the regulatory scheme would facilitate collusion to the extent identified in Part II.¹⁹²

1. *The Bounty as an Innovation Tax*

An important component of the innovation and competition policy of the Hatch-Waxman Act is the bounty provided by the 180-day exclusivity period. Without a bounty, the incentive to challenge patents is often much reduced. Normally, defensive nonmutual issue preclusion permits firms other than the original challenger to take advantage of a favorable legal judgment without repeating the time and expense of a suit.¹⁹³ If a favorable judgment is the only impediment to entry, then potential challengers will face a serious free-rider problem. Not only will a firm fail to internalize the full benefits of its challenge, since others can use the judgment as well, but in addition the gains will tend to be rapidly dissipated, as other firms enter and compete away the benefits of the favorable judgment.¹⁹⁴ This result has led commentators to conclude that patent challenges are underprovided, both in the decision to bring a challenge and in the incentive to pursue it vigorously.¹⁹⁵ The bounty provides a substantial boost to the incentive to challenge.

¹⁹¹ See H.R. REP. NO. 98-857, pt. 1, at 28 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2661. The House report mainly repeats the statutory language. There is no comparable Senate report.

¹⁹² This view has been captured in after-the-fact statements of members of Congress. See 148 CONG. REC. S7565, 7566 (daily ed. July 30, 2002) (statement of Sen. Hatch) (asserting that pay-for-delay settlements were unanticipated outcome); see also S. REP. NO. 107-167, at 4 (2002) (“Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law . . .”).

¹⁹³ The leading case establishing defensive nonmutual issue preclusion is *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 349 (1971). As it happens, *Blonder-Tongue* is itself a patent case, but the doctrine is widely applied. See 18A CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 4464 (2d ed. 2002) (collecting cases applying doctrine).

¹⁹⁴ Dissipation of the private benefits through post-judgment price competition is an important complication. With a pure public good, beneficiaries may agree in advance to contribute to its provision. Where post-provision rivalry is important, however, there must be in addition some way to limit the rivalrous use. Cf. Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, J. ECON. PERSP., Spring 2005, at 75, 89 (noting in passing that challengers might coordinate, but ruling out subsequent price coordination). An agreement on post-judgment prices raises antitrust concerns; it might also be ineffective if the incumbent remains within the market but outside the cartel.

¹⁹⁵ See Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 687–88 (2004) (recognizing public-good

The bounty's importance as an inducement to challenge, however, varies with the type of challenge. Issue preclusion has an important effect where the absence of a favorable judgment is all that stands in the way of entry. This is true of an invalidity challenge, such as the recent challenge involving Plavix. It is true also of noninfringement challenges that establish a route of production available to many firms. For example, a district court might arrive at a narrow construction of patent claims, resulting in a clear, noninfringing, widely available route to offering a bioequivalent drug.¹⁹⁶ In other cases, however, the noninfringement route pursued by the generic firm is not readily available to other firms, because it is difficult to accomplish or separately patentable. In that event, the bounty, though still valuable to the generic firm, may be less necessary as an inducement to trigger suit.

Consider, for example, K-Dur, the drug at issue in an antitrust challenge brought by the FTC—the case mentioned in the Introduction to this Article that divided the agency and the Solicitor General. K-Dur is no Plavix; its sales are measured in the hundreds of millions, not billions, of dollars.¹⁹⁷ Its active ingredient is an unpatented potassium salt used to replace an electrolyte lost from the body as a side effect of certain anti-hypertension drugs. K-Dur's advantage is a special patented coating that permits controlled release of the active ingredient.¹⁹⁸ Like Plavix, K-Dur is backed by a patent that, like any patent, is “probabilistic” and imperfect.¹⁹⁹ But the source of patent weakness is different. For K-Dur, there is a significant opportunity to

characteristics of patent challenges); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 333 (same); see also Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 952 (2004) (noting resulting asymmetry in plaintiff and defendant incentives).

¹⁹⁶ For an example demonstrating the close connection between invalidity and noninfringement in this context, see *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003), which offers alternative constructions: a broad reading, on which the patent was invalid, and a series of successively narrower readings, on which the generic firm's proposed drug did not infringe. As one would expect, *Blonder-Tongue*, 402 U.S. 313, applies to a noninfringement judgment. See Miller, *supra* note 195, at 729–30 & n 250 (collecting cases).

¹⁹⁷ \$190 million annually at the time of the settlement. See *In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651, Part II.B.2 (F.T.C. Dec. 8, 2003).

¹⁹⁸ See U.S. Patent No. 4,863,743 (filed Sept. 5, 1989).

¹⁹⁹ See Lemley & Shapiro, *supra* note 194, at 76 (emphasizing uncertain result of any patent challenge); see also Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 993 (1999) (noting importance of “probabilistic patents”).

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argue noninfringement, rather than invalidity—assuming, that is, that the filer can in fact come up with an alternative, noninfringing means of achieving bioequivalence. This is exactly what happened with K-Dur; a generic rival concluded that it could manufacture a bioequivalent controlled-release product without infringing the patent.²⁰⁰ The likelihood that *some* generic drug company will be able to do this may be fairly high; if it does so, it is *that* expertise, which may itself be protected by a patent, that forms part of the generic firm's ability to compete. This approach is less vulnerable to free-riding, less subject to a flood of profit-dissipating competitors, and less needful of the 180-day exclusivity to protect its bid for entry.

2. Entry Delays as an Innovation Subsidy

While the Hatch-Waxman regime promotes pre-expiration competition by means of litigation, a second set of provisions provides innovators with protection from pre-expiration competition.²⁰¹ First, if the innovator's drug contains a novel active ingredient, the FDA must not accept an ANDA-IV in the first four years after NDA approval.²⁰² This delay, sometimes referred to as data exclusivity, can be immensely valuable.²⁰³ For other new drugs, there is an analogous delay of approval (not ANDA submission) of three years.²⁰⁴ Second,

²⁰⁰ The generic firm contended that its product had a composition and viscosity different from that specified in the innovator's patent. See Schering Trial Brief, *supra* note 44, at 17–18.

²⁰¹ A generic rival could in theory evade these regulatory delays by filing a full-blown NDA instead, including the safety and efficacy studies, but typically this will not be worth the time and expense.

²⁰² See 21 U.S.C. § 355(j)(5)(D)(ii) (2000) (current version at 21 U.S.C. § 355(j)(5)(F)(ii) (Supp. III 2003)). As discussed *supra* note 48, the delay is five years for ANDAs with Paragraph I, II, or III certifications. *Id.*

²⁰³ The delay would not be valuable if the drug holds so little future promise, as evaluated during the first few years of marketing, that a generic firm would not otherwise have sought to initiate a challenge earlier than the four-year point.

²⁰⁴ The availability of this exclusivity depends upon the satisfaction of certain conditions discussed in THOMAS, *supra* note 35, at 352–53. As compared to the ordinary patent regime, the innovator's protection from ANDA filing and approval is a source of additional delay, though compared to the pre-1984 pharmaceutical regime, this provision arguably reflects a shift in the direction of increased competition. Prior to 1984, generic firms were not permitted to rely upon the innovator's clinical results establishing safety and efficacy. The necessity of repeating costly clinical tests, though not absolute, was a powerful deterrent to entry. See FTC STUDY, *supra* note 51, at 3–4 (discussing this problem).

The pre-1984 regime contained a further impediment that was swept away by the Hatch-Waxman Act. Even a generic manufacturer willing to undertake separate clinical studies was obliged to wait until patent expiration to commence their preparation, for such studies were held to be a “use” prohibited by the Patent Act. See Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that generic firm's pre-expiration testing violates Patent Act). The Hatch-Waxman Act provides a statutory “experi-

ANDA submission triggers an initial, ministerial review by the FDA, normally completed within sixty days.²⁰⁵ This is brief, but hardly trivial, since a single month's respite from competition may allocate hundreds of millions of dollars. Upon the completion of initial review, the generic firm sends notice of its filing to the innovator.²⁰⁶

If the innovator initiates a patent suit, further delays ensue.²⁰⁷ One source of delay not unique to pharmaceuticals is the duration of the patent suit, which normally takes several years but can take longer, particularly in the hands of an innovator committed to drawing out the proceedings. The pharmaceutical innovator, compared to a patentee in another industry, receives additional protection during the pendency of the suit: the automatic stay of FDA approval introduced in Part I. The stay lasts for at least the first thirty months after the innovator's receipt of notice, and under certain circumstances lasts longer.²⁰⁸ If the suit drags on too long, the stay will expire. The stay superficially resembles the preliminary injunction ordinarily available to patentees, but the pharmaceutical innovator need not show irrevocable harm or likelihood of success on the merits, nor post a bond from which the alleged infringer's damages are paid if the patentee subsequently loses. As a result, not only is the stay automatic, but its expected cost is much lower than that of an injunction.

mental use" exemption from infringement. See 35 U.S.C. § 271(e)(1) (2000); Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372, 2376–77 (2005) (applying § 271(e)(1)).

²⁰⁵ See 21 C.F.R. § 314.101(b)(1) (2006). The review is to confirm that the ANDA is sufficiently complete to permit substantive review. FDA regulations provide no deadline for completing this review, but as a matter of policy the FDA operates under the same sixty-day requirement applicable to NDAs. See § 314.101(a)(1) (establishing sixty-day deadline for NDAs). Upon completion of the review, the FDA notifies the ANDA-IV filer that its application has been received. See § 314.101(b)(2).

²⁰⁶ See 21 C.F.R. § 314.95(b) (2006) (explaining that applicant sends notice "when" it receives FDA's acknowledgement letter). As discussed *supra* note 120 and accompanying text, the generic firm must provide the NDA holder with a detailed statement of its factual and legal basis for its assertion of invalidity or noninfringement. 21 U.S.C. § 355(j)(2)(B)(iv)(II) (Supp. III 2003). The certification and statement is made with respect to each patent that the NDA holder (pursuant to FDA rule) associates with the drug in question, not only compositions of matter but also formulations and methods of use. § 355(b)(1) (2000 & Supp. III 2003). These are compiled in an FDA publication, *Approved Drug Products with Therapeutic Equivalence*, commonly known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A) (2000).

²⁰⁷ An additional process, running in parallel, is the FDA's evaluation of the ANDA to confirm compliance with its requirements. This process normally takes more than one year. James N. Czaban, Preserving and Leveraging Value from the IP/FDA Interface, http://www.buildingipvalue.com/n_us/154_157.htm (last visited Sept. 20, 2006) (estimating "two or more year FDA review time"). It does not normally delay the conclusion of an ANDA-IV challenge.

²⁰⁸ The lengthening occurs as explained in note 50 *supra*, when the generic firm files an ANDA-IV less than five years after the innovator's FDA approval.

The several years' delay caused by the stay is an important source of profits where a generic firm would otherwise enter prior to the district court's judgment. A generic firm would sometimes prefer not to "launch at risk," even if permitted to do so; if a court eventually concluded that the innovator's patent was valid and infringed, the generic firm would be responsible for lost profits. But if the generic firm's likelihood of winning is sufficiently high and the discount at which it must sell to compete sufficiently slight, launching at risk will be an attractive strategy.²⁰⁹ As matters stand, launches at risk do occur when the litigation has dragged on for so long that the stay expires, and such launches have brought early competition to Plavix²¹⁰ and other major drugs.²¹¹ More launches at risk would occur absent the

²⁰⁹ For example, suppose that the patent is valid and infringed with probability β , and that entry takes the simple, unrealistic form of stealing share from the incumbent by selling at a discount. The incumbent earns a margin m on each unit; the entrant earns m' . Entry implies a gain of m' on each unit but damages of m , payable with probability β . Entry is profitable provided $\beta < m'/m$.

This analysis does not factor in the bounty, which may incline a generic firm toward caution, since it can wait for the district court to rule, then enjoy the bounty with less risk of paying damages. (Eliminating the risk entirely requires waiting until the conclusion of the appeal.) Factors favoring earlier entry include the time value of money, the risk of a declining future market for the drug (particularly if a competing therapy is likely to become available), and the benefit of surprise in dealing with a threat from authorized generics (see the Conclusion for further discussion). Finally, a later ANDA filer may force the first filer's hand, for a later filer's victory triggers the first filer's exclusivity period.

²¹⁰ Carreyrou & Lublin, *supra* note 72. The generic firm's Plavix launch was eased by two provisions of an innovator-generic agreement not subject to the consent decree discussed in note 72 *supra*: a limit upon the damages payable by the generic firm if it subsequently loses the patent infringement suit, and a contractual delay in the innovator's pursuit of an injunction. *Id.* After a short period in which the generic firm flooded the market with its product, a district judge preliminarily enjoined further distribution pending a trial on the merits of the infringement suit. *Id.*

²¹¹ Examples include Allegra, Neurontin, Paxil, and Wellbutrin SR. See Barr Says Court Denies Preliminary Injunction to Halt Allegra Sales, *supra* note 57 (noting launch of generic Allegra even before trial); Abboud, *supra* note 57 (describing launch at risk of generic Neurontin); Apotex Launches Generic Paxil, Triggers GSK's Generic Version, DRUG INDUSTRY DAILY, Sept. 10, 2003 (on file with the *New York University Law Review*) (reporting launch of generic Paxil before judicial proceedings concluded); Eon Ships Generic Wellbutrin, Trips GSK's Authorized Generic, GENERIC LINE, Jan. 28, 2004 (on file with the *New York University Law Review*) (reporting launch of generic Wellbutrin SR before court proceedings completed).

Such launches were formerly rare. See Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 198 (1999) (noting infrequency of launches at risk upon expiration of stay without district court decision). Launches at risk are underappreciated. Shapiro associates pharmaceuticals with the case in which there is no interim competition. See Shapiro 2003a, *supra* note 15, at 405 & n.22 (describing launching under threat as exception rather than rule); *id.* at 407-08 & n.28 (discussing entry-date settlements on assumption that challenger will not enter while litigation is pending, and noting that this assumption fits facts of pharmaceutical industry well). Hovenkamp and co-authors downplay this possibility as well. See Hovenkamp et al. 2004,

stay.²¹²

Taken together, the delays set up by the Hatch-Waxman Act provide an important means for innovative drug makers to preserve the returns upon a new drug. For a new chemical entity backed by a patent, the delays provide about seven years of protection after the product is approved. Even if the drug were protected by *no* patent but had a new active ingredient, the delays would still secure about six years of protection.²¹³ A drug without a new active ingredient, like K-Dur, enjoys several years of protection, even if a challenge is immediate. Moreover, these figures understate the effect of delay enjoyed by an innovator. A drug must cross a certain threshold of profitability before a generic firm will find it worthwhile to prepare and file an ANDA-IV and then defend the ensuing patent suit. If a drug takes time to build demand, the generic firm will wait to file its challenge, and a substantial part of the delay is effectively held in reserve until that challenge occurs.

3. *The Combined Effect of Tax and Subsidy*

The combined effect of the tax and subsidy reflects contrary forces. Consumer access is promoted by the unique incentive to challenge patents. Innovation is supported by the term extensions, initial delay based upon data exclusivity, and automatic stay. But the two forces cannot readily be summed in an across-the-board manner that applies uniformly to all drugs. The combined effect is not functionally equivalent to a decrease or increase in the patent term. Increased competition is the more important factor for some drugs, increased innovation the more important factor for others. The overall result is a pivot in the reward structure—a relative increase in the returns on some drugs and decrease on others.

supra note 15, at 715–16 (“Defendants are required by law to stay out of the market while patent litigation proceeds”)

²¹² These are also the cases where an innovator would be least likely to secure a preliminary injunction, or would be responsible for the largest damages if it did secure an injunction and then lost the subsequent patent suit. A patentee’s decision to secure a preliminary injunction (if it can) resembles an entrant’s decision to launch at risk, in that each faces an expected penalty based upon the likelihood of losing the suit and the size of the other’s damages that must be reimbursed in the case of a loss. The two are dissimilar, however, in the key respect that seeking a preliminary injunction is here always profitable. The innovator’s profits saved are larger than the generic firm’s profits foregone, so that even if the patentee thought its loss certain, a preliminary injunction would still be desirable from the patentee’s standpoint. Ascertaining the proper level of damages, however, is a difficult question.

²¹³ Without a patent to challenge, the generic firm cannot file an ANDA-IV, and therefore must wait five years before its ANDA is accepted, *see supra* note 202, and likely another year or more for FDA approval, *see supra* note 107.

The factors determining the balance for a particular drug are its market importance, the likelihood that an innovator's patent would be found invalid or not infringed if challenged, and the extent to which other challengers could take advantage of the judgment absent the exclusivity period. Plavix and K-Dur illustrate the alternatives. For some drugs, it is the increased threat from competition that predominates. This is likely the case for most blockbusters. For a popular drug with a patent covering a novel active ingredient, such as Plavix, an invalidity challenge is economically feasible due to the large bounty prospect, but otherwise would not be feasible on account of the free-rider problem and the low likelihood of success. The delays dampen the effect to a substantial extent,²¹⁴ but the overall effect is a reduction in reward. For other drugs, it is the increased protection from competition that predominates. For a drug faced with an infringement challenge not readily replicated by other generic firms, the bounty is less necessary to induce a challenge. If the challenge would have occurred in any event, the major effect of the regime is to protect the innovation for several rewarding years before subjecting it to potential competition.

The variation across different drugs may achieve in a rough manner an efficient balance between innovation and access across a range of drug development projects. With respect to a drug like K-Dur, increased protection may be a necessary inducement to invest, since such a drug is highly vulnerable to the noninfringing results of reverse engineering, which may be initiated once the drug's commercial success is established. The initial exclusivity period, slow adjudication, and the automatic stay protect the profits on such a drug for a limited period. The stay is particularly important, given the likely attraction of launching at risk. This protection helps justify the drug's development and approval expense.

With respect to blockbusters, patent-busting might be unusually beneficial to consumers, relative to patent-busting on other drugs. That would be true if blockbusters have an unusually large amount of demand at lower price levels, relative to other drugs.²¹⁵ In that event, the consumer benefit from subjecting these drugs to early competition

²¹⁴ For example, a drug that earns the innovator \$1 billion per year without competition and nothing otherwise, for which at least seven years of patent term are remaining upon its approval, and which has a fifty percent likelihood of losing its patent suit against a generic rival, has expected profits that are \$3.5 billion (\$1 billion per year \times 7 years \times 50 percent) higher than would be the case under immediate entry.

²¹⁵ Such demand might result if popularity spawns widespread market awareness, or because treatments that manage chronic conditions—as most blockbusters do—have a large number of low-valuing consumers. The argument assumes that the firm cannot easily price discriminate among consumers.

is unusually high, and the decentralization of the challenge scheme is an attractive feature; entrusting the early-competition decision to the government would create a risk of capture by interested parties. The size and scope of the reduction in the incentive to innovate, moreover, depends upon the degree to which the innovator knows in advance whether the project, if successful, is likely to be a big success that would attract a challenge. If a drug maker never has any advance warning, then the dampening effect on innovative incentives will be spread thinly across all drug development projects. But to the extent the innovator *can* anticipate success,²¹⁶ the tax on innovation will be borne primarily by the projects that are prospective blockbusters. To the extent that such projects have not only a high value conditional on success but also a high expected value, the tax will have less deterrent effect upon innovation.

C. *The Industry-Specific Case Against Pay-for-Delay Settlements*

The particular shape of congressional intervention in the balance between innovation and access, together with important industry-specific features of the pay-for-delay problem in pharmaceuticals, serve to undercut the Patent Act-based case for an exception to the ordinary operation of antitrust law. The argument applies in different ways to the innovator-focused and infringer-focused arguments for an exception.

With respect to innovators, the practice in question is a poor fit with Patent Act policy, because permitting pay-for-delay settlements is a highly innovation-inefficient means of increasing the incentive to innovate. To see this, consider as a benchmark a competitive practice that had the effect of increasing the length of the patent term at no incremental expense to the patentee. Arranging a longer term might be expected to increase producer profits and consumer allocative losses in equal measure (assuming, among other things, that the producer faces the same demand curve in each period). If the social ben-

²¹⁶ Some evidence of awareness of future promise is provided by the prevalence of multiple drug development projects, running in parallel, which exploit the same chemical pathway. This is true, for example, of cholesterol-lowering statins such as Lipitor, Zocor, and Pravachol, and antidepressant selective serotonin reuptake inhibitors such as Paxil, Prozac, and Zoloft. See Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-on Drug Research and Development: Trends in Entry and the Timing of Development*, 22 PHARMACOECONOMICS (Supp. II) 1 (2004), available at http://www.who.int/intellectualproperty/submissions/Submission_DiMasi.pdf (describing parallel efforts to develop drugs in same therapeutic class, and characterizing these efforts as development race rather than process of post hoc imitation). This will tend to be the case when government or university research reveals the same promising pathway to multiple firms more or less simultaneously.

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efits of innovation increase proportionately with profits, then the ratio between innovation and deadweight loss is unchanged with respect to term length.

If instead, as is frequently presumed, additional profits have a *declining* impact upon the social benefits of incremental innovation, then a longer term entails a lower ratio—that is, less innovation “bang” for the additional deadweight loss “buck.” Such a practice is difficult to justify by reference to Patent Act policy, for the reason introduced in Part III.A. Congress’s selection of a particular patent term length implements a choice about the balance between innovation and acceptable deadweight loss. If Congress had chosen a longer term, it would have implemented a more innovation-protective policy with respect to patentees; but Congress did not do that. A “reasonable effectuation” of the Patent Act’s innovation protectiveness does not require permitting a practice that is less innovation-efficient than, but otherwise identical to, a major innovation-protective term of the Patent Act. Therefore, to the extent that a privately-arranged term lengthening is less innovation-efficient than the current period of exclusivity, it cannot be insulated from antitrust attack by reference to the policies of the Patent Act.²¹⁷

Pay-for-delay settlements resemble an increase in effective term length, but in an important respect they are even less innovation-efficient. In exchange for receiving a reprieve from competition, the patentee must make a sizable payment. This payment reduces its profits and hence the incremental innovation incentive gained by arranging for the extension.²¹⁸ This deficit in innovation efficiency makes the agreements more difficult to justify as a reasonable effectuation of the Patent Act. In short, the Patent Act’s general policy of innovation protectiveness has, at best, a weak claim to insulating pay-for-delay settlements from antitrust attack.

²¹⁷ This argument resembles the strategy employed in Kaplow, *supra* note 9, at 1825–26, in taking a congressional choice with respect to some element of patent policy, comparing it to a practice under consideration, and rejecting the practice if it has a lower ratio than that of a congressional choice. The project here differs from Kaplow’s, in that the ratio-based evaluation of innovation efficiency is made not to determine finally the antitrust treatment of a practice, but merely to see whether the Patent Act provides a basis for altering the ordinary result of antitrust law. Another difference is that in the special case considered here, there is no need to directly observe the ratio implied by the patent term and the ratio of the practice in question. Where policies are otherwise identical, the ratios are directly comparable on a relative basis even without knowing the size of either of them, and the practice can be unambiguously evaluated. A decisive comparison is unavailable, by contrast, where the practice has a *higher* ratio than that implied by the patent term, or is not readily comparable to an element of patent policy.

²¹⁸ The point is general: Gains from a practice that must be shared among, say, cartel members, dampen the dynamic benefit of increased profits.

Moving from the general case of patents to the specific case of pharmaceuticals further weakens the argument for insulation. As already noted, antitrust is *in pari materia* not only with patent law, but with industry-specific regulation as well. Compared to the Patent Act, the Hatch-Waxman Act provides within its domain a more specific and hence more relevant account of the congressionally implemented balance between innovation and competition.

The balance set by the Hatch-Waxman Act is a deliberate effort to promote consumer access through litigated challenges. For most drugs, the Hatch-Waxman Act is less innovation-protective than the Patent Act; as noted previously, the tax on blockbusters is a concession to consumer access at the expense of innovation. For a few drugs, it is actually more innovation-protective, thanks to the innovation subsidy provided by the industry-specific delays. In either case, the ordinary operation of the Act sets a particular balance between innovation and competition. The balance set for a particular drug is disrupted by a settlement favoring somewhat more innovation at the further expense of consumer access.

The disruption to the congressional balance caused by settlement, moreover, is difficult to understand in a way consistent with the Hatch-Waxman scheme. With the Patent Act, a general norm in favor of innovation might at least be relied upon; by contrast, the Hatch-Waxman Act provides a calibrated outcome for different types of drugs. The Patent Act is silent about the role of litigation and the extent to which litigation can be avoided in the interest of preserving profits. In the Hatch-Waxman Act, by contrast, the promotion and delay of litigation are central preoccupations of the regulatory regime. An open-ended permission for innovators to set innovation policy by self-help is less plausible, as Congress has taken explicit steps to fill those gaps. Since litigation is the *instrument* by which the regulatory arrangement accomplishes its ends, it is difficult to argue that an end-run on the instrument is consistent with the scheme. And given that the regime explicitly provides for innovation protection in certain cases—an effective lengthening of the patent term for certain drugs, but a limited one—it is implausible to attribute to that regime a tolerance for an additional, highly innovation-inefficient means to accrue additional profits.

The infringer's argument against antitrust liability is also weaker in the pharmaceutical context, compared to the general case. First, the generic firm lacks an innovator's interest. The generic firms simply make use of the Hatch-Waxman scheme to offer a bio-equivalent drug. Even if a Patent Act policy favoring innovation helps some infringers, it cannot be thought to apply here.

Limiting the generic firm's ability to extract a benefit from unpromising litigation has some effect on an infringer's incentives, though not on its innovation incentives. To be clear, a limitation on settlement does not force the generic firm to see the litigation to completion—it can simply walk away from the suit.²¹⁹ But a limitation on consumer-disregarding settlements does lower the value of the generic firm's abandonment option,²²⁰ an option that matters most when a party develops new information about its prospects during the course of litigation. The difference in reward implies that some marginal challenges will not be brought. There is little reason, however, to think that preserving the full value of this option is necessary to effectuate a Hatch-Waxman Act policy of promoting challenges, not least because the incentive to challenge is already so large.

Second, and again unlike many infringers outside the pharmaceutical context, the generic firm has deliberately stepped, not stumbled, into the infringement controversy. It does not move in uncertain terrain filled with hidden patent dangers; the patents protecting pharmaceutical innovations are open and notorious, compiled in an FDA publication, *Approved Drug Products with Therapeutic Equivalence*, commonly known as the "Orange Book."²²¹ The generic firm volunteers for and seeks out the challenge by filing the Paragraph IV certification, which invites a lawsuit by the innovator.²²² Here, and unusually, Congress has recruited and offered to compensate generic firms to bring patent challenges. Far from being unwilling private attorneys general, generic firms have been deputized, in effect, to act on the public's behalf. The explicit use of litigation to achieve the balance undercuts the preference for settlement sometimes discerned in ordinary patent policy.

In summary, the analysis in this Part reinforces the conclusion from Part II that pay-for-delay settlements are properly accorded a presumption of illegality as unreasonable restraints of trade. It also undermines, in a domain-specific way, the patent policy arguments sometimes thought to justify a patent-based exception to antitrust as a

²¹⁹ It is possible to imagine a more aggressive rule, in which the generic firm is prohibited from abandoning a challenge once initiated; compared to the assumption in the text, this would increase the fraction of challenges that result in early competition, but at the expense of some challenges not being brought. This possibility resembles proposals sometimes made that a price cut, once initiated, must be maintained for a certain period in order to discourage predation.

²²⁰ For an illuminating discussion of abandonment options in litigation, see generally Joseph A. Grundfest & Peter H. Huang, *The Unexpected Value of Litigation: A Real Options Perspective*, 58 STAN. L. REV. 1267 (2006).

²²¹ 21 U.S.C. § 355(j)(7)(A) (2000).

²²² See Hovenkamp et al. 2004, *supra* note 15, at 715–16 (emphasizing this feature).

general matter. Finally, the analysis offers industry-specific support for the proposition that *pharmaceutical* consumers do indeed have an entitlement to the average level of competition implied by litigation, a proposition more difficult to sustain as a general matter.

CONCLUSION

Examining pay-for-delay settlements from the perspective of regulatory design yields two main results. First, the industry-specific bounty renders feasible an allocatively harmful settlement in a surprisingly wide array of circumstances. Because only the first-filing generic firm has potential access to the exclusivity period, an innovator has an especially strong incentive to pay to neutralize that source of potential competition. Because a guaranteed bounty is a valuable source of compensation to a first-filing generic firm, settlements that divide the remaining patent term confer a noncash payment for delay. Allowing an innovator to make multimillion dollar payments up to the amount of saved litigation expense exacerbates the allocative harm.

Second, the Hatch-Waxman Act produces a specific pattern of encouragement to and limitations upon innovative activity. That industry-specific pattern, rather than the arguably innovation-protective policy of the Patent Act, provides the basis for an *in pari materia* analysis with antitrust law. The Hatch-Waxman Act's calibration between innovation and competition is disrupted if firms are free to engage in self-help. The resulting disruption is difficult to square with the policies that animate the Hatch-Waxman Act, particularly in light of the inefficiency of pay-for-delay settlements as a means to provide additional reward to innovators.

Beyond the analysis of pay-for-delay settlements and other competitive practices in the pharmaceutical industry, a careful engagement with regulatory facts and economic theory within a specific industry is a promising method of antitrust analysis. The approach advanced here requires a close look at the economic effects of the regulation and the legislative instrument by which it achieves those effects. The project entails two distinct though related inquiries: an inquiry into industry economics, including the technology of innovation and the dynamics of competition, and an inquiry into the effects of industry-specific regulation.

Such an economically aware and institutionally informed examination is particularly important in industries that are in a process of deregulation. Such industries are an area of renewed interest in antitrust, as exemplified by their inclusion in the work of the commission recently set up by Congress to consider alterations to existing antitrust

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law.²²³ Deregulation enlarges the domain of antitrust, as Herbert Hovenkamp has noted;²²⁴ it does so in part by altering the contours of liability. In some industries, the process of deregulation has occurred in an incomplete fashion, and partial deregulation may give rise to heightened antitrust concern.

Under partial deregulation, the regulatory regime manages the balance between innovation and competition by decentralized mechanisms, rather than by the central command of price regulation. Under full regulation, there may be little role for antitrust, given its redundancy upon a regulator actively managing the antitrust function. Under partial deregulation, however, redundancy is less likely. The use of a decentralized mechanism by Congress risks nullification by unilateral or concerted action by self-interested firms, with allocatively harmful effects. Where the mechanism is not well preserved by the industry-specific regulatory agency, there may be a heightened role for antitrust intervention.

One virtue of an industry-focused approach is the presence of built-in limiting principles. An antitrust decisionmaker can resolve one set of cases without having to reconsider an entire category of conduct. For example, a court can resolve pay-for-delay settlements in the pharmaceutical industry—a set of cases of great theoretical significance and practical importance—without reconsidering the relationship of antitrust and patent generally. Another consequence, of course, is that we therefore lack an answer to broader questions—here, whether consumer-disregarding settlements of patent litigation in other industries are actionable as antitrust violations. But in an area of legal and economic inquiry so complex, and in which we lack even basic information about the facts on the ground in other industries, including the prevalence and structure of such settlements, this limitation is a virtue rather than a vice.

²²³ See Memorandum from Regulated Indus. Study Group, Antitrust Modernization Comm'n to All Comm'rs 1 (May 4, 2005) (available at http://www.amc.gov/pdf/meetings/regulated_industries_study_plan.pdf), which sets three questions for examination about the proper role of antitrust in regulated industries:

- A. How should responsibility for enforcement of antitrust laws in regulated industries be divided between antitrust agencies and the regulatory agencies?
- B. What is the appropriate standard for determining the extent to which the antitrust laws apply to regulated industries where the regulatory structure contains no specific antitrust exemption and/or contains a specific antitrust savings clause?
- C. Should Congress and regulatory agencies set industry-specific standards for particular antitrust violations that may conflict with general standards for the same violations?

²²⁴ HERBERT HOVENKAMP, *THE ANTITRUST ENTERPRISE* 230 (2005) (“As deregulation turns more decision making back to the regulated firms, antitrust takes a more important part.”).

Approaching antitrust through deep investigation of the economic and regulatory structure of a single industry is not an entirely unfamiliar prospect. Economists and lawyers interested in competition policy often do focus upon an industry out of necessity, particularly where the presence of repeat defendants, and the resulting economies of scale, offer a natural basis for specialization; as with Alcoa in an earlier age, so with Microsoft today. But an industry-specific agenda runs counter to trends. The research agenda in antitrust is primarily driven on the one hand by work that cuts across many industries—for example that of industrial economists to understand the effects of a particular practice and efforts by legal scholars to reconcile antitrust and intellectual property law—and on the other hand by lawyers and economists focused on the proper resolution of a specific case.²²⁵

The difficulty of making sense of an enactment's effects heightens the importance of deep industry expertise. The FTC's role in pharmaceutical enforcement is illustrative. About a quarter of the FTC's competition investigations are devoted to pharmaceuticals.²²⁶ The Commission has produced comprehensive reports about industry competition²²⁷ and, more generally, the intersection of patent and antitrust.²²⁸ It has brought enforcement actions challenging a variety of industry practices²²⁹ and explained in other cases why, after consid-

²²⁵ For examples of the latter effort, see generally *THE ANTITRUST REVOLUTION: ECONOMICS, COMPETITION, AND POLICY* (John E. Kwoka, Jr. & Lawrence J. White eds., 4th ed. 2004).

²²⁶ Timothy J. Muris, Chairman, FTC, Remarks Before 7th Annual Competition in Health Care Forum: Everything Old Is New Again: Health Care and Competition in the 21st Century 3 n.13 (Nov. 7, 2002), available at <http://www.ftc.gov/speeches/muris/murishealthcarespeech0211.pdf> (noting that in 2001, twenty-five percent of new investigations involved pharmaceutical products).

²²⁷ See, e.g., *FTC STUDY*, *supra* note 51.

²²⁸ See FTC, Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, <http://www.ftc.gov/opp/intellect>, which collects the results of twenty-four days of hearings in 2002. The results are summarized in *FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>. See also William E. Kovacic & Andreas P. Reindl, *An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy*, 28 *FORDHAM INT'L L.J.* 1062, 1068–69 (2005) (advocating greater investment of resources in IP expertise for competition agencies working on issues at IP-antitrust interface).

²²⁹ In addition to pay-for-delay settlements, the challenged practices have included sham litigation, abusive Orange Book filings, and agreements among generic manufacturers. For a full account of recent FTC enforcement practices, see *HEALTH CARE SERVS. AND PRODS. DIV., BUREAU OF COMPETITION, FTC, OVERVIEW OF FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS* (2006), available at <http://www.ftc.gov/bc/0604rxupdate.pdf>.

eration, it had declined to do so.²³⁰ It sees the full range of cases due to its national enforcement scope and augments its stock of knowledge by combining the analyses of staff economists with information gleaned from civil investigatory demands of market players.²³¹

Such expertise is particularly important in dealing with the panoply of strategies employed by pharmaceutical firms. Apart from the settlement cases, the bulk of such strategies amount to beating competitors rather than joining them. Drug makers have displayed a great deal of ingenuity in preserving the profits from an innovative drug. The strategies include new-but-related drugs,²³² new patents on the same drug,²³³ and new distribution and trademark-backed branding

²³⁰ For example, Lilly, the manufacturer of Prozac, announced its intention to acquire a license from another company for a single-enantiomer version of Prozac (R-fluoxetine), in order to shift customers from regular Prozac, with respect to which generic competition loomed, to the single-enantiomer version. Sheila F. Anthony, Comm'r, FTC, Remarks Before the ABA "Antitrust and Intellectual Property: The Crossroads" Program: Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property (June 1, 2000), available at <http://www.ftc.gov/speeches/anthony/sfip00060.htm>. After an investigation, the FTC allowed the transaction to proceed unchallenged. *Id.* As the Commissioner subsequently explained, any case would have been premised upon a judgment about the relative efficacy of the two drugs, and the FTC declined to second-guess doctors and patients. *Id.*

²³¹ See, e.g., FTC STUDY, *supra* note 51. In addition, the 2003 amendments to the statutory scheme require that industry settlements be filed with the FTC on an ongoing basis, which has provided continuing intelligence about industry practices. See Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461-63 (2003); FTC STUDY UPDATE, *supra* note 70.

²³² A separately patentable alteration to an existing drug is profitable provided that doctors and patients can be convinced to switch over as protection on the old drug ends (due to expiration or successful challenge). The most famous transition is from the anti-heartburn drug Prilosec to Nexium, an enantiomer of Prilosec's active ingredient, omeprazole. See Malcolm Gladwell, *High Prices*, NEW YORKER, Oct. 25, 2004, at 86, 86 (describing transition).

²³³ For example, a firm may assert patents on metabolites (the compound a drug is converted to within the body), intermediates that appear during the production process, or alternative crystalline forms.

An important aspect of this strategy has involved an interaction with the regulatory system. As noted previously, an ANDA-IV must address every patent that is listed by the drug manufacturer in the Orange Book. 21 U.S.C. § 355(j)(7)(A) (2000). Adding additional patents after an ANDA-IV challenge has begun formerly obligated a generic challenger to amend its certification, which triggered further infringement challenges, which, in turn, was understood to trigger additional and later 30-month stays. The FTC criticized the practice in its study of generic competition, and 2003 legislation put an end to the practice of multiple stays. The filing of multiple stays by Bristol-Myers with respect to BuSpar was one of several activities that led to the consent decree discussed in note 72 *supra*. With respect to another drug, Paxil, indirect and direct purchaser class action suits resulted in settlements of \$65 million and \$100 million, respectively. See *Nichols v. SmithKline Beecham Corp.*, No. Civ. A. 00-6222, 2005 WL 950616, at *1, *26-27 (E.D. Pa. Apr. 22, 2005) (indirect); *Stop & Shop Supermarket Co. v. SmithKline Beecham Corp.*, No. Civ. A. 03-4578, 2005 WL 1213926, at *1 (E.D. Pa. May 19, 2005) (direct).

strategies. As one strategy is curtailed, others are introduced.²³⁴ Some of the strategies are very difficult to justify by reference to a plausible consumer benefit. That is not to say that such techniques are all illegal or even troubling—new drugs and price-lowering distribution strategies, for example, potentially provide considerable consumer benefit. But the proliferation of such strategies does give rise to a bewildering array of choices for antitrust enforcers.²³⁵

An important test of that expertise comes in the current debate over “authorized generics.” The basic idea is that an innovator, faced with competition from a first-filing generic firm, recruits an additional generic firm to sell an unbranded version of the drug under the innovator’s own license. The presence of an additional generic competitor, selling during and after the bounty period, lowers prices in the generic segment of the market.²³⁶ Consumers benefit in the short run from lower prices, and the innovator enjoys incremental profits from the additional revenue stream; only the independent generic firm loses out. Over the last several years, an authorized generic product has become a familiar accompaniment to a pre-expiration launch by a generic firm.²³⁷

²³⁴ Such a “hydraulic” process is familiar from other areas of law. See Samuel Issacharoff & Pamela S. Karlan, *The Hydraulics of Campaign Finance Reform*, 77 TEX. L. REV. 1705 (1999) (describing how efforts to constrain political actors redirect, but do not eliminate, their activities); Tim Wu, *When Code Isn’t Law*, 89 VA. L. REV. 679, 726–45 (2003) (describing responses to efforts to curtail file sharing).

²³⁵ One FTC Commissioner has colorfully analogized the FTC’s task to a game of Whack-a-Mole. Jon Leibowitz, Comm’r, FTC, Remarks Before the Antitrust in Health Care Conference: Health Care and the FTC: The Agency as Prosecutor and Policy Wonk 9 (May 15, 2005), available at <http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf> [hereinafter Health Care and the FTC].

²³⁶ This effect on the generic segment of the market is typically a fifty percent discount on the innovator’s price, compared to the thirty percent discount with just one generic firm. See QUANTIFYING THE IMPACT, *supra* note 116, at 4.

²³⁷ See, e.g., Leila Abboud, *Drug Makers Use New Tactic to Ding Generics*, WALL ST. J., Jan. 27, 2004, at B1. A fighting-brand pharmaceutical is not a complete novelty. In the 1990s, innovator firms engaged in a certain amount of own-brand generic sales. Then, too, the activity raised antitrust concern. See Morton I. Kamien & Israel Zang, *Virtual Patent Extension by Cannibalization*, 66 S. ECON. J. 117 (1999); Catherine Yang, *The Drugmakers vs. the Trustbusters*, BUS. WEEK, Sept. 5, 1994, at 67. In the late 1990s the innovators for the most part exited the generics business, as they discovered that selling generic drugs was not their forte, and as they improved in their ability to shift customers from one product to its successor. See Milt Freudenheim, *Prescription Drug Makers Reconsider Generics*, N.Y. TIMES, Sept. 11, 1997, at D1. The resurgence of authorized generics may be attributable to three features: the patent expiration of a large number of blockbuster drugs, which creates an unusually large opportunity for generic competition; an increase in the number of exclusivity periods granted, particularly as evergreening strategies involving later-added, weak patents are successfully challenged by generic firms; and the increased penetration of generic entry, which creates a sizable profit opportunity for the innovator, provided that the additional entry does not affect pricing and volume too much in the branded segment of the market.

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Generic drug makers complain that the use of authorized generics, in reducing the benefits of the 180-day exclusivity period, is contrary to the purpose of, and hence violates, the Hatch-Waxman Act.²³⁸ This argument has failed on a textual reading of the Act, which merely excludes subsequent ANDA filers.²³⁹ Generic firms have also argued that the use of authorized generics violates antitrust law by reducing generic profits to such an extent that a challenge is not worth pursuing, thus deterring generic entry. At least one court²⁴⁰ and one FTC commissioner²⁴¹ have entertained the possibility of an antitrust claim.

The underlying antitrust concern is that the practice, though beneficial in its short-run allocative effect, will discourage future entry, ultimately leading to higher prices.²⁴² Acting to deter a rival's procompetitive actions is a general strategy analogous to, for example, the price-matching policies of large retail stores.²⁴³ The structure of at least some authorized generic licenses provides for withdrawal should independent generic entry cease.²⁴⁴ The authorized generic mechanism also has a unique feature that potentially enhances its deterrence. If the innovator licenses an outside firm, its contract is an observable commitment to entry, which may provide a source of credibility. Such an ability to precommit might make seeing through the threat unnecessary in practice—though the direct profitability of the additional distribution mechanism may, aside from lessening the antitrust concern, make precommitment unnecessary.

²³⁸ See, e.g., *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52–53 (D.C. Cir. 2005) (describing challenge to authorized generic for Neurontin); *Mylan Pharm., Inc. v. FDA*, No. Civ. A. 104CV242, 2005 WL 2411674, at *1 (N.D. W. Va. Sept. 29, 2005) (describing challenge to authorized generic for Macrobid); *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 989 (N.D. Ill. 2003) (describing challenge to authorized generic for Paxil).

²³⁹ See *Teva*, 410 F.3d at 53–55.

²⁴⁰ See Vicki Smith, *Mylan to Press Drug Complaint—Pharmaceutical Company Targets “Authorized Generics,”* SAN JOSE MERCURY NEWS, Aug. 31, 2004, at 2C (reporting District Judge Irene Keeley's view, expressed during oral argument, that Procter & Gamble's use of authorized generic for Macrobid raises significant antitrust issue).

²⁴¹ See Health Care and the FTC, *supra* note 235, at 9–10.

²⁴² For discussions of the impact of authorized generics, see generally David Reiffen & Michael R. Ward, “Branded Generics” as a Strategy to Limit Cannibalization of Pharmaceutical Markets (Univ. of Tex. Dep't of Econ., Working Paper No. 05-004, 2005) and Ying Kong & James R. Seldon, *Pseudo-Generic Products and Barriers to Entry in Pharmaceutical Markets*, 25 REV. INDUS. ORG. 71 (2004).

²⁴³ See generally Aaron S. Edlin, *Do Guaranteed-Low-Price Policies Guarantee High Prices, and Can Antitrust Rise to the Challenge?*, 111 HARV. L. REV. 528 (1997) (discussing anticompetitive effects of price-matching policies).

²⁴⁴ See, e.g., *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 989 (N.D. Ill. 2003) (describing authorized generic license, whereby authorized generic must leave U.S. market if independent generic exits).

Unless authorized generics actually deter entry in practice, or—an important complication—slow the filing of ANDA-IVs or lessen the vigor of their pursuit, there is no basis for antitrust concern. Anecdotal evidence suggests that authorized generics have little practical effect on generic entry,²⁴⁵ but substantial empirical work is needed to resolve the issue decisively. The necessary data about filings is out of reach, some of it confidentially lodged with the FDA²⁴⁶ or scattered among the firms themselves. The FTC is uniquely positioned, due to its expertise and power, to collect and assess the relevant information, and it has indeed begun to do so.²⁴⁷

The underlying impulse to tailor innovation policy by industry resembles the parallel project by patent scholars to understand patent law in an industry-specific fashion.²⁴⁸ In both contexts, the perspective implies that a holding reached within a particular industry's factual setting is unlikely to have ready applicability to other industries. One important difference between the projects, however, is that the industry-specific approach in patent law operates primarily through judicial interpretation; it must necessarily do so, given the single statutory scheme that governs patent doctrine across most industries.

The approach here, by contrast, places more emphasis upon Congress and expert agencies. Congressional enactments govern the balance between innovation and competition, modulating the vigor of antitrust enforcement in an industry-specific fashion. The effect is to place the overall thrust of innovation policy more firmly in the hands of the legislative branch, perhaps quieting congressional complaints of “judicial circumvention” in other areas of competition policy.²⁴⁹ The competition regulator, meanwhile, plays an important role in decoding the meaning of a legislative enactment as it bears upon

²⁴⁵ For example, Apotex earned a large profit in its challenge to Paxil despite competition from an authorized generic. According to Apotex's own figures, its profits were reduced from the \$530-to-\$575 million range to the \$150-to-\$200 million range because of the authorized generic entry. See Comment of Apotex Corp., *supra* note 110, at 4.

²⁴⁶ The identity of an ANDA filer, for example, is confidential.

²⁴⁷ Press Release, FTC, FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs (Mar. 29, 2006), available at <http://www.ftc.gov/opa/2006/03/authgenerics.htm>.

²⁴⁸ See, e.g., Burk & Lemley, *supra* note 33, at 1576–80. But see R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341 (2003) (providing critique of Burk and Lemley approach).

²⁴⁹ See, e.g., Press Release, U.S. House of Representatives Comm. on the Judiciary, Sensenbrenner and Conyers Introduce Legislation to Strengthen Competition in Telecom Marketplace: Legislation Will Reduce Telecom Prices and Expand Choices for Consumers (May 20, 2004), available at <http://judiciary.house.gov/newscenter.aspx?A=309> (quoting House Judiciary Committee Chairman F. James Sensenbrenner, who described *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004), as act of “judicial circumvention” and proposed its legislative overrule).

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industry economics and antitrust law. That role is particularly important where, as in pharmaceuticals and other industries, courts need help in recognizing and tailoring antitrust analysis to the “distinctive economic and legal setting”²⁵⁰ of a regulated industry.

²⁵⁰ *Trunko*, 540 U.S. at 411–12 (quoting *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (citation and internal quotation marks omitted)).

Mr. RUSH. The chair thanks the gentleman. Now, the chair recognizes Ms. Joanne Handy for 5 minutes for the purposes of an opening statement.

STATEMENT OF JOANNE HANDY

Ms. HANDY. Mr. Chairman, members of the subcommittee, I am, as you know, Joanne Handy, a member of the AARP board, also a nurse and a health care provider. On behalf of our more than 40 million members, thank you for the chance to testify about H.R. 1706. AARP has endorsed this legislation, and we call on Congress to enact this legislation this year.

Older Americans, as has been referred to several times by members of the subcommittee, use prescription drugs more than any other segment of the U.S. population. Unfortunately the cost for brand name drug products continue to rise at rates that far exceed inflation, causing a strain on the budgets of both consumers and other health care payers, including the government.

Spiraling drug costs are particularly for older adults who are disproportionately affected by chronic disease and more likely to need multiple medications. When faced with higher drug costs, they frequently skip doses, reduce doses, and let prescriptions go unfilled. The result is preventable and expensive hospitalizations and adverse health outcomes.

This occurs far less often for those taking generic drugs, which have proven to be one of the safest and most effective ways for consumers to lower their prescription drug costs. AARP encourages its members to use generic drugs whenever possible. AARP strongly supports efforts that provide timely market entry of generic drugs. We are concerned, however, about the recent trends in reverse payments, which occurs when generic manufacturers receive anything of value in exchange for agreeing not to research, develop, manufacture, or sell its generic products.

These reverse payments delay market entry of new generic drugs, and thus increase the odds that older Americans will be forced to cut back or go without needed medicines because of the rising cost. AARP believes that H.R. 1706 is an appropriate remedy to end the problem of reverse payments. This legislation is needed because when brand and generic pharmaceutical companies engage in conduct that delays market entry of generic drugs, consumers and other health care payers pay higher prices. And as a result, older Americans are more likely to go without the drugs they need because of the higher costs.

Stopping or delaying market entry of the first generic drug prevents all the other generic drugs from competing and ultimately extends the brand name manufacturer's market exclusivity. This creates a powerful incentive for companies to negotiate, to collude with the first to file generic manufacturer to delay market entry of the generic product.

Legislation is necessary because, as you have heard, there have been recent court decisions that have held that reverse payment agreements do not violate the antitrust laws. These decisions have unquestionably lead to an increase of such agreements and hampered the Federal Trade Commission's ability to prevent these abuses.

In fact, the FTC has reported a marked increase in the number of questionable settlements. 50 percent of the 2006 settlement agreements between brand and generic manufacturers included some form of payment as well as an agreement to delay market entry. Ending these costly patient abuses is one essential component in our efforts to reduce skyrocketing brand name drugs prices and provide affordable comprehensive health care options to all Americans.

Again AARP strongly supports H.R. 1706. We are pleased to see the committee and members from both houses of Congress and both sides of the aisle moving forward on this issue. Thank you for inviting us to be here.

[The prepared statement of Ms. Handy follows:]



**TESTIMONY BEFORE THE
SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER
PROTECTION OF THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE**

**HEARING ON
THE PROTECTING CONSUMER ACCESS TO GENERIC DRUGS
ACT OF 2009**

MARCH 31, 2009

WASHINGTON, D. C.

**WITNESS: JOANNE HANDY
AARP BOARD MEMBER**

**For further information, contact:
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Mr. Chairman and Members of the Committee, I am Joanne Handy, a member of AARP's Board of Directors. On behalf of our more than 40 million members, thank you for the opportunity to testify today in support the "Protecting Consumer Access to Generic Drugs Act of 2009" (HR 1706). This legislation seeks to prevent patent settlements in which the generic pharmaceutical manufacturer receives anything of value in exchange for agreeing not to research, develop, manufacture, market, or sell its product (what some refer to as "reverse payments" or "exclusion payments").

Generic Drugs Provide and Affordable Prescription Drug Alternative

Older Americans use prescription drugs more than any other segment of the U.S. population. Unfortunately, costs for branded drug products continue to rise at rates that far exceed inflation, causing a strain on the budgets of consumers and other health care payers.

A recent AARP Public Policy Institute study revealed that, on average, pharmaceutical manufacturer prices for the 220 brand name drugs most widely used by Medicare beneficiaries have increased substantially higher since the implementation of Medicare Part D. In 2007, the average rate of increase in manufacturer prices for these widely used brand name drugs was more than two and one-half times the rate of general inflation.¹ For the 169 brand name drugs that have been on the market since 2002, this translates into a cumulative average price increase of 50.4 percent, over two and one-half times the general inflation rate of 19.0 percent over the same period.²

¹ David J. Gross, Stephen W. Schondelmeyer, and Leigh Purvis, Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries, 2002 to 2007, AARP Public Policy Institute Research Report #2008-05 (Washington, DC: AARP), March 2008.

² Id.

In contrast, generic prescription drugs are approximately one-third the cost of brand name prescription drugs³ and, importantly, prices on generic drugs are not rising nearly as quickly as their brand name counterparts. A recent AARP Public Policy Institute study revealed that, on average, manufacturer list prices for the 185 generic prescription drugs most widely used by Medicare beneficiaries have decreased between 2003 and 2007. In 2007, the average annual rate of change in manufacturer prices fell by 9.6 percent, compared to a general inflation rate of 2.9 percent.⁴

Generic drugs have proven to be one of the safest and most effective ways for consumers to lower their prescription drug costs. We encourage our members to use generic drugs whenever possible and their use is steadily increasing. In 1984, generic drugs accounted for 18.6 percent of all retail prescription drugs dispensed in the United States.⁵ Now, generic prescription drugs account for two-thirds of all prescriptions dispensed in the United States⁶ and 64 percent of prescriptions in the Medicare prescription drug benefit program.⁷

Spiraling drug costs are especially hard for older adults, who are disproportionately affected by chronic disease⁸ and more likely to need a chronic medication.⁹ When faced with higher drug costs they often skip doses, reduce

³ National Association of Chain Drug Stores, "Industry Facts-at-a-Glance," 2007. Available online at <http://www.nacds.org/wmspage.cfm?parm1=507>.

⁴ David J. Gross, Stephen W. Schondelmeyer, and Leigh Purvis, Rx Watchdog Report: Trends in Manufacturer Prices of Generic Prescription Drugs Used by Medicare Beneficiaries, 2003 to 2007, AARP Public Policy Institute Research Report #2008-08 (Washington, DC: AARP), May 2008.

⁵ Generic Drugs Research Report, AARP Public Policy Institute, publication IB61, May 2003.

⁶ Generic Pharmaceutical Association, "Industry Statistics," 2008. Available at www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm.

⁷ U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "October 30, 2008 Part D Symposium Fact Sheet," 2008.

⁸ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Healthy Aging: Preserving Function and Improving Quality of Life Among Older Americans," 2008, January 2008.

⁹ C. M. Roe, A. M. McNamara, and B. R. Motheral, "Use of Chronic Medications among a Large, Commercially-Insured U.S. Population," *Pharmacoepidemiology and Drug Safety* 11, no. 4: 301-309.

doses, and let prescriptions go unfilled.¹⁰ The result is preventable and expensive hospitalizations and adverse health outcomes.¹¹

This occurs far less often for those taking generics. Research has found that people whose initial prescription for a certain therapy was filled with a generic medicine had a 62 percent greater chance of staying on that medicine, and those whose initial prescription was for a preferred brand-name medicine had a 30 percent greater chance of staying on that medicine, versus someone whose initial prescription was for a non-preferred brand-name medicine.¹²

Reverse Payments Harm Consumers

Reverse payments delay market entry of new generics drugs, and thus increase the odds that older Americans will be forced to cut back on or go without needed medicines because of rising cost.

The Protecting Consumer Access to Generic Drugs Act of 2009 is an appropriate remedy to end the problem of reverse payments. First, the legislation would prohibit a patent infringement settlement in which the generic manufacturer receives anything of value in exchange for agreeing not to research, develop, manufacture, market, or sell the product that is the subject of the patent litigation.

¹⁰ J. M. Madden et al., "Cost-Related Medication Nonadherence and Spending on Basic Needs Following Implementation of Medicare Part D," *Journal of the American Medical Association* 299, no. 26: 1922–1928.

¹¹ H. Kohl and W. H. Shrank, "Increasing Generic Usage in Medicare Part D: The Role of Government," *Journal of the American Geriatric Society* 55: 1106–1109.

¹² W. H. Shrank, T. Hoang, S. L. Ettner, P. A. Glassman, K. Nair, D. DeLapp, J. Dirstine, J. Avorn, and S. M. Asch, "The Implications of Choice: Prescribing Generic or Preferred Pharmaceuticals Improves Medication Adherence for Chronic Conditions," *Archives of Internal Medicine* 166, no. 3: 332–337.

The legislation provides two common sense safe-harbors:

- (1) instances where the only value received by the generic manufacturer is the right to market the drug in question prior to the expiration of the patent; and
- (2) instances where the waiver of a patent infringement claim for damages is based on prior marketing of the drug.

In addition, the legislation grants the Federal Trade Commission (“FTC”) reasonable authority to establish additional safe-harbors if the FTC finds them “to be in furtherance of market competition and for the benefit of consumers.” The legislation also provides that if the generic and name brand manufacturer delay or prohibit competition through reverse payment settlements, the generic manufacturers forfeit the standard 180-day marketing exclusivity period.

These changes in law are sorely needed because when brand and generic pharmaceutical companies engage in conduct that delays market entry of generic drugs, consumers and other health care payers pay higher prices and older Americans are more likely to go without the drugs they need because of cost.

Under current law, the first manufacturer of a generic version of a brand name drug to establish that its drug does not infringe on an existing patent is granted a 180-day period of market exclusivity. After the 180-day period lapses, other generic makers may seek FDA approval to sell their generic versions of the brand name drug, thereby resulting in greater competition and lower drug costs.

Stopping or delaying market entry of the first generic drug thus prevents all other generic drugs from competing, thus extending the brand name manufacturer’s market exclusivity. This creates a powerful incentive for branded companies to collude with the first-to-file generic manufacturer to delay market entry of the generic product.

Supporters of reverse payments contend they are necessary to avoid the cost of patent litigation and that to prohibit such payments would chill patent settlements. However, while we recognize that patent litigation can be lengthy and expensive to the parties involved, this cost is dwarfed by the potential savings of timely access to generic drugs for consumers.

Reverse Payments are Counter to Congressional Intent

The Hatch-Waxman Act provides a means for the approval of generic drugs that has greatly increased approval of generics. Although generic drug entry has increased since the Act's passage, its purpose to enable lower cost generic drugs to reach consumers has not been fully realized. Provisions in the law intended to let brand manufacturers – through patent infringement suits – challenge a generic manufacturer's entry into the market have led to reverse payments, which negatively and unfairly impact consumers.

Since the passage of Hatch-Waxman, there have been several well documented instances in which brand manufacturers blocked generic competition by circumventing the Act. Senator Hatch, one of the original co-authors of the Hatch-Waxman Act, has stated that "I find these types of reverse payment collusive agreements appalling. ... We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs"¹³

In 2003, Congress attempted to prevent such evasions of Hatch-Waxman by providing in the Medicare Modernization Act that the Federal Trade Commission ("FTC") be notified of any patent case settlements involving prescription drugs.¹⁴ Unfortunately, the MMA provision did not end reverse payment settlements.

¹³ 148 Cong. Rec. S7566 (daily ed. July 20, 2002) (statement of Sen. Hatch).

¹⁴ Medicare Modernization Act, Pub; L. No. 108-173, 117 Stat. 2006.

Litigation Avenues to Address Reverse Payments Have Stalled

Recent court decisions holding that reverse payment agreements do not violate antitrust laws unquestionably have led to an increase of such agreements and hampered the FTC's ability to prevent these abuses. In one case, for example, the FTC found that Schering-Plough, the brand manufacturer of K-Dur, a potassium supplement commonly used to treat heart conditions, violated antitrust laws when it settled litigation with two generic drug manufacturers, Upsher-Smith Laboratories and American Home Products Corp. ("AHP").

Under the challenged agreement, the generic manufacturers agreed to delay market entry of their products in exchange for cash payments of \$60 million to Upsher and \$15 million to AHP. Schering-Plough appealed the FTC's Order to the Eleventh Circuit, which had just decided another antitrust drug case permitting such settlements, and overruled the FTC decision. The FTC appealed to the Supreme Court; but the Supreme Court declined review of the case, thus ending further avenues for litigation.

In a subsequent case challenging a settlement between the brand and generic makers of tamoxifen, a drug used in the treatment of breast cancer, the Second Circuit held that the challenged agreement was beyond the reach of antitrust laws. The court found that an agreement between a patent holder and an alleged infringer to settle Hatch-Waxman patent litigation would not violate antitrust laws unless, among other things, the patent litigation was a fraud, sham or otherwise baseless.¹⁵ Even though that standard is nearly impossible to meet, the Supreme Court declined to review the Tamoxifen case as well.

¹⁵ In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208-09 (2d Cir. 2006), cert. denied sub nom. Joblove v. Barr Labs., Inc., ___ U.S. ___, 127 S. Ct. 3001 (2007).

At present, U.S. Courts of Appeals for the Federal, Second and Eleventh Circuits have rejected antitrust claims challenging reverse payment settlements finding that reverse payment agreements are beyond the reach of antitrust scrutiny – in other words, patent protection trumps Hatch Waxman.¹⁶ The FTC has thus been hampered in its efforts to protect consumers from higher drug prices.

Since the Schering-Plough and Tamoxifen cases, the FTC is reporting a marked increase in the number of questionable settlements; fifty percent of the 2006 settlement agreements between brand and generic manufacturers included some form of payment as well as an agreement to delay generic market entry.¹⁷ With respect to first-filers (e.g., those who enjoy the 180-day period of exclusivity designed to entice non-infringing generics to come to market as soon as possible) 9 out of 11 of the settlements involved a payment by the brand company to the generic manufacturer and a restriction to market entry.

Health Care Reform

Ending these costly patent abuses is essential as we undertake comprehensive health reform efforts to provide all Americans with affordable health care options. AARP is committed to enacting comprehensive health care reform this year because the current health care system costs too much, wastes too much, makes too many mistakes, and provides too little value for far too many consumers. Health care reform will require a series of delivery system reforms – including legislation to prevent market abuses, such as reverse payment, which simply add extra costs to our health care. Health care consumers, and the

¹⁶ In Re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2d Cir. 2006), cert. denied sub nom. Joblove v. Barr Labs., Inc., ___ U.S. ___, 127 S. Ct. 3001 (2007); FTC v. Schering Plough Corp., 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S.Ct. 2929 (2006); Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1312 (11th Cir. 2003); In Re: Ciprofloxacin Hydrochloride Antitrust Litigation, No. 08-1097 (Fed. Cir. Oct. 18, 2008). In contrast, the Sixth Circuit held that such agreements are per se illegal. In Re CardizemCD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).

¹⁷ Prepared Statement of the Federal Trade Commission Before the Subcommittee on Commerce, Trade, and Consumer Protection Committee on Energy and Commerce, on Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to the Anticompetitive Patent Settlements in the Pharmaceutical Industry, May 2, 2007, at 3.

nation, simply can no longer afford these added costs, and we are pleased that the Administration's recent budget document supports efforts to prevent reverse payments.¹⁸ Additional steps to promote and encourage timely access to generic drugs are also necessary to contain costs without compromising quality as we undertake comprehensive health reform.

Since 2006, Medicare Part D has helped millions of older Americans afford medication vital to their health. Unfortunately, because critical legislation to lower drug prices has not been enacted, millions of Americans are struggling to afford their medication. Nearly 20 percent of Medicare beneficiaries under Part D delayed or did not fill a prescription because of costs – higher than any other insured group. For the 3.4 million Americans who fall into the “donut hole”, soaring drug prices – especially when their retirement income is shrinking – are putting their health and economic security at risk. AARP believes we must take concrete steps to close the donut hole by lowering drug prices for all Americans, such as through greater use of generics, drug price negotiation, and importation. Prescription drugs are a vital component to improving the health and quality of life for all Americans.

AARP is supporting the Promoting Innovation and Access to Life-Saving Medicine Act, HR 1427. This legislation would create a much-needed pathway for the FDA approval of comparable and generic biologic drugs. We urge Congress to enact this legislation as quickly as possible. We are concerned, however, that unless Congress also prohibits reverse payments, consumers and other health care payers will be denied savings from comparable and generic biologic products, just as currently exists in the traditional prescription drug market.

¹⁸ White House Office of Management and Budget, A New Era of Responsibility: Renewing America's Promise, (Feb. 26, 2009), at 28, available at http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf.

Conclusion

AARP strongly supports the Protecting Consumer Access to Generic Drugs Act of 2009. Our members, and all Americans, need Congress to enact this cost saving legislation this year. We are pleased to see the Subcommittee and Members of Congress from both sides of the aisle and both Houses of Congress moving forward on this issue.

Mr. RUSH. Thank you. Now, the chair recognizes Ms. Diane Bieri who is the general counsel for PhRMA for 5 minutes for the purposes of opening statement. Welcome.

STATEMENT OF DIANE BIERI

Ms. BIERI. Thank you. Chairman Rush, Congressman Stearns, and members of the subcommittee, thank you for the invitation to participate in today's hearing on legislation that could have a significant impact on pharmaceutical company settlements of patent disputes. My name is Diane Bieri, and I am the executive vice president and general counsel of PhRMA.

In 2008 alone, PhRMA members including both large and small biotech and pharmaceutical companies invested more than \$50 billion in discovering and developing new medicines. What is more, roughly 70 percent of this research was made right here in the United States, representing a significant number of American jobs and other contributions to the economy.

In the past 10 years, over 300 new medicines have made it through the increasingly complex FDA review process and into the hands of physicians and patients. These new medicines are increasing life expectancy, decreasing disability, and providing hope to patients and their loved ones who are fighting life-threatening and debilitating diseases such as cancer, cardiovascular disease, diabetes, rheumatoid arthritis, and many others.

America's biopharmaceutical companies are facing more challenges than ever in terms of bringing new medicines to market. It takes on average 10 to 15 years and more than \$1 billion to bring one new medicine to patients. That is why research-based companies and their investors need to be confident that the law will respect and uphold the critical role of intellectual property, including patents, in providing the opportunity to recoup these substantial investments.

Patent protection is the engine that allows America's research-based biopharmaceutical companies to take risks and strive to develop the next generation of life-saving and life-enhancing treatments.

Of course, it is important to remember that pharmaceutical products effectively have a shorter period of patent life than other types of products. Pharmaceutical companies must obtain FDA approval before marketing their products, and much of the patent term is spent before the medicine actually comes to market. Recognizing these challenges, the Hatch-Waxman Act of 1984 attempted to balance the interests of both innovative and generic companies.

The law made it easier for generics to come to market but also restored to innovators some of the patent time lost during the clinical research and regulatory review process. But even after Hatch-Waxman, the useful patent life of a pharmaceutical product is limited. For example, one study showed that for medicine whose generic competitors entered the market between 2002 and 2005, the average time on the market before generic competition was only 11.2 years.

In addition, you have to look at the tremendous increase in competition between brand medicines, but particularly between brand medicines and generics. Since passage of Hatch-Waxman, the generic industry share of the prescription drug market has jumped from less than 20 percent to over 71 percent today. This is, of course, due in part to the fact that Hatch-Waxman has spawned more patent challenges as it was meant to do.

Hatch-Waxman gives generic companies incentives to challenge patents as soon as four years after the brand medicine receives FDA approval, without requiring the generic to take the risk of actually marketing the product before the patent challenge is resolved.

Given this construct, patent challenges have become commonplace, but patent litigation is still lengthy, expensive, and risky for all concerned. Generic companies do not have perfect information when they bring challenges, and brand companies cannot be sure their view of the strength of their patents will carry the day at trial.

The rapid expansion in generic utilization has been fueled, in part, by the fact that innovators and generics have had the flexibility to resolve some of these patent suits in fair and appropriate ways without taking every case the whole way through trial and appeal.

There is no doubt that H.R. 1706 would significantly reduce that flexibility. Courts and experts tell us that patents settlements between brand and generic companies, even those that include some payment from the brand to the generic, can benefit consumers. Yet H.R. 1706 would prohibit a wide variety of patent settlements just because the brand company transfers something of value to the generic.

This kind of broad ban would chill all patent settlements and is likely to reduce innovation and also reduce the number of patent challenges filed. Broad limits on options for patent settlements would force both sides to spend valuable resources litigating rather than developing new medicines or bringing generic versions to market. Statistics from recent years show that innovators are likely to win over 50 percent of the cases litigated through appeal, which means that generic entry in those cases could not come until the patent expires.

In contrast, a settlement might include provisions allowing a generic product to come to market well before the patent expires and could produce other collateral benefits such as licenses for generics to market products unrelated to the patent dispute. Instead of a blanket rule banning certain types of patent settlements, enforcement agencies and courts should continue to evaluate settlements on a case-by-case basis to determine whether on the whole they benefit consumers.

The Medicare Drug Improvement and Modernization Act of 2003 enhanced the FTC and Department of Justice's ability to make those determinations. The approach preserves the delicate balance between intellectual property protection that fosters innovation and competition principles that encourage access to generic medicines and a strong healthy generic industry.

I look forward to answering any questions you may have, and PhRMA looks forward to working with you on this legislation. Thank you again for your attention to these important policy issues.

[The prepared statement of Ms. Bieri follows:]

Prepared Statement of Diane E. Bieri
Executive Vice President and General Counsel
Pharmaceutical Research and Manufacturers of America

Hearing on H.R. 1706, the *Protecting Consumer Access to
Generic Drugs Act of 2009*

Before the U.S. House of Representatives Subcommittee on Commerce, Trade
and Consumer Protection, of the Committee on Energy and Commerce

March 31, 2009

Chairman Rush, Ranking Member Radanovich, and Members of the Subcommittee:

Good morning. My name is Diane Bieri and I am the Executive Vice President and General Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA's member companies are leading research-based pharmaceutical and biotechnology companies that are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2008, PhRMA's member companies invested an estimated \$50.3 billion in research and development – an increase of over \$2 billion from 2007 – and were developing or seeking regulatory approval for 2,900 molecules that might eventually be used to treat U.S. patients. PhRMA companies are leading the way in the search for new and better treatments for patients. PhRMA appreciates the invitation to participate in today's hearing on H.R. 1706 and biopharmaceutical companies' settlements of patent disputes.

The biopharmaceutical companies that constitute PhRMA's membership range in size from small start-up research firms to multi-national, multi-billion dollar corporations, and encompass both research-based pharmaceutical and biotechnology companies. Regardless of their size, these companies face significant challenges relating to the discovery, development, testing, production, and commercialization of new medical treatments. Yet, data show that the drive for innovation remains strong, and the sector's R&D focus provides considerable value to the U.S. economy. At a time when many industries are seeking help just to stay afloat, pharmaceutical research companies are expending the vast majority of their R&D investment within America. In fact, PhRMA member companies dedicated roughly 70 percent of their \$50.3 billion R&D investment domestically last year.

In order to continue to foster this economic growth and the much-needed medical breakthroughs that will save lives and lower overall health care costs, we must continue to pursue public policies that promote innovation, and that requires the protection of legitimate patent rights. Patents allow biopharmaceutical companies and their investors an opportunity to recoup and secure the benefits of their significant investments. Two years ago, PhRMA President and CEO – and cancer survivor – Billy Tauzin submitted testimony to this Subcommittee about the critical role of patents in stimulating pharmaceutical innovation and the importance of preserving options to reach pro-consumer settlements of expensive and time-consuming patent litigation among brand and generic pharmaceutical companies. These points still hold true today, and PhRMA remains confident that a case-by-case approach to analyzing patent settlements serves the best interests of patients, health care, and competition.

Courts and experts have stated unequivocally and in increasing numbers that settlement of litigation – including patent litigation – should be encouraged and

can benefit consumers. Blanket prohibitions on certain types of settlements could force both sides to spend valuable resources that could be used for investing in innovation or bringing generics to market rather than litigating their patent disputes to judgment. Statistics show that innovators will win a significant number of those cases. In fact, innovator companies have prevailed in approximately 53 percent of the cases in which appeals were decided between 2004 and 2008. And a win by the patent holder means the generic almost certainly would not be able to enter the market before the patent expires unless it obtained permission from the patent holder. In addition, both innovator and generic companies would have to absorb – or pass on to consumers – the costs of increased litigation. In the face of these alternatives, it is better for companies, the courts and consumers if the parties are permitted to negotiate settlements that could bring the generic product to consumers before the patent expires and save considerable litigation costs.

H.R. 1706 envisions a per se ban on nearly all settlements in which the brand company gives something of value to the generic. This could stop pro-consumer settlements, reduce the value of patents, and reduce incentives for innovation. The sweeping prohibition could also have the unintended consequence of reducing generic companies' incentives to challenge patents in the first place, as they will have to consider that their options of settling patent litigation will be dramatically reduced.

Instead of an across-the-board ban, enforcement agencies and courts should continue to evaluate patent settlements on a case-by-case basis, looking at all relevant facts including the scope of the patent. In the Medicare Prescription Drug, Improvement, and Modernization Act, Congress expanded the ability of the Federal Trade Commission and the Department of Justice to evaluate patent settlement agreements between brand and generic companies before the generic is due to come on the market. This approach gives the agencies and courts the chance to consider all the relevant facts and circumstances and address settlements that would harm consumers without eliminating those that will promote competition.

I. Patents Are Essential To Pharmaceutical Innovation

Intellectual property protection has deep roots in the United States, all the way back to the protection authorized by Article I of the U.S. Constitution. Patents are crucial because they make it possible for society to realize the benefits of genius, creativity and effort. Since our patent system was created in 1790, it has been key to critical advances in science and technology. Of all of the advances in the last century, from aviation to the Internet, few have been as important and valuable to the preservation and enhancement of life as pharmaceutical innovations. According to University of Chicago economists, "Over the last half century, improvements in health have been as valuable as all other sources of

economic growth combined."¹ New medicines have contributed to significant breakthroughs in the treatment of diseases such as cancer, HIV/AIDS and cardiovascular disease that formerly led often to death or significant disability.²

Innovators across industries rely on patents to ensure that their inventions are protected and that they will be given an opportunity to recover their research investments. For reasons explained in more detail below, patents are particularly important to the biopharmaceutical industry as compared to other industries. According to one commentator, without patent protection, an estimated 65 percent of pharmaceutical products would not have been brought to market, while the average across all other industries was 8 percent.³ Indeed, it is well-established that patents are significantly more important to pharmaceutical firms than for firms in other sectors in part due to the very high costs of development.⁴

Today, the United States is the clear global leader in biopharmaceutical investment, jobs, and product development, offering opportunities for high-quality and robust economic growth. However, the industry faces increasing challenges that reinforce the importance of robust patent protection to biopharmaceutical companies. In 2008, there were more than 2,900 molecules in development or awaiting approval for use by U.S. patients.⁵ Development of new medicines is a long and high-risk process, and it has become more costly and complex over the last decade. Without strong patent protection, biopharmaceutical companies, including many smaller companies, could neither make nor attract the significant investments that are needed to develop these new medicines.

Between 1960 and 2007, the average development time for new medicines increased from approximately eight years to between 10 and 15 years.⁶ At the same time, costs to bring new discoveries from laboratory to bedside have also increased. A recent study from the Tufts University Center for the Study of Drug Development estimates the average cost of developing a new medicine at \$1.3

¹ Kenin Murphy, Ph.D., and Robert Topel, Ph.D., *Measuring the Gains from Medical Research: An Economic Approach* (Chicago: The University of Chicago Press, 2003).

² See, e.g., American Society of Clinical Oncology, *Clinical Cancer Advances 2008: Major Research Advances in Cancer Treatment, Prevention and Screening*, *Journal of Clinical Oncology*, 22 December 2008 (9 advances relating to new medicines, better ways of using existing medicines, or newly discovered benefits of approved medicines are among 12 major advances in treatment of cancer in 2008 which "significantly altered the way cancer is understood or had an important impact on patient care"); Center for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2008 with Chartbook*, Table 41, (Hyattsville, MD: 2009) (since the approval of highly active anti-retroviral treatments in 1995, annual number of AIDS deaths has dropped by over 70 percent); DM Cutler, G Long, ER Berndt, et al., *The Value of Antihypertensive Drugs: A Perspective on Medical Innovation*, *Health Affairs*, 26 (2007): 97-110 (use of antihypertensive medicines prevented 86,000 premature deaths from cardiovascular disease in 2001, and 833,000 hospitalizations for heart attack and stroke in 2002).

³ Edwin Mansfield, *Patents and Innovation: An Empirical Study*, *Management Science* (February 1986) at 173-181.

⁴ Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 *JOURNAL OF INT'L ECONOMIC LAW* 849-60 (2002).

⁵ PhRMA, *Profile 2008* (2008), available at <http://www.phrma.org/files/2008%20Profile.pdf>.

⁶ *Id.*; Joseph A. DiMasi, *New Drug Development in the U.S. 1963-1999*, 69 *Clinical Pharmacology & Therapeutics* 286, 292 (2001).

billion (in 2005 dollars), including the cost of failures and capital. The same study estimates the cost to develop a biologic (a large molecule treatment produced by a biological system) at \$1.2 billion (in 2005 dollars).⁷ These staggering figures include the cost of the thousands of once-promising but ultimately failed initiatives—products that never made it to market. For every 5,000-10,000 compounds that enter the R&D pipeline, only 250 reach the pre-clinical stage. Of those compounds, only five progress to clinical study in humans, and ultimately only one receives regulatory approval.^{8/} Figure 1 illustrates this challenging path.

Figure 1. The Research and Development Process

Further, for those drugs or biologics that do reach human clinical trials, those trials have become more complex and more costly to perform. Today, clinical trials are longer, have more participants (who are difficult to recruit and retain), and involve more demanding and complex trial design and clinical protocols (including more procedures per patient and difficult-to-measure clinical endpoints). In addition, there is an increasing challenge of developing new therapies for complex diseases and more testing against comparator drugs.⁹ In light of these complexities, it may not be surprising that only two in 10 approved medicines bring in enough revenue to recoup the average cost of development.¹⁰ These dynamics reinforce the importance of strong intellectual property protection and appropriate incentives to ensuring a vital, innovative biopharmaceutical sector.

In addition, the regulatory environment for biopharmaceutical products has grown increasingly complex over the past decade, with significant new requirements introduced as recently as two years ago. For example, enhanced post-market surveillance requirements and the creation of Risk Evaluation and Mitigation Strategies enacted as part of the Food and Drug Administration Amendments Act of 2007 increase required investments associated with many marketed products.¹¹ These increased investments, while appropriate to promote regulatory compliance, also enhance the importance of patent protection to provide an opportunity to recoup increased costs for marketed drug products.

⁷ S.J. A. DiMasi, and H. G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* 28 (2007): 469–479.

⁸ PhRMA, *Drug Discovery and Development: Understanding the R&D Process* (2007), available at http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf.

⁹ Tufts University Center for the Study of Drug Development, *Growing Protocol Design Complexity Stresses Investigators, Volunteers*, Tufts Impact Report (Jan./Feb. 2008), available at http://csdd.tufts.edu/_documents/www/Doc_309_65_893.pdf.

¹⁰ John Vernon, Joseph Golec & Joseph DiMasi, *Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three Factor Model* (Jan. 2008) (submitted to the *Journal of Health Economics*).

¹¹ See generally Pub. L. No. 110-85.

II. Congress Has Attempted To Strike a Balance Between Policies That Foster Innovation and Those That Promote the Availability of Generic Pharmaceuticals

Patents are given due respect in the law. By Congressional enactment, an issued patent is afforded the presumption of validity.¹² In the antitrust context, courts have held that the antitrust laws should be interpreted not to supplant legitimate patent rights.¹³ Indeed, courts recognize that antitrust and intellectual property are “two bodies of law [that] are actually complementary, as both are aimed at encouraging innovation, industry, and competition.”¹⁴ Consistent with the antitrust laws, a patent holder may exclude others from producing a patented article, or may grant limited licenses.¹⁵ Generally, antitrust laws are implicated only when a restriction on use goes “outside the scope of the patent grant.”¹⁶

Even as we discuss the critical role of patents in pharmaceutical innovation, it is important to recognize that pharmaceutical products in effect receive a shorter period of useful patent term than other types of products. The basic patent term in the U.S. is 20 years from the date the patent application is filed. Innovators in other industries -- who don't have to wait for regulatory approval before going to market -- can benefit from the patent as soon as it is granted.

By comparison, pharmaceutical companies are required to obtain FDA approval before they can market their products. The R&D process takes an average of 10 to 15 years and involves many discrete steps and activities, including early discovery, to pre-clinical work, to clinical trials, to FDA review, and finally, to FDA approval.¹⁷ Even if we assume that a pharmaceutical company is in a position to file for a patent within the first few years of that process and that a patent issues about two and half years later, the additional time consumed by the FDA approval process means that the time the medicine is actually on the market before the patent expires will be less than the effective patent life of other products.

Congress has taken some steps to address this dilemma. The Drug Price Competition and Patent Term Restoration Act of 1984 (better known as “the Hatch-Waxman Act”)¹⁸ was designed to balance the interests of innovative and

¹² 35 U.S.C. § 282.

¹³ See *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) (“[T]he patent laws . . . are in *pari materia* with the antitrust laws and modify them *pro tanto*.”).

¹⁴ *Atari Games Corp. v. Nintendo, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990).

¹⁵ See, e.g., *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940).

¹⁶ *Monsanto v. McFarland*, 302 F.3d 1291, 1298 (Fed. Cir. 2002); see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (“The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.”).

¹⁷ J. A. DiMasi, “New Drug Development in U.S. 1963–1999,” *Clinical Pharmacology & Therapeutics* 69, no. 5 (2001): 286–296; M. Dickson and J. P. Gagnon, “Key Factors in the Rising Cost of New Drug Discovery and Development,” *Nature Reviews Drug Discovery* 3 (May 2004): 417–429; and J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs,” *Journal of Health Economics* 22 (2003): 151–185.

¹⁸ Pub. L. No. 98-417, 98 Stat. 1585 (1984), 21 U.S.C. 355, 35 U.S.C. 156, and 35 U.S.C. 271.

generic companies and granted innovator products market exclusivity for limited periods and restored some of their effective patent time lost during the clinical research and FDA regulatory review of the product. However, commentators examining the evolution of the pharmaceutical market post Hatch-Waxman have found the market exclusivity period (defined as the time from innovator approval to first generic entry into the market) for new molecular entities was in the range of 12 to 15 years, with products with larger sales at the time of first generic entry having lower average market exclusivity periods.¹⁹ For medicines with annual sales of more than \$100 million (which account for 90 percent of the sales of medicines exposed to generic competition) whose generic competitors entered the market in 2005, the average time on the market before generic competition was 11.5 years.²⁰ These market exclusivity periods “represent relatively short product life cycle return periods for products that typically take more than a decade to develop and whose sales revenues are critical to the returns to R&D for the overall portfolio of new drug introductions.”²¹

It is important to remember that, while a patentee holds an exclusive right to manufacture, distribute and sell the patented invention for a period of time, patents do not provide immunity from competition. As the Supreme Court recently held, citing to the actions of Congress and the antitrust enforcement agencies, a patent does not translate into presumed market, let alone monopoly, power in a relevant economic market.²² Pharmaceutical manufacturers always are free to – and often do – research and bring to market different innovative medicines to treat the same disease, and increasingly, there is strong competition between different patented products within the same therapeutic class. A recent study by the Tufts Center for the Study of Drug Development showed that the amount of time between the entry of the first and second drug in a class has fallen by about 78 percent since 1970.²³ In fact, the average length of time before a first-in-class drug faces its first direct competitor has dropped from 8.2 years in the 1970s to 1.8 years in 1995.²⁴

And of course, there is increasing and earlier competition among brand companies and generic companies as well. The same Hatch-Waxman Act that restores some of the patent life for innovative medicines also provides mechanisms to speed the development and approval of generic copies of those medicines. The law created the Abbreviated New Drug Application (ANDA), under which a generic product needs only to be shown to be “bioequivalent” to an innovator drug and can be approved without any additional research once the

¹⁹ Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 *Managerial and Decision Economics* 491-501 (2007).

²⁰ *Id.*

²¹ *Id.* at 497.

²² *Illinois Tool Works, Inc. v. Independent Ink, Inc.* 547 U.S. 28, 45-46 (2006) (“Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee. Today, we reach the same conclusion”).

²³ DiMasi JA, Paquette C. The Economics of Follow-On Drug Research and Development: Trends in Entry Rates and the Timing of Development, *Pharmacoeconomics* 2004, 22, suppl. 2, 1-13.

²⁴ *Op. Cit.*

innovator's patent and exclusivity periods have expired.²⁵ In addition, the Hatch-Waxman Act created a unique exception to patent law by allowing generic manufacturers to use innovator medicines still under patent to obtain bioequivalency data for their FDA applications (a use that otherwise was considered patent infringement).²⁶ This allows the generic company to forego the burden and expense of performing its own studies on safety or efficacy and puts it in a position to be ready to market its copies as soon as the innovator patents expire. The generic company may even seek approval to market a generic version of a drug prior to the expiration date of the innovator's patents, provided it certifies that the patents are invalid or will not be infringed by the manufacture, use, or sale of the generic drug.²⁷ This certification, known as a Paragraph IV certification, may be filed as early as four years after FDA approval of the brand product.

The Hatch-Waxman Act stimulated the development of a robust generic pharmaceutical industry in the U.S. Since the law's passage, the generic industry share of the prescription drug market has jumped from less than 20 percent to 71 percent today²⁸, up from about 60 percent when we testified before the Subcommittee just two years ago.²⁹ Before the 1984 law, it took three to five years for a generic copy to enter the market after the expiration of an innovator's patent. Today, generic copies often come to market almost as soon as the patent on the innovator product expires.³⁰ Prior to Hatch-Waxman, only 35 percent of top-selling innovator medicines had generic competition after their patents expired.³¹ Today, many more innovator medicines face such competition.³² In addition, there are increasing examples of generic companies challenging innovator patents before patent expiration. According to one commentator, "[m]ost ... patent challenges [brought by generic companies against the innovator's patents] now occur four years after market approval which is the earliest point in time that a generic firm can submit an ANDA filing with a [P]aragraph IV certification."³³ And when a generic version of a medicine becomes available for the first time, it can capture as much as 86 to 97 percent of the market within the first month.³⁴ This dramatic and rapid impact on brand

²⁵ 21 U.S.C. 355(j).

²⁶ 35 U.S.C. 271(e)(1).

²⁷ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

²⁸ IMS Health, National Prescription Audit, Dec 2008

²⁹ Prepared Statement of Billy Tauzin, President and Chief Executive Officer, PhRMA, Regarding H.R. 1902, before this Subcommittee on May 2, 2007 (citing Generic Pharmaceutical Association, "Statistics", available at [http://www.gphaonline.org/Content/Navigation Menu/About Generics/Statistics.default.htm](http://www.gphaonline.org/Content/Navigation%20Menu/About%20Generics/Statistics.default.htm) (accessed January 15, 2007)).

³⁰ Congressional Budget Office. *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (Washington, D.C., July 1988) ("1998 CBO Report").

³¹ 1998 CBO Report (citing Henry Grabowski and John Vernon, Longer Patents for Lower Imitation Barriers: The 1984 Drug Act, *American Economic Review*, vol. 76, no. 2, pp.195-98 (May 1986)).

³² *Id.*

³³ Henry G. Grabowski, *Data Exclusivity for New Biological Entities*, Duke University Department of Economics working paper (Jun. 2007) at 28, available at

<http://www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf>.

³⁴ Medco, 2008 Drug Trend Report (2008) at 9, available at <http://medco.mediaroom.com/file.php/162/2008+DRUG+TREND+REPORT.pdf>

market share increases the risk and uncertainty involved in innovative drug development.

III. Public Policy Favors Settlements of Expensive, Burdensome Patent Litigation

In this climate of increasing costs associated with discovering and bringing new innovative medicines to market, juxtaposed with growing brand-to-brand and generic-to-brand competition, research-based pharmaceutical companies obviously have strong incentives to defend their patents against potential infringers. Generic companies also have strong incentives to challenge the innovators' patents, particularly because the Hatch-Waxman statutory scheme permits them to mount such challenges without first bringing their product to market. Therefore, it should come as no surprise that patent litigation among brand and generic pharmaceutical companies is both common and costly.

Numerous courts have recognized that "public policy wisely encourages settlements."³⁵ Courts and experts likewise have stated unequivocally that settlement of patent litigation can benefit consumers. As the Eleventh Circuit has stated there is "no question that settlements provide a number of private and social benefits" when compared to the costs of litigation.³⁶ The Court of Appeals for the Federal Circuit agrees that "[t]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation."³⁷ And leading antitrust expert Herbert Hovenkamp explains that the general principle encouraging settlements is so strong that some agreements that would be unlawful outside of the litigation context may be lawful when used to settle a bona fide patent dispute.³⁸ In the words of the Federal Circuit, "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled – a monopoly over the manufacture and distribution of the patented invention."³⁹

It is basically a truism that patent litigation is complex, lengthy and extremely expensive for all concerned. U.S. patent litigation overall was estimated 10 years ago to cost about \$1 billion annually.⁴⁰ Another study found that the median expense for patent litigation with more than \$25 million dollars at risk is \$5 million.⁴¹ The costs of patent litigation in the pharmaceutical industry likewise are significant. And it is not uncommon for a patent dispute to last several years.⁴² Settlements allow both litigants and the court system to conserve resources that

³⁵ *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994).

³⁶ *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056, 1072 (11th Cir. 2005).

³⁷ *In re Ciprofloxacin*, 544 F.3d at 1333.

³⁸ Settlements Resolving Intellectual Property Disputes, 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046, at 265-66 (1999).

³⁹ *In re Ciprofloxacin*, 544 F.3d at 1337.

⁴⁰ Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale J. Reg. 359, 380 (1999).

⁴¹ Am. Intellectual Prop. Law Ass'n, *Report of the Economic Survey 2007*, at 26 (2007).

⁴² Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," July 2002, at iii ("On average, the time between the filing of a patent infringement lawsuit and a court of appeals decision in the case was 37 months and 20 days.").

can then be put to more efficient use, including, in the case of the innovator companies, further investment in developing new treatments.

Aside from these direct costs of patent litigation, the uncertainty surrounding an ongoing patent dispute can stall a company's business activities indefinitely. Particularly at early stages of a case, litigants face uncertainty over how the case will be resolved, because that resolution is dependent on a myriad of unknown factors, including a judge's interpretation of difficult legal questions and unpredictable juries. This uncertainty can chill productive activities that are affected by a case even if they are not directly implicated by it. For example, a pharmaceutical company with even a strong patent nevertheless might face an uncertain judgment in a case brought by a generic challenger, and therefore may delay or forego innovative activity because of the prospect of an adverse judgment.

Settlements create an environment of certainty, which allows parties to make business planning decisions with more efficiency and flexibility than can be achieved in the midst of an all-or-nothing legal dispute that may take years to resolve. It is therefore important that PhRMA members continue to have options to enter into procompetitive settlements, which allow them to get on with the business of developing new medicines for patients.

IV. A Rule That Bans The Transfer Of Anything of Value From a Brand to A Generic in Connection with Patent Settlements Would Make Settlements Less Likely and Less Efficient and Would Threaten Both Innovation and Generic Drug Development

H.R. 1706's ban against patent settlements where the brand company transfers something of value to the generic would chill all patent settlements. In fact, as Judge Richard Posner has pointed out, this broad description could almost cover any settlement agreement because a generic challenger logically would only settle in exchange for something of value.⁴³ And a law restricting parties' ability to settle their patent dispute would have significant adverse consequences for brand and generic companies and ultimately for patients. Fewer options for settlement would raise the cost of patent enforcement (and patent challenges) by forcing both sides to incur additional litigation costs. It could also reduce generic manufacturers' incentives to challenge patents in the first place by reducing their options in litigation against patent holders.

The narrow exceptions carved out from the sweeping prohibition in H.R. 1706 will not alleviate the bill's chilling effect on settlements. Similarly, the fact that the bill

⁴³ *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003); see also Letter from U.S. Department of Justice Office of Legislative Affairs, Office of the Assistant Attorney General to Senator Jon Kyl, Feb. 12, 2008 (2008 DOJ Letter) at p.2 ("[i]n any patent litigation, the principle means available to the patent holder to induce the generic company to settle the litigation is to offer something of value").

authorizes the FTC to undertake rulemaking to exempt additional settlements does not provide sufficient certainty that litigants' options for pro-consumer settlements will be preserved.

Settlements are not easily crafted or achieved. Often — as in the context of patent infringement litigation involving pharmaceuticals — the parties have a different risk-reward calculus, a different appetite for risk, and different litigation costs. Consider the incentives of the parties in a patent dispute within the Hatch-Waxman framework. The innovator and generic are likely to face significantly different risks and rewards from patent litigation. For example, the innovator stands to lose the market exclusivity through which it has the chance to recoup the hundreds of millions of dollars invested in making new products available to patients. On the other hand, the generic may risk losing comparatively little. The generic's development costs are just a fraction of the innovator's costs because the generic takes advantage of much of the innovator's development efforts.

Moreover, the generic typically is not exposed to liability for any infringement damages as a result of the Hatch-Waxman statutory scheme.⁴⁴ As described in a recent study by noted economists Laura D'Andrea Tyson, Jonathan Orszag and Bret Dickey, in a typical patent case outside of the Hatch-Waxman context, a patent infringer markets the product prior to being sued by the patent holder for infringement. The alleged infringer would owe significant damages if found liable, but the parties may agree to a settlement where the alleged infringer pays damages to the patent holder that are far less than the amount the patent holder claimed in the litigation. In these circumstances, the alleged infringer pays the patent holder, but value in fact flows from the patent holder to the infringer (measured in the reduced amount of damages the innovator accepts in order to resolve the case). So-called "[r]everse payment settlements can be thought of in the same way, but the Hatch-Waxman framework means the patent holder typically does not incur any damages from sales of the infringing products, and so the net payment flows from the branded manufacturer to the generic manufacturer."⁴⁵

The innovator and generic can also face lopsided benefits from winning. If the innovator wins, it merely maintains the status quo. If the generic wins, however, it is rewarded by profits from the sale of a new product.

The parties' differing risk exposure, however, should not suggest that the innovator always has more at stake, or that the innovator is always more willing

⁴⁴ *Schering-Plough*, 402 F.3d at 1074 (explaining that "the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement....Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude").

⁴⁵ B. Dickey, J. Orszag, L. Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, p.27 (Dec. 2008), available at http://www.compasslexecon.com/highlights/Pages/_12_17_08.aspx?year=2008 ("Dickey, Orszag & Tyson").

to settle. For example, the innovator may be less willing to settle precisely because of the value of the market exclusivity conferred by its patent. The innovator may be willing to take the risk of losing in return for a chance of a court judgment securing its entitlement to market exclusivity for the full life of its patent. On the other hand, the generic may have significant incentives to settle because it may not be able to afford the staggering costs of patent infringement litigation.

The parties' risk exposure and perceptions affect their willingness to settle as well as the settlement terms each party is willing to accept. When the parties' risk exposure and perceptions differ, as they are likely to in the context of brand-generic litigation under the Hatch-Waxman framework, settlement may be very difficult to achieve.⁴⁶ As the Chairman and CEO of generic manufacturer Barr Pharmaceuticals testified before the Senate Judiciary Committee in 2007, the ability to reach an agreement that provides for some consideration in addition to generic entry prior to patent expiration can be useful in "bridging the gap" that may exist based on different risk exposure and perceptions held by the parties.⁴⁷

Patent litigation — and settlement of patent cases — also cannot be viewed in a vacuum. Companies generally, and drug companies involved in patent litigation specifically, are often interacting on multiple levels, involving separate deals and perhaps disputes. Many times, they also have assets that are not involved in the suit that are more valued by the other party. For example, one of the parties may possess technology that can be more effectively marketed by the other party. The ability to license this technology, and offer that as part of a settlement, can facilitate the parties' efforts to reach and structure a mutually acceptable — and procompetitive — settlement. This has in fact been demonstrated in the very cases that have come before the courts.⁴⁸ It has also been borne out in statements by Barr Pharmaceutical's Downey, who testified that collateral agreements on some asset that is separate from the patented product in dispute often provide value to the patent holder and the generic challenger and also serve consumers by allowing the parties to reach a settlement that brings the generic product to market before patent expiration.⁴⁹ Likewise, Theodore Whitehouse, an attorney testifying before this Subcommittee in 2007 on behalf of generic manufacturer Teva Pharmaceuticals USA, Inc., explained that Teva had been able to achieve through settlements benefits for consumers that it could not have achieved by litigating the case to judgment, including early entry on

⁴⁶ *Schering-Plough*, 402 F.3d at 1073 ("Schering presented experts who testified to the litigation truism that settlements are not always possible. Indeed, Schering's experts agreed that ancillary agreements may be the only avenue to settlement.").

⁴⁷ Testimony of Bruce Downey, Senate Committee on the Judiciary Hearing, "Paying off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?", p.7, January 17, 2007 ("Downey Testimony").

⁴⁸ See, e.g., *Schering-Plough*, 402 F.3d at 1059-61 (discussing settlements in which assets were exchanged).

⁴⁹ Downey Testimony, pp. 7-9

products in addition to the one that was the subject of the suit.⁵⁰ Similarly, Tyson, Orszag and Dickey explain that “the parties’ valuations of the components of a collateral business arrangement may be quite different. This difference in valuation could be used to offset different expectations in the patent litigation to arrive at a settlement.”⁵¹

The parties to a patent dispute are, in short, often repeat players that have interactions or potential interactions on a number of different levels. Foreclosing the ability of innovators and generics to exchange assets that may or may not be involved in the litigation, as would be the case if there was a blanket prohibition on the exchange of *anything of value*, would put a straight jacket on the settlement negotiations. Not only would it make settlements less likely, but it also would make them less efficient. It would also harm consumers, since “Hatch-Waxman settlements . . . which result in the patentee’s purchase of a license for some of the alleged infringer’s other products may benefit the public by introducing a new rival into the market, facilitating competitive production and encouraging further innovation.”⁵²

Finally, a broad ban on payments of anything of value would open *any* transaction between the innovator and generic up to scrutiny. It is not hard to imagine an argument that a wholly separate license deal or other business transaction was in fact part of a patent settlement and therefore should be deemed illegal. Opening up this Pandora’s box of litigation would be expensive and wasteful.

For these reasons and others, courts and competition experts have expressed significant concerns about a rule that broadly condemns all settlements where the innovator transfers something of value to the generic. As the Eleventh Circuit stated in the *Schering-Plough* case:

Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic’s entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law.⁵³

⁵⁰ Testimony of Theodore Whitehouse, House Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy & Commerce Hearing on H.R. 1902, Hearing Tr. p. 145, May 2, 2007) (“Whitehouse Testimony”).

⁵¹ Dickey, Orszag & Tyson, p. 36.

⁵² *Schering-Plough*, 402 F.3d at 1075.

⁵³ *Schering-Plough*, 402 F.3d at 1076.

The Eleventh Circuit's concern that a ban on all payments from an innovator to a generic will have negative effects on settlements was echoed by the United States in its *amicus curiae* brief on the FTC's petition for *certiorari* in the *Schering* case and by the Department of Justice in its 2008 comments on proposed Senate legislation regarding patent settlements. In both its *amicus* brief and comments on the Senate legislation, the government stressed that "the public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation."⁵⁴ It further recognized that the Hatch-Waxman Act creates a unique litigation dynamic that makes some settlements reasonable.

Given the importance of settlement and the obstacles to reaching settlement, any limit on the ability of parties to achieve settlement must be approached with great caution. Any categorical limit on settlement options increases the risk that the parties may not be able to reach settlement or that the settlement will be less efficient – and ultimately worse for consumers – than prohibited alternatives.

Categorical limits on the ability to settle brand-generic lawsuits also increase the uncertainty over the scope and duration of patent protection. Faced with this increased uncertainty, innovator pharmaceutical companies likely will be less willing to make the astronomical investments necessary for developing and testing novel pharmaceuticals. Innovators, large and small, can only afford to make these investments because they have the opportunity to recoup them through market exclusivity guaranteed by patent protection. Innovators can therefore be expected to develop fewer new products under a regime that constrains settlement options.⁵⁵

This effect on innovators has been recognized by the courts and has been one of the key drivers in their refusal to find that competition principles compel a rule that would effectively prohibit nearly all transfers of value (including, but not limited to, reverse payments). As one court put it, "the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product."⁵⁶

The consequences of reduced innovation likely would in turn be felt throughout the health care system. Medicines represent just 10.5 cents of each dollar that is spent on healthcare, and only seven cents of that is attributable to brand name

⁵⁴ 2008 DOJ Letter at p.2; Letter Brief for the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (filed May 17, 2006).

⁵⁵ Dickey, Orszag & Tyson, p.37

⁵⁶ *Schering-Plough*, 402 F.3d at 1075.

medicines.⁵⁷ Yet evidence shows that new medicines *reduce* the cost of healthcare. One study found that for every dollar spent on newer medicines in place of older medicines, total healthcare spending is reduced by \$6.17.⁵⁸ Another found that every additional dollar spent on healthcare in the U.S. over the past 20 years has produced health gains worth \$2.40 to \$3.00.⁵⁹

Overly broad limits on the ability to settle patent litigation may also have detrimental effects on generics. As Judge Posner recognized, limits on settlement structure, like a rule prohibiting reverse payments, “would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anticompetitive.”⁶⁰ Counsel for generic manufacturer Teva Pharmaceuticals testified before this Subcommittee in 2007 that Paragraph IV cases at that time “involve[d] more difficult issues than they typically did a few years ago and may be more difficult for generic companies to win.”⁶¹ Similarly, Barr Pharmaceuticals CEO testified before the Senate Judiciary Committee that “[t]he generic challenger will lack the necessary resources to litigate every patent challenge to final judgment upon appeal, particularly when there is the risk that the challenger might ultimately win nothing.... A generic challenger’s ability to bring a Hatch-Waxman challenge depends in significant measure upon its having the flexibility to decide when, and on what terms, to compromise the litigation.”⁶² Moreover, limits on settlement will limit a generic’s ability to gain access to technology or other assets in the innovator’s possession that may improve the generic’s ability to bring to market other substitutes for brand-name products.

Similarly, sweeping limits on settlements will increase the possibility of a court ruling of infringement. An infringement ruling prevents a generic from making any sales until patent expiration and thus delays its ability to recoup its investment in developing its product. Generic manufacturers may, therefore, develop fewer generic drugs and may take longer to bring those drugs to market under a legislative regime which constrains settlement options.

Finally, fewer settlements mean that litigants will spend more time and money litigating. By spending more time and money on litigation, the litigants presumably will have to make corresponding cuts in other expenditures, including expenditures invested in new drug development.

⁵⁷ http://www.innovation.org/index.cfm/ImpactofInnovation/Controlling_Healthcare_Costs (accessed March 29, 2009).

⁵⁸ F. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, National Bureau of Economic Research Working Paper, No. 8996 (Cambridge, MA, NBER June 2002).

⁵⁹ MEDTAP Int’l, Inc., *The Value of Investment in Health Care: Better Care, Better Lives* (Bethesda, MD: MEDTAP 2003), <http://www.medtap.com/Products/policy.cfm> (accessed February 8, 2005).

⁶⁰ *Asahi Glass Co. v. Pentech Pharm.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

⁶¹ Whitehouse Testimony, Hearing Tr., p.146.

⁶² Downey Testimony, pp. 9-10

V. A Case-By-Case Approach By Courts And Enforcement Agencies Will Allow Procompetitive Patent Settlements to Proceed and Still Deter Settlements That Harm Consumers On Balance

We understand that the Subcommittee continues to question the best way forward in addressing the competitive nature of brand-generic settlements in patent litigation. PhRMA respectfully submits that a legislative solution may not be necessary, and, more importantly, a broad *per se* ban on almost all settlements involving transfer of anything of value from the innovator to the generic is not in the best interests of patients or competition. The antitrust agencies and courts are in the best position to evaluate the facts of particular cases and determine whether particular settlements are truly anticompetitive.

We urge the Subcommittee and other policymakers to continue to make policy choices that will balance patent and antitrust considerations and provide for both innovation and a strong generic industry. While the role of generics is important to our health care system, the existence of generics is dependent upon innovative pharmaceuticals being developed. Policies that incentivize research and development and allow innovator companies time to recoup their significant investment, while encouraging generic entry at the appropriate time, are essential to the lifeblood of both industries.

Fundamentally, a policy that would provide for a *per se* ban on all settlements that contain some payment from a brand manufacturer to a generic company would put additional stress on the drug development system. It would decrease the value of patent protection generally and decrease incentives for taking the risks necessary to develop new products. One court noted, "a rule prohibiting settlements of Hatch-Waxman litigation can have grave consequences for R&D and, in turn, severe consequences for consumers...."⁶³

Instead of a blanket rule banning certain types of patent settlements, enforcement agencies and courts should continue to evaluate these patent settlements on a case-by-case basis. Courts are in the best position to balance the deeply-instilled policy of settlements against a claim that a patent settlement unreasonably restrains trade and therefore harms consumers. Whether a particular patent settlement is appropriate turns on whether the settlement excludes competition beyond the scope of the patent's protection. As Hewitt Pate, the former head of the Department of Justice's Antitrust Division, has recognized, "[i]f a patent is valid and infringed, then any competitive entry allowed by a settlement is up to the patent holder."⁶⁴ This kind of analysis can only be done on a case-by-case basis.

⁶³ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d at 256.

⁶⁴ R. Hewitt Pate, Assistant Attorney General, Antitrust Division, Address to the American Intellectual Property Law Association, January 24, 2003.

And, of course, the enforcement agencies already have the authority and ability under current law to review and evaluate individual patent settlements. Under the Medicare Modernization Act, brand and generic companies settling patent litigation arising out of the generic company's Paragraph IV certification must file a copy of their settlement agreement or a written description of it with FTC and with the DOJ's Antitrust Division before the date when the generic product may enter the market. Thus, Congress has already given enforcement authorities the ability to review and evaluate patent settlement agreements between a brand and generic company on a case-by-case basis. Reports in the press and the FTC's own public reports indicate that the FTC maintains its interest in monitoring these agreements, and it retains the power to challenge any agreement that it deems anticompetitive. If the Subcommittee feels legislative action is necessary, additional steps could potentially be taken to facilitate agency or judicial review. But the proposed ban on an entire category of settlements would chill all settlements, even those that would allow generic entry before patent expiration or contain other provisions that facilitate the availability of products to help patients live longer, healthier lives.

Thank you again for the chance to speak with you today. PhRMA and its member companies believe it is crucial for this Subcommittee and other policymakers to find public policy solutions that will strike a balance between patent and antitrust considerations and will foster innovation while still allowing for a strong generic industry. We welcome your interest in this issue, and look forward to working with members of the Subcommittee and others in Congress as you address these and other important policy issues relating to innovation and access to medicines.

Mr. RUSH. The chair thanks Ms. Bieri, and it is now my honor to introduce and to allow Dr. Barry Sullivan 5 minutes for the purposes of opening—Sherman, I am sorry—Sherman 5 minutes for the purposes of opening statement. Dr. Sherman, you are recognized for 5 minutes.

STATEMENT OF BARRY SHERMAN

Mr. SHERMAN. OK, Mr. Chairman, members of the subcommittee, thank you for the opportunity to testify again today. Apotex Inc. is very eager to do its jobs of challenging weak patents and bringing to the market products as quickly as possible for the benefit of our customers, who are the pharmacy industry of America and through them to American consumers.

We are therefore eager to help elucidate the fundamental problem that is blocking generic entry, and that, in our view, is settlements by first filers that whereby they accept unduly late, very late entry dates, cheap their exclusivity and thereby block market entry to others such as us who would continue to fight and thereby gain much earlier market entry.

And the cost to the American consumer is enormous. Billions of dollars for individual products and certainly many tens of billions of dollars in total. One example is the drug Modafanil whereby the Cephalon settled with four generic suppliers challengers some years ago and thereby got delayed generic entry until the year 2012. The patent is very weak. We would be prepared to launch the product now if we could, and indeed, in Canada, we have already succeeded in the patent challenge. And the product is on the market in Canada as a generic sold by Apotex. So the problem is quite enormous.

There have been legislative initiatives including this one to address the problem by trying to prohibit reverse payments, settlements that include reverse payments. In our view, reverse payments per se are not the problem. They are simply a symptom of a problem.

Why are brand companies prepared to make large payments? It is not because they are fair payments to the particular company with whom they are settling. It is because when they settle with the first filer, they know the first filer retains the exclusivity and blocks all others. So they are paying not to get the one settlement, to get the entire block of the market until near patent expiry, and that is the fundamental problem.

In our view, there are two flaws that need to be addressed and can easily be addressed. The first is that the first filer who settles and doesn't do what was intended by the Hatch-Waxman gets to keep that exclusivity to block all others.

And the second problem is that these agreements almost always contain poison pill provisions whereby if a subsequent filer does succeed to get early entry, the settler simply accelerates entry and takes away the benefit to the subsequent filer who actually succeeded.

One example that brings the point home is the case of Altace Ramapril. The first filer was Cobalt. They settled for very late entry, but in 2007, Lupin won—even though they were not the first filer, won in the court of appeal. What then happened? Cobalt used

its poison pill provision to accelerate its entry, launch the product, and Lupin could not launch even though they were the ones who invested and won. So all of the benefit went to Cobalt, who had settled. None of the benefit went to the successful litigant who was not the first filer.

The message from that case is clear to all who would subsequently challenge a patent. Don't do it. It isn't worth it. You can't succeed. So the effect is that the litigation by those who would actually fight to win is paralyzed.

In our view, there are two simple amendments that are needed to fix this problem. The first amendment is to give a shared exclusivity to a subsequent filer who does fight and wins. And the second provision that is needed is to override the poison pill provisions which would, in essence, provide that if a first filer settles for very late entry, FDA can then not give final approval to that first filer until that date. And that date can then not be accelerated by reason of a subsequent win by a subsequent filer.

These two provisions would accomplish two very important things. Number one, it would give—when there is an anticompetitive settlement whereby a first filer has agreed to defer to a very late entry date, it would give an incentive to a subsequent filer to pick up the battle, challenge the patent and win and get earlier entry.

And the second effect would be that it would eliminate the anti-competitive settlements because if these provisions were enacted, a brand company would no longer make a reverse payment to a first filer because it wouldn't have the effect of blocking all challengers. It would only block the one, and therefore there would be no reason to make that big payment.

And secondly, it would tell the first filer they couldn't settle for too late a date because if it does, it will be stuck with that date. And then we will lose the opportunity launch if a second filer, subsequent filer, wins an earlier entry date.

So in our view, the attacking or trying to eliminate reverse payments really will not solve the problem. Anticompetitive settlements will continue with the same anticompetitive effect only without the reverse payments. And what is necessary to address the problem is to give shared exclusivity to a subsequent filer who does take up the battle and wins and to eliminate the poison pill provisions whereby a first filer who agrees to late market entry can then accelerate that entry on the basis of an earlier win by someone who does invest in the challenge and wins.

We very much urge the committee, subcommittee, to consider our suggestions because we have been at this a very long time. We understand what the issues are. We are fighting the battles every day. We are most eager to do the job, which the Hatch-Waxman provisions incentivized used to do, to fight, to win, to bring our products to market early.

We are blocked by these anticompetitive settlements, and these are the challenged that we are convinced are needed to solve the problem. Thank you very much.

[The prepared statement of Mr. Sherman follows:]



Testimony of Dr. Bernard C. Sherman, Ph.D, P. Eng.
CEO of Apotex Inc.

Hearing on HR 1706, The Protecting Consumer Access to Generic Drugs Act of 2009
Subcommittee on Commerce, Trade, and Consumer Protection
Energy and Commerce Committee
US House of Representatives

March 31, 2009

Introduction

Chairman Rush, Ranking Member Whitfield, Members of the Subcommittee, thank you very much for the opportunity to testify before you on anti-competitive patent settlements between brand and generic pharmaceutical companies. My name is Bernard Sherman. I am the CEO and Chairman of Apotex Inc. Apotex is the largest Canadian pharmaceutical manufacturer. We are also one of the largest generic drug manufacturers in the world. In the United States, we are the 5th largest generic drug manufacturer measured by sales. Our U.S headquarters is located in Weston, Florida. We also have a distribution center in Indianapolis, Indiana.

At Apotex, we believe generic companies should endeavor to bring generics to market at the earliest possible time, and that the legislative and regulatory framework should facilitate, not obstruct, early generic entry. Our record in advocating for such a public policy framework, from our opposition to patent settlements, our efforts in the courts to vacate anti-competitive settlements, our support for a district court trigger for exclusivity rather than an appellate trigger, our pursuit of declaratory judgment actions, and our pursuit of infringement verdicts even where there is no guaranteed benefit to us, is unique and unmatched among generic manufacturers.

Fixing Flaws in Hatch-Waxman Critical To Effectively Addressing the Problem

I testified before this Subcommittee in May 2007 in opposition to collusive agreements between generic and brand drug companies. I supported your legislation to end such anti-consumer practices due to its inclusion of a provision that addressed the ability of brand companies to delay generic competition by refusing to sue non first filers – the so called “declaratory judgment (DJ) problem.” At that hearing I also testified that in order for any legislation aimed at ending the settlement problem to be effective, it is *absolutely vital* that it address the fundamental flaws in the Hatch-Waxman Act that are the root cause of the settlement problem: (1) the ability of the first to file generic company who is eligible for 180 day marketing exclusivity to keep that exclusivity despite the fact that it has settled with its brand counterpart and given up the fight to

knock out weak patents that unduly block consumer access to generics, and; (2) the lack of any incentive for a generic who is not the first to file to fight to open a market blocked by a “parked” exclusivity because winning only causes the first to file to launch its product while the generic that won, and thereby opened the market early for consumers, gets nothing.

As my testimony today details, *these flaws can be corrected by making the first generic company to win a patent challenge at the district court level eligible to share the 180-day marketing exclusivity period along with the first company to submit an application with a patent challenge to the FDA.*

The Hatch-Waxman Incentive Problem

In my 2007 testimony, I stated that “Apotex very much wants to continue to fight for the interests of consumers, as intended by the Hatch-Waxman provisions. However, it should be clear, that we will be unable to continue to do what is right, unless Congress addresses the essential problems.” The vital importance of addressing the flaws was particularly evident to us at that time. Just two months prior, Apotex invalidated a patent on a blockbuster Pfizer drug, Norvasc[®], but, despite being the first to win the patent case, and thereby responsible for opening the market early for consumers, we were not the first to file an application with a patent challenge (known as paragraph iv certification after the appropriate section of the Hatch-Waxman Act) and therefore were not able to launch the product. The first filer, Mylan, who had lost a district court decision just a month prior to Apotex’s victory, was able to launch and reap the benefits from our success. Though Mylan had not entered into a settlement in that case, our victory and inability to launch shone a spotlight on the flaw in the Hatch-Waxman system that we identified as the root of the settlement problem: the lack of incentive for subsequent filers to prosecute the patent fight in the face of a settlement in which the generic company eligible for the Hatch-Waxman 180 day marketing exclusivity period blocks other generics from entering the market by “parking” its exclusivity in a collusive arrangement with its brand partner.

Just four months after I testified, the dynamic repeated itself in a case that did indeed involve a subsequent filer who invalidated a patent but was prevented from launching by a first filer who had settled and blocked the market by parking its exclusivity. In September of 2007, Lupin pharmaceuticals invalidated a patent covering King Pharmaceutical’s product Altace[®], a treatment for high blood pressure with nearly \$1 billion in annual sales. King, however, had previously settled with the first generic company to file its application with the FDA, Cobalt, who was entitled to the 180 day exclusivity period by virtue of being the first to submit its application with the Agency. Cobalt’s agreement with King in the settlement to delay its launch of generic Altace[®] thus bottlenecked the market. Because of Cobalt’s entitlement to the 180 day exclusivity period, no other generic company could enter the market until 6 months after Cobalt first entered with its product. The agreement included what is a *standard part of all settlements with first filers today*, an acceleration clause, or “poison pill,” which enabled

Cobalt to immediately enter the market at a date earlier than the delayed entry date agreed to in the settlement, in the event another generic challenger knocked out the patent.

Upon Lupin's victory, Cobalt immediately entered the market. Lupin was left with nothing despite being the party responsible for opening the market early for consumers. Cobalt, on the other hand, who had agreed to delay consumer access to the generic by abandoning its effort to knock out what proved to be a patent that never should have been issued in the first place, was able to "double dip". They were able to keep the money they got paid by the brand company to abandon the patent fight and then benefit from being the only generic on the market during the exclusivity period even though it was Lupin that opened the market early for consumers.

At first blush, the acceleration of Cobalt's entry into the market resulting from Lupin's victory may sound like a good outcome for consumers because it expedited access to the generic. However, no subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. ***Consumers are the biggest losers under this system.*** If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase. With it being futile for subsequent filers to invest in a patent challenge that is guaranteed to produce no return, Congress' objective of providing a means for subsequent filers to break through parked exclusivities will never be realized.

If Hatch-Waxman is to facilitate the early access to generics that it was originally intended to facilitate, further reform is necessary to provide the incentive for a subsequent filer to carry on the patent fight. Accordingly, Mr. Chairman, Apotex implores you to take advantage of the opportunity your legislation provides to address this fundamental flaw in the Hatch-Waxman Act. *We urge you to include in your legislation a provision that would enable the first generic to win the patent litigation to enter the market upon a district court victory, with shared exclusivity.*

Another Case in Point: The Anticompetitive Provigil® Settlements

While there are any number of cases that could be cited to illustrate how the systemic gaming of Hatch-Waxman is carried out and defended by generic and brand drug settlers, the Provigil® case epitomizes how the game is played. The "early" access to generic drugs settlements are purported to provide consumers by those defending these anti-consumer arrangements is in reality just the opposite: delayed entry. The benefits such settlements are alleged to provide consumers and taxpayers are a smokescreen. The costs these settlements impose on consumers are in actuality very substantial. Consider the following.

In the Provigil[®] case, Cephalon settled patent challenges with Barr, Teva, Mylan, and Ranbaxy. The four generic companies all filed applications challenging the disputed brand patent on the same day, December 24, 2002. Under the law they are therefore all eligible for 180-day exclusivity, a situation referred to as “shared exclusivity”. They were all sued by Cephalon on or about March 28, 2003. The disputed patent expires on October 6, 2014 but the product is protected for an additional 6 months by pediatric exclusivity, which runs to April 6, 2015. The settlements were reached in late 2005/early 2006. They allow for generic competition in 2012. Because the settlements allow for generic entry three years prior to the April 2015 expiration of pediatric exclusivity, this settlement is purported by the generic pharmaceutical industry to be “pro consumer” because it contains an “early” entry date.

The disputed patent in this case, however, is extremely weak. It is highly unlikely that Cephalon would have prevailed against all four generic challengers. Indeed, upon reaching the settlements with the four generics, Cephalon’s CEO Frank Baldino, Jr. crowed that “A lot of [Wall Street’s enthusiasm for Cephalon’s stock] is a result of the patent litigation getting resolved for Provigil[®]. We were able to get six more years of patent protection. That’s \$4 billion in sales that no one expected.”¹ The FTC chose this suit to prosecute in 2008 as a follow up to previous losses in the courts against settlers precisely because this purported “pro consumer” settlement left a weak patent in place to prevent other generics from entering the market.

An appeals court decision in favor of any one generic company would have triggered exclusivity for all of them. All four of them would have launched upon such a decision in any one of their cases. It typically takes four years to get to an appeals court decision. Thus if the patent challenges had been successfully pursued, generic competition with 5 companies (including an expected authorized generic) would likely have begun in 2007 or 2008 if not sooner. *That is 4 to 5 years earlier than the 2012 date allowed for in the “pro-consumer” settlements with the four first filers. The delay in access to generic Provigil[®] until 2012 resulting from these purportedly “pro consumer” settlements will cost consumers \$2.2 billion in unrealized savings.*²

The incentive for subsequent generic filers to have continued to fight to open this market when it should have been opened is non-existent. Just as in the Lupin case, any successful outcome by a subsequent filer will leave it with a loss on the investment because if they win, they will not be able to enter the market. All the settlements include the aforementioned “poison pill” acceleration clause.

Enabled by the market blockage created by these anti-consumer settlements, Cephalon has sharply increased the price of Provigil[®] in a strategy designed to switch consumers to its next generation drug, Nuvigil[®], before generic competition begins in 2012. On November 17, 2008, *The Wall Street Journal* reported that Provigil was “28%

¹ See <http://philadelphia.bizjournals.com/philadelphia/stories/2006/03/20/story1.html>

² According to IMS Health, 2008 sales of Provigil were approximately \$944 million. The figure for lost savings was determined by with the following assumptions: the generic price would be 50% of the brand price for the first year and 30% for subsequent years, and the generic penetration rate would be 90%.

more expensive than it was in March and 74% more expensive than four years ago...”
The strategy, continued *The Wall Street Journal*:

...works like this: Knowing that Provigil will face generic competition in 2012 as its patent nears expiration, Cephalon is planning to launch a longer-acting version of the drug called Nuvigil next year. To convert patients from Provigil to Nuvigil, Cephalon has suggested in investor presentation it will price Nuvigil lower than the sharply increased price of Provigil.

By the time copycat versions of Provigil hit the market the company is banking that most Provigil user will have switched to the less-expensive Nuvigil, which is patent-protected until 2023. In the meantime, Cephalon will have maximized its Provigil revenue with repeated price hikes.³

FTC Commissioner Jon Leibowitz hit the nail on the head upon the filing of the FTC’s suit against these settlements in 2008 when he asked, “Why would companies that make the hallmark of their business delivering low cost drugs actually prevent that result from happening here? The answer is as troubling as the settlements themselves. Here the non-relinquishing generics appear to be sending a clear signal to PhRMA companies: you can do business with us in the future; we will protect your monopolies.”⁴

A settlement that allows the generic to enter the market early when that early date is calculated against the expiration of a weak patent is not pro consumer. It is critical, Mr. Chairman, that any legislation addressing the patent settlement issue correct the incentive problem to ensure subsequent filers have an opportunity to achieve a return on their investment if they fight on and win. *Consumers and taxpayers will be the biggest beneficiaries of such a system as this system will make it more attractive for generics to fight to knock out weak patents rather than settle their challenges of them.* Were it not for this systemic Hatch-Waxman flaw, Apotex would likely already be on the market with a generic version of Provigil®. We have a tentative approval for the product but are blocked by the settlements.

In the meantime, as *The Wall Street Journal* detailed, consumers and taxpayers who are paying for this drug, which is used frequently by senior citizens and the military, are being gouged by sharp price increases. The Provigil® settlement – and the many others like it which allow for an “early” entry date of the generic – is anything but “pro-consumer.”⁵ I was so steamed by it that Apotex filed a suit against it on principle in

³ “How a Drug Maker Tries to Outwit Generics,” *The Wall Street Journal*, November 17, 2008.

⁴ See <http://www.ftc.gov/os/caselist/0610182/080213comment.pdf>

⁵ Generic companies have settled and agreed to delayed entry even in cases they have *won* in the district court. One example of this occurred just last year when Barr Labs settled a case and agreed to delay its entry into the market place after it invalidated a patent covering Boehringer Ingelheim’s Mirapex®, a treatment for Parkinson’s disease and Restless Leg Syndrome. A second example is Barr’s 1993 settlement with AstraZeneca, which it entered into after it won a district court decision invalidating a patent covering tamoxifen, a treatment of breast cancer. Barr and the Generic Pharmaceutical Association often cite the tamoxifen case as an example of a “pro consumer” settlement, because under the terms of the settlement, Barr was granted a license by Astra to sell tamoxifen in 1993. Barr did so at a price reported to

2006. That suit is regretfully languishing in the courts, Mr. Chairman, on the slow track to nowhere.⁶ It is essential that Congress intervene to end the ability of generic and brand companies to game the system through arrangements like the Provigil[®] settlement that block the market for years on end.

Settlement Problem Has Worsened Since 2007

The settlement problem, Mr. Chairman, has only worsened since the 2007 hearing this Subcommittee held on the issue. Settlements are becoming the norm in Hatch-Waxman patent challenges. According to a report released in February of this year by the Stanford Financial Group, the number of settlements doubled from 21 in 2007 to 42 in 2008. Settlements, moreover, are only going to continue to grow in the wake of the Lupin case, which drove home the futility of continuing the patent fight in the face of first filer settlements that include acceleration clauses. It is inevitable that there will be an increase in settlements by subsequent filers. FTC Chairman Jon Leibowitz again got it

be about 15% lower than the brand price. In support of their argument that the tamoxifen settlement was “pro consumer,” Barr and the Generic Pharmaceutical Association often point out that after Barr settled the case, other generic companies lost their attempts to invalidate the patent. Because of the settlement, they argue, Barr was able to provide a lower cost alternative to consumers earlier than the 2002 patent expiry. The settlement was pro consumer, they add, because the failure of the subsequent challengers to win their patent challenges shows Barr’s decision was the best one for consumers. What they don’t explain is that none of the other companies who attempted to knock the patent out after Barr settled the case could take advantage of what Barr had discovered that enabled them to knock out the tamoxifen patent. Barr and AstraZeneca sealed the case when they settled. There was a smoking gun in this case that others challengers were blocked from seeing. I know this because I was Chairman of Barr’s Board of Directors at the time. It is absurd to suggest the settlement was pro consumer. Generic prices drop to as much as 10% of the brand price or lower when full competition ensues following the expiration of the 180 day exclusivity period. Patients should have benefited from the lower prices full generic competition in the tamoxifen market would have generated at the end of 1993 had Barr launched after winning. Instead, full generic competition did not begin until the patent Barr had invalidated expired in 2002. The cost to patients and taxpayers was hundreds of millions if not billions of dollars.

⁶ The pace of both Apotex’s and the FTC’s suits against the Provigil[®] settlements underscore the inadequacy of the provision Congress added to Hatch Waxman in 2003 under which a generic company can be stripped of the 180 day exclusivity reward upon a finding by an appeals court that it entered into a settlement that violates anti-trust laws. It takes a tremendously long time before an appeals court decision in an antitrust case can be attained. In the Cipro[®] case in which Barr and Bayer settled, it took nearly 12 years from the time of the settlement was reached in January 1997 before the appeals court ruled in 2008. In the tamoxifen case in which Barr and AstraZeneca settled, it took nearly 13 years from the time of the settlement before an appeals court ruled (’93 settlement, ’06 decision). In the K-Dur[®] case in which Schering Plough and Upsher Smith settled it took nearly 8 years (’97 settlement, ’05 decision). In the Cardizem[®] case in which Andrx and Hoechst settled, it took nearly 6 years (’97 settlement, ’03 decision). In a class action case brought by several plaintiffs against Cephalon and the four generic settlers in the Provigil[®] case, a motion to dismiss was filed over two years ago and the judge has yet to rule on the motion. In the FTC’s case against Cephalon, a motion to dismiss was filed in June 2008 and the judge has not yet ruled. In the meantime, as *The Wall Street Journal* article detailed, Cephalon is working to switch patients from Provigil[®] to the next generation product Nuvigil[®]. Thus, as these examples show, by the time the required appeals court finding is reached, changes in the market place, such as the conversion by the brand company of the patient population to the next generation product, will have significantly reduced if not eliminated the opportunity for any savings from full generic competition.

exactly right when he stated upon the filing of a case by the Commission in January of this year against Watson, Par, Paddock and Solvay concerning their settlement of litigation over the drug AndroGel[®] that “Generic entry prior to patent expiration, which had been a common occurrence until the past few years, is at the risk of becoming the rare exception. Congress enacted the landmark 1984 Hatch-Waxman Act to encourage early generic entry and save consumers money, but these anticompetitive deals threaten to destroy that benefit and make crucial portions of the Hatch-Waxman Act extinct and all but name.”⁷

Solely Amending the Antitrust Laws is Not a Sufficient Solution to the Problem

Since the Subcommittee’s hearing on this matter in 2007, Mr. Chairman, there have also been developments in the litigation of “reverse payment” cases and antitrust cases in other regulated industries that strongly suggest that antitrust legislative reform alone is an insufficient means to address the patent settlement problem. The proposed legislation would enact a change to antitrust laws to declare reverse payments *per se* illegal. Solely enacting a change to the antitrust laws declaring reverse payments *per se* illegal will not be sufficient to stop anticompetitive settlements.

While we do not oppose this change, we urge Congress to appreciate that “reverse payments” are not the fundamental problem, but only a symptom of the problem. Eliminating reverse payments will not solve the problem of a first filer settling for late entry and blocking market entry by a subsequent filer who would otherwise fight for a much earlier entry date and win.

Thus the inclusion in your legislation of a provision granting shared exclusivity to a subsequent filer who is first to win would remain crucial to solving the problem.

Fixing Hatch-Waxman Essential: Problem Can Be Fixed ONLY By Giving Shared Exclusivity to the First to Win

As previously stated, Congress can correct the flaw in the Hatch-Waxman act that lies at the root of the settlement problem *by making the first generic to win eligible to share the exclusivity along with the first generic to simply file its application with the FDA.*

This proposal, Mr. Chairman, is anything but radical. It is how Hatch-Waxman was intended to work by Congress and the FDA when it was originally enacted. When it implemented the law after its passage in 1984, FDA awarded the exclusivity to the first generic to win the patent case, not the first to file. Subsequent court challenges, however, struck the first to win interpretation down, leaving in place a system which awards the exclusivity period to the first generic company to submit an application with a patent challenge to the FDA even if it is not the first generic company to win the litigation.

⁷ See <http://ftc.gov/speeches/leibowitz/090202watsonpharm.pdf>

Senator Hatch confirmed that the first to win interpretation was the correct interpretation in 2003 when Congress amended the Hatch-Waxman Act but failed to restore it to its original intent. Said Senator Hatch:

The intent of this section of the 1984 law was to award the 180-day head start to the first successful challenger of the innovator firm's patents. Unfortunately, we drafters of the statute employed language that has been interpreted by the courts to grant the 180-days of exclusivity to the first generic applicant to file an application with the FDA that challenges the patents...The mismatch between the rights accorded to the first applicants and the first successful challenger contributed to an atmosphere in which anti-competitive agreements were entered into between certain generic and pioneer firms.⁸

It should also be noted that the concept of expanding exclusivity to enable the first to win to share the exclusivity with the first to file is consistent with current law. Current law allows for shared exclusivity already in instances when multiple generic companies are first to file applications with patent challenges on the same day, as occurred in the Provigil[®] case.

District Court Victory Must Be the Trigger in First to Win Fix

For this proposal to be effective it is essential that *a victory at the district court level be sufficient* to make the generic company eligible to share the 180 day exclusivity reward. If the threshold is set at the appeals court level, the same lack of incentive subsequent filers currently have to continue the patent fight will persist unabated. The first filer will simply accelerate its entry into the market as soon as a subsequent filer wins at the district court level, leaving the successful subsequent filer in the same position as it is today – guaranteed to get nothing if it wins.

It is essential not to confuse the concepts of triggering the exclusivity of the first to file with granting shared exclusivity to the first to win. Even if the triggering of the first to file remains set at the appellate court level, it is crucial that the granting of shared exclusivity to the first to win occur upon a district court victory by the first to win, without awaiting affirmation on appeal.

There is no doubt whatsoever that implementing shared exclusivity for the first to win with a district court trigger will generate enormous savings for consumers as a result of generic drugs entering the market earlier than is possible under the existing Hatch-Waxman system. To the benefit of consumers, a subsequent generic filer who is first to win would almost certainly enter the market upon a favorable district court decision even though such a decision could be reversed on appeal. The odds of the case being reversed against the generic are extremely low. The aforementioned Stanford Financial Group Report on generic litigation success rates found that only 2 of 92 cases in which the

⁸ See *Congressional Record*, December 9, 2003, p 16105

generic company prevailed were reversed against the generic. FTC data reinforce the Stanford report's findings. In its 2002 study "Generic Drug Entry Prior to Patent Expiry," which analyzed the outcome of generic challenges between 1992 and 2002, the FTC found that district court decisions favorable to the generic company were upheld 92% of the time (13 out of 14).⁹

Generic companies are very well aware that a large number of brand patents are weak and would be knocked out if they fully prosecuted the patent fight. For instance, in April 2008, the general patent counsel for Teva Pharmaceuticals stated "A large portion of these patents should never have been registered in the first place."¹⁰ In fact, first to file generic companies are using the threat of at risk launches to cajole brand companies into entering into anticompetitive settlements. Brand companies have taken note of generic companies' increased willingness to launch at risk. They know the threat is more real than it has ever been. The willingness of generic companies to launch at risk, particularly on a blockbuster drug, sends an unmistakable message: the patents generics are challenging are weak. If a generic company is willing to launch at risk before even a district court decision, it most certainly follows that it will be willing to launch after a district court victory. Yet the generic industry is fighting tooth and nail to preserve its ability to enter into settlements that will permit generic companies to preserve weak patents in settlements that block consumer access to generics for years longer than is necessary or right.

The Stanford Financial Group report found that generics won their cases about 50 percent of the time. Other data, including the 2002 FTC study which found generic companies prevailed in 73% of the cases ultimately resolved by a court decision, show even higher generic success rates.¹¹ Thus if generics win at least half their challenges, it stands to follow that in half the cases that are settled, consumers would have had access to generics much earlier than the purported "early" or "pro consumer" dates the generic industry asserts can only be attained with certainty by settling. With generic companies being well aware of the weakness of brand patents, the public should be benefiting from more generic victories in the courts and earlier consumer access to generics, not more settlements and later generic access. Yet, the data shows that settlements are on the rise. And they are on the rise because by settling, the generic company can eliminate all the risk of losing the litigation without giving up the 180 day exclusivity reward that was supposed to be earned by knocking out the same weak patents they are leaving in place in collusive agreements with their brand partners to delay full and fair generic competition. Elimination of the risk of losing by the generic company is not just a payment in and of itself, but the *primary* form of payment in Hatch-Waxman settlements. *Banning reverse payments without addressing the incentive problem will therefore not effectively prevent*

⁹ "Generic Drug Entry Prior to Patent Expiration: An FTC Study," July 2002, p 21. <http://www.ftc.gov/2002/07/genericdrugstudy.pdf>

¹⁰ See "Teva's patent marathon runner," Globes [on line], April 24, 2008. www.globes.co.il/serveEN/globes/docView.asp?did=1000336068&fid=1724.

¹¹ July 2002 FTC Study, p. 20. A 2006 study also documented this trend, finding that patent holders in the pharmaceutical industry were successful on the merits in only 30% of Federal Circuit decisions from 2002 through 2004. See Paul Janicke & Lilan Ren, "Who Wins Patent Infringement Cases?" 34 AIPLA Quart. J.1.20 (2006).

market blockages. Generic companies will still settle cases that leave weak patents in place. Congress must create a viable mechanism – allowing the first generic to win in the district court to gain shared exclusivity – for subsequent filers to break through parked exclusivities even if reverse payments are banned.

Apotex's example, Mr. Chairman, shows that if the system is changed in the manner we are suggesting, consumers will benefit from the incentives the new statutory framework would create for generic companies to pursue patent challenges instead of settling them. The data published in the Stanford Financial Group report demonstrates the point.

The report analyzed the results of nearly 280 challenges by generics from 2000 to 2008. The report considered the outcome for the generic company successful if the generic company won the case, settled the case, or the case was dropped (I do not agree that a settlement should be counted as a success, but that is how the report measured success). According to this measurement system, Apotex is the least successful generic challenger. The implication is that Wall Street thinks Apotex would be a bad investment because Apotex settles very few cases.

The report, however, also includes data on the number of times generic companies were successful in overturning district court cases that had gone against the generic. Of the 10 such cases identified in the report, Apotex led all companies with four victories on appeal. In reality, we were responsible for 5. Apotex was also involved with one of the victories (Prozac[®]) attributed to the company with the next highest total (Barr Labs: 2)¹². I was Chairman of Barr's Board of Directors at the time and developed the Prozac[®] case. Profits from the victory were split 50/50 between Apotex and Barr. In short, the data clearly reflects our commitment to fighting for consumers as was originally intended by the Hatch-Waxman Act.

I want to be clear that I am not suggesting that generics should be forced to fully prosecute every patent challenge. We are not opposed to generics settling cases and believe the right to settle should be preserved. But the original intent of Hatch-Waxman is unambiguous: to get generic drugs into the market as fast as possible. If a generic company believes the best it can do is to reach a settlement that allows it to enter the market a few months prior to the expiration of a patent it should take that deal. But that deal must not be allowed to block another generic that is willing to continue the patent fight in the face of that settlement, does so, and wins.

What Apotex's litigation record shows, Mr. Chairman, is that a generic company that is willing to vigorously pursue the patent case can both profit and produce much greater savings for consumers than a system in which every case is settled. Consistent

¹² Barr won the Prozac case only after Eli Lilly rejected the offer of Barr's CEO to settle the case for \$200 million. See "Trial is Getting Underway Today in Prozac Patent Lawsuit," *New York Times*, 1/25/99. Had Barr had its way, the case would have been settled and the billions of dollars in savings for consumers that were realized as a result of the full prosecution of the patent case would never have been realized.

with Hatch-Waxman's original intent, generics should be rewarded for knocking out weak patents and opening markets earlier, not for letting weak patents stand and delaying consumer access to generics, as is the case today. A system that gives shared exclusivity to the first to win *with a district court trigger* will correct this perversion of Hatch-Waxman by providing subsequent filers with the needed incentive to carry on the patent fight in the face of a settlement – incentive that is non-existent under today's statutory framework. In so doing, this change will end the settlement problem by making it possible for generics to reach consumers even earlier than the purported "early" dates the generic drug industry says it is providing in settlements that allow for generic entry a few months earlier than the expiration of a patent that would have been knocked out years prior had the patent fight been fully prosecuted.

As I testified to in 2007 and reiterated again today, we urge Congress to make it possible for Apotex and other generic companies to operate in a manner consistent with the original intent of the Hatch-Waxman Act. Implementing a first to win system with a district court trigger will accomplish this goal.

Also Essential to Neutralize "Poison Pill" Provisions in Settlements

As explained earlier in this testimony, the use of "poison pill" provisions which allow a first filer who has settled to accelerate its entry into the market upon a victory by a subsequent filer is a standard component of every settlement today. These "poison pills" undermine the incentive of subsequent filers to carry on the patent fight and empower first filers to accept later entry dates. Acceptance of later entry dates in settlements is possible because the "poison pill" guarantees the first filer's ability to retain exclusivity no matter how long the period of delay it agrees to is.

To be effective, legislation addressing the settlement problem must not only give shared exclusivity to the first to win but must also ban these "poison pills". Banning "poison pills" will accomplish two essential goals. Firstly, it will ensure the subsequent filer has adequate incentive to carry on the patent fight in the face of a settlement. Secondly, it will shorten the period of delay first filers are willing to accept in settlements. For if they agree to a lengthy delay in a settlement and a subsequent filer wins and is permitted to enter the market, the first filer will then find itself far behind its competitors instead of ahead of them. This will serve the public's interest by ensuring that when generic companies negotiate settlements of patent challenges with brand companies, they are incentivized to negotiate for market entry at the earliest possible time.

This correction can be implemented by providing that FDA cannot grant final approval or must suspend final approval for the first filer until the date to which the first filer has agreed to accept delayed market entry, without acceleration by a "poison pill" provision.

Declaratory Judgment (DJ) Problem

Before closing, Mr. Chairman, I also want to urge you to retain in your legislation the provision that corrects the DJ problem by making both the dismissal of a DJ action for lack of subject matter jurisdiction and the execution of a covenant not to sue triggering events for the first filer's exclusivity. However, it is essential to supplement this provision by granting shared exclusivity to the subsequent filer who has obtained dismissal of the DJ action and/or the covenant not to sue.

In the 2003 amendments to Hatch-Waxman, Congress included a provision intended to redress the inability of generic companies to bring declaratory judgment actions in instances where the brand company declined to sue the generic company for patent infringement, a common and effective tactic used by brand companies to delay generic competition.¹³ The provision proved to be less than effective until a 2007 holding by the Supreme Court in *MedImmune v. Genentech* that enhanced the ability of generics to get DJs under the 2003 provision added to Hatch-Waxman by Congress for this purpose. *See* 549 U.S. 118 (2007) In that case the Supreme Court held that the Federal Circuit was being too restrictive in deciding when a declaratory judgment can be maintained thereby improving the ability of generic drug companies to bring DJ actions under the 2003 amendments to Hatch-Waxman. The DJ problem, however, is by no means resolved. The provision is not functioning as Congress intended.

While the Federal Circuit did indeed rule in *Caraco v. Forest* that a subsequent generic company can bring a declaratory judgment action even if the brand company promises not to assert its patents against that applicant, the Federal Circuit reached the opposite conclusion in *Janssen v. Apotex* despite the two cases containing an extremely similar set of circumstances. *See Caraco Pharm. Labs. v. Forest Labs.*, No. 2007-1404 (Fed. Cir. 2008); *Janssen Pharmaceuticals, N.V. v. Apotex, Inc.*, No. 2008-1062 (Fed. Cir. 2008) Apotex was also denied a DJ in another post *MedImmune* case in which the

¹³ The inability to get DJs when not sued for infringement prevents generic companies from resolving patent liability issues prior to launching products, which in turn stifles competition; generic companies are confronted with the choice of launching products at risk and potentially being held liable for treble damages if they do so, are subsequently sued, and lose, or not launching at all until all liability issues are resolved. Generic companies' inability to get DJs also has made it exceedingly easy for brand companies to game the Hatch-Waxman Act's forfeiture provisions as added by the MMA. In order for a subsequent filer to put a first-filer in a "use it or lose it" position regarding 180-day exclusivity under the MMA amendments, the subsequent filer is required to win an appeals court decision before the first-filer does. If the subsequent filer achieves an appeals court victory on the same set of patents the first-filer has certified to qualifying the first-filer for exclusivity, the first-filer has 75 days to launch its product or it forfeits its exclusivity. Brand companies seeking to preserve a market blocked by a parked exclusivity simply refrain from suing subsequent generic applicants, thus denying them the ability to litigate the patents they are required to litigate in order to have any chance to put the first-filer in a "use it or lose it" position regarding its 180 exclusivity reward. As the body of this section of the testimony discusses as well, even if the DJ issue is resolved definitively through a legislative solution, there is no less of a need to correct the systemic flaws in the Hatch-Waxman Act identified in this testimony in order to resolve the settlement problem.

brand company provided a covenant not to sue. *See Merck v. Apotex*, 488 F. Supp. 2d 418 (D. Del 2007) So although the ability of generic companies to bring DJ actions has improved in the wake of the MedImmune decision¹⁴, the question of just when generic manufacturers can and can not get DJs has not been resolved definitively. Legislation is needed to resolve the matter once and for all. The provision in your legislation that makes both dismissal of a DJ action for lack of subject matter jurisdiction and execution of a covenant not to sue triggering events for the first filer's exclusivity would effectively address this issue.

I would emphasize, however, that as important as it is for the DJ provision to function as Congress intended, the status of that provision is irrelevant to resolving the patent settlement problem if its resolution is not coupled with the correction of the fundamental flaw in the Hatch-Waxman statute that is the cause of the problem: the failure of the statute to provide any incentive for non first filers to continue the patent fight when blocked by a first filer's exclusivity.

Even if a subsequent generic filer can get a DJ and thereby attain a court decision on a disputed patent's validity or infringement status, a victory by the subsequent filer guarantees that the first filer who delayed its entry date in a settlement will immediately launch upon the victory of the subsequent filer in order to protect its exclusivity. A fully functioning DJ provision would do absolutely nothing to correct this problem.

Conclusion

As detailed in this testimony, in Apotex's view, it is critical to recognize that the primary anticompetitive aspects of settlements are those that eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry in the face of a settlement in which the first filer has blocked the market by parking its exclusivity.

We thus urge the Subcommittee to work for legislation that includes all of the following features:

1. An amendment that gives shared exclusivity to a generic challenger who, although not first to file an application with a patent challenge with the FDA, is first to succeed in addressing the listed patents at the district court level.
2. An amendment that overrides the "poison pill" provision in any settlement whereby the generic who settles for a delayed entry date can accelerate that date on the basis of a victory of a subsequent filer who was first to win, which as aforesaid can be affected by providing that FDA cannot

¹⁴ After the MedImmune decision, the Federal Circuit, in *Teva v. Novartis*, 482 F.3d 1330 (2007), reversed a District Court decision denying Teva a DJ in case where Novartis sued Teva on only one of 5 patents listed in the FDA's Orange Book. As a result of the reversal, Teva was able to bring a DJ against the four patents Novartis had filed suit against.

grant final approval for the first filer until the delayed entry date to which the first filer has agreed.

3. A provision that makes both dismissal of a DJ action for lack of subject matter jurisdiction and execution of a covenant not to sue triggering events for the first filer's exclusivity, as proposed in your legislation.

Including these proposals in your legislation will achieve our shared goal of ending the ability of generic and brand drug companies to unduly delay timely consumer access to generic drugs through anti-consumer and anti-competitive agreements that bottleneck the market. The savings for consumers and taxpayers will be massive – untold billions of dollars in lower drug costs. Apotex, as always, stands ready to assist you in bringing these savings to fruition.

Thank you, Mr. Chairman, for the opportunity to once again testify on this important consumer issue. I look forward to any questions the Members of the Subcommittee may have.

Mr. RUSH. The chair thanks the gentleman. Now the last witness, the chair recognizes for 5 minutes Mr. Whitehouse. You are recognized now for 5 minutes for the purposes of opening statement.

STATEMENT OF TED WHITEHOUSE

Mr. WHITEHOUSE. Thank you. Chairman Rush and Congressman Stearns and members of the subcommittee, good morning. I am Ted Whitehouse. Now it is good afternoon. I am a partner at Willkie Farr and Gallagher and appearing today on behalf of Teva Pharmaceuticals, which, as you know, is the leading pharmaceutical company that participates both on the generic and the brand sides of the industry. Teva and I appreciate the opportunity to appear and be heard on these important issues.

As I think you know, Teva has been an active participant in the last Congress and in the current Congress in the deliberations on the matters at issue in this hearing. We hope it has been apparent to everyone that Teva is very concerned about this and similar legislative proposals but also very willing to work constructively with Congress and the FTC in an effort to ensure that the concerns being raised here are addressed without doing harm to the vital concerns and incentives at the heart of Hatch-Waxman.

Teva believes that the intricately crafted Hatch-Waxman process that Congress put in place 25 years ago has worked and is working very well. Teva's basic position is that no new legislation is needed. Teva is therefore opposed to H.R. 1706. Teva believes the ability to reach reasonable, timely and pro-consumer settlements in Hatch-Waxman paragraph four litigations is absolutely essential to Teva's efforts to bring low-cost generic drugs to market as soon as possible. And that is Teva's fundamental business, to work to bring products to market as soon as possible.

From the perspectives of consumers, settlements that result in bringing products to market sooner with more certainty than might otherwise be the case are a very good thing. Teva believes that the members and staff should give particular attention to a recent paper written by three prominent economists including Dr. Laura D'Andrea Tyson, a professor of economics at Berkeley who served as a chair of the counsel of economic advisors and is director of the National Economic Council in the Clinton Administration. She is joining the Obama Administration to advise on tax policy as we understand it.

This paper, copies of which we believe have been distributed to all members and their staff, confirms on the basis of economic analysis and theory some of the conclusions that Teva reached from this practical experience. First, that settlements can be good for consumers. Second, that reasonable settlements are more likely to be achieved if parties have more than one or two issues over which to bargain. And third the paper emphasized the importance of case-by-case analysis of settlements rather than a blanket ban on particular terms.

As Dr. Tyson's coauthor said in a letter sent yesterday to the chair and ranking member, "a broad ban on certain types of patent settlements, such as that considered in the proposed legislation, will likely make American consumers worse off."

Teva does not contend that all Hatch-Waxman settlements are necessarily good for consumers, but it takes strong issue with the legislation that would have prevented Teva from engaging in any of the recent settlements that Teva reached that produced real benefits for consumers. For example, 10 settlements entered into by Teva between 1999 and 2007 took approximately 80 years of the lives of the patents at issue and will end up saving consumers more than \$67 billion.

Teva believes that more serious considerations should be given to legislative alternatives that were extensively discussed in the last Congress, such as mandatory expedited review by the courts or a more formal expedited FTC pre-effective review process. If the subcommittee determines to proceed with the approach embodied in H.R. 1706, Teva strongly urges that the exceptions or carveouts in the bill be broadened to make clear that at least the kinds of terms that Teva has successfully employed in the past to reach settlements that produced real benefits for consumers remain permissible.

And those provisions include, among other things, early generic entry on other products in addition to the one in suit, a full release for damages and a covenant not to sue on all patents on the generic products involved in the settlement, a limited exclusive license, and case-by-case authority for the FTC.

Now, most of H.R. 1706 is directed to patent settlements; however, section four addresses a different set of issues not tied or limited to patent settlements. Essentially section four would broaden the circumstances under which the first generic company to challenge a brand company's patents could lose or forfeit the 180 days of marketing exclusivity provided to first filers under Hatch-Waxman.

As you have heard today, there are people in the industry who don't like the 180-day exclusivity provisions, but it is important to be very clear that those provisions have been in Hatch-Waxman from the start and are absolutely essential to the incentive structure that has brought this country the vibrantly competitive and publicly beneficial generic drug industry from which consumers, third-party payers, and the federal and state governments benefit every day.

I respectfully invite your attention to my written statement for a full explanation of Teva's concerns relating to these complex provisions in section four. But very briefly, by way of example, as written, subsection CC would result in forfeitures of exclusivity before anyone has been cleared to enter the market. Proposed subsection DD, we believe, is confusingly unclear and potentially very overbroad.

On all of these issues, Teva hopes to continue an active and constructive dialogue with members of Congress and their staff and with FTC commissioners and the FTC staff, all with a view of trying to address any legitimate concerns while carefully preserving all that is good and necessary about the existing and highly successful Hatch-Waxman process.

Thank you very much, and I would be pleased to answer any questions that you may have.

[The prepared statement of Mr. Whitehouse follows:]

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Testimony of

THEODORE C. WHITEHOUSE

of

Willkie Farr & Gallagher LLP

on behalf of

TEVA PHARMACEUTICALS USA, INC.

Concerning

H.R. 1706,

“Protecting Consumer Access to
Generic Drugs Act of 2009”

Before the

Subcommittee on Commerce, Trade, and Consumer Protection
of the
Committee on Energy and Commerce
of the
United States House of Representatives

31 March 2009

SUMMARY

- This testimony is submitted on behalf of Teva Pharmaceuticals USA, Inc., the largest *generic* pharmaceutical company in the US and the company with the most experience with Hatch-Waxman Paragraph IV patent challenges.
- Based on its considerable experience with Hatch-Waxman litigation, Teva strongly believes that settlements of those cases are an absolutely necessary part of the Hatch-Waxman process and that it is essential to have an adequate range of terms over which to bargain to reach necessary and pro-consumer settlements like those in which Teva has engaged. Recent analysis by prominent economists supports this belief.
- Teva's settlements have brought major benefits to consumers by making possible the present and future launch of products an aggregate of at least 80 years before the expiration of relevant patents, thereby saving consumers more than \$67 billion. H.R. 1706 as currently drafted would ban the very settlement terms that have enabled Teva to bring generic drugs to market years before they might otherwise have become available to consumers.
- Teva does not believe that legislation like that embodied in H.R. 1706 is necessary or desirable. However, recognizing the concerns raised by the FTC and in Congress with respect to perceived anticompetitive abuses in particular settlements, Teva has worked and will continue to work with members and staff in both houses of Congress to develop and refine legislative options that do not severely restrict the kinds of settlements that help to bring products to market for the benefit of consumers.
- The outcome of pharmaceutical patent litigation may be more uncertain today than it has been in the past and the need for the flexibility to settle when circumstances warrant is more important than ever.
- Alternative forms of legislation providing for expedited review of settlements before they become effective, either by the court handling the patent litigation or by the FTC through a process similar to current Hart-Scott-Rodino merger review procedures, would be less potentially disruptive to the Hatch-Waxman process than a ban on particular kinds of settlement terms.
- H.R. 1706 imposes too stringent a limitation on settlements. At a minimum, it needs to be revised to allow for the kinds of settlements by which Teva has brought great benefits to consumers.
- The provisions of H.R. 1706 relating to forfeiture of the 180-day exclusivity for first filers are at least unnecessary and potentially very damaging to the core incentives underlying the Hatch-Waxman process by, among other things, causing a forfeiture of exclusivity before anyone has been cleared to enter the market.

Chairman Rush, Ranking Member Radanovich, and members of the Subcommittee, good morning. My name is Theodore Whitehouse and I am a partner in the law firm of Willkie Farr & Gallagher LLP, specializing in litigation with a particular focus on antitrust law. I have had the privilege of serving for several years as an antitrust lawyer for Teva Pharmaceuticals USA, Inc. ("Teva"), a leading pharmaceutical company that participates in both the generic and the branded sides of the industry. Teva appreciates the opportunity to appear and be heard on the important issues being considered here today.

Teva is in the business of bringing low-cost generic drugs to market as soon as possible. Teva believes that the ability to reach reasonable and pro-consumer settlements in Hatch-Waxman patent litigation is absolutely essential to Teva's efforts to bring low-cost generic drugs to market as soon as possible. From a consumer welfare standpoint, settlements that result in bringing products to market sooner and with more certainty than might otherwise have been the case are a good thing. As a practical matter, settlement is more likely to be achieved if the parties have the ability to bargain over a variety of terms than would be the case if the parties are forced to bargain over only one issue. Because H.R. 1706 would, in Teva's view, unduly restrict the terms over which parties to Hatch-Waxman litigation may bargain to reach a settlement, Teva does not support H.R. 1706 as currently drafted.

In the testimony that follows, I propose to elaborate on these points and focus on specific concerns with the proposed legislation. I will begin by noting

that Teva believes that legislation providing for expedited prior review of patent settlements by a court or the Federal Trade Commission (“FTC”) would be preferable to legislation categorically banning certain kinds of settlements. I will then explain how H.R. 1706 in its current form would unnecessarily ban some of the kinds of provisions that Teva has found to be necessary and useful in reaching pro-consumer settlements in the past. Finally, I will address briefly the provisions of H.R. 1706 that would amend the Food, Drug, and Cosmetics Act (“FDCA”) so as to impose additional restrictions on the availability of the 180-day period of marketing exclusivity that is a crucial component of the incentive structure on which the entire Hatch-Waxman process depends.

I. TEVA AND ITS POSITION ON THESE ISSUES

Teva and its affiliates together constitute the largest *generic* pharmaceutical company in the world and the largest pharmaceutical company of any kind in the United States in terms of number of prescriptions filled. One result of that status is that Teva is the most active initiator of Paragraph IV Hatch-Waxman patent challenges and therefore has a lot of experience with litigating and settling the patent infringement cases that often result from challenging the patents on branded drugs. Based on that experience, Teva strongly believes that the ability to settle such cases is an absolutely necessary part of the Hatch-Waxman process.

Teva’s experience confirms that it is essential to have an adequate range of terms over which to bargain in order to reach necessary and pro-consumer settlements. Given that the parties are likely to disagree about the relative

strengths of their respective cases, a negotiation for settlement limited to only one variable is highly likely to fail because the parties will not be able to reach the agreement about the relative strength of their cases that is necessary to reach agreement on that one variable. The ability to negotiate over multiple variables increases the likelihood that the parties' differences can be bridged.

Teva believes that the Hatch-Waxman process works very well under the existing law as interpreted by the courts. The process is producing the savings to consumers, third-party payers, and the government that it was supposed to produce. Teva does not believe that legislation of the sort reflected in H.R. 1706 is necessary or desirable and is, therefore, opposed to H.R. 1706. However, Teva is very aware that there is strong sentiment from some members of Congress and elsewhere that action by Congress is needed to address perceived anticompetitive abuses in particular settlements. Teva worked closely with members and staff of the House and the Senate in the last Congress, and plans to continue to work constructively with members and staff of both houses in the current Congress, in an effort to ensure that legislation motivated by a desire to ban what are perceived as bad settlements does not also ban good, necessary, and socially beneficial settlements.

II. THE HATCH-WAXMAN PROCESS

The Hatch-Waxman amendments to the FDCA were intended to promote the introduction of low-cost generic drugs for the benefit of consumers. A central feature of those amendments is a process that enables generic drug companies to challenge the patents claimed to protect brand-

name drugs. That process is designed to encourage generic companies to incur the expense and risk of designing around patents or facing patent litigation by certifying to a belief that the branded drug company's patents are not a legitimate obstacle to generic competition, either because the generic company's proposed product does not infringe or because the patents are invalid or unenforceable. That is called a Paragraph IV certification. The Hatch-Waxman amendments offer the first generic company to make a Paragraph IV certification a 180-day period of marketing exclusivity as the incentive to identify opportunities to enter into the market before the expiration of the brand company's patents listed in the Food and Drug Administration ("FDA") Orange Book.

Under the Hatch-Waxman amendments, submitting a Paragraph IV certification often results in a patent infringement lawsuit being brought by the branded company against the generic company. Because patent litigation is expensive and can consume a large amount of the time of key company personnel -- and the resources of generic companies are, of course, finite -- generic companies must have the flexibility to reevaluate their position in Paragraph IV litigations as those cases proceed. Such reevaluation may lead reasonably to the conclusion that the prospects for success, when balanced against the costs of litigation and the other potential products to which the resources being consumed by the litigation might more productively be directed, are such that the case should be settled.

In this regard, Teva takes issue with Professor Hemphill's assertion that Congress intended in Hatch-Waxman to promote litigation.¹ Congress intended Hatch-Waxman to promote increased availability of generic drugs to consumers. While the initiation of litigation is a necessary instrument to pursuing that goal for many branded products, losing -- or walking away empty-handed from -- litigation does not further that goal. In particular cases, the statutory goal of Hatch-Waxman is more readily served by a timely and appropriate settlement than by continuing to litigate.

III. TEVA'S EXPERIENCE WITH HATCH-WAXMAN LITIGATION

Teva has been involved in more Hatch-Waxman Paragraph IV litigation than any other generic company and therefore has substantial experience with litigating and settling such cases. Teva has litigated many cases to final judgments, but Teva believes that it is essential that it be able to settle these cases where appropriate. Taking away the ability to settle and redirect efforts to other, more promising alternatives will make generic companies less willing to commit to Paragraph IV patent challenges with respect to some products. That result would be detrimental to consumers' interests in timely availability of generic drugs.

Much of the criticism of settlements in Paragraph IV cases is based on an implicit assumption that, but for the settlement, the generic company would have ended up winning the case. Any such assumption would be unreasonable and unfounded. There is no evidence of any pattern or practice

¹ C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1612-16 (Nov. 2006).

of generic companies surrendering on the brink of victory or anything of the sort; Teva certainly has not done so. There are prominent recent examples of cases in which generic companies have ended up losing their cases and in those cases consumers would likely have been better off with a settlement than with having to wait out the expiration of the patent before generic competition could begin. For example, in the Plavix (clopidigrel bisulfate) litigation, Apotex and the brand company tried to settle on terms that ultimately contemplated entry at least six months prior to patent expiration but were prevented from doing so by the FTC and a consortium of state attorneys general. With Plavix sales averaging over \$360 million per month in 2008, consumers and taxpayers would have saved many millions of dollars if Apotex had been able to settle on those terms. Instead, Apotex went forward with the litigation and ultimately lost the case.

Teva's experience makes clear that it is not easy to settle Paragraph IV cases. An artificial and unnecessarily restrictive limit on the terms available to be negotiated in such settlements will increase the likelihood that cases will be litigated rather than being settled on terms that are more favorable to consumers than a loss by the generic company.

Teva's practical experience in this regard is consistent with formal economic analysis. A recent and thoughtful paper by three leading economists confirms that pro-consumer outcomes in Paragraph IV patent litigation are more likely if the parties to those litigations have a sufficient number of terms

over which to bargain, and that restricting parties to negotiating only over an entry date will prevent otherwise pro-consumer outcomes.²

In my testimony before this Subcommittee in May 2007, I provided some data on consumer benefits from Teva's actual experience. Those figures showed that, between 1999 and 2007, Teva launched, pursuant to settlements, ten generic products on which it was the first generic firm to challenge the branded company's patent. Each of the ten settlements provided for entry earlier than the expiration of the patents, permitting launches of products an aggregate of 83.4 years before patent expiration, and brought and will bring over \$67 billion in savings to consumers. In five of its ten settlements, Teva brought its product to market in the same year as the settlements were reached. In four of its settlements, Teva secured the additional consumer benefit of early market entry on a product not at issue in the litigation being settled.

A settlement of the Paragraph IV litigation can often be the most pro-consumer outcome available to a generic company. Any settlement that produces some form of early entry is going to be preferable from a consumer perspective to a loss of the litigation by the generic company and the consequent delay of entry until the patent expires. Further, as noted above, some of Teva's settlements have produced pro-consumer results that could not have been obtained from litigating the case to judgment, such as (1) early entry

² See Brett Dickey, Jonathan Orszag, and Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry* (Dec. 2008), a paper funded by the Pharmaceutical Research and Manufacturers of America (PhRMA).

on products in addition to the one in suit, (2) protection for consumers in the event that the brand company undertakes to convert the market to another product, and (3) obtaining a comprehensive release and covenant not to sue covering all patents on the product at issue, not just the patent in suit, thereby assuring entry without further litigation.

One argument that has sometimes been advanced in the recent discussions about patent settlements is that generic companies are so likely to win Paragraph IV challenges that they have no good reason to settle. That argument is typically based on statistics purportedly showing that, in the early years of Hatch-Waxman litigation, generic companies won over 70 percent of such cases. If this statistic was ever accurate, it is certainly not so today.

Paragraph IV cases today involve more difficult issues than they typically did even just a few years ago and may be more difficult and more expensive for generic companies to win. Paragraph IV litigation used to be primarily focused on issues of infringement but, in recent years, the predominant issues involve validity of the patents. In 1999, only 18 percent of Teva's Paragraph IV litigations were primarily focused on invalidity issues and 82 percent of those cases were focused primarily on issues of noninfringement. By contrast, in 2005, those percentages literally flipped, with invalidity cases accounting for 86 percent of the total and noninfringement cases accounting for 14 percent. That is very significant because, in general, invalidity cases are more difficult and expensive to win than are noninfringement cases. Also, an increasing proportion of the cases being litigated involves challenges to the basic

compound patent rather than intrinsically easier issues involving more peripheral patents. During this same period, Teva believes that brand companies have become more sophisticated in their patenting and patent litigation strategies. What this means is that there is greater uncertainty about the outcome when Paragraph IV litigation is initiated than there used to be and a greater need to be able to reassess and move on to other more promising opportunities when events in the litigation make that advisable.³

IV. POTENTIAL LEGISLATIVE ALTERNATIVES REGARDING PATENT SETTLEMENTS

As Teva understands the situation, the introduction of H.R. 1706 and the convening of this hearing today reflect a concern that some settlements of Paragraph IV Hatch-Waxman litigation have not been procompetitive or otherwise in consumers' best interests. To the extent that there is a problem that requires legislative attention, Teva is aware of at least two broad categories of solutions that have been advanced to address it. The first category of solutions would involve establishing formal procedures (in addition to those that already exist under the 2003 MMA amendments to Hatch-Waxman) to ensure that some responsible public official or agency has an opportunity and an obligation to evaluate the competitive effects of a proposed settlement before

³ Teva's view that patent litigation is becoming more difficult and complex is corroborated by recent remarks before a March 18, 2009 Federal Circuit Bar Association/George Washington University Law School symposium by Chief Judge Michel of the United States Court of Appeals for the Federal Circuit. Mike Scarcella, *Clerk Call*, Legal Times, Mar. 23, 2009 (Patent cases are more complex now than in 1993.).

it becomes effective. The second category of solutions -- exemplified by H.R. 1706 -- would categorically ban certain kinds of settlements.

A. Formal Court or Agency Expedited Review Procedures

The first category of potential measures to address the perceived problem of bad patent settlements -- and the one that seems least likely to disrupt the existing and successful Hatch-Waxman process -- involves mechanisms to ensure that settlements are reviewed by a court or administrative agency on an expedited basis to ensure that they conform to the standards already established in the antitrust, patent, and Food and Drug laws. One approach that has been suggested would be for the court before which the litigation being settled is pending to have an explicit mandate to review the settlement to ensure that it is lawful. The court before which the case is pending is in the best position to assess the relative strengths of the parties' respective cases and to determine whether the settlement reasonably reflects those and other relevant factors.

An alternative or supplement to court review would involve more formal expedited review processes before the FTC. Already, as a result of the 2003 MMA amendments,⁴ all settlements of Paragraph IV Hatch-Waxman litigation are required to be filed with the FTC and the Antitrust Division of the Department of Justice. In Teva's experience, all such agreements are carefully reviewed by lawyers and economists at the FTC. A potential legislative approach that has been suggested would be for the FTC to have a more formal

⁴ Pub. L. No. 108-173, 117 Stat. 2066 (2003).

and structured review process for patent settlements, perhaps involving procedures similar to the Hart-Scott-Rodino procedures that have long governed large corporate mergers.⁵ Under that kind of process, parties to a settlement of a Paragraph IV litigation would have to file their settlement agreement and it would not become effective for a reasonable period of time so as to let the FTC review it before it could be actually carried out by the parties.

Teva believes that, if Congress concludes that legislation is needed to address bad settlements of Paragraph IV litigation, serious consideration ought first to be given to establishing mechanisms to ensure that all settlements are given timely review by the courts or the FTC. Teva believes that such mechanisms could adequately and non-disruptively address any perceived problems with bad patent settlements. Teva and others have previously suggested draft legislative language that would establish such mechanisms.

B. Comments and Suggestions on H.R. 1706

H.R. 1706, like similar legislation pending in the Senate,⁶ would broadly prohibit certain kinds of patent settlements (so-called “reverse-payment” settlements), subject to limited exceptions. The legislation would broadly ban any settlement in which any form of benefit flows to or through the generic company with only limited exceptions. Among other things, this means that all ten of the pro-consumer Teva settlements that I described earlier as having brought more than 80 years of time off the relevant patents and over \$67

⁵ 15 U.S.C. § 18a (2009); 16 C.F.R. §§ 801-803 (2009).

⁶ S. 369, 111th Cong. (1st Sess. 2009)

billion in savings to consumers would have been prohibited had H.R. 1706 been the law.

The legislative approach reflected in H.R. 1706 implicitly assumes that the parties to Paragraph IV litigation can reach pro-consumer settlements with only a very limited number of terms over which to bargain -- essentially, limited only to an agreement to entry on some date prior to the expiration of the patent in issue and waiver of damages for launches at risk that precede an unfavorable judgment in the patent litigation. Teva's experience is that restricting the terms of a potential settlement too narrowly will reduce the likelihood that any settlement will be reached and will thus create an undesirable risk that entry will not occur at all before patent expiration. Teva strongly urges that any legislation in this area at least allow for the sorts of pro-consumer settlements to which Teva has been a party.

As currently drafted, H.R. 1706 would allow a settlement to be based on early entry only with respect to the patent and product in suit. That limitation is likely to be a significant problem for at least two reasons.

First, as a litigator, I can tell you that it is typical for the parties on opposite sides of litigation to have very different views of the strength of each of their cases. In those circumstances, a negotiation for settlement limited to only one variable has a high likelihood of failure because the parties will not be able to reach the consensus about the strength of their respective cases necessary to agree on that one variable. The ability to work with more variables increases the likelihood that the parties' differences can be bridged.

Second, branded drug companies often have strategic reasons that have nothing to do with the merits of the pending patent infringement lawsuit for refusing to negotiate generic entry earlier than a date that is too late for fully competitive entry as to the product in suit. Under those circumstances, a settlement based only on the entry date prescribed by the brand company for the product in suit would make little sense but a settlement providing also for early entry on some other product might make for a commercially sensible settlement that is in the best interests of consumers.

H.R. 1706 desirably provides for settlements to include a waiver of damages for prior marketing of the ANDA drug. We understand this provision to be intended to address, for example, the situation in which a generic company launches at risk on the basis of a favorable lower court decision and then finds it necessary to settle following an unfavorable ruling on appeal. Teva has had actual experience with such a situation and strongly supports making provision for it in any legislation on this issue. However, Teva's experience suggests that broader language is necessary to make clear that settlements may permissibly include a complete release and covenant not to sue as to all patents on the product in suit so as to eliminate the risk that the branded company will settle and then later brandish other patents not asserted in the initial suit as a means to forestall generic entry. Also, consistently with the point as to other drug products in the time-off-the-patent provision, above, Teva believes that the release provision should clearly allow a full release and covenant not to sue as to such other products.

As many of those present are well aware, branded drug companies have recently adopted a strategy of releasing so-called “authorized generics” during the 180-day period of market exclusivity provided by the Hatch-Waxman law to the first filer of a Paragraph IV ANDA. The purpose and effect of such product releases by the branded companies are to diminish the value of the 180-day first-filer exclusivity to generic companies with the obvious goal of discouraging generic companies from pursuing the patent challenges that the Hatch-Waxman amendments were designed to encourage. To mitigate the effects of this undesirable practice, Teva believes that any legislation on these issues should specifically allow the parties to a settlement of a Paragraph IV litigation to agree through the means of an exclusive license for a limited duration that the branded company will not engage in this undesirable practice. Such a license is, of course, permissible under the current law.

Teva’s experience also makes clear that generic companies should have the opportunity to purchase finished product from the brand company for sale by the generic company as part of a settlement. Such purchases have no apparent anticompetitive potential and are an important means for dealing with uncertainties about timely FDA approval of ANDAs.

Section 3 of H.R. 1706 contemplates FTC rulemaking to establish other potential carve-outs from the general prohibition. Teva supports that idea but also believes that it would be desirable to give the FTC specific authority to approve settlements on a case-by-case basis, notwithstanding the general

prohibition, to avoid undue delay and to ensure that pro-competitive settlements are not blocked.

V. PROVISIONS OF H.R. 1706 RELATING TO FORFEITURE OF EXCLUSIVITY

In addition to the provisions directed to settlements of Paragraph IV Hatch-Waxman litigation, Section 4 of H.R. 1706 contains proposed amendments to core provisions of Hatch-Waxman amendments codified in the FDCA. Those proposed amendments to Hatch-Waxman are not limited to -- or necessarily related to -- settlements, and Teva believes that they could have substantial negative effects on the carefully balanced incentive structures that are at the very heart of the Hatch-Waxman process.

As noted previously in this testimony, the Hatch-Waxman amendments to the FDCA provide that a generic company that is the first to challenge a brand company's patent on a drug is entitled to 180 days of market exclusivity when it brings the generic product to market. The particular provisions of the FDCA that are proposed to be amended⁷ are very complex and deal with the circumstances under which a generic company entitled to 180 days of first-to-file exclusivity may lose, or forfeit, that exclusivity. It is important to note at the outset that the law as it exists today already addresses the situation in which a settlement agreement is held to be unlawfully anticompetitive: Under that circumstance, exclusivity is already required to be forfeited.⁸

⁷ 21 U.S.C. § 355(j)(5)(D)(i)(I)(BB) (2009).

⁸ 21 U.S.C. § 355(j)(5)(D)(i)(V) (2009).

Under current law, the first applicant forfeits its 180-day generic exclusivity period if it fails to commence commercial marketing within a specified time following certain enumerated events. This “commercial marketing” forfeiture provision attempts to strike a balance between avoiding forcing the first applicant to launch at risk of patent damages and allowing the first applicant to wait indefinitely to begin marketing, while retaining its exclusivity rights. In general terms, the provision states that the first applicant will not be forced to launch its product at risk of patent damages in order to maintain its 180 days of exclusivity unless the first applicant or another applicant with tentative ANDA approval has obtained a final court decision (or a settlement order or consent decree that enters a final judgment that includes a finding) that each of the relevant patents is invalid or not infringed.⁹ In essence, therefore, the statute provides that a first applicant is not required to make the difficult choice between launching at risk or forfeiting its 180-day exclusivity unless and until all of the patent barriers that were subject of the first filer’s Paragraph IV certification have been removed with respect to at least one tentatively approved ANDA product.

Section 4 of the proposed bill would expand the failure to market forfeiture provision, by providing that the mere dismissal of a declaratory judgment action for lack of subject matter jurisdiction, whether with or without prejudice, could lead to a forfeiture. This represents a dramatic and dangerous

⁹ The existing failure to market provisions also include the situation in which the NDA holder withdraws the listed patent from the FDA’s Orange Book.

departure from current law. Under this proposed amendment, for the first time, the first applicant could effectively be forced to launch its product at the risk of massive patent damages in order to maintain its 180 days of exclusivity, even though none of the patent barriers has been removed with respect to any ANDA applicant, and irrespective of whether the first applicant is in litigation with the NDA holder or has settled its case.

This amendment is clearly unnecessary, given the recent decisions of the U.S. Supreme Court and the Court of Appeals for the Federal Circuit favoring declaratory judgment jurisdiction in the Hatch-Waxman context.¹⁰ Even Apotex, Inc., an outspoken proponent of this forfeiture provision, has acknowledged that, “[t]he January 2007 Supreme Court Ruling in the *MedImmune v. Genentech* case appears to have resolved the inability of generic companies to obtain declaratory judgments when branded companies decline to sue generics for patent infringement”¹¹

In addition, the proposed amendment would strongly discourage first applicants from ever filing their own declaratory judgment actions, for fear that a judicial determination that the court lacks subject matter jurisdiction would work a forfeiture of their own 180 days of exclusivity. And, it would create a

¹⁰ See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, n.11 (2007); *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008); *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007).

¹¹ Apotex, Inc., *Patent Settlements Between Brand and Generic Pharmaceutical Companies: Parked Exclusivity & Lack of Incentive for Subsequent Generic Filers to Fight On Are the Problems, Not “Reverse Payments”* at 6 n.3.

perverse incentive for subsequent applicants to encourage challenges to the justiciability of their own declaratory judgment actions, because a dismissal for lack of subject matter jurisdiction would constitute the simplest, least expensive, and most immediate path for working a forfeiture of the first applicant's exclusivity -- as contrasted with the far more expensive and difficult task of actually having to prevail in a final court decision on the merits that is no longer subject to appeal.

More fundamentally, the proposed amendment ignores the critically important legal distinction between a dismissal for lack of subject matter jurisdiction -- which does not address the merits of the underlying patent dispute -- and a final court decision finding that a patent is invalid or not infringed. There may be public policy justifications for a rule that a first applicant cannot sit on its 180-days of exclusivity after it or a subsequent filer has obtained a judicial determination that all of the patents that were the subject of the first applicant's Paragraph IV certification are invalid or not infringed with respect to at least one tentatively approved ANDA. There is, however, no basis in either law or logic to force a first applicant to lose its exclusivity or risk potentially catastrophic patent damages, merely because a court determines that its or another applicant's declaratory judgment action does not satisfy the Constitutional prerequisites for judicial resolution.

The second proposed amendment to the forfeiture provisions of the FDCA -- captioned subsection DD -- seems to contemplate stripping the first filer of an ANDA of the exclusivity it has earned if some other applicant for authority

to make the same generic drug purchases or otherwise obtains from the brand company and files with the FDA a covenant not to sue. The circumstances under which that would be a fair and appropriate result are not apparent to Teva.

CONCLUSION

Teva appreciates the opportunity to be heard today and welcomes the opportunity to maintain a continuing and constructive dialogue on these important issues with Members and their staffs.

Thank you.

Mr. RUSH. The chair thanks Mr. Whitehouse, and now the chair will begin the round of questioning by recognizing himself for 5 minutes for the purposes of questioning the witnesses. And I just want to ask the witnesses if we need to go into a second round of questions, the chair is willing to do that if the witnesses can make themselves available for an additional round of questioning from the members of the subcommittee.

Chair recognizes himself for 5 minutes. Exclusion payment settlements are unique to the pharmaceutical industry. In all other industries, as I stated in my opening statement, patents are usually settled in two ways. One, the accused infringement pays a royalty to the patent holder or two, the two parties agree to an early entry date. It is my belief and has been stated earlier that only in the pharmaceutical industry do we see a very unusual behavior of a patent holder, which the brand name drug company suing the accused infringer, the generic company, and then paying the accused infringer to stay off the market. Only in the pharmaceutical industry.

I am going to ask Commissioner Rosch, do these types of settlements happen in any other sector? And while you are answering that, think about this question: why are these settlements unique to the drug industry? And what keeps them from occurring in other industries or commercial sectors? And how does the framework of Hatch-Waxman impede or enhances this kind of activity? Those are the questions I have for you.

Mr. ROSCH. Thank you, Mr. Chairman. Let me take them up one by one. First of all, yes I do believe that these kinds of settlements, that is to say the kinds of settlements with which this legislation is concerned, are unique to the pharmaceutical industry.

I think I take issue with characterizing them as payment settlements. They are not that. They are reverse payment settlements. They are settlements in which the holder of the patent actually pays the person who is alleging infringement some money or other thing of value. We do not frankly see that kind of settlement in any other industry. So that is the answer to the first question.

Second, why don't we see it in any other industry? It is not because we consider either the branded or the generics to be nefarious. It is simply a matter of economics. Now what am I talking about in terms of economics? First, state substitution laws as well as various kinds of formularies very much encourage switching, switching to a lower cost drug from a branded drug that is under patent.

Second, because of that encouragement, generic drugs are inclined and incentivized to switch their drugs as quickly as possible. And to do that, they are willing to actually take a haircut on their prices, well below that that the brand charges because the brand is able to charge monopoly prices.

Third, that threatens however the brand tremendously because the brand's drug is still under patent, and it is able to avail itself of monopoly pricing, brand monopoly pricing, as well as brand monopoly profits.

Fourth, because it is so threatened, the brand is willing and incentivized to go ahead and share some of those profits with the

generic. And that is what happens when it offers a reverse payment. It is, in fact, a sharing some of those profits with the generic.

So finally, the reverse payment settlement is a win-win proposition for both the brand and the generic. It helps the brand on the one hand maintain its patent monopoly. And secondly however what it does is to incentivize the generic to abandon its challenge to the patent monopoly and therefore to eschew the kind of pro-consumer activity that the Hatch-Waxman Act was originally designed to encourage.

There is nothing wrong with the original Hatch-Waxman Act. To the contrary, its incentives were perfectly aligned. It gave the brands something. It gave the generics something for challenging the brands. The problem is not with the Act. The problem is with the court decisions, which have ignored the teaching of the Supreme Court as well as what the framers of the Act had in mind in enacting the Act to begin with.

Mr. RUSH. The chairman's time has ended, and now the chair recognizes my friend from Florida, Mr. Stearns, for 5 minutes for the purpose—

Mr. STEARNS. Thank you, Mr. Chairman. I ask unanimous consent that the letter that was sent to you and Mr. Radanovich, the academic study that draws reference by—that Mr. Whitehouse mentioned, draws out the complexity of determining whether reverse payment settlements are anti-consumer and demonstrate that these settlements are actually pro-consumer in most cases be made part of the record.

Mr. RUSH. Hearing no objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. STEARNS. This is an interesting hearing, Mr. Chairman. You have the pharmaceutical industry, and as I understand it, the generic drug industry is aligned together. It is the most unlikely alliance here. Mr. Whitehead and others I represent—I mean as I understand it from my staff, Dr. Sherman, that you are alone here. That most of the generics—isn't that true, Dr. Sherman, that most of the generics are supporting—are not supporting this bill. Is that true, Mr. Whitehead? Most of the generic companies are not supporting this bill?

Mr. WHITEHOUSE. That is correct.

Mr. STEARNS. OK, and then the pharmaceuticals obviously, Ms. Bieri, do not support it. So I say to Mr. Rosch, you have here the pharmaceuticals against the bill, the generics against the bill in this case, you pointed out, pretty in detail how the courts have ruled that the Hatch-Waxman bill is working and that these reverse payments that you use—you don't like my term the settlement payment—that they actually are acceptable legal remedy and they are not anticompetitive. Isn't that true, Mr. Rosch?

Mr. ROSCH. Some of the courts have done that.

Mr. STEARNS. No, but in general, didn't all the courts show that these agreements are not anticompetitive?

Mr. ROSCH. No, that is not correct. The Sixth Circuit in the Cardizem case held that they were in fact per se illegal. The Eleventh Circuit and the Second Circuit however have held otherwise as a matter of policy. And as I said before, I think it is Congress's authority to make policy, not—

Mr. STEARNS. Did you say the Supreme Court wouldn't even rule on this because it was decided by the lower courts?

Mr. ROSCH. No, the Supreme Court did not rule on it because, as you know, the Supreme Court doesn't take—doesn't review all circuit court decisions.

Mr. STEARNS. Well, wouldn't you say the majority of courts have ruled that this is not anticompetitive?

Mr. ROSCH. Two to one, you are correct.

Mr. STEARNS. Two to one, OK. So we establish two to one the courts. So what this bill is trying to do is circumvent the courts where the courts have heard legal arguments on both sides and a two-to-one majority have said that this reverse payment that you use, which I say is a settlement payment, is not anticompetitive. Is that a true statement?

Mr. ROSCH. No, it is not correct. First of all, because the Supreme Court has held in other contexts, that is to say when they are not part of a settlement, that exactly—

Mr. STEARNS. But not in this context?

Mr. ROSCH. No, the Supreme Court has not addressed this—

Mr. STEARNS. That is what I am saying, OK. You know I think when you look at the statistics that before the Hatch-Waxman only 19 percent of the generic industry share the prescription drug benefit was only 19 percent. After the Hatch-Waxman, it went up to 70 percent. So that would show that it is working. I hear no evidence that if we pass this bill that you are going to go from 70 to 80 to 90 percent. In fact, you might go lower. And, Mr. Whitehead, if this bill passes, the statistics I just gave you before the Hatch-Waxman went to 70 percent, do you think the statistics will go lower if this bill is passed?

Mr. WHITEHOUSE. We believe it is documented in this economic study that—

Mr. STEARNS. Yes.

Mr. WHITEHOUSE [continuing]. There is a very real risk that there will be disincentive to the generic companies.

Mr. STEARNS. So why would we want to do harm then with something that the court says is not anticompetitive? We have both people involved have indicated they don't want it to happen, and we have a study to say the overwhelming statistic that it is going up to 70 percent is working. And we have a study that says in fact, if you pass this bill, that consumers will have less choice. And so it is a little interesting to me. Mr. Rosch, here is a question for you.

Mr. ROSCH. Thank you.

Mr. STEARNS. When you have statistics where it says that a study claims that in all patent litigation initiated between 1992 and 2000, the generic prevailed in 73 percent of the challenged drug products. But I don't think that is telling the whole story. How many of these wins resulted in actual generic products coming on the market?

Mr. ROSCH. Well, let us assume that it is 45 percent as—

Mr. STEARNS. No, let us just take 73 percent as the—

Mr. ROSCH. OK.

Mr. STEARNS [continuing]. Statistic that is used. Of that 73 percent, how many of those resulted in actual products being put on—

Mr. ROSCH. I can't—

Mr. STEARNS. You know what? I can tell you it is probably low because if a product consists of color, shape, compound, and dissolution, and they might win three of the cases. They say OK, we won on color, shape and dissolution, dissipation let us say, but the actual content of that, the compound itself they lose on, they can't do anything.

Mr. ROSCH. Well, let us assume it is 45 percent as you suggested earlier.

Mr. STEARNS. OK.

Mr. ROSCH. Let us assume it is 45 percent. That means that in 45 percent of the cases, these reverse payments are actually operating to hurt consumers. If it is—

Mr. STEARNS. No, well ultimately with reverse payment, settlement payment, my terms, with that means that generic drug finally comes on. Otherwise, it would be, I think you mentioned, 80 years or somebody in the panel said it would take 80 years of litigation. So you suddenly have this litigation abruptly stopped. You have in six months the possibility of generic coming on the market, and this whole litigation process ends.

Mr. ROSCH. Well, there is nothing in the bill that would chill settlements at all. There were lots of settlements that were made before the court ruled. And Schering, there have been a number of settlements recently.

Mr. STEARNS. OK, I just want—there is no evidence of reverse settlements have actually reduced cost.

Mr. RUSH. The time of the gentleman has ended. The chair now recognizes Mr. Stupak for 7 minutes for the purposes of questioning the witnesses.

Mr. STUPAK. Thank you, Mr. Chairman. Dr. Sherman, let me ask you this question. In June of 2008, Pfizer reached a settlement with Ranbaxi concerning Lipitor, the world's top selling drug. According to press reports, the settlement delayed the entry of generic here in the United States until November of 2011, up to 20 months later than many analysts had been anticipating.

The settlement of litigation here in the United States was part of a global settlement in which Pfizer granted licenses to Ranbaxi authorizing Ranbaxi to sell generic Lipitor in seven other pharmaceutical markets, Australia, Canada, Belgium, Germany, Italy, the Netherlands, and Sweden. The deal is reported to allow Ranbaxi to sell generic in those seven countries two to four months earlier than the patents expire. It was also reported that the deal would make generic Lipitor available in Canada earlier than in the U.S.

Pfizer also dropped its challenge to Ranbaxi's current sale of generic Lipitor in four countries, Brunei, Malaysia, Peru, and Vietnam. Both Pfizer and Ranbaxi said the agreement did not involve any payments. It seems to me that this global deal was full of payments. Under the settlement, market entry for Lipitor appears to have been permitted earlier in a host of countries than here in the United States, which coincidentally happens to be the largest market in the world.

So I have three questions if I may. If we pass legislation solely banning reverse payments, will we see more arrangements like this where delayed entry in United States is tied to settlement of litiga-

tion permitting earlier access to generic in markets outside the United States? Secondly, won't companies attempt to evade the payment ban by taking the position that settlements outside the United States are not subject to U.S. requirements that settlement reported to the Federal Trade Commission? And third, that the Federal Trade Commission prosecutes them for any such effort, won't the length of time it takes to do so be so long that any opportunity for savings from generic competition really be lost?

Mr. SHERMAN. Yes, I have to say that—

Mr. STUPAK. I would ask you to turn on your mike please.

Mr. SHERMAN. I am sorry. My concern is not only that reverse payments are not the fundamental problem. It is the ability to block other generics by reason of keeping the exclusivity. That is the fundamental problem. But there is no question in my mind that no matter how one tries to stop reverse payments by legislation, not only is it—even if it worked, it wouldn't have the significant effect.

But it can't work because the creative minds of thieves are without limit, and there is no question that deals can be simultaneously done outside of the United States, and Lipitor is not the only example. For example, Ben Lefaxine, Effexor XR is another example. Some years ago, Teva settled with Wyeth and agreed to a very late entry in the United States. And at the same time, they settled the Canadian litigation allowed them on the market in Canada through their Nova Pharm division. So Canadian consumers have had low-cost generic Effexor XR for years, where it is delayed in the United States under two agreements that were entered simultaneously, one outside of the United States. And that probably is beyond the purview of the American courts because the American courts don't have jurisdiction over foreign countries operating abroad. And there is no way to stop simultaneous signature of agreements that appear to be unrelated or that can be said to be unrelated.

Also attempts to block anticompetitive agreements by the FTC taking action will be futile because they will become mute by the time it is decided. It may be decided five years after an agreement is signed that it is improper, but in the meantime, there is no other generic firm because that agreement is there, able to justify investing to challenge the patent or bring the product to market. So even if a challenge to an agreement were to work, it would be moot by the time it happened.

So the concern that we have is not only that attempts to block anticompetitive deals by banning reverse payments won't be affected, but it is not really addressing the fundamental problem. That is not the payment itself but the fact that these deals, whereby the subsequent filers who would fight, can't fight because they can't get on the market. That is the problem that has to be addressed. Give shared exclusivity with subsequent filer who wins. That solves the whole problem. The problem disappears, and consumers will get the benefit.

Mr. STUPAK. Well, let me ask this one. I am going to ask Professor Hemphill if he could answer this one. H.R. 1706 only prohibits a very specific type of provision exclusive payments in drug patent settlements. That is the bill only prohibits the brand name

drug from paying or providing value to the generic company in exchange for the generic company delaying market entry.

The bill does not ban legal settlements in general. History has shown us that drug companies are perfectly capable of settling their patent disputes without exclusion payments. When the Federal Trade Commission and states crack down on these types of settlements in 2000, they disappeared, and drug companies settled their cases just like any other companies do in other industries. However, when the courts then invalidated the FTC's enforcement efforts in 2005, exclusion payment settlements came back with a vengeance.

So, Professor, doesn't this show that drug companies are perfectly capable of settling their patent disputes like any other company? And is there any evidence from the settlements from 2000 to 2005 which did not contain reverse payments, were they any more costly or difficult to achieve than settlements with reverse payments?

Mr. HEMPHILL. That is a terrific question. It is difficult to get to the very bottom of the question using publicly available information, though based on the work that I have done as to settlements—with respect to information that it is the public domain, the answer does seem to be yes, that is, just as you have suggested, drug companies during that interregnum when the FTC rules seem to be in effect did seem able to settle, just not able to settle in an anticompetitive manner.

Mr. STUPAK. Right, OK. Commissioner Rosch, did you care to—did you find the settlements during this period to be more costly or more difficult to achieve by drug companies during that 2000/2005 period when your enforcement mechanism was there?

Mr. ROSCH. No, we did not.

Mr. STUPAK. Anyone else care to comment on that? Ms. Bieri, did your companies find it more difficult or more costly to sell when we did not have that five-year period of time?

Ms. BIERI. Thank you, Congressman. I would just say that I think Mr. Hemphill is right, that the publicly available data aren't sufficient to show that for a fact. And I would—

Mr. STUPAK. How about your internal data on behalf of PhRMA? You must track that, do you not?

Ms. BIERI. No, we do not track the number of settlements each year.

Mr. STUPAK. OK.

Mr. RUSH. The gentleman's time has ended.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. RUSH. The chair now recognizes the gentleman from Nebraska, Mr. Terry, for 5 minutes.

Mr. TERRY. Thank you, Mr. Chairman. I am one of the, I think, maybe two or three trial attorneys on this side of the aisle. Omaha, you are right. I knew there was something I liked about you. And settled hundreds of cases, wrote, read settlement agreements. But I got to tell you this one is a little out of the box for me, so I am going to have to kind of take some small steps and ask you some generic questions, pun intended. That is as good as it gets up here, folks, so—

Mr. Rosch, just so I understand the scope of things, how many—just take in the last five years, how many of these reverse settlements have occurred? 5, 10, 500?

Mr. ROSCH. At least 103 that I know about, Congressman. Our staff reviewed that many at least, including, I should add, reverse payment settlements in which there were side deals plus a date certain for entry. So they were not always just payments of money, but there were 103 of them. And our staff found that all but a couple of them were very suspect.

Mr. TERRY. Now, I am sorry, out of the 103, you found that 103 of them were suspect?

Mr. ROSCH. No, two of them were not suspect.

Mr. TERRY. Were not? So 101 of them—

Mr. ROSCH. Were.

Mr. TERRY [continuing]. Fell into the category of being suspect?

Mr. ROSCH. I guess that is why I have some problems with Teva's thesis because they would like to exempt a lot of side agreements.

Mr. TERRY. OK, now as I understand, when the brand name files their patent, I mean there is a date certain there of when that patent ceases to exist and a generic can come in. I mean that is very easy to find that information, right?

Mr. ROSCH. Yes, but—

Mr. TERRY. OK, what is the but?

Mr. ROSCH. The but is that there is also provision in the statute that, for a certain period of time after the brand is entered, it will basically get a free pass. Normally, that is five years, but it can go up to seven years in the case of some pediatric drugs where there are relatively few sales.

In addition to that, they get something that you and I never saw in our lifetimes as litigators, and that is that they get a certain period of stay time with respect to an automatic, if you will preliminary injunction. And there is nothing like that—

Mr. TERRY. How long—

Mr. ROSCH [continuing]. In any other patent—

Mr. TERRY [continuing]. Would that stay time average?

Mr. ROSCH. I believe—

Mr. TERRY. And who gives that stay time? That is not statutory.

Mr. ROSCH. It is statutory.

Mr. TERRY. That is statutory?

Mr. ROSCH. That is.

Mr. TERRY. So statutorily, they get an extra amount of time because of—

Mr. ROSCH. It is 30 months.

Mr. TERRY. Thirty months. So I guess is there then not clarity on when the dates that the patent runs out that the generic can just jump into the market without legal issue?

Mr. ROSCH. No, again this is a matter of the statute. The statute allows what is called the first filer—

Mr. TERRY. Right.

Mr. ROSCH [continuing]. Who goes to the FDA first, and certifies that it is not infringing or that the patent is invalid.

Mr. TERRY. That is where—can I interrupt there?

Mr. ROSCH. Yes.

Mr. TERRY. Because that is where part of my confusion is coming in. If the date for the patent has run out, why do they have to declare or somehow adjudicate that there is something wrong with the patent?

Mr. ROSCH. Because the statute contemplates that before the patent runs out the generic will be incentivized to challenge patents which are not valid or infringed or in which validity or infringement is questioned.

Mr. TERRY. Well, even though they may be incentive, they still have to find something wrong with the patent.

Mr. ROSCH. Correct.

Mr. TERRY. Unless they want to wait until the end of the patent date. So it seems to me that if they are incentivized to attack the validity of the patent because we want to have a policy that gets those generics out there sooner than the end date.

Mr. ROSCH. Yes.

Mr. TERRY. I am not sure if I would agree with the premise that these are reverse payments. Out of the 103 then, let me just jump to my conclusion for my—I am out of time but—

Mr. ROSCH. Surely.

Mr. TERRY [continuing]. Let me ask this question. How many out of the 101 nefarious reverse settlements actually made the date that the generic got to the market sooner than the clear date that the name brand patent ran out?

Mr. ROSCH. The answer is, I believe, in almost all of those cases, it was sooner, but I would suggest most respectfully that that is not the question. Brand names do not pay tens or hundreds of millions of dollars in reverse payments to generics in order to accelerate their entry into the market. They don't do that. What instead they are doing is they are paying to keep that—to skew if you will the incentives of the generic to prevent the generic from actually challenging a patent that should be challenged. So that is the pernicious part.

There is nothing wrong—I want to emphasize that. There is nothing wrong with the incentives created by Hatch-Waxman. The problem is created by the reverse payment settlement.

Mr. RUSH. The gentleman's time has expired. The chair now recognizes the gentlelady from Illinois, Ms. Schakowsky, for five minutes.

Ms. SCHAKOWSKY. Let me just say that over 30 years ago, I was involved in, because I was a director of a senior citizen organization, working to get the state of Illinois to pass generic drug legislation in the hopes that it would reduce the cost, which has proven to be true. My colleague and friend Mr. Stearns was talking about how incredible it was that the generic drug, or at least the first filers anyway, and the pharmaceutical companies were on the same side.

Obviously the problem is that they are because both are benefiting to the detriment, it seems, of the consumers. Mr. Whitehouse, you were probably citing this study, and you certainly didn't mean to imply that because Laura Tyson was an author that the Obama Administration is supporting this point of view, did you?

Mr. WHITEHOUSE. Not at all. I—

Ms. SCHAKOWSKY. OK, and who paid for this study?

Mr. WHITEHOUSE. My understanding is that it was—funding was provided by Ms. Bieri's association, PhRMA.

Ms. SCHAKOWSKY. PhRMA.

Mr. WHITEHOUSE. But they make clear that they express their independent views.

Ms. SCHAKOWSKY. I just think that is important to note for the record, that the study that is being cited was paid for by the pharmaceutical industry. Let me ask the commissioner, Rosch—is it Rosch, I am sorry?

Mr. ROSCH. That is perfectly fine.

Ms. SCHAKOWSKY. What is it really though?

Mr. ROSCH. Rosch.

Ms. SCHAKOWSKY. OK, Rosch.

Mr. ROSCH. Like the chairman's.

Ms. SCHAKOWSKY. No, you should accept your real name. OK, sorry. That the suggestions made by Dr. Sherman, he proposed that maybe we would consider two amendments to the legislation. Do you—or Mr. Hemphill, if you want to comment on that—think that would improve the legislation and why?

Mr. ROSCH. Well, again I am just speaking for myself, Congresswoman, but I am very reluctant to reduce the 180-day exclusivity period or to water it down at all or to dilute it at all because I think that is the carrot. That is the incentive for the generic to challenge.

Ms. SCHAKOWSKY. Yes, but if this first filer makes a deal and then the second filer—well, maybe you can explain it better—

Mr. ROSCH. That is why I don't want—that is why I want to ban reverse payments because that—

Ms. SCHAKOWSKY. Period?

Mr. ROSCH. Period.

Ms. SCHAKOWSKY. OK. Well, why is your suggestion preferable then, Dr. Sherman?

Mr. SHERMAN. We are not suggesting that the 180 days be reduced. We are suggesting that it go to or be shared by the person who actually earns it, the one who actually carries the challenge and succeeds in invalidating the patent. Right now, the first filer can settle and keeps the 180 exclusivity, which is a huge reward, for doing nothing, for agreeing not to challenge a patent and for agreeing with the brand company to defer generic entry until just before patent expires at enormous cost to consumer. They are not earning it.

So we are saying in a case where a first filer has settled, it is not entitled to that exclusivity, but let them keep it anyway. Let us just give a shared exclusivity to the person who then picks up the challenge, does what Congress intended, invests in challenging the patent, and succeeds. If you don't do that, there is no incentive for anybody to pick up the challenge and to get early entry into the market in the face of a settlement by a first filer who has agreed to undermine the system and accept very late—

Ms. SCHAKOWSKY. OK, Mr. Hemphill, does that make any sense?

Mr. HEMPHILL. So the underlying policy concern is a real one that a first filer could settle, retain the exclusivity, and that that would create public policy problems. Perhaps a simpler solution, a

solution actually suggested by Apotex two years ago would be that upon settlement, the exclusivity is simply forfeited.

My concern about adding a new layer of exclusivity in addition to the possibly of diluting existing incentives is this is an extremely complicated scheme as it is. A lot of the problems result from manipulation of the 180 days. Doubling the set of possible—or multiplying the set of possible holders of exclusivity, I think, promises some confusion and complexity.

To forfeit your alternative, which Apotex in the past suggested in response to the same policy concerns, strikes me as a simpler and maybe easier to implement alternative.

Ms. SCHAKOWSKY. OK.

Mr. SHERMAN. May I answer that? We did propose that two years ago, and it certainly would be better than what we have now, simply a forfeiture of exclusivity. But the problem there is then there is no incentive for a subsequent filer to take up the advantage, to take up the battle. And that is the very thing that the full regime is intended to incentivize. So giving a shared exclusivity to a subsequent who does take up the battle is better because then you are going to have someone investing to do it, and that will result in earlier entry into the market for generics. It is very—

Ms. SCHAKOWSKY. OK, I appreciate this back and forth. Thank you.

Mr. RUSH. The chair now will recognize the ranking member of the subcommittee, Mr. Radanovich, for 5 minutes for questions.

Mr. RADANOVICH. Thank you so much, Mr. Chairman, and I beg the forgiveness of the committee. I had a prior constituent water issue that needed to be addressed. I am a little bit late to this hearing. But I want to thank the panel for being here. I do have a couple of quick questions.

First of all, to the honorable Mr. Rosch, Ms. Handy testified that H.R. 1706 creates two safe harbors. The first that the only value allowed for a generic is the right to market a drug prior to patent expiration. Second, the generic cannot be sued for infringement, thereby insulating them from any damages. A settlement is usually an agreement where both parties receive consideration. However, it seems that the considerations are entirely one-sided. What would be the benefit to the brand company to settle in this situation, number one? And number two, why would a brand company ever choose not to prosecute their patent to the fullest to see litigation through to the bitter end?

Mr. ROSCH. Well, with respect to the first issue, I think it really goes to whether or not side agreements should be or are covered by this legislation. And the answer is, as I indicated earlier, based on our own studies internally, side agreements can indeed end up being a part of the problem. So that is the answer to the first part of the question.

The answer to the second part of the question really goes to the extent to which you want to incentivize—it seems to me you want to incentivize the generic to actually challenge what may be an invalid or a patent that is not being infringed. And again my view is that you want to give the—my own personal view is you want to give the generic the broadest possible incentive in that regard, which is what I think you do with the 180 days.

Mr. RADANOVICH. Um-hum, thank you very much. Ms. Bieri, is it? Ms. Bieri?

Ms. BIERI. Yes.

Mr. RADANOVICH. Thank you. Why is it so important for innovative pharmaceutical companies to retain the ability to settle patent litigation with generic companies?

Ms. BIERI. Thank you, Congressman. Litigation is risky and expensive, and to—it incurs significant cost for both the brand companies and the generic companies. Companies have to have a way to resolve their disputes without taking them the whole way to trial. And so for both parties to this litigation, it is important to have the flexibility to be able to come to mutual arrangements that are still within the scope of the patent and therefore beneficial to consumers and ultimately which will bring these medicines, generic medicines, to the market before the patent expires but still be a fair arrangement for both parties to the settlement.

Mr. RADANOVICH. Wouldn't the brand companies be better off if they successfully defended their patents in court?

Ms. BIERI. That would be true if, in fact, the outcome of litigation were always certain. But litigation is risky, expensive, and uncertain. And businesses like certainty as you well know. So it is often better for the brand company to, within the scope of its patent, have a date certain by which it knows that the generic will come on the market.

Mr. RADANOVICH. I see. Yes. Question for the panel, anybody who cares to respond. Our government and our American companies engage in daily fights against intellectual property theft. It seems, however, that a number of our witnesses are arguing for less stringent IP protections when it comes to pharmaceuticals. I think that we could agree that life-saving innovation must be encouraged, but it seems, however, that you are arguing that the IP rights of some innovators are less worthy of protection afforded by the law than perhaps Hollywood or Silicon Valley or Nashville.

Many can defensively disagree, but I would like to hear any of your thoughts on the issues of intellectual property in general. Mr. Hemphill?

Mr. HEMPHILL. Yes, I guess just to start, I think it is not true at all that the proposed bill here runs any risk of treating pharmaceutical companies, brand or generic as second class citizens. As the matters stand, we have a very complicated regime that is already very different from what anybody else gets. Commissioner Rosch mentioned a few moments ago the special 30-month stay granted to a brand name firm, even if the patent is extremely trivial. A patent term extension, of course, is another example.

There are examples on the other side, but to think of this as an example of second class citizenship for PhRMA companies, I think, is far from the fact here.

Mr. RADANOVICH. OK, anybody else care to comment? Dr. Sherman?

Mr. SHERMAN. Yes, what distinguishes pharmaceuticals from other industries is this unique provision whereby the first filer has exclusivity to block others. So what you have when you have, under this regime, a brand company and the first filer negotiating, the parties that are not at the table are the public and the other ge-

neric firms who would be prepared to continue to fight. And the settlement to which they are not a party, affects them because it precludes the other generics from fighting to win because they are blocked by the continuing exclusivity. And the consumers aren't at the table, and they are the ones who are paying the billions of dollars of extra money as a result of the settlement.

So sure, this bill would treat pharmaceutical differently because it would ban reverse payments, but the question that should be asked is why are they happening in this industry? And it is happening because the present regime permits a first filer to settle on behalf of all of the generic industries and consumers who are not at the table.

So the way to fix it is not to have special provisions that bar reverse payments but to stop—to fix the regime so that a first filer who settles is settling only for himself and is not blocking another generic who would, in fact, continue to invest and fight for earlier entry.

Mr. RADANOVICH. Thank you.

Mr. RUSH. The gentleman's time has concluded.

Mr. RADANOVICH. Thank you, Mr. Chairman.

Mr. RUSH. The chair now recognizes the gentleman from Louisiana, Mr. Scalise, for 5 minutes.

Mr. SCALISE. Thank you, Mr. Chairman. The first question just open up to the whole panel. If you can explain or give an example of a case where Congress has actually specified that a certain industry specific private settlement would be illegal. Start with Mr. Whitehouse and work down.

Mr. WHITEHOUSE. We are certainly not aware of any, and we think in fact it is important to recognize and these economic papers do point out, make the important point, that this isn't unique to PhRMA, that every settlement and any litigation, as any litigator will tell you, involves some mutuality of consideration, or there wouldn't be a deal. And so it is the technicality of how the money or the compensation moves in any particular transaction. It is an artifact, but it is in the end of any interest because a settlement is not going to happen unless both sides are getting something out of it.

Mr. SCALISE. Mr. Sherman?

Mr. SHERMAN. Well, again, the problem is that this industry is unique because the first filer in this case who settles is settling on behalf of everybody and entering into an agreement which blocks all others from getting to market. That is what distinguishes this industry, and that is what is wrong. That is what should be fixed.

Mr. SCALISE. Do you know of any other cases in other industries where this type of proposal that is brought forward is—

Mr. SHERMAN. No, because there is no other industry where somebody gets an exclusivity by reason of doing a challenge and can block all others. That is the problem.

Mr. SCALISE. Not sure that that is the case, but Ms. Bieri?

Ms. BIERI. Congressman, I am not aware of any other industry in which a bill target settlements of a particular type. I would say that the courts, when they look at these, and to some extent the agencies, have approached these on a case-by-case basis so that they start from the proposition that settlements are pro-competi-

tive if, in fact, they would allow the generic to enter prior to the expiration of the patent. And if in fact they don't, then they may be anticompetitive. So they pursue a case-by-case analysis which to us is more sensible than a per se ban.

Mr. SCALISE. Ms. Handy.

Ms. HANDY. Respectfully, Congressman, I don't know the answer, but I think whether or not it occurs, the issue is whether it is good for consumers.

Mr. SCALISE. And we will get into that later in the questioning. Thanks. Mr. Hemphill.

Mr. HEMPHILL. Yes, the litigation, the settlements, and the proposed fix are all industry specific and unusual.

Mr. SCALISE. Unusual. Thank you. Mr. Rosch?

Mr. ROSCH. That is correct.

Mr. SCALISE. All right. Well, thank you.

Mr. ROSCH. But the——

Mr. SCALISE. First round. Well, let me ask Mr. Rosch and then——

Mr. ROSCH. As has been pointed out, however, Congressman, this industry is very unusual as well.

Mr. SCALISE. I am sure, and many are in their own rights. Many industries are. According to your reports on settlements, there have been over 50 settlements filed with the FTC in the last three years. Your testimony, I think, said a large number of them have side agreements, yet of those 50, the FTC has not filed legal challenges against any of them. And private plaintiffs have brought suits against only two of them. Why has the FTC not challenged any of those settlements?

Mr. ROSCH. It is quite simple, Congressman. We are trying to pick those settlements which we think are more pernicious and we think we can win. We want to win one of these cases because we feel that we are not only the guardians of consumers in this fight but also the guardians of you folks who enacted Hatch-Waxman.

Mr. SCALISE. I guess that means you don't feel you could have won the other ones that have been filed.

Mr. ROSCH. No, I don't mean to leave that impression. What I do mean to leave is the impression that the ones that we have challenged, we think, are the ones that are most obviously pernicious to consumers and most——

Mr. SCALISE. But obviously you make a calculated decision then if you don't—you only bring a suit if you feel that you can win.

Mr. ROSCH. No, that is not necessarily——

Mr. SCALISE. But that is what you just said.

Mr. ROSCH. If we had unlimited resources, we would probably be challenging all of them, but we don't.

Mr. SCALISE. Well, the same is the case with the generic company that brings a case to court as well. They don't have unlimited resources either, but obviously they feel they have merit. And that is why they bring the case, and then this bill would remove their ability to settle. Several settlements, including those involving Prozac and Tamoxifen have saved consumers and taxpayers billions of dollars. Looking back, do you believe such settlements were anticompetitive merely because they contained some type of settlement or reverse payment as you call it?

Mr. ROSCH. Do I think that Tamoxifen and—

Mr. SCALISE. Well, do you feel that those settlements were anti-competitive? They were legal. They would be illegal under this bill, yet they did save consumers billions of dollars. So how do you justify trying to take away that ability to save consumers billions of dollars, as has been the case in past settlements?

Mr. ROSCH. We certainly thought Tamoxifen was a bad settlement. We thought that was an anticompetitive settlement, and we saw nothing, no data whatever, that would suggest to us that it could save consumers billions of dollars.

Mr. SCALISE. Mr. Whitehouse—I know I am running out of time—experts have testified that collateral agreements, side business deals like these licenses or co-promotion agreements on products unrelated to the patented product in dispute can help the litigants in the patent suit bridge the gap and reach a settlement on patent litigation. Have you experienced that? You have taken some of these cases before.

Mr. WHITEHOUSE. Yes, absolutely. That is crucial to the point that we have made in our testimony is that the ability to reach these settlements and bring these products to market sooner in cases that we must not forget we could have lost. I mean everybody sort of assumes if we didn't settle, we would have won. It is very important to remember that something else could have happened. We could have lost, and the consumers would not have any benefit until the expiration of the patent. And so the opportunity to come up with these alternative or additional terms that enable the parties to bridge their different perceptions of the case bring about a settlement that on average and typically will bring these products to market sooner to the benefit of consumers.

Mr. SCALISE. I see I am out of time. I yield back.

Mr. RUSH. Chair now recognizes Dr. Gingrey for 5 minutes.

Mr. GINGREY. Mr. Chairman, thank you very much, and direct my question to Commissioner Rosch. Commissioner Rosch, I think you have been very forthright in your response to the questions throughout the hearing. Having said that, I guess you are anticipating I am fixing to blast you.

Mr. ROSCH. Yes.

Mr. GINGREY. Not really but—

Mr. ROSCH. I call it piling on.

Mr. GINGREY. Yes.

Mr. ROSCH. That is fine.

Mr. GINGREY. But in a number of ways, I do find your testimony to be counterintuitive. You say that the reverse payment settlements negatively impact consumers by delaying entry of generic drugs to the market. Based on the testimony of the other witnesses, many times these reverse payment settlements, they actually allow the patent holding company and the generic company to negotiate terms by which the generic can begin being marketed before the expiration of the patent. Presumably because of the unique nature of patent law in this area, the settlements actually help consumers, it would seem to me.

But what then is anticompetitive or anti-consumer about this kind of settlement? And before you respond to that, a quick second. I think it was Mr. Radanovich that was asking you about the ques-

tion about side deals, and you may have talked about other consideration in a settlement not including reverse payments.

Mr. ROSCH. Payment of dollars, correct.

Mr. GINGREY. Yes, but this bill, as I understand it, would prohibit any of that, not just dollar payments, reverse payments, but any other side deals. So if this bill passes, then what incentive would the brand name company have to settle? Certainly it would appear none whatsoever to negotiate with the generics. So two questions, and go ahead.

Mr. ROSCH. OK, I think you are correct about the bill. As I read it, it would indeed go to side deals as well as to direct payments of money. As I said before, that doesn't really trouble me because our staff has taken a look at these agreements, including side deals, and they have concluded that, except in a very small number of instances, those side deals are anti-consumer and they are anti-competitive.

And incidentally, Congressman, there is nothing at all unique about banning this kind of deal within the context of a settlement. The United States Supreme Court said that an anticompetitive aspect of a settlement agreement could be struck down as per se illegal many, many years ago in the Singer case. So this is not brand new.

But let me get to sort of the first part of your question. Why, I ask myself, if indeed the effect of a reverse payment settlement would be to stifle entry, early entry, to delay early entry, why are these deals occurring? We are seeing them. Why is the brand willing to pay, as I say, millions of dollars in these settlements? And I would suggest to you that the reason is to delay entry because the brand is enjoying patent monopoly profits and prices. It is kind of as simple as that.

Now, should we be litigating these cases on a case-by-case basis? I would suggest to you that we should not. There is already in the bill sort of a safety net if you will in our rulemaking authority. If we find that some of these deals shouldn't—that we shouldn't be challenging them on a case-by-case basis, we can carve those out as a safe harbor.

Mr. GINGREY. Commissioner, reclaim my time, and I am down to 45 seconds because this is going to segue—

Mr. ROSCH. I didn't mean to—

Mr. GINGREY. No, I appreciate your response. Segue into my question that I wanted to ask Ms. Bieri and Mr. Whitehouse. As representatives of PhRMA and the generic drug companies respectively, you know through practical implementation that both the FTC and the Department of Justice already had the ability to challenge any settlements that—and I think that is what the commissioner was about to say—that are anticompetitive and thus harm consumers.

If the blanket ban on settlements, and H.R. 1706 is implemented, what incentive do your respective industries have to settle patent litigation out of court? And how would that affect consumers?

Ms. BIERI. Thank you. I will begin by saying that I think because litigation is risky and expensive, I think there would still be incentives for companies to try to settle patent litigation even if H.R. 1706 were to pass. Unfortunately the options for them to do so are

what would be very limited. And so you would be left in a situation where the brand and the generic company would be only able to negotiate over the date of entry for the generic.

This is the heart of the patent dispute and obviously the parties are going to have very different views on that point. And so in many of these cases we think it would be unable to reach an agreement, and the case would then have to proceed to litigation. And recent statistics show that in most of those cases, at least the majority, the brand company would ultimately be able to defend its patents. And so generic entry would be delayed.

Mr. GINGREY. And, Mr. Whitehouse—Mr. Chairman, if you would bear with me, if Mr. Whitehouse can respond to that question as well.

Mr. WHITEHOUSE. Yes, Congressman. And the important point to focus upon here is that if you make it harder to settle, you are going to reduce the incentive to bring these cases in the first place. And the whole point of Hatch-Waxman was to precipitate litigation over doubtful patents and bring generic products to market sooner, if you diminish in any way the incentive in the generic companies to initiate those litigations, which is an inevitable consequence of making it harder to settle them, that is inherently anti-consumer and undesirable. And that is why we are opposed to this mechanism.

Mr. RUSH. The chair initially offered that we would go into a second round of questioning, but there is a vote on the floor, and in light of this fact, the chair wants to call this subcommittee hearing to an adjournment. But before he does that, he wants to make sure that the witnesses recognize the fact that we are indebted to you so deeply because of your—the investment of your time into this matter. You have really shed some tremendous light on this issue, and we will be referring to your statements more so in time for the duration of this legislative process on this particular matter.

I just want to also alert you that we ask that you should be prepared to receive and respond to written questions submitted by members of the subcommittee, and I want for the record to remain open for 10 days to receive additional statements.

And the final matter is that the ranking member of the subcommittee, Mr. Radanovich, has an opening statement that he wants to place into the record, and with hearing no objection, it is so ordered.

[The information was unavailable at the time of printing.]

Mr. RUSH. This subcommittee is now adjourned. Thank you very much.

[Whereupon, at 1:20 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**An Economic Assessment of Patent Settlements
in the Pharmaceutical Industry**

– by –

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Executive Summary

- Consumers benefit from the availability of innovative new products and from lower prices. In the pharmaceutical industry, both the development of new medicines and price competition from manufacturers of generic drugs provide substantial consumer benefits. Competition policy towards the pharmaceutical industry must therefore represent a balance between protecting incentives for manufacturers of branded drugs to innovate and facilitating entry by manufacturers of lower-priced generic drugs.
- The current framework for patent litigation between branded and generic pharmaceutical manufacturers, established by the Hatch-Waxman Amendments in 1984, is an important component of this balance. Generic manufacturers must notify branded manufacturers before launching a potentially infringing generic product, providing branded manufacturers an opportunity to sue for patent infringement before the generic enters the market. In many cases, litigation is resolved with a settlement between the parties. These settlements may include the following types of provisions:
 - A negotiated date upon which the generic manufacturer will enter the market (with or without royalty payments to the branded manufacturer);
 - Cash payments from the branded manufacturer to the generic;
 - Business transactions between the branded and generic manufacturer such as cross-licensing or supply agreements; and
 - Agreement by the branded manufacturer not to launch or license an authorized generic for some period after generic entry.
- In recent years, patent settlements between branded and generic manufacturers involving “reverse payments” from branded manufacturers to generic manufacturers have received close antitrust scrutiny, driven by concerns that such settlements harm consumers by delaying the entry of lower-priced generic drugs. It appears that such settlements will be a focus of the Obama Administration’s antitrust enforcement policy. Yet there is a growing consensus among the courts that such settlements are anticompetitive only under narrow sets of circumstances. This paper presents an analytical framework for evaluating the competitive effects of these settlements.
- On the one hand, settlements of litigation – including patent settlements – can provide clear competitive benefits. Litigation imposes substantial costs upon the litigating parties and on society as a whole. Settlements also reduce risk associated with litigation. Because settlements can lower costs and uncertainty, economists agree that settlements can be procompetitive.
- On the other hand, under certain conditions, patent settlements between branded and generic manufacturers can be anticompetitive. Ultimately, the competitive effects of a particular settlement will depend importantly upon the underlying strength of the patent. If the patent is strong, and likely to be found valid and infringed, then even a settlement with an agreed-upon entry date well into the future but before patent

expiration may bring generic drugs to market sooner than continued litigation and generate lower prices for consumers. In contrast, if the patent is weak, and likely to be found invalid and/or non-infringed, then even a settlement with an entry date not far in the future may delay generic entry and harm consumers. Assessing the strength or weakness of a patent in real-world patent litigation is complex – indeed, the precise strength of a patent is subject to the vagaries of the litigation system and is ultimately unknowable even to the parties themselves. Nevertheless, such an assessment is necessary at some level in assessing whether a patent settlement is pro- or anticompetitive.

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

parties will be unable to reach agreement on a settlement – even if that settlement would benefit consumers.

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

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

I. INTRODUCTION

In recent years, the Federal Trade Commission (“FTC”) has been closely scrutinizing patent settlements between branded and generic manufacturers involving “reverse payments” from branded manufacturers to generic manufacturers. The FTC has been concerned that such settlements harm consumers by delaying the entry of lower-priced generic drugs.

Despite what appears to be a growing consensus among the courts that such settlements are anticompetitive only under narrow sets of circumstances, it is likely that antitrust scrutiny will only increase in the next several years. In 2007, then-Candidate Obama specifically pointed to concerns over such settlements in laying out his views on antitrust enforcement policy.⁵ Jon Leibowitz, the current Chairman of the Federal Trade Commission, recently called eliminating anticompetitive patent settlements “one of the most important objectives for antitrust enforcement in America today.”⁶ Bills that would outlaw settlements involving payments from branded to generic manufacturers were introduced in the U.S. Senate and House of Representatives in recent months.⁷

In this paper, we present an analytical framework for evaluating the competitive effects of patent settlements, including those involving reverse payments, and demonstrate that these settlements can benefit consumers. Thus, we conclude that while continued scrutiny of such settlements is important, broad brush treatments are inappropriate and only a more individualized evaluation can correctly determine the competitive effects of a particular settlement agreement.

II. COMPETITION IN THE PHARMACEUTICAL INDUSTRY

Innovative branded pharmaceutical firms can benefit consumers by developing new drugs. Generic pharmaceutical firms can benefit consumers by offering competition

⁵ Statement of Senator Barack Obama for the American Antitrust Institute, September 2007, p. 2 (available at http://www.antitrustinstitute.org/archives/files/aai-%20Presidential%20campaign%20-%20Obama%209-07_092720071759.pdf).

⁶ Concurring Statement of Commissioner Jon Leibowitz re: *Federal Trade Commission v. Watson Pharmaceuticals et. al.*, February 2, 2009 (available at <http://www.ftc.gov/speeches/leibowitz/090202watsonpharm.pdf>).

⁷ The Preserve Access to Affordable Generics Act was introduced by Senators Kohl and Grassley in February 2009 (see http://kohl.senate.gov/newsroom/pressrelease.cfm?customel_dataPageID_1464=2126), and the Protecting Consumer Access to Generic Drugs Act of 2009 was introduced by Representative Rush in March 2009 (see http://thomas.loc.gov/home/gpoxmlc111/h1706_ih.xml).

that drives down prices. Thus, the challenge of competition policy in this area (as in all highly innovative industries) is to benefit consumers by striking the appropriate balance between providing sufficient rewards to encourage innovation, followed after a time by a transition to a more competitive market with lower prices.

A. Innovation and Patent Protection

Innovation is the lifeblood of the pharmaceutical industry. In 2007, the pharmaceutical and biotechnology industries invested nearly \$60 billion in research and development (“R&D”).⁸ As described by the Congressional Budget Office (“CBO”):

The pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm.⁹

Since 1990, R&D by pharmaceutical manufacturers has led to the approval of an average of roughly 30 new drugs (molecular entities) and dozens of newly approved formulations or other modifications of existing drugs each year.¹⁰

Protection of the intellectual property underlying these innovations is critical to providing incentives for pharmaceutical manufacturers to continue to invest in, and develop, new drugs. The research and development process is lengthy, costly, and uncertain. Only a tiny fraction of medicines tested are eventually approved for patient use,¹¹ and only 20 to 30 percent of those approved eventually recoup their R&D

⁸ Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2008*, March 2008, pp. 2-3. See also Congressional Budget Office, “Research and Development in the Pharmaceutical Industry,” October 2006, pp. 7-9 (“CBO 2006”).

⁹ CBO 2006, p. 9.

¹⁰ U.S. Food and Drug Administration, “CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type” (<http://www.fda.gov/cder/rdmt/pstable.htm>); U.S. Food and Drug Administration, “CDER Drug and Biologic Approvals for Calendar Year 2005” (<http://www.fda.gov/cder/rdmt/InternetNDA05.htm>); U.S. Food and Drug Administration, “CDER Drug and Biologic Approvals for Calendar Year 2006” (<http://www.fda.gov/cder/rdmt/InternetNDA06.htm>); U.S. Food and Drug Administration, “CDER Drug and Biologic Approvals for Calendar Year 2007” (<http://www.fda.gov/cder/rdmt/InternetNDA07.htm>).

¹¹ For example, one report indicates that only 1 of every 5,000 medicines tested is eventually approved (Tufts Center for the Study of Drug Development, “Backgrounder: How New Drugs Move Throughout the Development and Approval Process,” November 1, 2001).

investment.¹² Development of a new drug entails considerable time and expense. These development costs have been rising significantly. Recent studies estimate that the average new drug took 10 to 15 years¹³ and cost over \$1.3 billion (including both direct costs and opportunity costs) to develop.¹⁴ Strong protection of intellectual property, and the potential rewards that come with it, provide incentives for pharmaceutical companies to undertake such large development costs.

B. Generic Competition

After a branded drug loses patent protection (or a generic manufacturer is able to produce a non-infringing generic version), generic manufacturers often bring bioequivalent versions of branded drugs to market. Numerous economic studies have consistently found that entry of a competing generic manufacturer typically leads to lower average prices, and that this price competition typically intensifies with the entry of additional manufacturers.¹⁵ 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

¹² Vernon, John M., Golec, Joseph H., and DiMasi, Joseph A., "Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three Factor Model," *Tufts Center for the Study of Drug Development Working Paper*, 2008, p. 3 (concluding that 20 percent cover their R&D expenses); Grabowski, Henry G., Vernon, John M., and DiMasi, Joseph A., "Returns on Research and Development for 1990s New Drug Introductions," *PharmacoEconomics*, 20(3), March 2002, p. 17 (concluding that 30 percent do).

¹³ CBO 2006, p. 20. See also DiMasi, Joseph A., Hansen, Ronald W., and Grabowski, Henry G., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 22(2), March 2003, pp. 164-165.

¹⁴ DiMasi, Joseph A. and Grabowski, Henry G., "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics*, 28, 2007, pp. 469-79. See also CBO 2006, and Adams, Christopher P. and Brantner, Van V., "Estimating the Cost of New Drug Development: Is It Really \$802 Million?" *Health Affairs*, 25(2), 2006, pp. 420-428.

¹⁵ See, for example, Grabowski, Henry G. and Vernon, John M., "Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law and Economics*, 35, October 1992, pp. 331-350. Other articles reaching similar findings include: Frank, R. G. and Salkever, D. S., "Pricing, Patent Loss and the Market for Pharmaceuticals," *Southern Economic Journal*, 59(2), 1992, pp. 165-179; Caves, Richard E., Whinston, Michael D., and Hurwitz, Mark A., "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics*, 1991, pp. 1-48; Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, pp. 28-33 ("CBO 1998"). As Grabowski and Vernon (1992) and others have found, branded manufacturers may increase 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.

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.¹⁶

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

C. The Hatch-Waxman Amendments

1. Introduction

In 1984, the U.S. Congress passed the Hatch-Waxman Amendments (“Hatch-Waxman”)¹⁷ to the Federal Food, Drug, and Cosmetic Act of 1938, which sought to balance the importance of innovation and generic entry. Hatch-Waxman established the current framework for patent litigation in the pharmaceutical industry, and although this framework has been modified since 1984, it largely remains intact. Any analysis of the economics of patent settlements must begin with an understanding of this framework.

2. FDA approval prior to Hatch-Waxman

Since 1962, the Food and Drug Administration (“FDA”) has required pharmaceutical companies to prove that new branded drugs are “safe and effective” prior to approval. Branded drug manufacturers provide such evidence by conducting costly and lengthy clinical trials. The process of conducting clinical trials and obtaining FDA approval decreases the effective life of pharmaceutical patents substantially, because approval is typically received many years after a patent is granted.¹⁸ Before Hatch-Waxman, the FDA also required generic manufacturers to conduct their own safety and

¹⁶ CBO 1998, p. 13.

¹⁷ More formally, the law was known as the Drug Price Competition and Patent Term Restoration Act of 1984.

¹⁸ CBO 1998, p. 39.

efficacy studies. Generic manufacturers could not begin their safety and efficacy studies until patents on the brand-name drug had expired.

3. Overview of Hatch-Waxman

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

On the one hand, Hatch-Waxman sought to increase patent protection and to strengthen the incentives of branded manufacturers to innovate. Recognizing that the lengthy FDA approval process often substantially reduced the effective life of pharmaceutical patents, Hatch-Waxman allowed branded manufacturers to apply to extend the life of these patents to regain some of the patent life lost by clinical trials and the FDA approval process.¹⁹

On the other hand, Hatch-Waxman attempted to encourage generic competition. It streamlined the approval process for generic manufacturers, thereby reducing the costs of obtaining FDA approval and speeding their time to market. More specifically, Hatch-Waxman allowed generic pharmaceutical companies to submit an Abbreviated New Drug Application (ANDA), simply referencing the safety and efficacy results submitted by the branded company rather than conducting new clinical trials, so long as the generic drug could demonstrate “bioequivalence,” which means that the rate and extent of absorption of the generic drug is not significantly different from that of the brand-name drug when administered with the same dosage. Branded manufacturers were required to file information about any relevant patents with the FDA. In addition, the ANDA filer must certify one of the following:

- (1) the required patent information has not been filed by the branded manufacturer

¹⁹ Specifically, the branded manufacturer could apply for an extension on one patent equal to half of the time spent on clinical trials plus all of the time spent in FDA review, subject to a maximum extension of five years and a maximum effective patent life of 14 years. See Grabowski, Henry G. and Kyle, Margaret, “Generic Competition and Market Exclusivity Periods in Pharmaceuticals,” *Managerial and Decision Economics* 28, 2007, p. 492. Additionally, regardless of whether a new drug has patent protection, upon approval of an NDA for a New Chemical Entity, a drug will receive a 5-year term of exclusivity from the FDA. During this exclusivity period an ANDA that references the brand manufacturer’s NDA cannot be submitted (except after four years if there is a patent challenge). See: U.S. Food and Drug Administration, “Frequently Asked Questions on Patents and Exclusivity” (<http://www.fda.gov/cder/ob/faqs.htm#How>).

- (2) the patent has expired;
- (3) the patent will expire, identifying the expiration date; or
- (4) the patent is invalid and/or not infringed.

The latter representation is known as a Paragraph IV certification.

Since Hatch-Waxman, competition from generic drugs has grown significantly. The generic share of prescriptions has grown from 19 percent in 1984 to nearly 67 percent today.²⁰

4. Patent litigation under Hatch-Waxman

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

Second, the earliest generic pharmaceutical company to file an ANDA with a Paragraph IV certification for a particular drug is awarded a "180-day exclusivity period," during which time the FDA may not approve any Paragraph IV ANDAs filed subsequently for the same drug.²¹ The start of the 180-day exclusivity period is triggered

²⁰ See, for example, Generic Pharmaceutical Association (GPhA), "Annual Report 2008: Generics: The Right Choice for Better Health," 2008, p. 6; GPhA, "Industry History" (available at <http://www.gphaonline.org/Content/NavigationMenu/AboutUS/History.htm>).

²¹ 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.

by commercial marketing of the first filer's product.²² If the first filer does not exercise its exclusivity in a timely fashion, a variety of circumstances can lead to the forfeiture of its eligibility for exclusivity.²³ The substantial profits available during the 180-day period of exclusive marketing (in which the exclusive generic can charge a higher price than it could in the face of competition from other generic manufacturers and capture a larger share of sales) provide generic firms with an additional incentive to be first to challenge potentially invalid patents or to invent around the patented technology by developing a non-infringing alternative.

D. Patent Litigation and Settlement Agreements

ANDA filings frequently result in patent litigation. From 1998 to 2000, roughly 20 percent of filed ANDAs contained Paragraph IV certifications, where the generic manufacturer claimed that the branded manufacturers' patent(s) were invalid or not infringed.²⁴ A study by the FTC of ANDA filings between 1992 and 2000 found that a Paragraph IV certification resulted in patent litigation nearly 75 percent of the time.²⁵

In general, the vast majority of patent litigation is resolved through a settlement between the parties.²⁶ Settlements between branded and generic pharmaceutical manufacturers are common. From 1992 to 2000, nearly 40 percent of litigations against the first ANDA filer resulted in settlement.²⁷ Similarly, Barr, one of the largest generic manufacturers, has settled nearly half of the 30 patent cases that it has been involved with (and the vast majority of cases that are not still pending) in the last 15 years.²⁸

²² 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.

²³ "Medicare Prescription Drug, Improvement, and Modernization Act of 2003," §1102 (a)(2)(D)(i)(I)(aa)(AA) ("2003 MMA").

²⁴ Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration: An FTC Study," (2002), p. 10 ("FTC 2002").

²⁵ FTC 2002, pp. 13-15.

²⁶ See, for example, Shapiro, Carl, "Antitrust Limits to Patent Settlements." *RAND Journal of Economics*, 43(2), 2003, pp. 391-411 ("Shapiro (2003)").

²⁷ FTC 2002, pp. 15-16.

²⁸ Testimony of Bruce Downey, "Paying Off Generics to Prevent Competition With Brand Name Drugs: Should It Be Prohibited?" *Hearing Before the Committee on the Judiciary, United States Senate, Serial No. J-110-4, 2007*, p. 23. ("Testimony of Bruce Downey") Specifically, Mr. Downey testified that this has been true during his tenure as CEO, which began in 1993.

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

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

Pharmaceutical manufacturers settling patent litigation are required to report information on those settlements to the FTC and DOJ, and the FTC publishes annual reports summarizing those settlements.²⁹ The following table provides a summary of the FTC's classification of settlements that have been entered into over the last several years between branded and generic pharmaceutical manufacturers.³⁰

	Total Settlements	Settlements Allowing Immediate Generic Entry	Settlements Not Allowing Immediate Generic Entry	
			With No Compensation to Generic	With Compensation to the Generic ³¹
FY 2004	14	9	5	0
FY 2005	11	7	1	3
FY 2006	28	8	6	14
FY 2007	33	8	11	14

²⁹ This requirement was created by the 2003 MMA and effective in FY 2004.

³⁰ Federal Trade Commission, "Summary of Agreements Filed in FY 2004," Figure II; Federal Trade Commission, "Summary of Agreements Filed in FY 2005," p. 3; Federal Trade Commission, "Summary of Agreements Filed in FY 2006," pp. 3-4; Federal Trade Commission, "Summary of Agreements Filed in FY 2007," p. 3 and Figure III.

³¹ As defined by the FTC, compensation may be in the form of cash, an ancillary business transaction, or an agreement by the branded manufacturer not to launch or license an authorized generic for some period after generic entry. According to the FTC reports, many of these settlements also include compensation to the branded manufacturer – the reports do not provide sufficient information to determine whether there was a net payment to the generic.

III. COMPETITIVE EFFECTS OF PATENT SETTLEMENTS: SHORT-RUN

A. Overview

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

Settlements of litigation provide clear potential benefits. After all, litigation imposes substantial costs. Costs to litigating parties include (1) direct litigation costs such as legal fees, (2) indirect costs such as requiring attention of company executives and distracting them from their responsibilities of running the business, and (3) indirect costs due to uncertainty.³² Additional costs to society as a whole include increased congestion of the court system and corporate resources focused on private dispute resolution as opposed to innovation and production activities. Moreover, as firms generally pass on at least some portion of costs incurred, consumers ultimately bear some of these costs.

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

While patent settlements between branded and generic manufacturers have clear potential benefits, they also can harm competition and consumers under certain conditions. The potential for anticompetitive effects is increased when the settlement is with the first generic filer, rather than a subsequent generic filer, and the first filer does not relinquish its exclusivity. As described above, under Hatch-Waxman, the first generic filer receives 180 days of marketing exclusivity. This creates the potential for anticompetitive effect to the extent that delaying entry by the first filer could delay entry by all other generics as well. Prior to 2003, when much of the concern over patent settlements in the pharmaceutical industry originated, a settlement agreement did not affect 180-day exclusivity. Thus, a settlement with a first filer specifying an entry date well into the future could also prevent other generics from entering before that date (unless a subsequent-filing generic obtained a court decision that its product did not infringe or that the patent was invalid. Recognizing the potential anticompetitive effects of such a situation, a 2003 law introduced additional restrictions on “parking” the 180-

³² See, for example, Shapiro (2003), p. 394; Bessen, James E. and Meurer, Michael J., “The Private Costs of Patent Litigation,” *2nd Annual Conference on Empirical Legal Studies Paper*, February 1, 2008, p. 2.

day exclusivity. Importantly, the law was changed such that if the branded and generic manufacturers reach a settlement agreement, the settlement is challenged by the FTC or DOJ, and the agreement is determined to violate the antitrust laws, then the generic manufacturer forfeits its exclusivity.³³ This change substantially lessens the antitrust concerns with such settlements.

Ultimately, the competitive effects of a particular settlement will depend importantly upon the strength of the underlying patent.³⁴ A patent gives the branded manufacturer the right, within certain boundaries, to exclude competition.³⁵ If the patent is quite strong, and likely to be found valid and infringed, then even a settlement with an agreed-upon entry date well into the future but before patent expiration may bring generic drugs to market sooner than the expected outcome from continued litigation and generate lower prices for consumers. Moreover, there are frequently several generic manufacturers challenging a brand-name patent at any given time. Where this is the case, a settlement agreement with the first-filing generic has even less potential for anticompetitive effect where the brand-name patent is weak. While the incentive may not be as strong as that of the first filer (due to the 180-day exclusivity), other generic manufacturers continue to have an incentive to continue their challenge of patents they believe are invalid or that they do not infringe.³⁶

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

³³ 2003 MMA.

³⁴ Some courts have considered not the subjective assessments of the parties but what a “reasonable person” would think. *See, e.g., Asahi Glass Co., Ltd v. Pentech Pharm., Inc*, 289 F. Supp. 2d 986, 992-993.

³⁵ See Shapiro (2003) for a discussion of patents as probabilistic property rights.

³⁶ The 180-day exclusivity provides a motivation for generic manufacturers to bear the cost and risk associated with developing generic versions of branded drugs and challenging branded patents. But at the time of a settlement with the first-filing generic, many subsequent generic entrants may have already incurred many of these costs. Thus, even relatively small profits expected by a subsequent filer could provide the incentive to continue to challenge the branded patent.

B. Economic Framework

1. Basic Model

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

The standard economic model of settlements compares each settling party's economic gains from settling to its economic gains from continuing the litigation.³⁷ One then compares these two sets of settlement terms to determine the range of settlement terms that both parties would find preferable to continued litigation – in other words, those settlement terms that would feasibly lead to the end of the litigation.

Once the range of feasible settlements is established, one needs to determine which of these settlements, if any, would benefit consumers.³⁸ After all, consumers are not a party to the settlements, and so one might imagine that there could be settlements which benefit branded and generic manufacturer that do not benefit consumers.

For expositional purposes, we start with a highly simplified model of a patent settlement between branded and generic manufacturer. Assume:

- The parties are considering settlement at the beginning of Year 1
- The patent expires at the end of Year 10
- The generic manufacturer both believes that it has and in fact has a 50 percent chance of winning the patent case (and the branded manufacturer also has, and perceives, a 50 percent chance)
- There are no costs to litigation

³⁷ For a general discussion of the settlement decision, see Cooter, Robert and Rubinfeld, Daniel L., "Economic Analysis of Legal Disputes and their Resolution," *Journal of Economic Literature*, September 1989, pp. 1067-1097.

³⁸ In this paper, the term "consumers" is used to represent those that ultimately pay for prescription drugs. In reality, this is a combination of patients, private insurers, and government.

- The only settlement tool available is the date of generic entry (*i.e.*, lump sum payments, royalty payments, and other business transactions are not allowed).³⁹

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

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

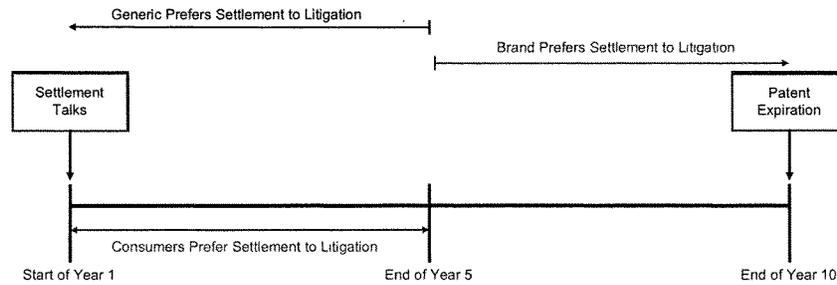
In this simple framework, the only tool the parties can use in settlement negotiations is the date of entry of the generic. As shown in Figure 1, the branded manufacturer would agree to a settlement with generic entry at any point after the end of Year 5, whereas the generic manufacturer would agree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

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

³⁹ Other assumptions include: (1) Total prescriptions are constant in each year, as is the share of prescriptions by the branded and generic manufacturers after generic entry. (2) There is perfect information, so both parties know the ultimate chance of winning. (3) Both parties are risk neutral. (4) There is no time value of money for either party. (5) After entry, there will be only one generic competitor.

demonstrate that doing so leads to a range of reasonable conditions under which patent settlements can benefit consumers.

Figure 1
Settlement with Generic Entry Date



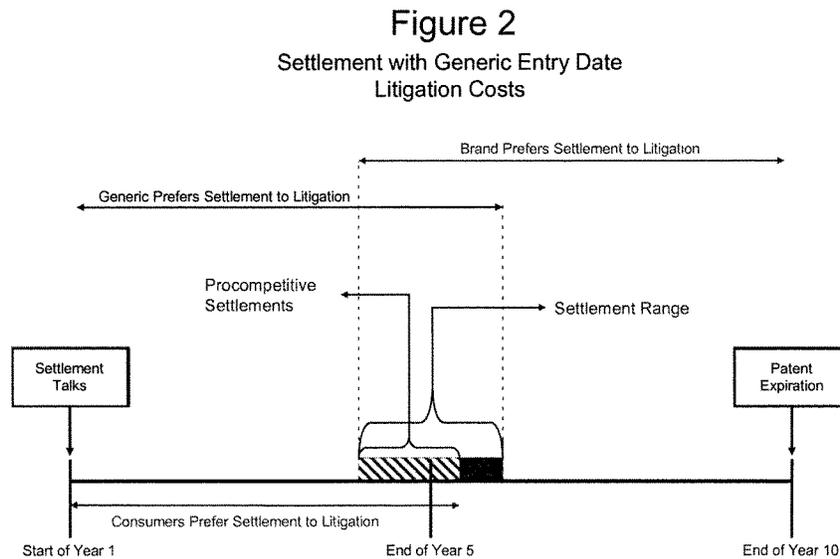
Note: There are no settlements that both the Brand and Generic prefer to Litigation

2. Litigation costs

A primary motivation for parties to settle litigation is that it is costly. The oversimplified model presented above ignores this motivation. We now introduce litigation costs into the model and show that it leads to a range of settlements that would be agreeable to both the branded and generic manufacturers and could also make consumers better off.

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

of settlements that would be agreeable to both parties.⁴⁰ In this way, litigation costs create the possibility of some settlements – those that would lead the generic to enter before the end of Year 5 – that would benefit consumers. Accounting for the fact that part of litigation costs are ultimately borne by consumers broadens the range of procompetitive settlements.



Of course, the particular size of settlement ranges shown in these figures is not meant to convey the relative likelihood of any particular type of settlement, but simply to demonstrate the economic logic that certain kinds of settlements exist. Indeed, what seems to be a clear distinction between procompetitive and anticompetitive in these diagrams is in fact quite difficult to distinguish in the real world. Recall that our example

⁴⁰ Because annual profits for the generic are lower than annual pre-generic entry profits for the branded manufacturer, the generic would be willing to give up more time in the market to avoid those costs, assuming litigation costs for the brand and the generic are similar.

assumes a 50 percent chance that the generic manufacturer will win the patent litigation – and that everyone knows that probability. But the precise strength of the patent is not knowable to the antitrust analyst or even the parties themselves. It will depend on a wide range of factors that affect the outcome of litigation, including the documentary evidence, the quality of presentations by counsel, the testimony of company witnesses, the testimony of expert witnesses, and the particular judge and jury assigned to the case. Whereas settlements with entry after Year 5 could harm consumers under the assumptions we have presented, such settlements could in fact be procompetitive if the generic manufacturer’s chance of winning the patent litigation was only, say, 30 percent.

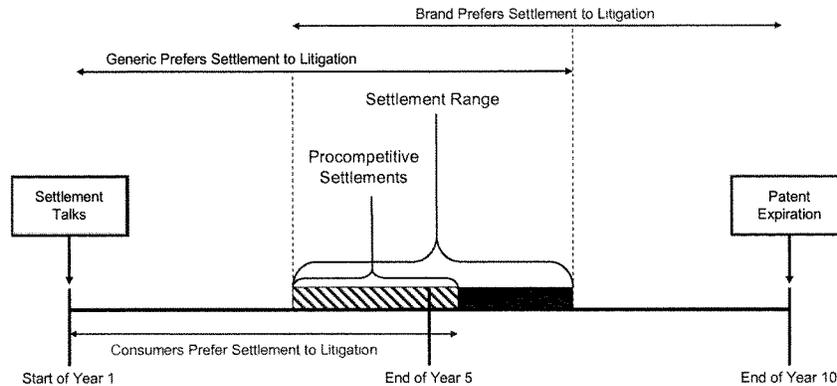
3. *Risk aversion*

Another cost of litigation is the substantial uncertainty that it creates. Economists model the cost of uncertainty using the concepts of “risk aversion” and “risk premiums.”⁴¹ For example, a risk-averse economic actor will prefer to receive \$2 with certainty, rather than a 50 percent chance at \$1 and a 50 percent chance at \$3. That is, risk-averse individuals prefer a certain outcome to uncertain outcomes with the same average or expected value but some degree of variance. A risk premium is the amount of money that a party would pay to avoid taking a risk. In the example above, the risk premium is the amount the individual would pay in order to receive the \$2 with certainty rather than the option with 50-50 odds. The concept of a risk premium allows us to model uncertainty in the same way we do other litigation costs – where the risk premium is the additional cost to the parties created by the uncertainty. Thus, just as in the discussion of litigation costs above, both branded and generic manufacturers would accept lower expected profits under a settlement relative to continued litigation to avoid heightened uncertainty. As shown in Figure 3, the effects are similar to those with litigation costs.⁴²

⁴¹ See Pindyck, Robert S. and Rubinfeld, Daniel L., *Microeconomics*, 7th Edition, 2009, Section 5.2.

⁴² Similarly, if consumers are risk averse, accounting for this would broaden the range of procompetitive settlements.

Figure 3
 Settlement with Generic Entry Date
 Risk Aversion and Litigation Costs



Is it reasonable to assume that large pharmaceutical companies are risk averse? After all, a basic tenet of financial economics holds that a large firm and/or a firm owned by (and effectively managed for) well-diversified shareholders should be risk neutral. The risk from a particular litigation can be effectively eliminated through diversification—in this case, by investing in many projects or holding many stocks. However, this argument ignores two important realities. First, it ignores the so-called principal-agent problem that can exist between the managers of the firm (in this case, the executives with decision-making power over the decision to settle or continue litigating) and the shareholders of the firm.⁴³ While the firm's shareholders may be risk neutral, because they can diversify their risks over many investments, managers whose jobs and salaries depend to some extent on their current employer may be risk averse, instead. Second, not all pharmaceutical companies – not even all branded manufacturers – are large firms

⁴³ For a general discussion of the principal-agent problem see, for example, Pindyck, Robert S. and Rubinfeld, Daniel L., *Microeconomics*, 7th Edition, 2009, Section 17.4.

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

4. *Information asymmetries*

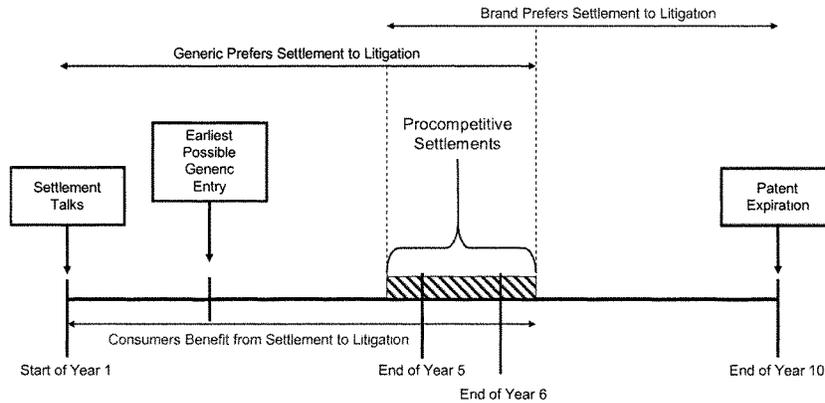
Information asymmetries are another important component of settlement decisions. Both the branded and the generic manufacturer are likely to have information that the other party does not possess. The generic manufacturer, for example, may have better information about its ability to manufacture a generic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

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

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

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

Figure 4
Settlement with Generic Entry Date
Information Asymmetry and Litigation Costs



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

Litigation costs, risk aversion, and information asymmetries are only three of the potential real-world complexities that can give rise to procompetitive patent settlements

between the branded and generic manufacturer. For example, the preceding section has assumed that both parties have identical expectations as to the outcome of the litigation. It is highly likely, however, that the parties' expectations will differ at least to some extent – and perhaps greatly – and these differences can have important effects on the ability of the parties to reach settlement and the effects of those settlements on consumers. In the next section, we explore these and other issues in the specific context of reverse payment settlements.

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

A. Overview

While the possibility of the procompetitive nature of patent settlements is generally recognized by economists, antitrust agencies, and the courts, one category of settlements – so-called “reverse payment” settlements – has generated extensive debate in recent years. In these settlements, the parties settle the patent litigation and the branded manufacturer (1) allows the generic manufacturer to enter at or after a particular date in the future (prior to the expiration of the patent) and (2) pays some form of compensation to the generic manufacturer. That compensation can be in the form of cash payments or through a payment associated with some other business transaction (*e.g.*, a cross-licensing agreement) where the branded manufacturer might allegedly “overpay” the generic manufacturer or the generic manufacturer might allegedly “underpay” the branded manufacturer.

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

B. Regulatory and Judicial Enforcement

1. History

The FTC began scrutinizing reverse payment settlements in the late 1990s. Its initial challenges were directed at settlements where the brand-name manufacturer paid cash to the generic manufacturer to settle patent litigation. These challenges resulted in several consent decrees.⁴⁴

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

The case has a long legal history, in which the disagreements over this issue are on full display. The FTC brought suit against the three companies, alleging that the royalty payments were simply disguised payments to delay generic entry and that the patent settlement agreements were anticompetitive. In 2002, the FTC's Administrative Law Judge ruled that the appropriate legal standard was a "rule of reason" analysis, and that under such an analysis the patent settlement agreements at issue were not anticompetitive.⁴⁵ The FTC appealed this decision to the full Commission, which reversed the decision and concluded that the payments were indeed anticompetitive.⁴⁶ 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

⁴⁴ FTC Decision and Order, *In the Matter of Abbott Laboratories*, No. C-3945 (May 22, 2000); FTC Decision and Order, *In the Matter of Hoechst, Carderm, and Andrx*, No. 9293 (May 8, 2001). Many of these cases were followed by private suits by direct and indirect purchasers.

⁴⁵ Initial Decision, *In the Matter of Schering-Plough Corp.*, et al, 136 F.T.C. 956, 1092 (2002) (No. 9297).

⁴⁶ Opinion of the Commission, *In the Matter of Schering-Plough Corp. et al*, 136 F.T.C. at 957.

ultimately the determination of competitive effects depends upon the strength of the patent.⁴⁷ The FTC appealed to the Supreme Court, which declined to hear the case.

2. Current status

After these developments, reverse payment settlements are now treated quite differently by the various regulatory agencies and Courts. The FTC has clearly expressed that it views reverse payment settlements as essentially *per se* illegal.⁴⁸ Despite the adverse ruling by the Eleventh Circuit in *Schering*, the FTC has continued to demonstrate an interest in challenging reverse payment settlements.⁴⁹ The DOJ submitted a brief urging the Supreme Court *not* to hear the *Schering* case – a position at odds with the FTC’s view.⁵⁰ Elsewhere, the DOJ has explained that “...settlements between an ANDA filer and the patent holder [even those with a reverse payment] also can benefit consumer welfare. Accordingly, the Department of Justice does not believe *per se* liability under the antitrust laws is the appropriate standard.”⁵¹

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.⁵² In stark contrast, the other three circuit courts to address this issue have given reverse payment settlements significant latitude. In both the *Schering* (described above) and *Valley Drug* cases, the Eleventh Circuit relied on a standard that acknowledges the potentially procompetitive nature of these settlements and would give significant latitude as long as the branded patent litigation was not objectively baseless.⁵³

⁴⁷ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

⁴⁸ See, for example, Opinion of the Commission, *In the Matter of Schering-Plough Corp. et al*, 136 F.T.C. at 957, prohibiting settlements “under which the generic receives ‘anything of value’” (carving out an exception for payments up to \$2 million linked to litigation costs).

⁴⁹ See, e.g., Oral Statement of FTC Commissioner Jon Leibowitz, Hearing of the House Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, May 2, 2007.

⁵⁰ On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit, Brief For The United States As Amicus Curiae, *FTC v. Schering-Plough Corp. et al*, 548 U.S. 919 (2006) (No. 05-273).

⁵¹ U.S. Department of Justice, Office of the Assistant Attorney General, Letter to the Honorable Jon Kyl, February 12, 2008.

⁵² *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.* (In re Cardizem CD Antitrust Litig.), 332 F.3d 896 (6th Cir. Mich. 2003).

⁵³ The *Valley Drug* case involved an “interim settlement” of a patent suit between Abbott and Geneva over generic Hytrin. See *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294 (11th Cir. Fla. 2003). Whereas the focus of our paper is on final settlements – where the settlement resolved the litigation – in an interim

Similarly, the Second Circuit applied a rule of reason standard in the *Tamoxifen* case when affirming the trial court opinion that the settlements were not anticompetitive.⁵⁴

Recently, the Federal Circuit applied a similar standard in the *Cipro* case.⁵⁵ In 1991, Bayer entered into an agreement with generic manufacturers Barr Labs, Hoechst Marion Roussel, and The Rugby Group settling patent litigation over Cipro. Under the settlement agreement, Barr certified that it would not market its generic version prior to the expiration of Bayer's patent. Bayer paid Barr a lump sum payment and agreed to either supply Barr with Cipro for resale, or make payments to Barr through December 2003. Consistent with the decisions by the Second and Eleventh Circuits, the Federal Circuit concluded that a rule of reason approach was appropriate and that "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." The appellate court affirmed the trial court's conclusion after a similar inquiry, that the plaintiffs had not shown that the agreement was anticompetitive.

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

Before presenting our economic analysis of reverse payment settlements, it is useful to examine the "reverse payment" moniker itself. Such settlements were baptized by commentators who believe that a payment from the branded manufacturer to the generic manufacturer flows the "wrong" way. In a typical settlement of a patent lawsuit, this argument points out, the alleged infringer pays the patent holder (a lump-sum payment and/or a license fee), while in a reverse payment settlement the patent holder (branded manufacturer) pays the alleged infringer (generic manufacturer).

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

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

⁵⁴ *In Re: Tamoxifen Citrate Antitrust Litigation*, 29 F.3d 370 (2d Cir. 2005).

⁵⁵ *In Re: Ciproflaxin Hydrochloride Antitrust Litigation* (Fed Cir. 2008).

manufacturer) can sue the alleged infringer (generic manufacturer) before the alleged infringer markets a product.⁵⁶

In the typical patent case – indeed, in any patent case – the alleged infringer is going to require some compensation for abandoning the litigation.⁵⁷ In a typical case where the patent infringer has been on the market for a significant period of time and would owe significant damages if found liable, the parties may agree to a settlement where the infringer pays damages to the patent holder, but those damages are far less than the damages the patent holder is seeking. In this case, the patent holder pays the infringer to settle the lawsuit by accepting lower damages – this payment is just obscured by the fact that on net some cash flows from the infringer to the patent holder. Reverse payment settlements can be thought of in the same way, but the Hatch-Waxman framework means the patent holder typically does not incur any damages from sales of the infringing products, and so the net payment flows from the branded manufacturer to the generic manufacturer. Since nothing nefarious can be gleaned from the simple fact that the payment flows in a particular direction, one must examine the underlying economics of these settlement agreements.

Similarly, the term “exclusion payments” does not accurately reflect the nature of many of these deals. If the branded manufacturer holds an ultimately valid patent, and the parties settlement allows the generic manufacturer to enter the market prior to patent expiration (but after the generic manufacturer preferred to enter), then the generic was not “excluded” in any meaningful way. The patent itself provided the ability to exclude, not the payment.

D. Basic Economic Model

The framework presented above for an analysis of patent settlements can be used to evaluate reverse payment settlements as well. We start with the highly simplified case

⁵⁶ Generic manufacturers can “enter at risk” – that is enter before final judgment in the patent litigation – but this is the exception rather than the rule. For example, Mr. Downey testified that Barr never enters at risk (Testimony of Bruce Downey, p. 24).

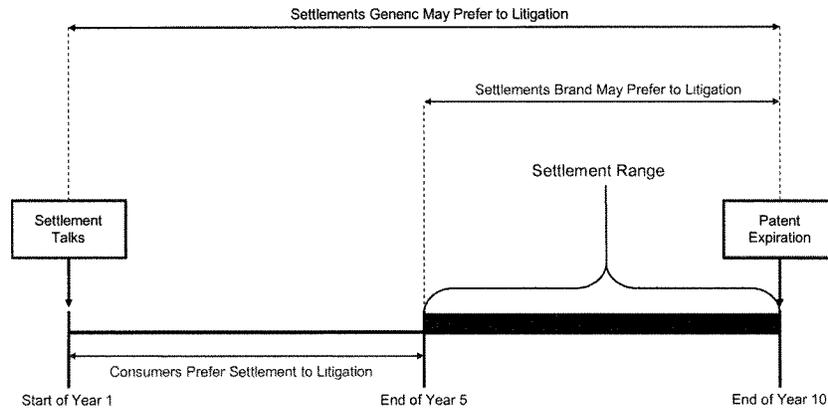
⁵⁷ Crane, Daniel A., “Correspondence: Ease Over Accuracy in Assessing Patent Settlements,” *Minnesota Law Review*, 88, 2004, pp. 698-711; Schildkraut, Marc G., “Patent-Splitting Settlements and the Reverse Payment Fallacy,” *Antitrust Law Journal*, 71(3), 2004, pp. 1033-1068.

outlined in Figure 1 – no litigation costs, full information, and risk neutrality – and relax only the assumption requiring the only term of settlement to be the date of generic entry and allow settlements to include cash payments. How will this affect the range of settlements?

Monopoly profits (profits when only the brand is in the market), will typically be larger than profits when the brand and the generic are both in the market. Of course, branded pharmaceuticals are not necessarily monopolies before the entry of generics, because patents give only a limited right to exclude identical competition and because they may compete with other branded or generic manufacturers. Nonetheless, thinking about analogy to monopoly profits can provide intuition as to why the parties may have an incentive to agree to delay generic entry. A year of delay will be worth more to the branded manufacturer (because it gains a year of “monopoly” profits) than it costs the generic manufacturer (because it loses a year of contested profits), so there will be settlements that delay entry beyond Year 5 that both parties prefer to litigation. As shown in Figure 5, this expands the range of settlements that the brand and generic manufacturers could potentially agree to, but only to include generic entry dates later than Year 5. Consumers will be clearly worse off under these settlements. Of course, without knowing the precise strength of the patent, observed terms of a particular settlement agreement could be consistent with delayed generic entry, as shown in Figure 5, or with a procompetitive settlement where generic entry occurs sooner than would be expected with litigation.

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

Figure 5
Settlement with Generic Entry Date and Cash Payment



E. Introducing Real-World Complexities to the Basic Model⁵⁸

1. Overview

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

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

⁵⁸ This section draws on the work of Robert Willig and John Bigelow. See Willig, Robert D. and Bigelow, John P., "Antitrust Policy Toward Agreements that Settle Patent Litigation," *The Antitrust Bulletin*, pp. 655-698, (Fall 2004); Bigelow, John P. and Willig, Robert D., "'Reverse Payments' in Settlements of Patent Litigation: Schering Plough, K-Dur and the FTC," *The Antitrust Revolution: Economics, Competition, and Policy*, 5th Edition (2008) ("Bigelow and Willig (2008)").

Shapiro (2003) explained:

This is not to say that such payments are necessarily anticompetitive if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as ‘reverse cash payments’ may be important in more complex settings for successful settlement.⁵⁹

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.⁶⁰

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.”⁶¹

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

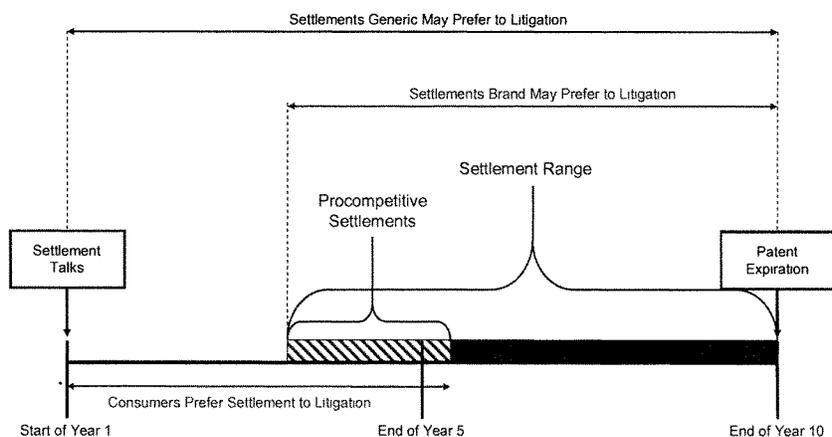
As described above, litigation costs and risk aversion can be important real-world factors to consider in evaluating patent settlements. Accounting for litigation costs and/or risk aversion expands the range of settlement agreements that each party is willing to accept. As shown in Figure 6, these factors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

⁵⁹ Shapiro (2003), p. 408.

⁶⁰ Bigelow and Willig (2008), p. 35.

⁶¹ Testimony of Bruce Downey, p. 28.

Figure 6
Settlement with Generic Entry Date and Cash Payment
Litigation Costs



3. Cash payments with a cash-strapped generic

Some observers have argued that, while reverse payment settlements can leave consumers better off than continued litigation, there is always a feasible alternative settlement without a payment (where the parties simply agree on an entry date) that will leave consumers better off than either litigation or a reverse payment settlement. Under this argument, a prohibition on reverse payment settlements would unambiguously leave consumers better off while still allowing the parties to reap the benefits of settlement. This argument ignores the complexities of settlement negotiations.⁶² In the presence of such complexities, additional flexibility in negotiations may be *essential* to enabling a

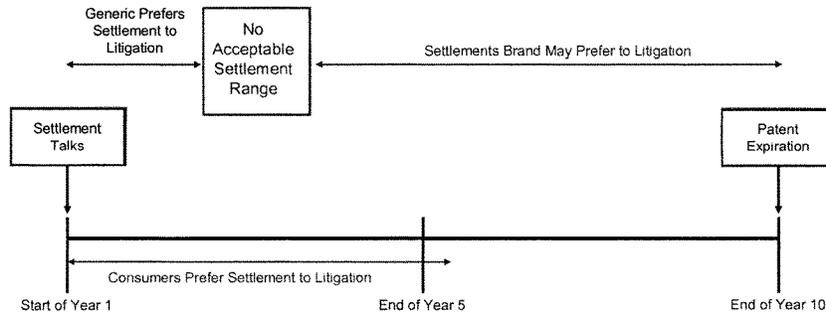
⁶² A related argument is that an alternative settlement with a different payment and a different entry date may be better for consumers. However, this argument ignores the fact that antitrust regulators consider the implications to competition of an agreement among competitors (such as a reverse payment settlement) versus a but-for world without the agreement, not against an optimal agreement. See Department of Justice and Federal Trade Commission, "Antitrust Guidelines for Collaborations Among Competitors," April 2000, p. 4, 7, and 10.

pro-consumer settlement between the parties. That is, under these circumstances, without a reverse payment the parties would be unable to reach a settlement at all.

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

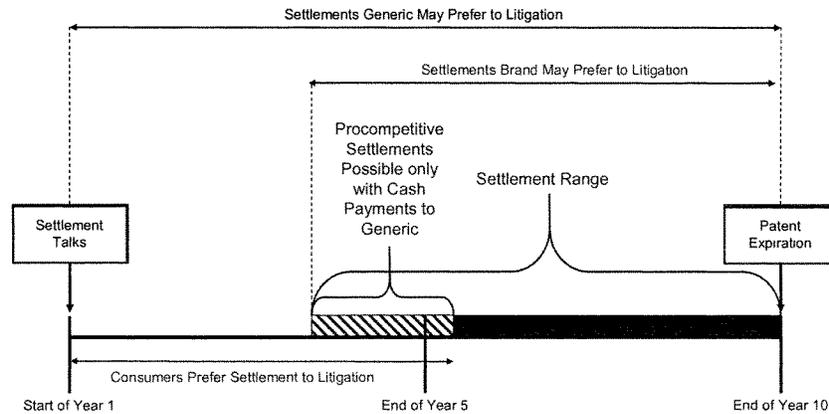
Figure 7a

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



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

Figure 7b
 Settlement with Generic Entry Date and Cash Payment
 Cash-Strapped Generic and Litigation Costs/Risk Aversion



A cash payment by the branded manufacturer may allow the branded and generic manufacturers to bridge the settlement gap shown in Figure 7a. The branded manufacturer would be willing to include a cash payment in the settlement in exchange for a later generic entry date. The generic manufacturer would be willing to accept later entry in exchange for a cash payment. As described above, the incremental profits that a branded manufacturer would receive because of postponed generic entry would be higher than the incremental profits that the generic manufacturer would lose from delaying its entry to a more competitive market. Thus, a given cash payment will move the range of entry dates that the branded manufacturer is willing to accept later in time, but it will move the dates the generic is willing to accept by an even greater amount. Such a payment will bring the parties closer together and could bridge the settlement gap between the two parties. As shown in Figure 7b, under these circumstances, reverse payments can lead to a range of settlements that would not have been otherwise feasible.

Importantly, many of these newly conceivable settlements would benefit consumers by resulting in a generic entry date earlier than that expected with continued litigation.

4. Cash payments with an optimistic generic

Cash payments can also help bridge settlement gaps arising under other circumstances. For example, imagine a generic manufacturer that, despite actual odds of winning the patent suit of only 50 percent, believes that it in fact has a 75 percent chance of winning. This mismatch of beliefs and actual probabilities could create a situation similar to that depicted in 7a, where (absent a reverse payment) the generic manufacturer would not be willing to accept any settlement terms the branded manufacturer would be willing to offer because the generic manufacturer has an unrealistic belief about its chance of winning if it holds out and continues to litigate. Just as with a cash-strapped generic, a reverse payment can potentially bridge the settlement gap and lead to a settlement that benefits consumers. Of course, it is possible that the branded manufacturer is also overly optimistic about its odds of success in the litigation, which would reduce the range of procompetitive settlements that a cash payment could generate. Our point here is not that these are the only scenarios that could play out, but rather that there are reasonable scenarios under which a patent settlement with a reverse payment can benefit consumers.

5. Cash payments with information asymmetries

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

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

Suppose there are two types of patents: “high-value” patents, where there is no chance that other branded competitors enter before the patent expires, and “low-value” patents, where there is a decent chance that such brand-name entry happens, significantly reducing the effective life, and the value, of the current patent. The branded manufacturer knows which type of patent it holds, but the generic manufacturer does not.⁶³ In the case of a low-value patent, agreeing to a compromise entry date may have little benefit to the generic because the market may be eliminated by future competition. So a generic may be wary of accepting a reasonable settlement offer because it worries that that settlement may indicate that in fact the patent is low value – and the generic would be better off continuing to litigate.

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

6. *Collateral business agreements*

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

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

⁶³ Economic models on this point often assume that the branded manufacturer knows the type of patent it holds with certainty. However, the results depend not upon this assumption (as there may be some uncertainty even on the part of the branded manufacturer) but only that the branded manufacturer will have better information on the type of the patent than the generic manufacturer.

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

Such collateral agreements can be helpful in facilitating settlements by allowing the parties to get around some of the complexities discussed above that may otherwise pose obstacles to successful settlements like information asymmetries and differences in expectations. Unlike cash, the parties' valuations of the components of a collateral business arrangement may be quite different. This difference in valuation could be used to offset different expectations in the patent litigation to arrive at a settlement. In addition, these collateral agreements could in and of themselves benefit consumers, bringing together business partnerships that would not be possible with continued litigation. But while these collateral agreements can serve to facilitate settlements, they could also, in theory, contain "effective" payments that are designed to delay entry of the generic, if the generic manufacturer is over-compensated for what it is providing or the branded manufacturer is under-compensated for what it is providing.

In recent years, patent settlements with collateral business agreements have received significant regulatory and legal scrutiny. For example, as described above, the agreement between Schering and Upsher that was challenged by the FTC did not involve an isolated cash payment to the generic. Rather, in settling the patent dispute, Schering also licensed five different products from Upsher, including Upsher's Niacor SR, in exchange for royalty payments of \$60 million.⁶⁴ 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.⁶⁵

Evaluating the competitive implications of settlements with collateral business arrangements is even more complicated than those with cash payments. Such an analysis first requires an evaluation of the collateral business transaction to determine a reasonable assessment of the market value of the transaction. To the extent that it is clear from the evidence that the generic was over-compensated or the brand was under-compensated,

⁶⁴ *Schering-Plough v. FTC*, 402 F.3d, at 1060.

⁶⁵ Ultimately, the Appeals Court concluded that the FTC did not convincingly demonstrate that the \$60 million was not simply a royalty payment within the range of fair market value for the licensed products. See *Schering-Plough v. FTC*, 402 F.3d, at 1068.

then the difference between the payment and the arms-length value of the transaction can be thought of in the same way as a “reverse payment.” Collateral business transactions, just like reverse payments, therefore can be anticompetitive, but they can also serve to produce procompetitive outcomes, some of which may not have been otherwise feasible.

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. Patent settlements can also have important long-run competitive effects. First, the scope of patent protection can affect future incentives for branded manufacturers to invest in additional R&D. Patents give patent holders, such as branded pharmaceutical manufacturers, the right to litigate claims against alleged infringers, and the right to settle such litigation – at least as long as such a settlement does not exclude competition beyond that allowed by the patent. Broad-brush limits on the types of patent settlements that are allowed by pharmaceutical manufacturers would likely result in a narrowing of the patent protection currently provided to patent holders. As described above, such patent protection is an important component of pharmaceutical manufacturers’ incentives to invest substantial sums in R&D and to introduce new medications. To the extent that limits on patent settlements reduce incentives to invest in pharmaceutical R&D, consumers may suffer significant adverse effects in the long-run, in the form of a smaller number of new medicines that become available.⁶⁶

Second, the availability of procompetitive settlements can provide further incentives to generic manufacturers to challenge branded patents and bring lower-priced generic drugs to market. Patent litigation can be expensive and risky, particularly for small firms. Restricting the range of settlement options will reduce the ability of generic manufacturers to settle these cases and increase the cost and risk of bringing a generic drug to market. On the margin, this will lower the incentives of generic pharmaceutical

⁶⁶ For a more extensive discussion of these effects, see Langenfeld, James and Li, Wenqing, “Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers,” *Antitrust Law Journal*, 70, 2003, pp. 777-818.

manufacturers to challenge branded patents in the first place.⁶⁷ 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 this depends upon the validity of the patent claims. A settlement agreement whereby the generic manufacturer agrees to enter in, say, five years – but five years before patent expiration – might be anticompetitive if the patent was weak (*i.e.*, if the generic had a high probability of winning at trial). But the same settlement terms might be procompetitive if the patent was strong (*i.e.*, if the generic had a low probability of winning at trial). Ultimately, an evaluation of the competitive effects of a patent settlement cannot avoid at least some investigation into the merits of the patent litigation.

While antitrust economists generally agree with this line of argument, some analysts have suggested prohibiting settlements with “reverse payments.” Several bills have been introduced in Congress that would do just that.⁶⁸

However, as we explain above, under many circumstances, patent settlements between branded and generic manufacturers – even those involving reverse payments – can benefit competition and consumers. An outright prohibition of reverse payment settlements would harm consumer welfare in a range of circumstances. Indeed, prohibiting settlements with cash payments could simply lead to a shift to settlements with other business arrangements which are even more complicated to evaluate, which makes enforcement of potentially anticompetitive arrangements even more difficult to assess. Efforts to prevent settlements with any compensation (whether in the form of cash or compensation from other business arrangements) flowing from the branded

⁶⁷ See, for example, Judge Posner's opinion in *Asahi Glass Co., Ltd. v. Pentech Pharm, Inc.*, 289 F. Supp. 2d 986, 994.

⁶⁸ See, most recently, the Preserve Access to Affordable Generics Act, S.369, 111th Cong. (2009) and the Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009).

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. But it is not at all clear that these savings would outweigh the harm created by eliminating potentially procompetitive settlements. “Quick look” or “safe harbor” approaches (whereby settlements with certain characteristics are presumptively anticompetitive or procompetitive, while leaving open the opportunity to rebut this presumption) could reduce these costs while still allowing procompetitive settlements.

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

Patent settlements between branded and generic pharmaceutical manufactures can be anticompetitive and should continue to be closely scrutinized by the antitrust authorities and the courts. Indeed, current law requires that the terms of any relevant patent settlement agreement be provided to the FTC and the DOJ. But painting all settlements with the same brush is likely to harm consumers. Instead, more individualized treatment is appropriate, whereby the competitive effects of a particular settlement are evaluated by applying an economic framework, such as that presented here, to the facts specific to that settlement.



Jonathan M. Orszag
Senior Managing Director

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March 30, 2009

The Honorable Bobby Rush
Chairman
Subcommittee on Commerce, Trade and Consumer Protection
House Committee on Energy and Commerce
Washington, D.C. 20515

The Honorable George Radanovich
Ranking Member
Subcommittee on Commerce, Trade and Consumer Protection
House Committee on Energy and Commerce
Washington, D.C. 20515

Dear Chairman Rush and Ranking Member Radanovich:

We are writing to you to provide you a copy of our study about the effects of patent settlements on consumer welfare.

We understand that you are considering the "Protecting Consumer Access to Generic Drugs Act of 2009," which would prohibit certain patent settlements between branded and generic pharmaceutical manufacturers. Our paper ("An Economic Assessment of Patent Settlements in the Pharmaceutical Industry"), co-authored with Laura D. Tyson, the former chair of President Clinton's National Economic Council, presents an economic framework for evaluating the effects of such patent settlements on consumer welfare.

While patent settlements have the potential to harm consumers and therefore warrant continued scrutiny by antitrust authorities and the courts, such settlements also have the potential to benefit consumers significantly by bringing generic drugs to market earlier than would occur with continued litigation.

We believe, therefore, that a broad ban on certain types of patent settlements, such as that considered in the proposed legislation, will likely make American consumers worse off.

If you have any questions about the attached paper, we would be more than happy to answer them.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Orszag".

Jonathan M. Orszag

A handwritten signature in black ink, appearing to read "Bret M. Dickey".

Bret M. Dickey

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May 5, 2009

The Honorable J. Thomas Rosch
 Commissioner
 Federal Trade Commission
 600 Pennsylvania Avenue, NW
 Washington, DC 20580

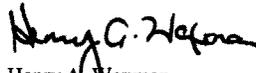
Dear Commissioner Rosch:

Thank you for appearing before the Subcommittee on Commerce, Trade, and Consumer Protection on March 31, 2009, at the hearing entitled "The Protecting Consumer Access to Generic Drugs Act of 2009".

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions and include the text of the question with your response, using separate pages for responses to each Member.

Please provide your responses by May 19, 2009, to Earley Green, Chief Clerk, in Room 2125 of the Rayburn House Office Building and via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,


 Henry A. Waxman
 Chairman

Attachment

The Honorable Steve Scalise

1. As an alternative to enacting a per se prohibition on reverse payments, what's wrong with having the judge who is presiding over the patent case take a look at the settlement and decide whether the settlement is in the public interest? Isn't the trial judge the person who is best equipped to make that determination?
2. Is FTC better equipped than private parties to know when to settle or litigate a patent case? Does FTC have some special patent expertise? I have to assume that the generic and branded companies are getting some of the best legal advice that can be had on the strengths and weaknesses of the patent. Why should we assume that they will not take advantage of this information in negotiating a settlement?
3. The Prozac case has often been used as an example of one of the most successful generic launches in the history of the generic drug industry, saving consumers billions of dollars. The litigation surrounding Prozac involved the settlement of an inequitable conduct claim for cash consideration, as discussed by the manufacturer's CEO in testimony before the Senate. If the current proposal H.R. 1709 had been law at the time, this type of settlement would have been illegal, and consumers would have been denied billions of dollars in savings. Do you think the Prozac settlement and subsequent launch was anti-competitive? Have you considered that the current proposal could cost consumers billions of dollars in savings?

Proposed Answers to Questions from the Honorable Steve Scalise
(May 19, 2009)

1. **As an alternative to enacting a per se prohibition on reverse payments, what's wrong with having the judge who is presiding over the patent case take a look at the settlement and decide whether the settlement is in the public interest? Isn't the trial judge the person who is best equipped to make that determination?**

The review of a proposed patent settlement does not focus principally on the merits of patent litigation, but on the settlement agreement itself and whether it is a lawful agreement. Settlements that involve payments to the defendants raise concerns about competition, an area in which, as Congress and the President intended when Congress created the FTC, the FTC does possess special expertise respecting antitrust matters.¹ Whether a reverse payment settlement of a patent dispute simply reflects a likelihood that the patent is valid and infringed or instead reflects a payment for delay of the alleged infringer's entry into the market (as compared with when that firm would have entered if it had continued to challenge the patent) is a question that necessarily involves the antitrust laws.

A reverse payment settlement is an extraordinary settlement that squarely implicates the antitrust laws. Ordinarily, a settlement of a patent dispute entails payment by the alleged infringer to the patent-holder, not vice versa. When there is such an extraordinary settlement, there is a basis for an inference that the payment is really a payment for delay of the alleged infringer's entry into the market as compared with when it would have entered if it had continued to challenge the patent. That is particularly so when as in most, if not all, of these cases, the alleged infringer has previously represented to both the FDA and the court that the patent is not valid or that it is not being infringed. If a reverse payment settlement is a payment for delay, then it constitutes a market division agreement, which the courts should be treating as a per se violation of the antitrust laws.

Moreover, faced with crowded dockets and jury trials, federal district courts have an incentive not possessed by the Commission to bless settlements, and especially settlements of patent disputes, which frequently involve complex issues. This is not to say that those courts will deliberately bless reverse settlements which they know to be collusive and contrary to the public interest. It is simply to recognize that they have an incentive to approve patent settlements that the Commission does not have.

¹ See, e.g., 51 Cong. Rec. 8977 (1914) (discussing need for FTC to have special expertise in resolving questions of antitrust law); *Hosp. Corp. of Am. v. Federal Trade Comm'n*, 807 F.2d 1381, 1386 (7th Cir. 1986) ("One of the main reasons for creating the Federal Trade Commission and giving it concurrent jurisdiction to enforce the Clayton Act was that Congress distrusted judicial determination of antitrust questions. It sought the assistance of an administrative body in resolving such questions and indeed expected the FTC to take the leading role in enforcing the Clayton Act . . .") (Posner, J.); *Federal Trade Comm'n v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1042 (D.C. Cir. 2008) (Tatel J., concurring, quoting Posner).

Finally, a vigorous application of competition analysis extends far beyond the patent issues before the court in the litigation. H.R. 1706 is intended to require application of such a standard for that reason.

2. **Is FTC better equipped than private parties to know when to settle or litigate a patent case? Does FTC have some special patent expertise? I have to assume that the generic and branded companies are getting some of the best legal advice that can be had on the strength and weaknesses of the patent. Why should we assume that they will not take advantage of this information in negotiating a settlement?**

The Commission does not possess expertise that is superior to the parties to patent disputes in determining whether a reverse payment settlement reflects the parties' views about the likelihood that the patent will be held valid and infringed. However, those parties each have economic incentives to settle patent litigation with reverse payments in ways or on terms that do not protect consumers. As a result, what is profitable for the parties means delayed generic entry and higher prescription drug prices for consumers. Again, reverse payment settlements are extraordinary settlements, entailing payments by the patent holder to the alleged infringer, instead of vice versa. If the parties to the dispute actually believe that the patent is likely to be held valid and infringed, it is counterintuitive that the holder of the patent would be paying the alleged infringer to settle the dispute. Instead, the patent holder is likely paying the alleged infringer to eliminate the risk of generic competition. That is especially true when, as in most, if not all of these cases, the alleged infringer has represented to the FDA and the court that the patent is not valid or that it is not being infringed.

3. **The Prozac case has often been used as an example of one of the most successful generic launches in the history of the generic drug industry, saving consumers billions of dollars. The litigation surrounding Prozac involved the settlement of an inequitable conduct claim for cash consideration, as discussed by the manufacturer's CEO in testimony before the Senate. If the current proposal H.R. 1706 had been law at the time, this type of settlement would have been illegal and consumers would have been denied billions of dollars in savings. Do you think the Prozac settlement and subsequent launch was anticompetitive? Have you considered that the current proposal could cost consumers billions of dollars in savings?**

The launch of generic Prozac occurred because of a successful patent litigation challenge by the generic firm, not because of a settlement. In May 2001, the Court of Appeals for the Federal Circuit upheld Barr Laboratories' claim that a patent on Prozac due to expire in 2003 was invalid for obviousness-type double patenting. *See Eli Lilly v. Barr Labs.*, 251 F.3d 955 (Fed. Cir. 2001). It was this litigation victory – not a settlement – that enabled consumers to reap billions of dollars in savings from generic Prozac. Indeed, Eli Lilly, the maker of Prozac, rejected an offer by Barr to settle the litigation and drop its patent challenge for \$200 million.¹

¹ See Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 5, available at <http://money.cnn.com/magazines/fortune/fortune_archive/2001/08/13/308077/index.htm>.

Had Lilly taken the deal, the billions in savings for consumers, and for the federal and state governments, would have been lost.

Your question asks for my views on an agreement that led to Barr's dropping one of its arguments, an inequitable conduct claim, prior to trial. I have not seen the terms of that agreement, so I cannot offer a definitive opinion on whether that agreement would fall within the prohibition of H.R. 1706.² But, as noted above, the settlement of the inequitable conduct claim did not resolve a patent infringement claim by Lilly against Barr, as Barr ultimately prevailed on its claim that a later-expiring Prozac patent was invalid. Since H.R. 1706 only covers final resolutions of patent infringement claims, it would appear that the Prozac agreement you are referring to would not fall within the bill's prohibition.

² Press reports indicate that the settlement involved Lilly paying a total of four million dollars to three generic companies. See *Settlement Reached in Prozac Patent Case*, January 26, 1999, available at <http://www.pharmaceuticalonline.com/article.mvc/SETTLEMENT-REACHED-IN-PROZAC-PATENT-CASE-0001>.

