S. HRG. 110–4

PAYING OFF GENERICS TO PREVENT COMPETITION WITH BRAND NAME DRUGS: SHOULD IT BE PROHIBITED?

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

JANUARY 17, 2007

Serial No. J–110–4

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

33–401 PDF WASHINGTON : 2007

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON THE JUDICIARY

PATRICK J. LEAHY, Vermont, *Chairman*

EDWARD M. KENNEDY, Massachusetts
JOSEPH R. BIDEN, JR., Delaware
HERB KOHL, Wisconsin
DIANNE FEINSTEIN, California
RUSSELL D. FEINGOLD, Wisconsin
CHARLES E. SCHUMER, New York
RICHARD J. DURBIN, Illinois
BENJAMIN L. CARDIN, Maryland
SHELDON WHITEHOUSE, Rhode Island

ARLEN SPECTER, Pennsylvania
ORRIN G. HATCH, Utah
CHARLES E. GRASSLEY, Iowa
JON KYL, Arizona
JEFF SESSIONS, Alabama
LINDSEY O. GRAHAM, South Carolina
JOHN CORNYN, Texas
SAM BROWNBACK, Kansas
TOM COBURN, Oklahoma

BRUCE A. COHEN, *Chief Counsel and Staff Director*
MICHAEL O'NEILL, *Republican Chief Counsel and Staff Director*

CONTENTS

STATEMENTS OF COMMITTEE MEMBERS

	Page
Feingold, Hon. Russell D., a U.S. Senator from the State of Wisconsin, prepared statement	97
Grassley, Hon. Charles E., a U.S. Senator from the State of Iowa	40
prepared statement	99
Hatch, Hon. Orrin G., a U.S. Senator from the State of Utah	30
Kohl, Hon. Herb, a U.S. Senator from the State of Wisconsin	5
Leahy, Hon. Patrick J., a U.S. Senator from the State of Vermont	1
prepared statement	116
Schumer, Hon. Charles E., a U.S. Senator from the State of New York	28
Specter, Hon. Arlen, a U.S. Senator from the State of Pennsylvania	3

WITNESSES

Downey, Bruce L., Chairman and Chief Executive Officer, Barr Pharmaceuticals, Inc., Washington, D.C.,	23
Hirsh, Merril, Partner, Ross, Dixon and Bell, LLP, Washington, D.C.	21
Leibowitz, Jon, Commissioner, Federal Trade Commission, Washington, D.C.	6
Tauzin, Billy, President and Chief Executive Officer, Pharmaceutical Research and Manufacturers of America (PhRMA) Washington, D.C.	18
Wroblewski, Michael, Project Director, Consumer Education and Outreach, Consumers Union, the Non-Profit Publisher of Consumer Reports, Washington, D.C.	16

QUESTIONS AND ANSWERS

Responses of Bruce L. Downey to questions submitted by Senators Schumer, Feinstein and Kohl	41
Responses of Merril Hirsh to questions submitted by Senators Kohl and Feinstein	45
Responses of Jon Leibowitz to questions submitted by Senators Kohl, Feinstein, Leahy and Hatch	71
Responses of Billy Tauzin to questions submitted by Senators Schumer, Feinstein and Kohl	76
Responses of Michael Wroblewski to questions submitted by Senators Kohl and Feinstein	83

SUBMISSIONS FOR THE RECORD

Downey, Bruce L., Chairman and Chief Executive Officer, Barr Pharmaceuticals, Inc., Washington, D.C., prepared statement	87
Hirsh, Merril, Partner, Ross, Dixon and Bell, LLP, Washington, D.C., prepared statement	100
Leibowitz, Jon, Commissioner, Federal Trade Commission, Washington, D.C., prepared statement	120
Tauzin, Billy, President and Chief Executive Officer, Pharmaceutical Research and Manufacturers of America (PhRMA) Washington, D.C., prepared statement	147
Wroblewski, Michael, Project Director, Consumer Education and Outreach, Consumers Union, the Non-Profit Publisher of Consumer Reports, prepared statement, Washington, D.C.	164

PAYING OFF GENERICS TO PREVENT COMPETITION WITH BRAND NAME DRUGS: SHOULD IT BE PROHIBITED?

WEDNESDAY, JANUARY 17, 2007

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Committee met, Pursuant to notice, at 10:02 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Kohl, Schumer, Cardin, Whitehouse, Specter, Hatch, and Grassley.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Good morning. This hearing today is the continuation of a longstanding, bipartisan effort by several members of this Committee to provide consumers more choices and lower-cost medicines. My focus is on making lower-cost generic medicines available not only to our families but to our seniors. The existing law is being misused by some brand-name and generic drug companies. The fact we have scheduled this hearing so early in this new Congress is a sign, I hope, that people realize that this is going to be a high priority for this Committee. It deserves to be and consumers want it to be.

We will examine the harmful effects of a type of collusion that limits consumer choices and that keeps consumer prices artificially high. Now, rarely do we have such a clear-cut opportunity to remove impediments that prevent competition and keep the marketplace from working as they should, to benefit consumers. Basically, as you know, we have had the situation where a drug company will actually pay a generic producer not to put a drug on the market so that they can keep the prices high.

Now, Congress never intended for brand-name drug companies to be able to pay off generic companies not to produce generic medicines. We never intended that. That would be a sham, it would be harmful to consumers, and it would be a crime.

In fact, the history and text of the Hatch-Waxman laws make it clear that the opposite of delay was the goal.

Now, it is no secret that prescription drug prices are rising. They are a source of considerable concern to many Americans, especially senior citizens and working families. In a marketplace that is free of manipulation—free of manipulation—generic drug prices can be

as much as 80 percent lower than the comparable brand-name version.

In June of last year, I sponsored a bill that was introduced by Senator Kohl of Wisconsin, also sponsored by Senators Grassley, Schumer, Feingold, and Johnson, which would have stopped these payoffs to delay access to generic medicines. Working with Senators Kohl and Grassley and with many others, we will try to enact a new version.

You know, it is unfortunate we even have to do this. As I said in June, there are still some companies driven by greed that may be keeping low-cost, life-saving generic drugs off the marketplace, off pharmacy shelves, and out of the hands of consumers by carefully crafted anticompetitive agreements.

Since some of these deals used to be done in secret, behind closed doors, I am glad that because of a bill that was reported out of this Committee, Congress is now aware of this problem. In 2001, I worked with Chairman Hatch and later with Senator Grassley to make sure that our law enforcement agencies—the Federal Trade Commission and the Department of Justice—at least were made aware of the secret, sometimes potentially criminal deals.

The New York Times and others published major investigative stories on how the manufacturer of a hypertension drug used to help prevent strokes and heart attacks—Cardizem CD—had made deals to pay a potential generic competitors $10 million every 3 months to stop it from developing a generic version of Cardizem. Of course they did. They were making a fortune, and they did not want those people who needed that drug to be able to buy a lower-cost generic. This led to my introduction of S. 754, the Drug Competition Act, which was reported out of this Committee and was finally passed as part of the Medicare Modernization Act Amendments with significant help from Senator Grassley.

The concept of that law is simple: It requires if a brand-name company and a generic firm enter into an agreement that is related to the sale of either the brand-name drug or its generic version, then both companies must file copies of any agreements with the FTC and with the Department of Justice so those agencies can enforce the law. Incidentally, once the Cardizem deal was exposed and challenged, the U.S. Circuit Court held that the "horizontal market allocation agreement...[was] per se illegal under the Sherman Act."

Now, Commissioner Leibowitz will testify about what the FTC has found regarding these deals—the deals between the brand-name companies and generic companies.

I will once again strongly support a legislative effort led by Senator Kohl and Senator Grassley to allow the FTC to do its job. Two subsequent circuit court decisions have undermined the Cardizem approach and relied on the general rule favoring settlements between private litigants, even though private corporate litigants have duties to their shareholders, not consumers, to maximize profits. The problem with respect to deals not to compete is that the interests of millions of senior citizens, millions of children, and millions of others are not taken into account. Those cases ignore the decision in Associated General in which the U.S. Supreme Court noted that "the Sherman Act was enacted to assure our customers

the benefits of price competition....” The focus is on consumers, not on whether private companies should be able to make back-room deals that harm consumers as part of a settlement of a lawsuit.

Our bipartisan bill will solve that problem by making payments by brand-name companies to delay introduction of a generic drug unlawful. My initial position is to follow this bright-line approach. I will be interested in hearing from others, of course, and it will be a major priority of this Committee.

[The prepared statement of Senator Leahy appears as a submission for the record.]

With that, I would yield to the distinguished senior Senator from Pennsylvania.

STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SPECTER. Thank you, Mr. Chairman.

This Judiciary Committee is used to hearings on important competing values and complex conceptual matters, and today's hearing is a top-drawer illustration of the issues which we confront and which are confronted here.

We have two very important values at issue here. One is to encourage pharmaceutical companies to develop life-saving drugs, and I can speak with some authority personally on that subject, having been the beneficiary of some very important drugs in battling Hodgkin's. Every 2 weeks I got a cocktail—not the kind of cocktail I would prefer. It was in the morning, and I did not like the ingredients, but it was life-saving. And the pharmaceutical companies take a decade or so to develop these drugs at a cost in the range, reportedly, of $1 billion. And only one out of thousands make it. They have a patent period no longer than 20 years to encourage them to develop further life-saving drugs. That is one very important value. On the other side of the issue is the matter of holding down costs so that these life-saving drugs in generic form can be available to more people to save their lives.

There are three studies which I think are worth noting at the outset of our hearing. One is a study, published by the Food and Drug Administration in 2005, that determined that once generics begin competing, prices fall by almost 50 percent. Second, according to the Generic Pharmaceutical Association, generic drugs account for 56 percent of all drug sales in the United States, while revenues from generic drugs are only one-tenth that of brand-name manufacturers. A third study, Pharmaceutical Care Management Association recently published findings that Medicare would save over $23 billion between now and 2010 by purchasing newly available generic drugs instead of the brand-name drugs that are currently purchased.

In my capacity as Chairman of the Appropriations Subcommittee dealing with the Department of Health and Human Services, I can attest to the grave difficulties of finding funding for very important medical matters like the National Institutes of Health and the Centers for Disease Control so that we deal with these kinds of savings that are very, very important.

The legal issues here are conceptually very complicated. We have had one circuit court, the Sixth Circuit, conclude that these settle-

ment agreements are so-called per se antitrust violations. That is fancy Latin for meaning all you have to show is the settlement agreement and there is a violation of the antitrust laws. Two other circuits—the Second and the Eleventh Circuit—have said that a rule of reason applies, so it is a balancing test. And the articulated rule of reason is this: that patent settlements are reasonable so long as the exclusionary effects of the settlement do not exceed the exclusionary effects of the patent.

I do not think this hearing will be quite long enough to determine what that succinctly stated formula means. I have an expert in antitrust law, Ivy Johnson, and she has been trying to explain it to me for several days. And I have had experience in the antitrust field in the private practice of law before coming to the Senate and considerable experience here on this Committee.

In reviewing the leading cases, *Cardizem*, where the Sixth Circuit said it was a per se violation, and *Valley Drugs* and *Schering-Plough*, where the Eleventh Circuit said it was rule of reason, and the *Tamoxifen* case, where the Second Circuit said it was rule of reason, involve extraordinarily complicated factual situations. One idea which occurs to me is whether when the lawsuits are settled where there is litigation between the generic maker and the patent holder, a condition of the settlement ought to be for the presiding judge to examine it and see if the settlement does or does not violate the antitrust laws, instead of inviting a later lawsuit where purchasers want lower costs and come in and sue the parties to the agreement.

The distinguished representative from the Federal Trade Commission, who performed—he just raised his eyebrows. You must agree with that—a lot of service for this Judiciary Committee and for Senator Kohl's Subcommittee, is going to testify, according to his written presentation, that there ought to be a per se violation. And the thought crosses my mind, if the FTC thinks that, why doesn't the FTC act on it?

There is a gesture of "Who knows?" And maybe it is more appropriately left to the Congress. Sometimes the gestures and the body language tell more than the long, verbose written and oral statements.

But as I look at this field, it is fraught with complexity on the competing values and fraught with complexity on what the parties have entered into. And I do think there is a burden on people making these settlements to show that they are not anticompetitive, because why settle the case unless it is in the advantage of the patent holder and raises a question which I am not prepared to answer: Is the generic company being bought off to the detriment of the public? But I commend the distinguished Chairman for convening this hearing and the work that Senator Kohl has done, and I regret that I am going to have to excuse myself early to attend a meeting by the National Security Counselor, who has invited a group of Senators to meet on the Iraq issue. We are being buffeted on all sides by complex issues.

Thank you, Mr. Chairman.

Chairman LEAHY. Thank you, Senator Specter, and I appreciate your being here for this because this will be a priority.

Before introducing Commissioner Leibowitz and swearing him in, I did want to yield to Senator Kohl, who will also take over and chair this hearing when I have to leave for another one of those similar kinds of things. There seems to be a lot of discussion in Washington about the war in Iraq of late, and I think that is a very good thing.

Senator Kohl?

STATEMENT OF HON. HERB KOHL, A U.S. SENATOR FROM THE STATE OF WISCONSIN

Senator KOHL. I thank you, Mr. Chairman, for calling this hearing here today. This hearing will examine legislation that you and I have sponsored, along with Senators Grassley and Schumer, that will end an anticompetitive abuse which denies millions of consumers access to generic drugs. Our bill does this by forbidding the collusive payoffs between brand-name drug companies and generics which are designed to keep low-cost alternatives off the market.

As health care costs continue to spiral upwards, the high price of prescription drugs leads the way. A recent independent study found that prescription drug spending has more than quadrupled since 1990. One way to tame the cost of prescription drugs is to promote the introduction of generic alternatives. Consumers realize substantial savings once generic drugs enter the market. One study estimates that every 1-percent increase in the use of generic drugs could save $4 billion annually in health care costs in our country.

Unfortunately, recent years have seen the growing practice of collusion between some brand-name drug manufacturers and generic manufacturers to prevent competition. This collusion consists of payments, often as much as hundreds of millions of dollars, made by brand-name companies to generic companies to settle patent litigation. In return for this money, the generic company promises to keep its competing drugs off the market. The brand-name company profits so much by delaying competition that it can easily afford to pay off the generic company. The losers, of course, are the American people who continue to pay unnecessarily high drug prices for years to come.

Just two examples of the benefits of early generic entry prior to patent expiration. No. 1, the generic version of Prozac, which entered the market in 2001, approximately 3 years before the patent expired, resulted in consumer savings of about $2.5 billion. No. 2, generic competition to Paxil in 2003, 3 years before the last patent would have expired, saved consumers about $2 billion.

The patent settlements targeted by our bill would eliminate such practices. The FTC has found that these agreements violate antitrust law. However, two circuit court decisions in 2005 allowed these agreements, regardless of their obvious anticompetitive impact, and the effect of these court decisions has been stark. In the year after these decisions, the FTC has found half of all patent settlements, 14 of 28, did involve payments from the brand-name to generic manufacturer in return for an agreement by the generic manufacturer to keep its drug off the market. In the year before these decisions, not a single patent settlement reported to the FTC contained such an agreement.

So I believe the time has now come to forbid these anticompetitive, anticonsumer, reverse payment patent settlements. The bill that we are introducing today does just that. It will state clearly and simply that it is unlawful under the antitrust laws for any drug maker to settle patent litigation by paying off a competitor in return for an agreement to keep a competing product off the market.

So I urge my colleagues to join us in supporting this legislation to end this anticompetitive practice that enriches drug companies at the expense of consumers. Offering consumers generic alternatives is essential to bringing high drug prices down, and we ought to have zero tolerance for efforts by big brand-name drug companies to pay off their competitors to keep competition off the market. These payoffs help big drug companies maximize their profits while ordinary consumers pay the price.

I am very pleased that we have a distinguished group of witnesses here today, and we are looking forward to their testimony.

Thank you, Mr. Chairman.

Chairman LEAHY. Thank you, Senator Kohl. And I know our first witness, Commissioner Leibowitz of the Federal Trade Commission, has had a long and distinguished public service. He was Democratic chief counsel and staff director for the U.S. Senate Antitrust Subcommittee from 1997 to 2000. He served as chief counsel and staff director for the Senate Subcommittee on Terrorism and Technology from 1995 to 1996 and the Senate Subcommittee on Juvenile Justice from 1991 to 1994. And very important to this Committee, he served as chief counsel to Senator Herb Kohl from 1989 to the year 2000. In the private sector, Mr. Leibowitz served most recently as vice President for Congressional affairs for the Motion Picture Association of America from 2000 to 2004. He is a Phi Beta Kappa graduate of the University of Wisconsin with a B.A. in American History, and he also graduate from the New York University School of Law in 1984.

Mr. Leibowitz, would you please stand so I can swear you in? Do you swear that the testimony you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

Mr. LEIBOWITZ. I do.

Chairman LEAHY. Thank you. And, Mr. Leibowitz, please go ahead with your testimony. I am going to switch seats with Senator Kohl because I will be leaving shortly after you finish.

STATEMENT OF JON LEIBOWITZ, COMMISSIONER, FEDERAL TRADE COMMISSION, WASHINGTON, D.C.

Mr. LEIBOWITZ. Thank you, Mr. Chairman.

Chairman Leahy, Ranking Member Specter, Senator Kohl, Senator Cardin, other members of the Committee, we applaud your early hearing on legislation to ensure that consumers continue to have access to low-priced generic drugs. It is critical to eliminate the pay-for-delay settlement tactics employed by the pharmaceutical industry. Simply put, companies should not be able to play "Deal or No Deal" at the expense of American consumers.

Mr. Chairman, I am particularly honored to return to the Committee for which I worked for so many years. In the introduction,

you made me sound much more impressive than I know myself to be, but I do appreciate it. I am honored to come back here.

But let me start with the usual disclaimer. The written statement that we submitted represents the views of the Commission. My oral testimony reflects my own views, and not necessarily the views of any other Commissioner.

There is a particular urgency to pharmaceutical competition issues today. Recent appellate decisions make it difficult to challenge so-called exclusion payments—that is, patent settlements in which the brand-name drug firm pays the generic firm to stay out of the market. If these decisions are allowed to stand, drug companies will enter into more and more of these agreements, and prescription drug costs, which slowed in 2005 after years of precipitous growth, will begin to rise again. These increased costs will burden not only individual consumers, but also the Federal Government's new Medicare program, State governments, and American businesses striving to compete in a global economy—like General Motors, which reports that employee health care costs add $1,500 to the price of each and every car that rolls off its assembly line.

Mr. Chairman, as our 2006 Patent Settlement Report released today confirms, this is not just a theoretical concern. In the past year, we have seen a dramatic increase in these types of settlements.

Now, when Congress enacted the Hatch-Waxman statute in 1984, you encouraged speedy introduction of generics by establishing mechanisms to challenge invalid or narrow patents on branded drugs. This statutory framework ensures that our pioneer drug firms remain the envy of the world—and they are—while also delivering enormous consumer savings. When the first generic enters the market, it generally does so at a 20- to 30-percent discount off of the brand price. Prices drop even further, by 80 percent or more, after other generic competitors go to market, usually 6 months later. Generic competition following successful patent challenges in just four products—and, Senator Kohl, you alluded to some of these—Prozac, Zantac, Paxil, and Platinol—is estimated to have saved consumers more than $9 billion alone.

But these benefits will be at risk, as will the legacy of Hatch-Waxman itself, if companies are able to settle litigation through arrangements in which brands can pay generics to sit it out. Sadly, the incentives to enter into such pernicious pay-for-delay agreements are substantial because generic entry causes the branded drug firm to lose far more in sales than the lower-priced generic could ever possibly earn. As a result, with these agreements both firms are better off than they would be if they competed. Of course, consumers are left holding the bag or, more appropriately, footing the bill.

For the past decade, the FTC has made challenging these pharmaceutical patent settlements a bipartisan priority. In 2000 and 2001, the Commission obtained two major consents involving anticompetitive payments between brands and generics. We put companies on notice that we would consider all available remedies, including disgorgement of profits, against this behavior in the future, and our actions stopped this conduct cold.

The Commission set forth rules that everyone understood. If you settle a case by paying off a generic to stay out of the market, we will not let you get away with it. As a result, to the best of our knowledge, there were plenty of settlements between 2000 and 2004 and no exclusion payments.

In 2003, the Commission ruled that a 1997 settlement with a payment from Schering-Plough, which is the brand, to Upsher-Smith, the generic, violated the antitrust laws. The case involved a potassium supplement widely used by older Americans taking medication for high blood pressure. The Eleventh Circuit reversed us in 2005, and the Second Circuit, in a 2–1 decision in the *Tamoxifen* case, which Senator Specter alluded to, issued a similar holding later that year. These decisions, which essentially allow a patent holder to compensate a generic except under very limited circumstances, have dramatically altered the legal landscape—and, we believe, to the detriment of consumers.

Mr. Chairman, how do we know this to be accurate? Well, thanks to the reporting requirement that you, Senator Leahy, and Senator Grassley included in the 2003 Medicare Modernization Act, the FTC reviews each and every Hatch-Waxman settlement. Tellingly, here is what the data for the last few years reveals.

As you can see from the chart, for fiscal year 2004 and the early part of fiscal year 2005, none of the nearly 20 agreements reported between brands and generics contained both a payment from the brand and an agreement by the generic to defer entry. In other words, the parties could—and they did—settle patent litigation without money flowing to the generic.

But data from fiscal year 2006 is far more disturbing. The report that we released this morning shows that half of all settlements, 14 out of 28, involve some form of compensation to the generic and an agreement by the generic not to market its product for a period of time. Almost all the settlements with first filers, 9 out of 11, involve similar restrictions. In other words, just before *Schering* and *Tamoxifen*, there were no such payments. Just after these decisions, it appears to be the new way of doing business.

Mr. Chairman, given how profitable these agreements are for both the brands and the generics, it is not surprising that the industry has reacted so quickly to recent court decisions. After all, they do have responsibilities to their shareholders. Nor should it be hard to predict what will happen if nothing changes. There will be more and more of these settlements with later and later entry dates. No longer will generic companies vie to be the first to bring a drug to market. Instead, they will vie to be the first to be paid not to compete.

From our perspective, we will continue to be vigilant in looking for ways to challenge anticompetitive settlements. It is a matter of public knowledge that we are looking to bring a case that will create a clearer split in the circuits and encourage the Supreme Court to resolve this issue. But that could take years and the outcome is uncertain.

A legislative approach could provide a swifter, more certain, and more comprehensive solution. For that reason, we strongly support legislation to prohibit these anticompetitive payments, and we strongly support the intent of the bipartisan bill to be introduced

by Senators Kohl, Leahy, Grassley, and others, which takes a bright-line approach to prohibiting these deals. Drafting such a measure is challenging. The deals are obviously very difficult or complex, so we are happy to work with you as the bill moves forward.

Mr. Chairman, we do have enormous respect for the pharmaceutical industry, both brands and generics. Brand drug companies pursue hundreds, perhaps thousands, of unsuccessful candidates for each one that comes to market, and these companies have brought significant health benefits to consumers—as Senator Specter said, life-saving drugs. For their part, generic drug companies have produced low-cost pharmaceuticals and pushed the brands to innovate even further and faster. And we are not opposed to all settlements. Let me try to briefly dispel that urban myth. We have brought only a handful of cases involving pharmaceutical agreements and none involving deals between 2000 and 2005—that is, before the *Schering* decision. But we do not and we cannot support settlements when brands and generics resolve their disputes at the expense of consumers.

Mr. Chairman, at a time when our Nation faces the challenge of rising health care costs, the antitrust laws and the Hatch-Waxman Act should be used to ensure innovation and lower prices. They should not be used to undermine competition, nor to evade congressional intent—though, of course, ultimately that is for you to decide.

Thank you so much. I am happy to answer questions.

Chairman LEAHY. I will be leaving now, as I said, turning over to Senator Kohl. I will submit some questions for the record. I am especially interested in your views on why the Justice Department declined the FTC's request on cert. after *Schering-Plough* to find out—to get some clarity. I would have thought that clarity would be in the interest of all of us, and I was surprised that they did not agree with you on that.

So, Senator Kohl, thank you very much.

Mr. LEIBOWITZ. Thank you, Senator.

Senator KOHL [PRESIDING.] Thank you, Chairman Leahy.

Commissioner Leibowitz, patent settlements between brand-name and generic drug manufacturers in which brand-name companies pay generic companies many millions of dollars to keep their product off the market, how does this harm consumers? And are you in a position to quantify in any way the amount of higher drug prices that consumers have had to pay as a result of some of these settlements?

Mr. LEIBOWITZ. Well, there was a CBO study from 1994 that said consumers save $8 to $10 billion a year from generic drugs. But now there are many, many more generics on the market, many more drugs on the market, and so we think the savings are substantially greater.

It is hard to quantify the harm that we see from what we believe are these anticompetitive exclusion payments, but what they tend to do, essentially, the brand will pay the generic some form of consideration—it could be a cash payment; it could be not offering an authorized generic; it could be a licensing deal—and the generic will stay out of the market longer. It will not enter sooner. And the

longer it stays it out of the market, of course, the more consumers are forced to pay higher prices for their drugs.

There is a huge incentive, obviously, to make these deals because the price goes down so much after the first generic and, really, subsequent generics enter. So there is always really a large "sweet spot" where the brand can pay the generic and the generic will earn more by not competing than by competing. And the brand will earn more by not having competition in the market, notwithstanding it has made this reverse payment.

Senator KOHL. Potentially, what will happen to the whole generic movement, in your opinion, if brand-name manufacturers are in a position to pay off generics to keep their product off the market and recognize how profitable this is to them, this whole generic movement which is saving consumers so much money, what will happen to it?

Mr. LEIBOWITZ. Well, I don't think you will see the end to the generic industry. Obviously, there are a number of generic drugs—hundreds, thousands—that are already out there. But what you would see is generic entry will be pushed back to the end of the patent of the brand—or 6 months before the patent of the brand—so it can retain that exclusivity. And I do not believe—although, again, this is for the three of you and the Committee to decide—we do not believe that that was the intent of Hatch-Waxman. The intent of Hatch-Waxman was to allow generics—when they were not infringing on the patent, or if the patent of the brand was invalid—to enter the market sooner and to bring these low-cost drugs to consumers.

Senator KOHL. Thank you.

Senator Specter, do you have questions?

Senator SPECTER. Yes, thank you very much, Mr. Chairman.

Commissioner Leibowitz, is there any latitude under existing law for a brand holder and a generic manufacturer to enter into an agreement which can be kept secret and not disclosed to the FTC or otherwise be made public, any latitude at all?

Mr. LEIBOWITZ. If it is a pharmaceutical patent settlement, under Hatch-Waxman, I do not believe that is possible. They must notify us under the Medicare Modernization Amendment that Senator Leahy, Senator Hatch, and this Committee passed in 2003.

Senator SPECTER. Commissioner, why not have the court which has the litigation on the underlying patent issue, litigation between the patent holder and the generic, make a decision as to whether there is an antitrust violation? We have a proliferation of cases in the Federal court. The dockets are very, very heavy. There are many illustrations where there is a public interest involved. If two private parties are involved and they come to a settlement, that is between them. But when there is a public interest involved, it is not unusual for the court to examine the public's interest and see if the public interest is being respected. Why not short-circuit all of this complex antitrust litigation by requiring the court to approve the settlement, taking into account the public interest?

Mr. LEIBOWITZ. Well, I think that is a very interesting approach, and I suppose you could—if you are interested in writing legislation to require the court to do that. Of course, we would want to work with you. But the courts have been very reluctant, as you

point out, to look into the merits of the patents themselves, in part because they are interested in settlement.

Senator SPECTER. But the courts are looking into it in extraordinarily complicated cases to read these decisions in *Schering-Plough* v. *FTC* or the *Tamoxifen* case or *Valley Drugs*, you have to have a chart to diagram it to figure out all the parties. And the patent is recognized in many cases right up to the expiration date. There are very complex considerations. Why burden another court? Why not have the court making the settlement make that part of its duty? They have already got the issues before them.

Mr. LEIBOWITZ. Well, I would make a couple of points in response to that. I mean, I think it is an interesting idea, and obviously you are troubled by these settlements, as I think the whole Committee is.

First of all, it is partly the substantive standard that courts are applying. As you pointed out, the Sixth Circuit in *Cardizem* applies a sort of per se illegality approach. The *Tamoxifen* court—the Second Circuit in a 2–1 decision—and the *Schering* court apply I would almost say something that is less than rule of reason—almost sham, fraud on the Patent Office or beyond the scope of the patent in years. So I think—

Senator SPECTER. Well, wait a minute. If the court says it is rule of reason, you call it sham?

Mr. LEIBOWITZ. Well, it also says that they are looking to see whether there is a sham or fraud. In the Commission's decision in *Schering*, the FTC decision that was reversed on appeal by the Eleventh Circuit, we took a rule-of-reason approach.

Senator SPECTER. Let me interrupt you to ask you two more questions because I only have 5 minutes. When the Congress intervenes to declare conduct a per se violation of the antitrust laws, an automatic violation, we do so where we have substantial certainty as to the anticompetitive effects as to what went on. When I read these cases and you have very distinguished courts—the Eleventh Circuit on two occasions and the Second Circuit on one occasion—examining these complex factual situations—which we can't anticipate. No way we can anticipate in the law the varieties of what will come up. And they come to a conclusion that it is not anticompetitive after going through it on a detailed case-by-case analysis. Is it wise for the Congress to make a sweeping generalization to have a per se violation?

Now, the second question before my red light goes on. Once the red light goes on, you are not limited. I would like you to address, after you answer that question, what is meant by patent settlements are reasonable so long as the exclusionary effects of the settlement do not exclude the exclusionary effects of the patent?

Mr. LEIBOWITZ. The exclusionary effects of the settlement and the exclusionary effects of the patent. All right—

Senator SPECTER. Well, that is not my phraseology. That is what the courts have said.

Mr. LEIBOWITZ. Well, I think it points out how to answer your second question first—you said that you and your staffer had been trying to figure out exactly what the court was trying to say—and we have been trying to figure out the meaning of that case for quite

some time ourselves. It is a very, very complicated decision, and these settlement agreements are also very complicated.

Jumping back to your first question on per se illegality, the way I read Senator Kohl's bill—I have not seen the newest iteration, but I read the bill that was introduced last year—it does not really call these deals per se illegal. It is a bright-line approach to say you can have settlements, but what you cannot do is have compensation flowing from the brand to the generic and an agreement by the generic which inherently pushes the generic toward a later entry date. And you can see, based on the chart, from 2004, before *Schering* and *Tamoxifen*, we did not see any of these deals which we would label as sort of exclusionary payments. In 2006, fiscal year 2006, after *Schering* and *Tamoxifen*, 14 out of the 28 final settlements we have looked at have resulted in what we would all call an exclusionary payment, compensation from the brand to the generic, agreement by the generic to defer entry. In terms of the first filer—and if you can lock in the first generic who files, you can often—you can pretty much—ensure subsequent generics will not be able to enter. The settlements with first filers have gone from 0 out of 8 in fiscal year 2004 before *Schering* and *Tamoxifen*, to, I think, 9 out of 11, more than 80 percent of the time.

Senator SPECTER. Well, Mr. Chairman, I am going to have to excuse myself, as I said earlier. The National Security Counselor has scheduled a meeting with Senators to talk about Iraq. But I leave this side of the podium with the distinguished Senator Hatch, who is the author of Hatch-Waxman, 1984. He is a real veteran around here, having chaired the Committee, and he knows this field backward and forwards. So I leave our side in Senator Hatch's hands.

Mr. LEIBOWITZ. Thank you, Senator Specter.

Senator HATCH. Thank you very much.

Senator KOHL. Thank you very much, Senator Specter.

Senator Hatch? Then Senator Whitehouse following you.

Senator HATCH. Thank you.

Well, Jon, welcome back to the Committee.

Mr. LEIBOWITZ. Thank you.

Senator HATCH. We are happy to have you here. We appreciate your service. In my view, the principal concern regarding settlement practices identified—

Senator KOHL. Your speaker, Orrin? Your speaker is not on.

Senator HATCH. I am sorry.

Mr. LEIBOWITZ. That is OK.

Senator HATCH. Did you hear me?

Mr. LEIBOWITZ. Yes.

Senator HATCH. OK. Other witnesses, they appear to raise two distinct sets of policy issues. Now, the first set of issues arises from the core concern that settlements predicated on an agreement in which the brand-name companies confers something of value to a generic company, a generic drug company, in exchange for a promise not to enter the market until some future date precludes the consumer benefits that would result from earlier entry by the specific generic drug company that would be a party to the litigation.

The second set of issues arises from the operation of a principle that grants the first generic company to file an ANDA, an Abbreviated New Drug Application, a 180-day period of marketing exclu-

sivity which generally precludes the FDA from granting approval to competing generics until after the 180-day period has ended.

Mr. LEIBOWITZ. That is right, Senator. Sometimes we call that the "bottleneck problem."

Senator HATCH. Right. Thus, a settlement in which the generic company entitled to the exclusivity period agrees to delay its entry into the market can effectively prevent competitive entry by any other generic company. Now, while the majority of today's witnesses favor addressing one or both of these problems, there are significant differences of opinion regarding the approaches that have been proposed by members of the panel, as well as by academic experts and various Members of Congress.

Now, the principal difference voiced here today involves whether a bright-line rule prohibiting reverse payments is appropriate or whether some form of case-by-case analysis is necessary to allow litigants the flexibility to enter into settlements that potentially allow competitive entry prior to expiration of the patent at issue, which arguably provides consumer benefits that would be less certain if more cases were litigated to conclusion due to restrictions on the ability of litigants to settle prior to final judgment.

Now, it seems to me that, in addition to the options of engaging in case-by-case review of settlements or adopting a bright-line rule prohibiting reverse payments, there is a third potential approach to resolving this issue. Now, this third approach would involve removing some of the unintended consequences and perverse incentives arising from the manner in which the grant of the 180-day exclusivity period currently operates.

As nearly as I can tell, the most serious antitrust implications arise from the scenario where a settlement agreement not only prevents a single generic company from entering the market, but by virtue of the 180-day exclusivity period effectively prevents entry by any other generic competitor.

Now, a variety of suggestions have been made regarding how do you resolve or how to resolve this problem. For example, some suggest conditioning the exclusivity period on the ability of the generic company to mount a successful defense in court. This would preclude any other or any generic company that enters into a settlement from getting the benefit of the exclusivity period. Others have suggested a stronger "use it or lose it" provision that would ensure forfeiture of the exclusivity period if the first generic to apply for approval did not enter the market within a reasonable period of time. And, of course, the whole purpose of Hatch-Waxman was to get them into the market quickly and without having to pay practically $1 billion per drug approval that the PhRMA company has had to pay, which caused PhRMA during the negotiations on this tremendous angst, as you can imagine. They felt like—it was a very, very serious set of negotiations.

Mr. LEIBOWITZ. Sure.

Senator HATCH. Conducted in my office.

Now, Commissioner, if as many allege a significant portion of a reverse payment settlement is predicated on the ability to deter entry, then my question is whether it is sufficient to remove the ability of the parties to the settlement to obtain an exclusionary benefit from such an agreement or whether an outright prohibition

of reverse payments is necessary. And I would like your opinion on that.

Mr. LEIBOWITZ. Well—

Senator HATCH. Now, let me just add one other thing.

Mr. LEIBOWITZ. Sure.

Senator HATCH. Additionally, if you would expand on your discussion of the benefits of a bright-line rule as opposed to a case-by-case analysis, I think all of us up here would appreciate it as well.

Mr. LEIBOWITZ. Well, Senator, we appreciate your concern about these exclusionary payments and the thoughtful way that you are trying to sort of look at stopping them. I read your statement from 2003 where you called some of these deals "appalling," and we want to work with you on whatever approach you want to take.

The benefits of a bright-line approach are fairly simple. First of all, you stop the problem, right? There will not be any payments from a brand—compensation flowing from a brand to a generic—and the generic deferring entry. And we have seen from 2004 to 2006 a sea change—

Senator HATCH. That also stops legitimate deals, too.

Mr. LEIBOWITZ. Well, I would not say that. We have a period of time from 2000 to 2004 where most of the industry—or the industry—believe—that all of these deals were illegal, and there were plenty of settlements during that time. I think that there were 18 in 2004 and 2005 alone before the *Schering* decision. We do not believe you would stop legitimate deals. What you would have is sort of a migration of a delayed entry date plus—from a delayed entry date plus money—to a less delayed entry date, to a different entry date, shorter, and consumers getting the benefits sooner.

The other benefit you get from the bright-line test is certainty because businesses know what they can and cannot do. And those, it seems to me, are the principal benefits of a bright-line test.

Now, I want to think a little bit about your approach and get back to you on it.

Senator HATCH. Would you?

Mr. LEIBOWITZ. It is an interesting idea, but keep in mind that there is always going to be—there may still be a huge incentive for the brands to pay the generics and the generics to stay out of the market, even if they are paying multiple generics, because of the economics of this industry. So let us get back to you on that, and we want to work with your staff.

Senator HATCH. Well, I have to admit I don't think either side would very much like that suggestion either.

Mr. LEIBOWITZ. Well, we have managed to unify the brands and generics, but only in opposition to our position on exclusion payments. So welcome to the club, Senator.

Senator HATCH. I have been there. I am in the club.

[Laugher.}

Mr. LEIBOWITZ. We are happy in our lonely eminence, though.

Senator HATCH. Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Hatch.

Senator Whitehouse?

Senator WHITEHOUSE. Thank you, Mr. Chairman.

I had a question in response to your description of the manner in which the financial incentives of these transactions operate on the generics and on the brands, and the conclusion that they encourage anticompetitive effects and really not legitimate purposes from a consumer perspective.

To turn that on its head, can you think of any legitimate purpose for these types of pay-to-delay settlements that would cause public harm if there were to be an outright prohibition?

Mr. LEIBOWITZ. Well, again, there is a legitimate purpose to these payments. The legitimate purpose is to settle cases. But what we think in these instances in the aggregate—not necessarily with respect to each individual instance, but in the aggregate—they inherently give the patent holder, the brand, more protection than the brand ought to have. That is the problem. If you take the money or the compensation out of the equation and you make companies pick a date, an entry date based on the strength of their case—which is what happened in dozens of agreements between 2000 and early 2005—we think that consumers will be served because they will get earlier entry and cheaper drugs; drugs will go down by 20 or 30 percent with the first generic and up to 80 or 90 percent 6 months later when multiple generics come in.

We think in the aggregate the public is not served by these deals. If you take a bright-line approach—and we are, of course, willing to look at other approaches—but if you take a bright-line approach, you will encourage early generic entry, and consumers will be able to get more affordable drugs sooner rather than later. And we really do believe, as Senator Hatch alluded to, that this is really what Hatch-Waxman was all about, which has been a wonderful piece of legislation that has allowed profits for the brands and the generics, but has created a vibrant generic industry.

Senator WHITEHOUSE. Other than the public purpose of allowing cases to settle more rapidly, is there any other public purpose served by these agreements?

Mr. LEIBOWITZ. For these exclusionary agreements? No, I do not believe there is another public purpose. That is my sense, at least.

Senator WHITEHOUSE. OK. Thank you.

Mr. LEIBOWITZ. Thank you, Senator.

Senator WHITEHOUSE. Thank you, Chairman.

Senator KOHL. We thank you so much, Commissioner Leibowitz. You have added a lot to the discussion, and we appreciate your being here today.

Mr. LEIBOWITZ. Thank you so much, Senator.

[The prepared statement of Mr. Leibowitz appears as a submission for the record.]

Senator KOHL. We have a second panel, and we would like to call the four witnesses on that panel to step forward.

Our first witness is Hon. Bill Tauzin, who is President and Chief Executive Officer of PhRMA. Prior to joining PhRMA, Mr. Tauzin was a 12-term member of the U.S. House of Representatives representing Louisiana's 3rd Congressional District. Mr. Tauzin served as Chairman of the Energy and Commerce Committee from 2001 to 2004, and Mr. Tauzin graduated from Nicholls State University and earned his law degree from LSU.

Our second witness is Mr. Merril Hirsh. Mr. Hirsh is a partner at Ross, Dixon and Bell, LLP, in Washington. He has also worked as a trial attorney in the Civil Division of the U.S. Department of Justice, and he has authored several well-known articles on antitrust law.

Also joining us today is Mr. Bruce Downey, Chief Executive Officer of Barr Pharmaceuticals. Mr. Downey has received several awards for special achievements during his time in Government service, and he is Chairman of the Board of Directors for the Generic Pharmaceutical Association. Mr. Downey graduated with honors from Miami University in Ohio, and he received his law degree from Ohio State.

Finally, we will hear from Mr. Michael Wroblewski of Consumers Union, the non-profit publisher of Consumer Reports. Prior to joining Consumer Reports, Mr. Wroblewski acted as Assistant General Counsel for Policy Studies at the FTC and as attorney adviser. Mr. Wroblewski is a graduate of Loyola College and received his J.D. from the University of Texas School of Law and his MPA from the Lyndon Baines Johnson School of Public Affairs in 1992.

We hope, gentlemen, that you will limit your testimony to 5 minutes, and before you begin, I would like you to rise and take the oath of office, please. Please raise your right hand, and do you swear that the testimony you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

Mr. TAUZIN. I do.

Mr. HIRSH. I do.

Mr. DOWNEY. I do.

Mr. WROBLEWSKI. I do.

Senator KOHL. We thank you so much.

We will start with you, Mr. Wroblewski.

STATEMENT OF MICHAEL WROBLEWSKI, PROJECT DIRECTOR, CONSUMER EDUCATION AND OUTREACH, CONSUMERS UNION, THE NON-PROFIT PUBLISHER OF CONSUMER REPORTS, WASHINGTON, D.C.

Mr. WROBLEWSKI. Mr. Chairman, members of the Committee, thank you for the invitation to testify today. Consumers Union is the independent non-profit publisher of Consumer Reports. We investigate and report extensively on the issues surrounding the costs, safety, and effectiveness of prescription drugs so that we can provide our 7.3 million subscribers with expert advice to help them manage their health. Consumers Union publications carry no advertising, and we receive no commercial support.

The hearing today asks the question, "Should paying generics to prevent competition with brand drugs be prohibited?" Consumers Union responds with an emphatic "Yes." We strongly support prompt Congressional action to create a bright-line rule to end the use of patent settlements in which a brand-name company compensates a generic applicant to delay market entry. These settlements can deny consumers access to lower-priced generic drugs for many years. They also jeopardize the health of millions of Americans who have difficulty obtaining safe and effective medicines at competitive prices. I would like to highlight three reasons for our support.

First, generic drugs are critical to managing health care costs today. Health care costs continue to surge at double or triple the rate of inflation, in part due to the high cost and rate of inflation of brand-name prescription drugs. Generic drugs can dampen health inflation because they cost up to 70 or 80 percent less than the brand-name drug.

We have started a free public education initiative, "Consumer Reports Best Buy Drugs," to provide consumers with reliable, easy-to-understand advice about the safest, most effective, and lowest-cost prescription drug available. We currently provide information for 16 different classes of medicine, and we will expand to more classes in the future. Consumers can use this information to check to see if there is a safe, effective, and low-cost alternative to any medicine that they are taking. We encourage consumers to talk to their doctors about this information. Access to these low-cost generic drugs saves consumers substantial sums.

The second reason we support legislation is to counter the incentives that we heard about this morning that brand-name and generic companies have to enter lucrative settlement agreements. It is an economic fact that the brand company's total profits from sales of its brand drug prior to generic entry exceed the combined profits of the brand and the generic company after generic entry occurs. The upshot is that the brand-name company has a powerful incentive to pay the generic to delay entry. The payment is still less than the amount it would lose if the generic applicant entered the market.

The generic applicant, on the other hand, also gains by earning more from the settlement than it would by competing in the market. These incentives are inadvertently exacerbated by the 180-day marketing exclusivity provision of the Hatch-Waxman Act. Any settlement with the first filer blocks any subsequent generic entrants from coming into the market. So the brand-name company can forestall generic competition for years by settling with just the first-filed generic. And the generic who is first in line has powerful incentives to ask for a payment because not only will it get the payment, but it also retains its 180 days of marketing exclusivity. The irony, of course, is that the intent behind the act was to speed generic entry, not to provide the generic a windfall to delay its market entry.

The third reason we support legislation is because the courts, we believe, will not fix this in a timely manner. Two recent appellate court decisions have taken a lenient view, in our view, of these patent settlements. As a result of these rulings, a patent holder can now pay whatever it takes to buy off a generic applicant during the life of the patent. These rulings, in our view, are based on two fault premises.

First, the courts seemed to require that unless the patent can be proved to be invalid or not infringed, a court cannot declare a settlement illegal. This test, we believe, as the FTC discussed in its *Schering* opinion, may sound good in theory, but it is nearly impossible to make work from a practical point of view.

Second, these courts have elevated the generally held principle that public policy favors settlements above the statutory incentives in the act that encourage generic applicants to challenge weak pat-

ents. Industry experience shows that Congress struck the right balance when it established these statutory incentives.

Between 1992 and 2000, generic companies that challenged weak patents won their cases 73 percent of the time. Indeed, these challenges have resulted in generic entry earlier than what otherwise would have occurred absent the generic challenge.

For all three of these reasons, we urge Congress to act now so that consumers get the benefit of timely generic competition.

Thank you very much, and I would be happy to take any questions that you have now or at the end of the panel.

[The prepared statement of Mr. Wroblewski appears as a submission for the record.]

Senator KOHL. Thank you, Mr. Wroblewski. We will first hear testimony from Mr. Tauzin and then Mr. Hirsh and then Mr. Downey.

STATEMENT OF BILLY TAUZIN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA), WASHINGTON, D.C.

Mr. TAUZIN. Senator Kohl, thank you. This is my first opportunity to testify before Congress, and I welcome the chance to be before your Committee. Senator Hatch, Senator Whitehouse, I also thank you for the chance.

Let me first acknowledge something. I am not only the President of PhRMA; I also a cancer survivor, like Senator Specter. Just 2 years ago, I finished chemotherapy following a cancer that left me with about a 5-percent chance of survival. And yet, after that year of chemotherapy, with a brand-new miracle drug that came out of this industry, I am with you today and with my family, and I have them to thank for that.

And so, like Senator Specter, I am deeply concerned not only from my position as a representative of this industry but also as a patient who is still next week going through another cancer test, as I have to go through it every 4 months.

I am interested in making sure that the process by which these new miracle drugs are brought to market is not severely damaged by changes in public policy, that we take very careful concern for the patent protection that is provided, the incentive to spend the $50 billion that was spent last year in trying to find a new cancer drugs that saves lives today.

So let me start by doing what Senator Specter did in his opening statement, which is to illustrate that this is about a 14.2-year process. When a company that is inventing a new drug that is going to save our lives or battle disease for us first files for its patent and it gets its patent approved, it needs another 14.2 years of that patent life just to bring it to market, to do all the testing, the clinical analysis, the proof to the FDA, the proof to itself that it has a product that is both efficacious and also worth the risk, because every drug, every medicine, has certain risks attached to it, certain side effects. It has got to make sure before it brings it to market that it is safe and effective, in effect. So it uses about 14 years of its patent life and spending about $1 billion to bring that drug to market so that my life could be saved 2 years ago.

That is the story. But that is not the end of the story. The next chart shows you what happens next in comparison to other products that are invented in our society. What happens next is that after the final market approval, there is only about 5 or 6 years left, generally, on the patent life of a brand-new drug, a cancer-fighting drug. And if you get the benefit of patent term restoration that comes from Hatch-Waxman, the maximum ever you can have on your patent life is about 14 years. The average today is 11 to 12 years.

Now, I am going to ask one of my colleagues to pass out a pen to you. It is a little cheap pen. It does not violate your rules so you can keep it as a gift. There are some words on it. It says, "This pen's patents have more protection than those for cancer medicine." And I am going to illustrate to you how true that is.

By the way, unfortunately, this pen is made in Mexico, like so many products that we buy in America. But it was patented here in this country.

I am going to prove it to you. This pen and other products we manufacture, invent and manufacture in this country, go through the same patent approval process as a drug, except they do not have to go through 14 years of testing to see whether they are safe and effective. They go to market immediately. So the guy who invents this pen starts selling it the day after he gets his patent approved, protected by the patent. The drug, on the other hand, has to spend about 14 years in testing. And so the effective protection for this pen is about 17½ years. The protection for the patent on a new medicine that saves my life and saves yours is about 11 to 12 years.

Now, the settlements we are talking about, Senator Kohl, involve challenges to those patents. Hatch-Waxman allows that challenge to come as early as 4 years after the drug goes to market. It involves a challenge to the patent. It involves somebody saying, "Your patent is invalid. You did not do it right." It involves somebody saying, you know, "We are going to copy your work, copy your drug, and put it on the market as a generic product because we think our drug does not infringe on your patent," or, "Your patent is invalid." Start with that proposition. It is a challenge to the patent, and a desire to enter the marketplace before you would ordinarily be entitled to enter the marketplace.

Now, Hatch-Waxman encourages that, and before Hatch-Waxman, about 20 percent of the drugs sold in America were generic drugs. Today 60 percent are generic drugs, according to the latest numbers. The utility and usefulness of generic drugs in America exceeds that of any country in the world. Generic drugs are very important to the marketplace of health care in this country. We can see that. We admit that. We support that.

What we are asking today is, however, to think very carefully about whether or not you interfere with, in a broad and overreaching way, the ability of generic drugs and patent drugs to settle these kind of cases that challenge the validity of patents.

Now, why do we ask you to be careful? One, I am not here to defend bad or ugly settlements that do not meet a test of antitrust law. They ought to be discarded, and the FTC has that authority today to invalidate any of those settlements. Every settlement has

to be turned over to the FTC and the Justice Department. Somebody gets a second look at it, and they can say, "No, sorry. That settlement violates antitrust law. We turn it down." The FTC does that. It is hard work. They do not like to do it. I understand that.

Sometimes the courts will overturn them, as they did in *Schering-Plough*. Sometimes the courts will agree with them. But this Congress several years ago declared that any one of these settlements have to go through that test. If you want to put them through a different test, fine. But to outlaw them completely does something I hope we don't do for the sake of consumers, not just for drugs companies, but for patients like me. What those settlements very often do is bring generic drugs sooner to the marketplace than they would be allowed to if those patents were respected until the end of their patent term.

What very often a good settlement does is end costly litigation that consumers pay for in the end and end uncertainty in the marketplace, which is critical for this model to work, and allow generic drugs on the marketplace sooner than later.

Now, you heard a number saying, well, the companies lose 73 percent of the cases. That is not true. Seventy-three percent of the cases represents the times the company lost, including the times the company settled. If you look at current rates, you will see that companies are winning more cases than losing them now. And the reason they are winning them more is they are learning from their past mistakes. They are learning how to write better patents and defend them more properly.

So if you don't allow settlements, if you don't allow the good settlements that are in the interest of the consumer to go forward, the ones the FTC would approve, the ones the Justice Department would approve, you may have the reverse effect of hurting consumers by denying them the chance to get a generic into the marketplace even during a valid patent term. That is what settlements do.

So here I am at the Clint Eastwood moment. Clint Eastwood made some great films. One I love is "The Good, The Bad and the Ugly." Now, he was like you. He was a law keeper—a law maker and a law keeper and a law enforcer. And he rode into town, and his job was to kill the bad and the ugly, but to protect the good. And so I ask you one thing on behalf of patients like me and all of us who depend upon this process to keep these miracle drugs flowing, and there are 2,000 more in the pipeline right now, 600 new cancer medicines in the pipeline right now. If we are going to keep this model working and new cancer drugs patented and approved and the new drugs for diabetes and heart failure and everything else, I ask you please not to shoot the good while you are trying to kill the bad and the ugly.

The process ought to pick the bad settlements out and kill them. It ought to pick the bad and the ugly and say you cannot go forward. But you ought not sweep away the good settlements that end unnecessary litigation that is very expensive. Some expert testified 27 cents of every dollar spent in research and development is spent in court fighting over this stuff instead. You ought not throw out the good settlements that work to bring generics sooner to the marketplace than later because it ends the disputes, ends the litiga-

tion, ends the payment to lawyers, and instead flows these products to patients who need them.

Don't shoot the good. Let's just keep shooting the bad and the ugly.

Thank you, sir.

[The prepared statement of Mr. Tauzin appears as a submission for the record.]

Senator KOHL. Thank you, Mr. Tauzin.

Mr. Hirsh?

STATEMENT OF MERRIL HIRSH, PARTNER, ROSS, DIXON AND BELL, LLP, WASHINGTON, D.C.

Mr. HIRSH. Thank you, Senator. I want to thank the Committee and its staff for affording me the opportunity to comment on the proposed Preserve Access to Generics Act. Although on this issue my law firm has generally represented the interests of companies who pay the cost of drugs through self-insurance, the views I express today are my own and not necessarily those of either my firm or any of its clients. In fact, my firm represents both plaintiffs and defendants in various types of litigation, and I hope that whatever thoughts I can convey to the Committee reflect the experience of having been on both sides.

On March 20, 2006, the Philadelphia Business Journal reported on an interview with the chief executive officer of Cephalon, Incorporated. Cephalon had settled patent challenges to Provigil, a drug for sleep disorders, by paying a total of at least $136 million to several of its generic competitors. By settling, Cephalon avoided a ruling on the generics' arguments that Cephalon's patent was invalid and that the patent was not infringed in any event by the generic substitutes.

As the CEO explained to analysts about the settlement, "A lot of [Wall Street's enthusiasm for Cephalon's stock] is a result of 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."

Now, you would ordinarily think that paying off a competitor to obtain 6 more years of patent protection and $4 billion more in sales than you expected would be viewed as anticompetitive, and there is currently a lawsuit pending arguing that this violates the antitrust laws. The defendants in that case, however, have moved to dismiss it. They are arguing that, even when the CEO admits that the payments achieve patent protection no one expected, these payments cannot, as a matter of law, violate the current antitrust laws.

I think defendants should lose that motion, but honestly, illogical as the motion seems, it is not frivolous, given the current state of the law. The plaintiffs in the *Tamoxifen* case have petitioned the Supreme Court for a review of the Second Circuit's decision that people have discussed here that otherwise may effectively immunize brand and generic companies from paying any amount of money to resolve any patent case that was not a sham case to begin with. And, as the FTC has reported and Commissioner Leibowitz discussed today, a recent spate of reverse payment settlements shows companies clearly emboldened to make these settle-

ments unless and until they are told not to. These reverse payment settlements are indeed anticompetitive, and they defeat the purposes of the Hatch-Waxman Act.

Now, I think it is impossible not to be moved by Representative Tauzin's personal story and his basic point of attempting to capture the good and only deal with the bad and the ugly. The problem is that reverse payment settlements are the bad in this case, and, in fact, the preservation of reverse payment settlements doesn't preserve the type of protections he is talking about to the patents.

What reverse payment settlements do is create a tremendous incentive to do two things: first, to have generic companines pick patent fights in the hopes of being able to be paid off for dropping them; and, second, to settle those fights in ways that do no justice to the Hatch-Waxman Act and provide no benefits to consumers.

Brand companies are not made better off by a system that encourages people to sue them without the risk of putting drugs onto market in the hopes of being paid off with enormous amounts of money available to pay them. That does not lead to fewer lawsuits. It leads to more lawsuits. And more lawsuits are not better. In fact, not having lawsuits in the first place is better than settling lawsuits after they are brought.

Second, once lawsuits are brought, reverse payment settlements are not the only way to settle them. They are a convenient way to settle them. They are convenient because there is an extraordinary incentive, as everyone has discussed today. A delay for some of these drugs involves a million dollars a day—a million dollars a day for each day the generic entry is excluded, a million dollars in additional sales. There is an enormous incentive for companies who legitimately are interested in profit for their shareholders to engage in a sharing of this money rather than a result that actually brings down the cost for consumers.

If you eliminate the reverse payment settlements, and this is the reason you need a bright-line rule to solve this problem, you eliminate that possibility. You allow for lawsuits being brought where there are genuine patent challenges. This is where the generic genuinely intends to market the product and not just hold up the brand company. The brand and generic companies are forced to negotiate at arm's-length over when the generic can come in, and their agreement harnesses the market force of an arm's-length negotiation, not just to benefit the parties involved, but to benefit consumers.

Courts are unable to deal with this problem because it involves a policy judgment that is Congress' to make. That is why I strongly support the legislation before the Committee.

Thank you, Senator.

[The prepared statement of Mr. Hirsh appears as a submission for the record.]

Senator KOHL. Thank you, Mr. Hirsh.

Mr. Downey?

STATEMENT OF BRUCE L. DOWNEY, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, BARR PHARMACEUTICALS, INC., WASHINGTON, D.C.

Mr. DOWNEY. Thank you, Senator. It is very nice to be here today appearing before the Senate Judiciary Committee again. I am the Chairman and Chief Executive Officer of Barr Pharmaceuticals, one of the largest generic companies in the country. We are also probably the most prolific challenger of brand patents. In my tenure at Barr, we have brought over 30 cases challenging the patents protecting pharmaceutical products. We have completed about half of those cases; about half are still pending. Of those we completed, 14 were settled, and 13 of those settlements brought products to market prior to patent expiry—that is, that shortened patent life of the brand product allowed us to get into the market and compete earlier than we otherwise could.

Now, we have also taken some cases to trial, and I think in the statements of the Senators and the testimony of my colleagues, two of our cases have been prominently mentioned. One is the Prozac case, and it has been the poster child of what should happen; that is, you should take a case to trial, win it, and bring a product to market. The second was our *Tamoxifen* case. It has been the poster child for what is wrong. You should not settle a case in exchange for consideration other than early entry. I want to examine those two cases in detail because both of those cases brought significant value to consumers, and both of those settlements would have been impossible if this legislation were to pass. Let me start with the Prozac case because I think that is the most misunderstood.

We brought the case against the Prozac patent. There were three claims: one, it was invalid for double patenting; two, it was invalid because of the best mode rule; and, third, it was invalid because of the inequitable conduct of the Lilly Company at the Patent Office. We lost the double patenting and best mode arguments in summary judgment before the district court. We thought those were our best claims. The judge dismissed them, and we were stuck now with our inequitable conduct claim, which we thought was the weakest. The judge set it down for trial. To take that case to trial on appeal would have taken an additional year before we could get our other claims before the court of appeals. And we settled that claim on the eve of trial for a cash payment, which would have been prohibited by this legislation. But taking that payment, settling that claim, allowed us to appeal the best mode and double patenting claim to the court of appeals, which we ultimately won. It shortened the case by a year, allowed us to bring generic Prozac to market a year earlier than we could if we had gone to trial on inequitable conduct. And that reverse payment saved consumers about a billion and a half dollars. So in that case, the reverse payment actually had the exact effect that all of the other witnesses supporting the legislation want it to have.

Now, in *Tamoxifen*, we tried the case and we won, and our opponents appealed. All of our strong arguments, in my opinion, we lost at trial, and we had one argument remaining for the court of appeals, and that was the inequitable conduct case. We settled that on appeal because we thought we were going to lose. We took payment, we took a license, and we entered the market early with

Tamoxifen. And over the course of our license, we saved consumers about $300 million on that product.

Now, this was a great laboratory experiment because, following our case where we accepted this payment, which others think is illegal, three other generic companies tried to challenge that patent. All three of them went to trial. All three of them lost. All three of them went to the court of appeals, and all three of them lost. I believe had we not settled the case and entered the product with our license from Zeneca, we also would have lost and consumers would have been harmed.

So those two cases where we accepted what are called reverse payments saved consumers nearly $2 billion that otherwise would have been impossible. So I think the legislation will have very serious unintended consequences. It will reduce the number of patent cases we bring. It will force us to take each of the cases that are brought to trial and sort of fight to the death. And then, finally, it will prohibit settlements that shorten the patent life and bring products to market sooner than we otherwise could.

You know, it is not really the reverse payment that keeps products off the market. It is the patent. The patent is a monopoly granted by the Government that is entitled to a presumption of validity. It can only be overturned by a showing of clear and convincing evidence. You know, we do not bring products to market in the face of a patent because of the damages we risk. And I also disagree with the success rate that has been given here. It is not 70 percent. Our success rate in cases that have gone to trial is like 40 percent, and that is in part because we have reached reasoned settlements that shorten the patent life, we get less than we would get if we win, we get more than we would get if we lose, and that benefit is transferred to consumers. They get more than they would get if we lose the case; they get less than if we would win it. I think that is the way all settlements are. They are a compromise. Each side gets something. In this case, we compromised on the length of the patent term. We shortened the patent life. We were in earlier. Other people can challenge the patent if they want.

Now, there is an anomaly, Senator Hatch, and I will point to that in the 180-day exclusionary provision. The MMA of 2004 does have sort of a loophole that makes it hard for second challengers to challenge the patent, and I would like to work with the Committee to help solve that problem. But it is not solved by the proposed legislation. The proposed legislation deals with settlements and not with the bottleneck loophole.

I would be happy to take any questions that you have.

[The prepared statement of Mr. Downey appears as a submission for the record.]

Senator KOHL. Thank you.

A questions for Mr. Tauzin. Your organization, as we all know, represents many large pharmaceutical companies. Isn't it just common sense, Mr. Tauzin, that if a brand-name drug company can forestall competition by paying a generic company some fraction of its profits on a drug that it will do so?

Mr. TAUZIN. Not necessarily. Again, remember, Senator Kohl, this is a patent dispute fight. If it has a great patent and that patent language has been tested and fought out in court before and

proven to be valid, it has great incentive to go ahead and say, "No, I am sorry. We are not going to settle with you. We are going to defend our patent all the way, and we are going to prevail because we have got a great patent."

Now, if there is any kind of question about it, the incentives flow in both directions. I think you have heard the arguments from the generic association about why they have an incentive to settle on some cases, where they think they might have a chance of losing, and yet they can get their generic drug to market a little quicker if they settle.

In the case of the patent company, if they think there is some doubt about winning the case, they do what all lawyers do when fighting a case. You figure out whether your risk of losing merits the risk of settlement. In that case, very often in that discussion a settlement is reached where a generic does come into the market, even in the face of what otherwise they believe is a valid patent.

But the incentives flow in both directions, and they are going to be different in every case. And in some cases, as you pointed out, as Mr. Leibowitz pointed out, those settlements need to be examined to see whether or not they reach a public interest standard. I agree with that.

But the bottom line is that the incentives work in both directions, and in some cases, in some 50-some-odd percent of the cases lately, the patent companies go all the way to trial because they believe they have a valid patent and they have a right to depend upon it.

Mr. Leibowitz, by the way, is not against patents, I do not believe. I do not believe he is against patent protection. Neither is this Committee. He worked for the Motion Picture Association and got a 95-year patent on Mickey Mouse. You know, on the other hand, a drug that saved my life and others' lives may get only 11 or 12 years of protection. That is our concern. If you mess with that model too much, you begin damaging the incentive to go out and spend the billion to invest in new medicine. That is happening all over the world. That is why 70 percent of the new medicines invented in the world are invented here in America, because we still, to the extent we can, give some reward for somebody spending those billions of dollars to invent those new medicines.

So all we ask is that whatever you do in this area—and we will work with you to try to find a solution that makes sense for everyone here—is that we do not end up throwing out the good with the bad.

Senator KOHL. Mr. Downey, the FTC reports that in the year after the two court decisions that we have covered here today, allowing these reverse payment settlements, half of all patent settlements contained terms in which the brand-name company paid generic in return for the generic's agreement in keeping the drug off the market. And as we have discussed, in the year before that court decision, no patent settlements contained any such terms. So doesn't this data indicate that going forward, unless we do something about that by way of our legislation, increasingly there are going to be financial settlements arrived at?

Mr. DOWNEY. Well, I do not believe the data is exactly right. First, I would say the later settlements where there were pay-

ments, it is not the payment that keeps the product off the market. It is the patent. And in one of those cases—it happens to be ours I know about—there was a compromise where we entered the market years before patent expiry, but some number of years in the future, there was 12, 15 years left on the patent, and we compromised at a point sort of halfway in between.

In addition to that, we had some other arrangement with the brand company. We think that is very pro-competitive—pro-competitive in two parts: one, because we shortened the patent life; and, two, because we got this collateral benefit in the other part of the deal—all of which was submitted to the FTC, and if they think it is improper, they could challenge it. I think they would lose, but that data has been made available as a requirement under existing law.

Also, I disagree that the years before those cases there were not settlements that involved other consideration, because I know we had at least one.

Senator KOHL. Mr. Wroblewski, would you like to comment on this question? Then Mr. Hirsh.

Mr. WROBLEWSKI. The only thing I would like to add is the statistic rate that I quoted in my testimony in terms of how frequently the generic challenger wins, that statistic comes from looking at all of the court cases—not including the settlements—but just the court cases. Between 1992 and 2000, there were 30 decisions of a court, and in 22 of those instances, the generic won. So that is the 73 percent. That study ended in 2000, 2001, and that has not yet been updated.

I am familiar with a study by the American Intellectual Property Law Committee that has basically come up with the same 70-percent number by looking at the defendant winning in patent litigations, the challenger basically, in a broader spectrum of industries, and it has been right around 70 percent.

So I think I will stick with, you know, that the incentive has provided—has not been misused to challenge patents, as they are picking the right patents to challenge.

Mr. TAUZIN. Senator, if I could jump in, we are using data from 2004 to 2006. That is much later than this study which did not include settlements. And the data between 2004 to 2006 indicates innovative companies prevailed at the appellate level 52 percent of the time.

Senator KOHL. All right. Mr. Hirsh, do you want to make a comment?

Mr. HIRSH. Yes. I think where the disconnect is going on in this discussion is as follows: As a lawyer handling commercial cases and intellectual property cases, you are frequently faced with the situation where one of the possible outcomes you can negotiate is anticompetitive. Negotiations inherently look for win-wins between parties because there are ways of narrowing gaps between people who would otherwise disagree. And I don't know any commercial litigator who has not been in some situation where at some point you look at someone across a table and you say, "Well, we could do that, but we can't because it violates the antitrust laws. We need to find another solution."

What happens in those circumstances is not that the case does not settle. What happens in those situations is it settles in a way that is lawful.

In a Hatch-Waxman settlement, the question is what is the money part being paid for. As Commissioner Leibowitz talked about the question, nobody is against having cases brought that are legitimate. Nobody is against having brand companies defend patents to the end if they think they are right, or both parties bringing them to litigation and getting a litigated result if they think they are right, or settling those cases.

If they settle the case on the basis that they cannot exchange money, the terms of the negotiation is over when can the generic enter the market, with the generic incentivized to enter the market sooner. The sooner the generic can enter into the market, the sooner the generic can share in some of the profits that come from the drug.

If there is money that changes hands in addition to that, what is the brand company paying the generic the money for? It is understandable that the brand is willing to pay it. It is understandable that the generic is happy to take it. But the logical terms of the negotiation is that the brand is paying the benefit of having less competition, of moving the entry date back.

Now, it is quite correct, as Mr. Downey points out, you have settlements that have components of both: there is a payment, and the generic can come in before the end of the patent. There are situations in which the generic may not feel that they have a 100-percent winning case and they would rather settle.

The problem with the reverse payment is what you are paying for is to have that settlement have the effect of having the generic come in later. That is what the money is being exchanged hands for, and that is what is anticompetitive. If you eliminate that incentive, the case will still settle if the parties think they are weak, and the case will not settle if the parties think their cases are strong. What will happen is that the settlement will reflect the strength of the patent instead of ignoring that. That is why it is better.

Senator KOHL. Thank you. Before we—I am sorry. Mr. Tauzin, go ahead.

Mr. TAUZIN. Can I just add one thing? There is a great dispute as to whether or not, when you eliminate the exchange of things of value, you are going to encourage or discourage settlements. I can tell you in the *Schering-Plough* case, for example, there was a licensing agreement that went along with the settlement. If you could not do that licensing agreement, our information is that settlement probably would not have gone forward. That is the one the FTC disapproved of and the court approved of. That is a case where the settlement did bring the generic product into the marketplace sooner.

You are going to get a dispute over that, and you will always have that. That is our point, that case-by-case when you look at them, you are going to see some cases where a settlement made sense for the consumer and another case where it possibly did not, where you ought to say, sorry, that cannot go forward. That is a different matter.

Senator KOHL. Last comment, Mr. Downey.

Mr. DOWNEY. Yes, a very important point here. The collateral agreements that narrow the gap are not always cash payments. In fact, they rarely are in our case. They involve some other asset that has a different value for us than it does the brand. Sometimes, for example, we have purchased a product from the brand at a price we think is favorable—it is an asset that is not key to them—as part of the settlement where we have shortened the patent life. In other cases, we have licensed a patent from a brand as part of a settlement where we have shortened the patent life. In other cases, we have agreed to co-promote products for the brand company as part of the settlement where we have shortened the patent life. In other cases, we have entered into an R&D agreement with a brand company as part of a settlement where we shortened the patent life.

So these collateral agreements provide value to us, value to the brand, and simultaneously allow us to shorten the patent life. And the reason they are very important is the parties cannot always agree, in fact, seldom agree on the probability of success. And so you have some rough approximation—we might think it is 50 percent, they might think they are going to win 70 percent of the time—and you bridge that gap through these agreements that provide value to both us and to the brand company and ultimately to the consumer as these things work their way through the system.

It is very important that these other opportunities be allowed, or the settlements really are not going to happen. That is why I think the law as it is drafted would take every case to trial, every case to appeal, and there would be very, very few settlements.

Senator KOHL. Very good. Before we turn to Senator Hatch, Senator Schumer has requested a minute or two to make some comments before he has to leave.

STATEMENT OF HON. CHARLES E. SCHUMER, A U.S. SENATOR FROM THE STATE OF NEW YORK

Senator SCHUMER. Thank you, Mr. Chairman. I apologize. Finance is voting on the minimum wage, and they do not allow proxy voting. That is the only Committee I am on that does not allow proxy voting, so I apologize and thank you both for your indulgence. And thank you for having the hearing today.

As you know, Mr. Chairman, I asked the Committee to hold a hearing on this issue last May, and I am very pleased that you in always your wisdom have chosen it as one of the first hearings in the new 110th Congress. Many of us in this room are strong proponents of competition that leads to lower drug prices for consumers, most notably my friend Senator Hatch, who paved the way in 1984 with the bipartisan Hatch-Waxman Act. And in 2003, I authored with Senator McCain a law that closed loopholes that had gradually been opened up since Hatch-Waxman was passed in 1984. I worked closely, as Mr. Barr knows, with the generic drug industry to try and close those loopholes. They helped restore the integrity of Hatch-Waxman and preserved access of consumers to generic drugs.

But it seems that every time we close a door on ways to game the system, PhRMA opens up a window, and I really regret to say

that in this one, they are joined by many of my friends in the generic drug industry.

Hatch-Waxman was written to help consumers, to lower the price of drugs for everyday people, not to pad profits for company shareholders. When the law is allowed to function properly, consumers win, $8 to $10 billion a year worth. But time and time again, we have needed to amend this law because the industry, instead of spending its time innovating new drugs, comes up with new ways to exploit loopholes and increases its profit share at the expense of consumers. Usually, these loopholes pit brand drug companies against generics, but this time they are actually working together to leave consumers out in the cold. So now we are seeing instances where some brand drug companies are working with some generic drug companies to make anticompetitive deals that benefit everyone except the consumer. Give money to the generic company to go away so that the brand company can continue to enjoy a monopoly on the market. And, you know, I do not entirely blame the generic drug company. Being sued is no fun. Any company threatened with or actually faced with a lawsuit has good reason to find a quick way out. And these companies, face the facts, even though they do a lot of good and bring the cost of drugs down, are not public servants. You are supposed to serve your shareholders. And so if the company sees an opportunity, the generic company, to increase their profits, they are legally bound to do so. But we are not, and that is where the Government comes in, because we are the only player in this game who has the power to protect the consumer, preserve competition, and restore the playing field to its original condition.

There is simply no reason to allow these anticonsumer settlements. Companies only utilize them when the opportunity exists, and otherwise they function as the Hatch-Waxman law had intended. For 5 out of the last 7 years, it has been illegal for generic companies to accept money, as Mr. Downey noted, in exchange for staying out of the market. Yet competition did not drop off. In fact, the number of patent challenges actually increased during the time these particular settlements were outlawed, from 35 challenges in 2001 to 97 in 2004. It was not until two courts suddenly legalized these payoffs in 2005 that all of a sudden the industry cannot survive without them. And let me reiterate: The Leahy-Kohl-Grassley-Schumer bill will not prohibit drug companies from reaching settlements. It only prohibits settlements in which a brand company pays a generic company to stay off the market, something that generic companies in every other instance fight tooth and nail. They want to get into the market. And here all of a sudden they are saying, Oh, no, give us some money and we will stay away. And who is hurt? The consumer.

So there is no reason to make these specific settlements illegal. We just need to make sure that the bright line we all keep talking about is the right line and that we do not accidentally trap settlements that are pro-consumer in with the bad ones. When consumers have access to lower-cost drugs, we all win. But as long as we let stand the appellate court decisions that encourage brand and generic companies to split up the pie between them and not

give the consumer even a forkful, we are accepting higher drug prices for the average American.

Mr. Chairman, I am proud to have worked with you and your very capable staff over the last several months on this issue and proud to be a cosponsor of the act. I look forward to continue to working with you to prohibit settlements that harm the consumer, and I would ask unanimous consent, because now they are beeping me and I have got to go to vote, to submit written questions for the record.

Thank you, Mr. Chairman. Thank you, Senator Hatch.

Senator KOHL. Senator Hatch?

STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATEMENT OF UTAH

Senator HATCH. Well, Hatch-Waxman was not written just for consumers. It was written for consumers. It was written to create the modern generic drug industry, which it did. Like you say, it went from about 16 percent to now close to 60 percent.

It was written to provide some of the solutions that Mr. Tauzin mentioned of loss of patent life that just was not fair. If you create a widget or a pen, you have got 20 years of patent life. Like you say, 17½ years and you can have market exclusivity for that pen that you used here today. Drug companies are spending up to $1 billion for every drug they create and lose up to 15 years of patent life, leaving them 5 years left in some cases. So we did a classic compromise by—and the bill is called the Drug Price Competition Patent Term Restoration bill." And because of that, PhRMA has done very well. Generics have become dominant in the drug field without killing PhRMA, and consumers have benefited greatly.

Now, what we are concerned about here is there are some things that are wrong with the way this works, and Mr. Wroblewski and Mr. Hirsh raise some issues here. And so do Mr. Tauzin and Mr. Downey.

Now, interestingly enough, I know—I believe I know all four of you, but I specifically know Mr. Downey and Mr. Tauzin very well. Mr. Tauzin and I sat for hours and hours month after month on that Medicare Modernization Act, and I saw a real master in action there trying to bring about a way whereby consumers would benefit, which they certainly have.

Mr. Downey has been one of the leaders, and he took a company that was not all that dominant to where it is not only dominant in the generic drug industry, but also becoming very influential in the area of the PhRMA industry as well. And I commend you for that.

But, you know, let's be honest about it. This I don't think should be a question between a bright line and doing nothing. There may be some way that we can do this so that consumers benefit, generics benefit, brand-name companies benefit. If we take the incentives away, which the House bill just did a week ago—we are the leading pharmaceutical country in the world because we have—even with the fact that we lose so many years of patent life, because of a robust set of PhRMA companies and set of generic companies.

Well, my principal question for the panel is the same, and I will start with you, Mr. Tauzin, and I for one know both of you have benefited from very important drug discoveries. And thank God for that. You are both tremendous people, leading your industries in what I consider to be tremendously influential ways. And I believe that you two consumer advocates are doing the same for your people.

But my principal question for the panel is the same one that I focused on with Commissioner Leibowitz. I would like each of you to expand on the arguments regarding the relative merits of a bright-line rule versus a case-by-case review—you will notice I did not say do nothing, but a case-by-case review—and then I would like each of you to address the question of whether it would be sufficient to reduce the incentives to enter into settlements predicated on reverse payments by modifying the 180-day exclusivity period.

Now, it seems to me that changing the way the exclusivity period operates would substantially reduce the incentives to agree to reverse payments agreements, or whether you believe adopting a bright-line rule—and I take it the two in the middle probably do agree with that—whether that bright-line rule is necessary.

I would also be interested in hearing specific changes to the 180-day exclusivity period that you would support.

Why don't we start with you, Mr. Downey, and then go across the table. And then I have a couple of questions for Mr. Downey, if I could, before this is over.

Mr. DOWNEY. Well, as I have testified, we oppose the bright-line rule. We think it has very serious unintended consequences that are negative for our company, for our industry, and for consumers, and I—

Senator HATCH. Well, you have argued that the bill would prohibit several of the statements which occurred over the past decade, even those which have allowed generics to enter the market earlier than would have been possible had the lawsuit not been brought or lost.

Mr. DOWNEY. It probably would have prohibited half a dozen or more of the settlements that we have that brought the products to market earlier than patent—

Senator HATCH. Would you provide the Committee with the cost to consumers if this legislation had been in effect in the last 10 years, this proposed legislation?

Mr. DOWNEY. Yes, we can provide that, and I have said just in the two cases—

Senator HATCH. Could you do that for us?

Mr. DOWNEY. The two instances I testified about, *Prozac* and *Tamoxifen*, those two alone saved consumers over a billion and a half dollars, and clearly would not have been available had we not settled.

Senator HATCH. Almost $2 billion, actually.

Mr. DOWNEY. Well, *Prozac* was decided a year early. We would have still gotten some benefit in *Prozac*, but the year accelerated would have been lost without the settlement.

Senator HATCH. OK.

Mr. DOWNEY. Now, I also heard from Senator Specter what I thought was a very interesting idea in the case-by-case method,

and that is to have the settlements presented to the court for approval at the time they are entered into. That is something that is very standard procedure in securities litigation and class action litigation to ensure that members of the class are adequately protected by the settlement. And I think it would be entirely appropriate to have those settlements presented to the court for the court's review. I think that would be an excellent suggestion or alternative to the proposed legislation.

Senator HATCH. The court could decide at that time whether it was a violation—

Mr. DOWNEY. Yes, they could decide at the time whether it was a violation or not. You know, without taking too much time, I think there is a very clear area of the law—and this applies to patents all over, you know, whether it is electronics, automotives, plastics, whatever—and that is, patent holders have a monopoly that is granted by the Government, and they can settle cases so long as they do not expand that monopoly power that has already been granted; that is, they cannot expand its scope or the duration of the patent.

If you take the *Andrx* case, the Sixth Circuit case, which ruled that something was per se legal, that case did expand the patent, and it was properly found to be unlawful under existing law. The *Tamoxifen* case and the *Valley Drug* case did not expand the scope of the patent and properly determined under existing law to be valid, and I think that kind of analysis could be handled by the court very readily and under existing law and then there is no need for legislation.

Senator HATCH. Before I move across the table, let me just say while you are talking, why can't the money that is now paid as a pharmaceutical patent settlement—or pharmaceutical patent settlements, why can't that money always be translated into additional days of early market entry for the generic company?

Mr. DOWNEY. Because the parties generally have a different view of the case in two different respects: one, the strength of the case; and, second, the value of the entry for the generic and the cost of allowing that entry from the brand. And those variables change over time, as you learn more about the case or as new products get introduced or whatever. So there is a huge amount of uncertainty. Just restricting it to that one variable of early entry, I think it is very hard to bridge the gap on these variables. We have had settlement discussions in 20- some cases that I have conducted and settled about three-quarters of them. And when we cannot settle, it is because you cannot bridge that gap.

What these collateral arrangements do, whether it is an R&D partnership, whether it is buying a product, licensing a patent, these other exchanges of value have different—those assets have different value for the two parties, and you are able to bridge the gap that you cannot bridge on the early entry through these collateral agreements. In every case that we have settled, except *Prozac*, we got early entry, and that reduced the patent life, demonstrably pro-competitive, and many of the settlements had these other collateral issues. The only ones that get settled for early entry only are two kinds of cases: one, where the product itself is very small, or where the remaining patent life is very short. In those two

cases, we have settled maybe a half a dozen times for early entry only without some collateral agreement. The rest of the time the complexity that I have just described makes it impossible to bridge the gap on early entry alone, and it is most readily bridged by these collateral agreements, which we have done a number of.

Senator HATCH. All right. Thank you.

Mr. Wroblewski?

Mr. WROBLEWSKI. Three thoughts to relate to you.

First, in terms of why we support the bright-line rule, other than what we talked about in the testimony, in the written testimony, when you go back and you look at really the only comprehensive study of agreements in which each agreement has been examined, settlement agreement, which is in the FTC's Generic Drug Study, from the period 1992 through 2002 every settlement agreement that had some type of compensation being paid from the brand company to the generic company, in nearly every one of them the entry date was actually at the date when the patent expired. There may be anecdotal evidence in terms of maybe entry comes in 6 months before the patent expires. But if you look at the evidence—and the only evidence that is really out there in terms of an examination of each agreement—my concern is that in the future they will just push the generic entry basically in line with when the patent expires. That, of course, goes against the entire intent in my reading of Hatch-Waxman.

Senator HATCH. But if the court had a right to review that, I think the court would find that offensive.

Mr. WROBLEWSKI. Sure. My only concern with having a court review it is, unlike the idea of when, say in an antitrust case, the judge is looking to see whether the class action settlement is fair, it is really applying the same law that it has just had the trial on. In this particular instance, you are asking a patent judge who has just been looking at the patent issues to now apply a whole different—a new set of laws. They are going to have to look at antitrust law to measure whether the settlement is in the public interest. And my concern with that is, with the split in circuits between the Sixth Circuit and the Second Circuit, which law, what law is the patent judge now going to apply when looking at the settlement agreement from an antitrust point of view?

My concern with using kind of a case-by-case analysis is that my reading of *Tamoxifen* and the *Schering* decision, the Eleventh Circuit's *Schering* decision, I do not really believe that the courts have given sufficient deference to Congress in terms of the incentives that have been put into Hatch-Waxman to encourage early challenges.

For what other purpose was the 180 days implemented but to encourage generic challenges? And so I do not think the Congress—or I do not think the courts have kind of given that deference to the law that has really kind of altered the balance of the way patents work in this particular industry. And it is within Congress's ability, and it is in your right, to alter the patent rights as you see fit.

My last comment is on the 180 days, whether there are suggestions to change it. I think when Congress amended Hatch-Waxman back in 2003 and we had this whole discussion then, I think at the

time, talking about whether to go back to the successful defense that the FDA had used or the use it or lose it, I think we can keep the use-it-or-lose approach to the 180 days. I do agree with Mr. Downey in terms of making sure that there is a way to trigger—having a second generic being able to trigger that 180 days so, you know, it does not cause the bottleneck, the 180 does not cause the bottleneck. And I think we have put in our testimony, as I am sure he has in his, ways to amend that 180-day trigger. But I would not amend the entire structure that was settled in 2003.

You know, the one thing I keep kind of looking back at, when Congress looked at that in 2003, the state of the world in terms of these types of settlement agreements was that you had two district courts who had basically said these are per se illegal. You know, these appellate courts in *Tamoxifen* and in the *Schering* case had not yet ruled, and Congress thought the only way to—it is my reading that Congress thought the only way—that we should keep that, that that is a fine balance to have. So the per se rule was actually in effect back in 2003. It is only subsequent events that have changed that through the two court decisions.

So I would leave Hatch-Waxman as it stands with that one amendment to change the trigger to eliminate the bottleneck.

Senator HATCH. Well, if you will recall, the Schumer-McCain bill passed overwhelmingly. It only had one vote against it in the Senate. Guess who that vote was?

Mr. WROBLEWSKI. I do remember, yes.

Senator HATCH. And it never passed. To me it was a great overreach and would have screwed up Hatch-Waxman. This is a very complex bill, but it has worked very, very well. And it took a lot of time to negotiate this and a lot of fights. And one time I threatened to kill all of the people representing PhRMA and the generic industry. I literally did. I had a bad tooth that needed a root canal, and I was in no mood, and they were arguing and yelling around, and I just threatened to kill them all. Frankly, that seemed to bring them together a little bit.

[Laughter.]

Senator HATCH. Mr. Hirsh, you are next.

Mr. HIRSH. Senator Hatch, I guess I should begin by saying I absolutely agree that this is a wonderful piece of legislation and has achieved a great deal, and I am not just saying that because you threaten to kill witnesses.

[Laughter.]

Senator HATCH. Well, I have not threatened you yet.

Mr. HIRSH. Let me address what I think are the points that you are raising and that are being raised in response.

The first issue really relates to a patent being a monopoly, and it goes back to Senator Specter's remarks at the beginning about what did the Eleventh Circuit mean when they had this phrase about, "exceeding the scope of the patent".

The difficulty you have in these settlements is the following: Everybody agrees if a patent covers Drug A and you enter into a settlement where you also agree not to compete about Drug B, you are off the reservation. I mean, there is no case that is going to accept that result: that is beyond the scope of the patent. That is not really the issue, and it is not what we are here discussing.

The issue is this: Suppose you have patents where privately, like the example I gave during my oral testimony and in my written testimony about Cephalon, where the companies believe there is a 30-percent chance that the brand company will prevail in this fight—or you can give it another percentage, 40, 50, 60. If the law says you can avoid that fight going to resolution by having the brand company pay the generic to drop the fight, what you are saying is if the cases went to resolution, the brand company would win whatever percentage, 3 out of 10, 4 out of 10—say there are 10 cases, 5 or 6—and they would lose in the remaining number of cases.

Let's take the number 5 for convenience. If you allow the payment from the brand to the generic, you are allowing a situation in which all 10 of those cases result in zero competition and zero benefits for the consumer. If you have those cases go to litigation, you end up with the result that 5 of them expect to come to the result that there is competition and 5 not. If you have a settlement in which they cannot negotiate on the basis of money, but instead have to argue about the length of the time on the patent, you end up with an agreement in which at arm's—length the generic and the brand company have weighed the strength of the patent and come in with a time of entry that reflects the weakness of the patent.

Now, Mr. Downey says, well, we have got these settlements with collateral agreements, and Representative Tauzin gave the example of *Schering-Plough*. *Schering-Plough* is really a good example on the collateral agreements of what I do not understand this legislation to raise as a problem, which is there may well be win-wins between brand and generics on other things. In *Schering-Plough*, there was a cross license. The generics had some drugs under patent, and the brand company—in that case, *Schering-Plough*—paid money and they said, "We are paying for the cross license."

Now, there is a factual dispute in the case—and nobody here is going to be able to sort it out—as to whether that was a real payment or not—whether these cross licenses were worth it. But if those cross licenses are worth it, if they are legitimate, that is not a situation where the brand is paying off for the generic. The brand is paying the generic for a license. That is a legitimate deal. And if that is a win-win and that you helps you close the settlement, it helps you close the settlement, and there is nothing that I understand in this bill that necessarily prohibits that. The problem is when the money is not being paid for that. When it is not being paid for some other value, that is what creates the problem.

Now, as for the 180-day provision, that is a glitch in the statute. It is something that should be fixed, but it does not solve this problem for a number of reasons. First of all, even if you have a situation where you can have multiple generics come in to challenge the patent, there is enough money to enter into settlements with all of the generics. That is exactly what happened in *Cephalon*, and there is not—it is in some ways worse to have—five sets of patent litigation settled with reverse payment settlements. It involves more litigation, more payments by the brand company, and no more competition in that scenario than any other scenario. So it does not really address the incentive to do it.

Second, the 180-day provision really does create a special incentive for competition. It is one of the brilliant aspects of the legislation itself. Every other generic manufacturer has less incentive to compete than the one you are settling with if they are the ones holding the 180-day exclusivity provision. So you already enter into a deal that in any other setting—"Pick off your main competitor and pay them not to compete" are words for an antitrust violation. There is no reason why you should permit that, and so the two are really different problems.

The final point is the alternative of having a court review it. Conceptually, it is a conceivable resolution to the problem. It has some weaknesses. First of all, it does not get you the benefits of a bright-line rule in stopping the lawsuits in the first place and making the process legitimate. And it does not allow, ironically, the market solution of having the arm's-length resolution. Instead what you have is a superimposed solution of what the court thinks a resolution is right. And often per se rules are opposed for the opposite reason. We do not want courts to do that.

But a second basic problem with it is the one that Mr. Wroblewski talked about, which is "what standard should be applied?" It does not solve the entire problem. If you simply say we will have courts look at it, look at it as they did in *Tamoxifen*, look at it as they are going to do in *Cephalon*, who knows what they are going to do with it; look at it as they did in *Schering-Plough*; look at it as they did in *Cardizem*. If the court does not have any guidance to do it, you solve no problem at all by saying let's have the court look at it. The court still needs to be instructed.

Senator HATCH. Well, but one standard by making this a pro se violation—I mean per se, excuse me, violation, that may not work well either.

Mr. HIRSH. I think it does because I think what you are eliminating by the reverse payment is what you want to eliminate. It is a situation in which a payment is the problem. It is not the settlement. Once you eliminate the payment, you have incentivized the brand and generic to reach a competitive settlement, and that is fine. And they can settle by saying, "I have something of value to sell to you, and you are willing to pay for it."

Senator HATCH. So that just creates more litigation.

Mr. HIRSH. No, it does not because, first of all, when—currently under the system, if you have a blockbuster drug, if you have a drug that is selling a billion dollars a year, there is an inherent incentive for a generic company to come up with any argument to file an ANDA-IV. It is true they have to show that it is a bioequivalent. It is not no work at all. But there is a huge incentive to come in there. Why? Because if they can pick any plausible fight at all, they have something that has potential value to it, which is $2 billion of potential sales of a competitor with an awful lot of money to pay off.

Now, any plaintiff's lawyer will tell you if you have got a pot of gold to go after, if you look at securities suits with the market capitalization involved in securities suits, people bring them because there is an enormous amount of money at the end, and far less because there is tremendous merit in every single one of the cases that is being brought. We are incentivizing people to go after that

money as opposed to a system that incentivizes people to come in when they really genuinely want to compete and settle the case by agreeing for a time for competition to start. If you take away the payment they will agree they will come in and genuinely compete.

Imagine what would happen to securities litigation if you eliminated a damage remedy. You would not have more litigation. You would have vastly less if you had just injunctive relief.

So the system creates a bad incentive for that type of litigation and less focusing on what the genuine disputes are, less teeing up the right issues for the right dispute with a resolution that harnesses the market.

Senator HATCH. Let me hear from Mr. Tauzin, and I am sorry I have taken so longer here, but these are important questions, and your responses are very important to us.

Mr. TAUZIN. Senator Hatch, Senator Kohl, let me first set some records straight.

One, we are not again generic companies. I am holding up a generic pill made by Teva that I take, that a half-hour before surgery prevented me from having to go through serious surgery this summer on my liver, and I proudly take it every day. It is a good drug. It is a copy of a patented drug that somebody else spent a lot of money to develop, and it is now on the market as a generic, and I am using it. You know, I have got some interest in this as well on a personal level.

Second, we are not just talking about big brand companies and small generic companies. In some cases, we are talking about big generic companies and very small innovators who are members of our association. We have got some companies who just had their first drug approved in our association. And there are lots of small, innovative companies that haven't had their first drug approved, and they have been in business for 10 or 12 years. They are still waiting for that first approval. And so these are contests very often over the patent life of those drugs that involve different size players. It is not just big and little, as you might, you know, think ordinarily.

Third, we are talking about a patent life that the patent holder is entitled to unless his patent is invalid. We are not talking about settlements that extend the patent life beyond what the law gives them. So, you know, you hear comments in here that seem to indicate we are somehow settling cases to keep generic drugs of the market even longer than the patent life that the law allows for the inventor. That is not true. We are simply talking about whether or not the patent life is going to be shortened for the inventor because of a dispute over whether it is a valid patent, done properly, or the new generic company that wants to come in is not infringing. That is a debate. And in those cases, there are issues, obviously, that will yield to settlement rather than to litigation. So that is what we are talking about.

Now, could we help make sure those settlements are in the public interest? Yes, I think there are some ideas that you have discussed today that we would love to talk to you some more about.

I am a little concerned, Senator Hatch, about the 180-day provision. It was one of the beautiful elements of Hatch-Waxman that really encouraged generic companies to come in and test patents.

Senator HATCH. It is a critical element.

Mr. TAUZIN. Yes, and it is part of the balance. That has produced 60-percent generic use in this country, bigger than any country in the world, again. So I would be concerned about messing with it too much.

On the idea of letting the judge who is handling the dispute under whatever standard that makes sense review it, that is worth discussing. That might be an idea that works.

First of all, even Senator Schumer indicated, you know, even though he favors a bright line, he has indicated there are good settlements, and we ought to have some review to see which one is a good one and which one is a bad one. My concern, again, is that if you begin saying what elements of a settlement you cannot ever have, you may make some of these settlements impossible. And, therefore, you may hurt consumers in the end, and you may require small innovators to stay in court longer than they should, at great expense, to protect their patents and, therefore, damage their viability.

You may damage generic companies by forcing them to stay in court longer than they should to get a resolution of the legal issues involved.

So, Senator Hatch, Senator Specter, I respectfully say we would love to sit down and talk some more and visit and see whether there is some other solution. Senator Kohl, I—

Senator HATCH. Well, we would love to hear from all of you.

Mr. TAUZIN. I am just concerned about saying here is an element you cannot have in a settlement just because it looks bad. If it looks bad but it really is good for consumers, maybe the court ought to have the right to say that. If it just looks bad and it is bad, kick it out. It should not be there.

In the end, the judgment ought to be that this helps resolve legal disputes that create uncertainty create legal fights that last too long, cost the companies, cost consumers unnecessarily and in favor of settlements that end these disputes, and let Hatch-Waxman work the way it was intended to by allowing generic companies to enter into the field when they should have a right to be there.

Senator HATCH. Mr. Chairman, I love both sides of the industry and consumers, and, frankly, these matters are not simple matters. This is complex. Hatch-Waxman is complex. There are not too many people that understand it at all in the Congress of the United States. I have to say there are some very good staffers who do in many respects.

But there has been a lot to think about here today, but I have got to tell you these two industries have done so much for America, no question about it. And I get tired of people picking on one or the other, to be honest with you. Both have served this country well.

But there are wrongs, and when there are, current laws many times take care of them. But there needs to be some tinkering here. Even you admit, Mr. Tauzin, that there are bad deals sometimes, and I think you would agree with that, Mr. Downey, as well.

Mr. DOWNEY. We do.

Senator HATCH. And if the law is not taking care of those bad deals, then we have to come up with a way of doing it.

In the case of you, Mr. Wroblewski, and you, Mr. Hirsh, we would like your ideas on this. Personally, I am having some troubles with having a one-size-fits-all answer to this. I have got an open mind on it, and you have certainly—not that I mean that much, but the fact of the matter is that I would like to see if there is some way that we can bring everybody together still in the best interests of the two manufacturers and the consumers as well.

Mr. TAUZIN. Senator, would you indulge me just 1 second longer? I just want to give you an insight that came to me in the last several years since I have been in this job. I have had a chance to go visit a lot of the young scientists working on these new medicines. There is a guy in California, a young scientist working on a medicine for hepatitis B and C, and there are 500 million people on this planet who are going to die from those diseases, about 10 years before they effect on you, kill you. This guy is working on a solution. One guy.

All I am asking you to consider is the long-term effects of what you do in terms of that process, because there are patients all over the world waiting for that scientists and others to invent the drug that eventually the generic companies will copy and bring in at a cheaper cost later on, but who are spending years and years of their life and who dream of nothing else but finding the answer to hepatitis B or C or whatever disease plagues us.

There is a balance here. You talked about it. All we ask is that we make sure this model does not break down, because if it breaks down, for the sake of patients who are currently getting the benefit of a medicine, if we give up what is happening in terms of the incredible research to find the new medicines that are going to take care of those diseases that wreck us and ruin us, that you got to be a little careful that you do not damage that model to the point where it does not work anymore. We are on that brink right.

Senator HATCH. Well, Mr. Chairman, I am sorry I have taken so long, but I do not want either of these industries hurt. There are some people here who think PhRMA is all big businesses. I think you have made a pretty good case that it is a wide variety of businesses, including big businesses. There are some very big generics right now. Yours is one of them, Barr, Teva, a number of others.

In the end, if we hurt these companies by bad legislation, we are going to hurt the consumer in the end. On the other hand, if we allow really what is improper activities to continue—and I have to say I have been pretty forthright about some of what I consider to be improper activities—then we hurt the consumer even more.

So we have to find some way of resolving these problems so that the system works, but we certainly do not want to kill our industry. I love the Washington Post coming out against the House bill over there, which seems to be a political retribution bill more than a bill to protect consumers. And the Post recognized, as I have noticed they do, they recognize that we do not want to kill these industries. We are the leaders in the world today, and our hope for the future of controlling health care costs is going to be just how successful you folks are and what we can do with stem cell research and bio as we go down through the years. And if we are successful in those, especially bio and stem cell research, if we are successful in individual therapies based upon genetics for individual

people, I got to tell you, we might be able to avoid an awful lot of Medicaid and Medicare costs that are going to swamp the Federal budget in the future unless we can find some ways around it.

So I want to commend you for the work that you do, and I am sorry I have taken so long, but—actually, you have taken most of the time. I have just been very reasonable.

[Laughter.]

Senator HATCH. But this has been an extremely interesting hearing to me, and I just want to compliment all of you, and compliment you, Mr. Chairman. I am going to really enjoy working with you, as I always have, and this is a very important hearing, and I hope we will hold some others as well on other matters.

Senator KOHL. Thank you for your contribution, Senator Hatch.

Senator Grassley?

STATEMENT OF CHARLES E. GRASSLEY, A U.S. SENATOR FROM THE STATE OF IOWA

Senator GRASSLEY. Mr. Chairman, I am not going to ask any questions. First of all, I did not think I was going to be able to be here at all. I am very interested in this subject and am a cosponsor of the bill, but I was working with Senator Baucus to get a small business tax provision out of the Finance Committee, which we just got done, so it would be ready for the minimum wage bill. But now that this Committee was still meeting, I wanted to stop by and let everybody know that I am going to continue working with the Chairman of the Committee and other members of this Committee on this legislation. I think it is needed. I would not preclude the possibility of compromise and listening to every point of view as just expressed by Senator Hatch. But I think there is a lot in this area that needs to be done, and I think the most important thing is to make sure that the marketplace works and is not frustrated from the standpoint of when patents have expired, we ought to expect generics to get to market as soon as possible.

So in the process of doing that, I wanted to stop by and express my support and regret why I could not be here for the entire hearing. I will have a chance to be briefed on everything that was said. And I assume that it is Chairman Leahy's intent to move ahead with this legislation. I, at least, hope so.

So I thank Senator Leahy and you for your work and for putting my statement in the record. Thank you.

[The prepared statement of Senator Grassley appears as a submission for the record.]

Senator KOHL. Thank you very much, Senator Grassley.

Gentlemen, we appreciate your being here, as well as Commissioner Leibowitz. This has been a very good hearing on a very complicated and a very important topic. You have shed a lot of light with your discussion this morning. We appreciate the time you have given us and the wisdom that you have brought to the issue. Thank you so much.

The hearing is adjourned.

[Whereupon, at 12:10 p.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

Barr Laboratories, Inc.

Suite 722, 444 North Capitol Street, NW, Washington, DC 20001 • 202/393-6599, Fax 202/638-3386

The Hon. Patrick Leahy
Chairman, Judiciary Committee
United States Senate
Attn:. Nikole Burroughs
224 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Senate Judiciary Committee -- January 17, 2007 Hearing Questions

Dear Senator Leahy:

I am writing to answer the questions submitted to me after my January 17, 2007 testimony before the Judiciary Committee on behalf of Barr Pharmaceuticals. I have set forth the answers to the best of my ability to each of the questions, which are repeated below for ease of reference, preceded by the name of the senator who submitted the question.

Questions and Answers

By Senator Kohl: *In your view, are there any circumstances in which consumers are benefited by a patent settlement in which a generic firm agrees to keep its drug off the market in return for a cash payment from a brand name manufacturer? If you believe there are such circumstances, please explain. If you believe there are no such circumstances, why wouldn't you support a bill banning such settlements?*

Yes, I do believe there are circumstances in which consumers are benefited by patent settlements in which a generic firm settles its patent challenge, thus relinquishing its right to market a generic product immediately, yet often securing the right to market a competing product years before the brand name manufacturer's patent would otherwise expire.

For example, in the case of my company's Prozac challenge, we settled our case in the district court, which had dismissed all but our inequitable conduct claim, for a cash payment. That settlement allowed us to immediately appeal the court's decision. We ultimately prevailed, a result that saved consumers about a billion and a half dollars. Our cash settlement at the trial court level not only facilitated an appellate court decision, it benefited consumers by enabling us to bring a generic version to market at least a year earlier than would have been possible if we had been forced to litigate the inequitable conduct claim to its conclusion at the trial court level. Obviously, that year of savings would have been lost if the restrictions in the proposed legislation had been in place.

Another example is Tamoxifen. There, in addition to monetary consideration, we obtained a license that enabled us to enter the market with a competing product and saved consumers about $300 million, despite the fact that subsequent generic companies brought

similar patent challenges and lost. Again, those savings would have been lost if the restrictions in the proposed legislation had been in place.

By Senator Kohl: *The FTC reports that in the year after the two court decisions allowing these "reverse payment" patent settlements, half of all patent settlements contained terms in which the brand name company paid the generic money in return for the generic's agreement to keep its drug off the market. The year before the court decision, no patent settlements contained such terms. Doesn't this data show that such "reverse payment" settlements are likely to become increasingly common in the years ahead?*

We are at a disadvantage to analyze or discuss the conclusions reached by the FTC because we do not have access to the universe of settlement agreements the FTC has been able to analyze. Those settlements are typically confidential and it is my understanding that they were submitted to the FTC as confidential. The FTC's own reports in turn do not identify the specific settlements or terms, so it is very difficult to comment on settlements other than those involving my own company.

However, based on my knowledge of my own company's challenges, I believe the FTC's statement may not be completely accurate. My company did in fact enter into settlements involving monetary consideration *prior to* the *Schering* decision. Two of those settlements, involving Cipro and tamoxifen, were upheld by the courts. Another, involving Prozac, led to our eventual generic launch of Prozac which has been lauded as an example of the Hatch-Waxman process at its best. These three settlements led to consumer savings in excess of $2 billion.

In any event, I do not believe that looking at just one year (the year before the *Schering* decision, for example) provides an adequate sample. These cases take years to litigate, so a one-year window may not be the most informative method for identifying trends. I know that prior to the *Schering* decision my company in fact settled several cases in which monetary consideration was part of the settlement. Moreover, it would not surprise me for there to be more settlements, including more settlements including monetary consideration, in the past two years simply because there have been an increasing number of patent challenges during this time period.

By Senator Feinstein: *In your prepared statement and your testimony, you seemed to oppose Senator Kohl's legislation on the grounds that it would prohibit all settlements in which a brand-name company gives a thing of value to a generic drug manufacturer. You also seemed to object that the bill would be an obstacle to settlements that included collateral agreements involving payments for unrelated products. Senator Kohl's bill, however, is not that broad: it would only bar settlements that involve both a payment of a something of value to the generic and an agreement by the generic to delay the development or marketing of the generic product.*

- *How would you propose modifying the bill to make it more narrowly targeted at only the settlements that are anticompetitive?*

- *Would the bill as currently written prohibit a settlement with a bona fide collateral agreement involving a payment from the brand-name company to the generic, if that settlement did not include an agreement by the generic to delay bringing the generic product to market?*

The bill as currently written would in fact ban anything "of value" to a generic manufacturer *unless* the generic company also received the right to enter the market *immediately*. That would make settlement impossible, since the brand-name company would never agree to immediate entry in settling rather than litigating to the end. Ironically, the legislation may have the unintended consequence of discouraging brand manufacturers from ever settling patent challenges, a result, as demonstrated over the last decade, which would not be in the interest of consumers. Any patent settlement will inevitably involve the generic company accepting less than *immediate* entry, and therefore "agreeing to delay" marketing its product. Unfortunately, the bill as written would in effect ban the receipt of "anything of value" by the generic company, making it impossible to settle these kinds of cases. For example, if the brand-name company has a patent that does not expire for ten years, and the generic company obtains through a settlement the right to enter the market in five years the generic company has not delayed but *accelerated* entry. Under the bill as drafted, this accelerated entry would not be possible because other consideration (*i.e.*, anything of value) is also part of the settlement.

By Senator Schumer: *Mr. Downey, you stated in your testimony that the proposed legislation would "harm the public by chilling patent challenges." Yet from 2000 to 2004, the five years during which the anti-competitive settlements targeted by this legislation were not allowed, there were plenty of patent challenges filed. In fact, the number of patent challenges almost tripled during the period that anti-competitive settlements were prohibited. Can you please explain why we did not see a chilling effect during this period?*

I respectfully disagree that the settlements that would be targeted by this legislation were "not allowed" from 2000 to 2004. In fact, my company vigorously litigated the Cipro case during that time period, in which we ultimately prevailed, with the court upholding our settlement that involved both early entry and monetary consideration.

By Senator Schumer: *Congressman Tauzin and Mr. Downey, you have each stated that you oppose the legislation before us today. Do you believe that there are any anti-competitive patent settlements?*

I believe that there can be anti-competitive patent settlements, and that is why it is proper for the government to challenge such settlements on a case-by-case basis when they see fit. A settlement that expanded the brand-name company's rights beyond the relevant patent or patents could be anti-competitive under the rule of reason. A settlement that was a sham could be anti-competitive. Each would have to be examined on its own terms. I do not have access to all the terms of *other* company's settlements, but I do not believe any of my company's settlements

were anti-competitive. But speaking of whether there can be theoretical patent settlements that would be anti-competitive, I would say "yes."

By Senator Schumer: *The brand company Cephalon negotiated agreements with four generic companies, including Mr. Downey's company, regarding the sleep medication Provigil. The generic companies agreed to stay off the market until October 2011 in exchange for a total of $136 million in payments. Cephalon paid $136 million in order to save six years worth of revenues for a drug that makes $500 million a year. Can you tell me how the consumer benefited from this settlement?*

Cephalon's patent on Provigil will not expire until 2014. My company's settlement agreement thus benefited consumers by giving us the right to enter with a competing modafinil product as early as October 2011 -- *three years earlier* than if we had never challenged the patent or if we had lost in court. Moreover, given that the case was not filed until 2005,and would have taken several years to litigate, even if Barr had prevailed, it could not have entered the market before 2009. Thus, the settlement guaranteed a right to enter in 2011 rather than a possible date of 2009 if Barr had won, or 2014 if Barr had lost. My company did not agree to "stay off the market." Under current law, we cannot enter the market because of Cephalon's patent until 2014. As a result of our settlement, we will be able to enter the market *three years early, and we believe* those three years of *accelerated* entry will greatly benefit consumers.

Please do not hesitate if I can provide any further assistance.

Sincerely,

Bruce Downey
Chairman and CEO
Barr Pharmaceuticals, Inc.

cc: Nikole_Burroughs@judiciary-dem.senate.gov

ROSS, DIXON & BELL, LLP

2001 K Street, N.W. • Washington, D.C. 20006-1040 • p (202) 662-2000 f (202) 662-2190

MERRIL HIRSH
DIRECT DIAL (202) 662-2032
DIRECT FAX 202-662-2190
EMAIL MHIRSH@RDBLAW.COM

February 8, 2007

BY MESSENGER AND ELECTRONIC MAIL

United States Senate
Committee of the Judiciary
Washington, D.C. 20510-6275

Attn: Ms. Nikole Burroughs
Hearing Clerk
224 Dirksen Senate Office Building

Re: Answers to Written Questions

Dear Ms. Burroughs:

As Chairman Leahy requested in his January 25, 2007 letter, attached are answers to the written questions submitted by Committee Members. Please call me if you have questions.

Thanks again for your assistance.

Sincerely,

Merril Hirsh

Enclosure
349029 v 2

Senator Kohl's Follow-Up Questions from Hearing on "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?"

1. Do you have an estimate of how much consumers are paying as a result of these "reverse payment" patent settlements which have the effect of keeping generic competition off the market?

RESPONSE: I believe that the answer would be in the billions of dollars each year. In your opening statement, you noted that savings from three years of early entry of generic competition for Prozac and Paxil alone saved consumers respectively about $2.5 billion and $2 billion. During his testimony, Commissioner Leibowitz added the examples of Zantac and Platinol and reported that the early entry for just these four products "is established to have saved consumers more than $9 billion alone." I have no reason to dispute these figures. Had entry been delayed by reverse payment, that money would have been lost to consumers.

There is every reason to believe that the losses currently to consumers are at least as large and probably larger. As the FTC recently reported, in FY 2006, there were 14 agreements in which brand and generic companies settled patent litigation with reverse payment settlements on 8 different branded pharmaceutical products. "Each of these agreements involved a product with 2005 U.S. annual sales exceeding $125 million; eight of the agreements involved products with 2005 U.S. annual sales of more than $450 million." Bureau of Competition, FTC, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements filed in FY 2006, at 4 (2007) (available http://www.ftc.gov/reports/mmact/MMAreport2006.pdf).

Beyond this general estimate, it is difficult to be more precise about how much consumers have lost to date. To conduct this analysis, you would need to know, first, the amount of revenue the brand company can be expected to obtain from the drugs, and then, the lower amount consumers would be expected to pay after competition. It is possible to estimate the

second of these figures (the lower prices after competition). As Commissioner Leibowitz noted during his testimony, although the price reduction might vary somewhat from drug to drug, "[w]hen the first generic enters the market, it generally does so at a 20- to 30- percent discount off the brand price. Prices drop even further – by 80 percent or more – after other generic competitors go to market, usually 6 months later."

The first figure (the expected sales of the drug) would probably also be obtainable, but (for confidentiality reasons) the FTC's report does not actually identify the drugs, the specific amount of sales of each or the extent to which generic entry has been delayed. Accordingly, I do not have access to that specific information.

Once this analysis has been conducted, there are at least two ways of looking at the effect of reverse payments. One would be to compare the results of the reverse payment settlement to what would be expected had cases gone to judgment in litigation. Another would be to compare those results to what would be expected had the parties instead settled by having the generic company enter the market earlier, without the inducement of a payment to stay out of the market.

Each of these approaches would require some additional information. A comparison with the expected result in litigation would require an assessment of the likelihood of success in the litigation. A comparison with the expected result in settlement would require assessing what expected settlement would be in a world in which the reverse payment portion was outlawed. It is fair to say that we would expect the generic company, without the reverse payment, to insist on entering the market sooner – and where the reverse payments are currently large, we would expect that entry to occur significantly sooner. However, it would require more data to determine the precise effect.

In one important way, however, the problem is much larger than any of these figures suggest. As you have noted in your third question (below), given the current state of the law, there is every reason to think that brand and generic companies will routinely use reverse payment settlements to resolve patent disputes – and, in particular, use them in situations when the brand company most expects to lose its case. If this remains the law, the use of reverse payment settlements threatens to eliminate, going forward, all of the gains derived from the ANDA-IV process under Hatch-Waxman. Obviously, that loss to consumers would be staggering.

2. In your view, are there any circumstances in which consumers are benefited by a patent settlement in which a generic firm agrees to keep its drug off the market in return for a cash payment from a brand name manufacturer?

RESPONSE: I do not believe that there are genuine circumstances in which consumers are benefited by the component of the settlement in which cash is being paid for the generic company's agreement to stay out of the market. I also believe that, in any event, this component of an agreement is, like any other agreement among competitors not to compete, so inherently unlikely to benefit consumers that it is better to bar it through a bright-line rule.

During his testimony at the hearing, Mr. Downey noted that some settlements may involve *other* components that help consumers. He gave examples of settlements that, in his view, allowed Barr to enter the market before the expiration of patents that Barr had concluded ultimately would have been upheld on appeal.

I would not second-guess Mr. Downey's statements about how Barr assessed the merits of these cases. And it is certainly possible that these settlements, in *some* ways, benefit consumers. But the assertion that a settlement benefited consumers in *some* ways, does not show that it was good for consumers to have – *as a component of the settlement* – a provision in which

the brand company paid the generic *not* to compete. In those settlements, the brand company was willing to forego a benefit in order to avoid an adjudication of the patent dispute; and Barr was willing to accept some benefit in exchange for dropping its challenge. Because the brand company was able to make some of that settlement in cash, Barr did not have to insist on as early an entry date in order to receive the benefit that it did. Consumers were not made better off because this was possible. They were made worse off.

In my written testimony and in the article I attached to it, I talked about the main argument people have made in the literature in response to this argument. People have attempted to argue that, in theory, there could be situations in which the only way to settle a case is to have the brand company make a payoff. As the attached article explains in more detail, there are a number of responses to this argument. Merril Hirsh and Dan Zoloth Dorfman, "I Didn't Say Orphan Often: The Benefits of a Bright-Line Rule Banning Brand to Generic Payments in Hatch-Waxman Patent Settlements," ABA ANTITRUST HEALTH CARE CHRONICLE, Vol. 19, No. 2 (Summer 2005). (Available at http://www.rdblaw.com/files/News/b2383914-25ae-41ca-8785-0bd69e9e07dd/Preview/NewsAttachment/72fbb496-9eb9-48bf-a618-12c4e5152e1c/Health%20Care%20Chronicle%20Summer%202005.pdf). I would respectfully ask that this article be made part of the record.

But the most basic response is that this discussion really is theoretical. As you note in your final question, we went almost overnight from a situation in which brand and generics managed to settle cases with *no* reverse payments, to a situation in which now they use reverse payments frequently.

This huge shift did not happen because something made it suddenly impossible in 2006 to settle cases without reverse payments. It happened because court cases suggested that brand and

generic companies might be able to get away with these settlements. In 2005 and 2006, coinciding with the decision against the FTC's position by the Eleventh Circuit in *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006), and the decisions upholding a reverse-payment settlement in *In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121 (E.D. N.Y. 2003), *aff'd* 429 F.2d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), brand and generic companies reversed course and entered into fourteen new reverse payment settlements. *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 2006 (2007) (available http://www.ftc.gov/reports/mmact/MMAreport2006.pdf).

If several years of cases can be resolved without reverse payments only to have reverse payment settlements return after the legal winds change, reverse payments must not be "essential." Brand and generic companies will enter them if they can. As history has demonstrated, if they cannot, they will resolve their disputes in a different way.

3. The FTC reports that in the year after the two court decisions allowing these "reverse payment" patent settlements half of all patent settlements contained terms in which the brand name company paid the generic money in return for the generic's agreement to keep its drug off the market. The year before the court decision, no patent settlement contained such terms. Doesn't this data show that such "reverse payment" settlements are likely to become increasingly common unless our legislation is enacted?

RESPONSE: I think that it is near certain that "reverse payment" settlements will become common in the absence of legislation or a Supreme Court decision rejecting the reasoning of the *Tamoxifen* and *Schering-Plough* decisions. For the companies involved, the economics is very simple. Drug sales tend to be very inelastic – the amount of a prescription drug sold does not increase very much when the price goes down. If a drug has sales of $1

billion a year, and the price would be reduced by even 50 percent by the advent of full competition, full competition reduces total revenues by about $500 million a year, and creates a market in which the brand is vying with the generic companies to share that revenue. If, for example, the brand company expects to retain 2/3 of the market, its own revenue goes from $1 billion a year to about $333 million a year (2/3 of $500 million). That is a loss of almost $2 million in revenue each *day* competition is delayed.

If the brand and generic companies believe that there is any reasonable possibility of fighting off an antitrust challenge to this arrangement, they have an enormous incentive to try to do so. The FTC's experience with *Schering-Plough* shows that the agency can be entirely vigilant; it can scrutinize the settlements; it can enforce its view of the law; but it still may not be able to protect consumers when the companies agreeing to the reverse payment settlements take the obvious course of challenging the FTC's decision in a friendly United States Circuit Court of Appeals. The weaker the brand company's patent position, the more likely the brand company is to want to use a "reverse payment" settlement to preserve this extraordinary amount of revenue.

There is no certainty that the Supreme Court will solve this problem, or that it will do so soon. The Supreme Court takes a very small percentage of the cases presented to it. And because there is nothing currently in the Hatch-Waxman Act that expressly prohibits reverse payment settlements, any request for Supreme Court review would have to be based upon the argument that, in general, as a matter of antitrust law, these settlements are illegal. Although I would hope that the Supreme Court would take the case and so find, it is possible for the Court to conclude that although these settlements may be bad as a matter of policy, it is for Congress (and not the courts) to decide what the policy should be. In the meantime, customers are paying the enormous price.

Questions Submitted by Dianne Feinstein
Following the January 17, 2007 Senate Judiciary Committee Hearing
"Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?"

The Eleventh Circuit held in the *Schering-Plough* case that there was no antitrust violation when a settlement between a name-brand pharmaceutical company and a generic manufacturer prevented the generic company from marketing the competing generic product – because the settlement did not stifle any competition beyond what the patent already prohibited. To reach this conclusion, the court relied on a presumption that patents are valid.

- *To reach a conclusion that such a settlement is inherently anticompetitive, do we have to assume that the patent is* ***not*** *valid?*
- *If yes, why should we start from an assumption that the patent in question is not valid?*

RESPONSE: This question, I believe, helps to clarify an important issue that has led to a lot of confusion: Condemning reverse payment settlements does *not* require assuming that the patent is invalid. There is no conflict between, on the one hand, assuming that patents are valid and, on the other hand, preventing brand and generic companies from *settling* patent disputes by paying the generic company not to compete.

All litigation involves issues on which one side or the other has a burden of proof. In most litigation, there is something to be said for both side's positions and certainly parties are entitled to rely on legal presumptions. But it is not true that just because a party may benefit from a presumption, or, more generally, have a legitimate position in litigation, it is empowered to settle the lawsuit by an agreement to eliminate competition.

Whatever the respective merits of their cases, the parties that enter into reverse payment settlements have decided that they want to settle. They can settle in two basic ways: One way is that the brand company can pay the generic to drop the lawsuit. This works to its benefit because it funds the settlement using the monopoly rent being paid by consumers. But it ensures that consumers receive no benefit at all. Another way is that the brand company and generic can

negotiate over *when* the generic company will enter the market. This settles the dispute by affording the generic the benefit of being able to market the product. But it benefits consumers by resulting in competition. Telling the parties that they can only settle in the second way does not affect the presumption of validity of the patent.

Reverse-payment settlements dramatically change the results this litigation would be expected to achieve. The fact that a patent is presumed to be valid does not mean that the patentholder has more than a 50 percent chance of success at any given point. It just means that the burden falls on the challenger to show that the patent is not valid. The evidence of invalidity could be anywhere from non-existent to overwhelming. (In addition, many patent disputes do not involve, or do not involve only, the question of whether a patent is valid. The major or even exclusive issue is often whether the generic company is *infringing* the patent. There is no presumption that a product *infringes* a patent).

Assume, however, you have ten cases, and in each of them the patentholder has a 60 percent chance of success. That means that we would expect – even *with* the presumption of validity – that, if all ten went to resolution, the patentholder would lose four of them. If you allow reverse payment settlements, you allow a result in which there is *no* competition in *any* of these cases. If you eliminate reverse payment settlements, you either have the cases going to resolution (in which case you get the competition in the four cases), or you have settlements in which your expected resolution is that the generic company will be allowed to compete on each drug 40 percent sooner than the generic company would otherwise. Both of those results avoid allowing the parties to use a payoff to afford patents more exclusive power than they actually have – even with the presumption. And reverse payments allow the patentholder to maintain the monopoly even when its position had only a 30 percent chance of success, or less.

In the real world, negotiations are more complicated. Parties may be risk averse; some may press better bargains than others. But the point is that, when the generic company is not being paid off, it has no incentive to stay out of the market. It has the incentive to compete as much as possible. The parties determine the actual date on which the generic company enters, not by a collusive negotiation designed to preserve a monopoly, but at arm's-length.

In fact, even if we agreed that, in a significant percentage of these cases, the brand company was destined to win the patent case, that still would not mean that, as a matter of policy, we should allow the brand company to pay off the generic for dropping the challenge. Companies cannot usually defend agreements not to compete by arguing "no harm, no foul." In *United States v. Reicher*, 983 F.2d 168 (10th Cir. 1992), for example, the court found that a defendant was properly convicted of criminal bid rigging even though the ostensible "competitor" with whom it rigged the bid would have been unable to perform the contract. As the court explained "[d]espite its ultimate inability to perform the contract, [the competitor] held itself out as a competitor for the purposes of rigging what was supposed to be a competitive bidding process. This is exactly the sort of 'threat to the central nervous system of the economy,' that the antitrust laws are meant to address." 983 F.2d at 170 (*quoting United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 226 n.59 (1940)). In *United States v. MMR Corp.*, 907 F.2d 489 (5th Cir. 1990), *cert. denied*, 499 U.S. 936 (1991), the court upheld a criminal price fixing conviction in a case where a company agreed not to bid on a prime contract in exchange for a subcontract from the bid winner. There, as in *Reicher*, it did not matter that the company that agreed not to bid had never handled such a large project on its own, or that the job greatly exceeded its bonding capacity. 907 F.2d at 492, 497. *See also United States v. Finis P. Ernest, Inc.*, 509 F.2d 1256, 1262 (7th Cir.), *cert. denied*, 423 U.S. 893 (1975) (to similar effect).

Similarly, it is not a defense to price fixing to argue that the price set was "reasonable." "The aim and result of every price-fixing agreement, if effective, is the elimination of one form of competition. The power to fix prices, whether reasonably exercised or not, involves power to control the market and to fix arbitrary and unreasonable prices.... Agreements which create such potential power may well be held to be in themselves unreasonable or unlawful restraints, without the necessity of minute inquiry whether a particular price is reasonable or unreasonable as fixed..." *United States v. Trenton Potteries,* 273 U.S. 392, 397 (1927). *Accord Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 986 (9th Cir. 2000) (citing *Trenton Potteries* as reflecting the "long-established rule" that "[f]oremost in the category of *per se* violations is horizontal price-fixing among competitors"). *See also NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 133 (1998); *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (price fixing and divisions of markets are illegal *per se* "without elaborate inquiry as to the precise harm they have caused or the business excuse for their use").

Accordingly, even as we recognize that patents are presumed to be valid, we should not want to have a system in which parties can be paid off not to challenge them. Agreements not to challenge patents, just like "[p]rice-fixing of any kind[,] distorts in a basic way the competitive process the antitrust laws were meant to protect." *USA Petroleum Co. v. Atl. Richfield Co.*, 859 F.2d 687, 692 (9th Cir. 1988), *rev'd on other grounds*, 495 U.S. 328 (1990). If we allow reverse payments, we are preventing the market from operating to solve the problem. That is wrong, by itself, even if our best guess is that the market might have happened to have reached the same result without the agreement.

Attached is a copy of an article that provides some additional detail that I hope might be helpful in addressing these issues. Merril Hirsh and Dan Zoloth Dorfman, "I Didn't Say Orphan

Often: The Benefits of a Bright-Line Rule Banning Brand to Generic Payments in Hatch-Waxman Patent Settlements," ABA ANTITRUST HEALTH CARE CHRONICLE, Vol. 19, No. 2 (Summer 2005). (Available at http://www.rdblaw.com/files/News/b2383914-25ae-41ca-8785-0bd69e9e07dd/Preview/NewsAttachment/72fbb496-9eb9-48bf-a618-12c4e5152e1c/Health%20Care%20Chronicle%20Summer%202005.pdf). I would respectfully ask that this article be made part of the record.

I Didn't Say Orphan Often: The Benefits of A Bright-Line Rule Barring Brand to Generic Payments In Hatch-Waxman Patent Settlements

by Merril Hirsh and Dan Zoloth Dorfman[1]

The debate over the potential anticompetitive aspects of settlements of patent litigation between branded and generic drugs continues to rage, Schering-Plough notwithstanding. In this issue of the Chronicle we present a paper by Merril Hirsch and Dan Dorfman, arguing for a brighter line in the tests determining whether the settlement is merely a contrivance to share monopoly profits, and responsive comments by Karen Bokat and George Gordon, highlighting other ways to look at the issue.

GENERAL: I ask you, have you ever known what it is to be an orphan?

KING: Often!

GENERAL: Yes, orphan. Have you ever known what it is to be one?

KING: I say, often.

ALL: (disgusted) Often, often, often. (Turning away)

GENERAL: I don't think we quite understand one another. I ask you, have you ever known what it is to be an orphan, and you say "orphan." As I understand you, you are merely repeating the word "orphan" to show that you understand me.

KING: I didn't repeat the word often.

GENERAL: Pardon me, you did indeed.

KING: I only repeated it once.

GENERAL: True, but you repeated it.

KING: But not often.

GENERAL: Stop! I think I see where we are getting confused. When you said "orphan," did you mean "orphan", a person who has lost his parents, or "often," frequently?

KING: Ah! I beg pardon- I see what you mean – frequently.

GENERAL: Ah! you said "often," frequently.

KING: No, only once.

GENERAL: (irritated) Exactly- you said "often," frequently, only once.

– W.S. Gilbert, The Pirates of Penzance

INTRODUCTION

Everyone pretty much agrees on the basic situation: A brand-name drug company, claiming patent protection for one of its popular products, settles an infringement lawsuit against a drug company that has asserted a right to compete against the brand with its generic version of the drug. Among other things, the brand-name company agrees to pay money to the generic and the generic agrees not to bring its product to market and compete with the brand for some period of time.[2] Beyond that, the contentious discussions of the antitrust implications of these settlements – the subject of so much court time[3] and law journal pages[4] – often [frequently] seem the equivalent of this colloquy between the Pirate King and the Major General.[5] Much of the heat and controversy on the issue comes from courts, scholars, and plaintiffs' and defense antitrust bars talking past each other – asking two fundamentally different questions and getting fundamentally different answers.[6] The question favored by the antitrust defense bar, some scholars,[7] and some courts including, most notably, the Eleventh Circuit,[8] focuses on comparing the settlement with the alternative of litigation. This side essentially asks, "Is it bad for pharmaceutical competitors to agree to a mutually satisfactory arrangement including 'reverse payments' to resolve the uncertainty and cost of patent litigation?" "No," some courts answer.[9] "No" or at least "probably not," answer commentators like Kevin McDonald and Marc Schildkraut.[10] A payment from the patent holder to the generic company in settlement of patent claims, this side argues, is only uncharitably called a "reverse payment." In

Continued on page 5

[1] Merril Hirsh and Dan Zoloth Dorfman are attorneys in, respectively, the Washington, D.C. and Chicago offices of Ross, Dixon & Bell, LLP. They represent both plaintiffs and defendants in commercial and insurance litigation, including plaintiff purchasers in antitrust litigation arising out of Hatch-Waxman patent settlements. The views (and musical tastes) expressed in this article are their own and do not necessarily reflect those of Ross, Dixon & Bell, LLP or any of its clients. The authors drafted this article in connection with the ABA Antitrust Section's May 12-13 Conference on Antitrust in Health Care and invite comments and questions from those who are interested. All rights reserved, but re-publication may be permitted upon request.

Published in Antitrust Health Care Chronicle, Volume 19, No. 2, Summer 2005.
© 2005 by the American Bar Association. Reproduced with permission. All rights reserved.

Continued on page 2

fact, they maintain, such a payment merely reflects the same type of adjustment to consideration that takes place in other patent settlements in which the patent holder has a damage claim from defendant's prior sales, and accepts less than he might have received if successful in the litigation.[11] Accordingly, these settlement do not necessarily raise antitrust concerns, at least as long as the settlement terms are reasonable and, perhaps, as long as the patent position was not so frivolous in the first place as to constitute "sham patent" litigation.[12]

Hence, the Eleventh Circuit's three-part test: When faced with an antitrust challenge to a Hatch-Waxman settlement between pioneer and generic drug manufacturers, a court should first examine "the scope of the exclusionary potential of the patent." Then, the court should look at "the extent to which the agreements exceed that scope," and, lastly, at "the resulting anticompetitive effects."[13] If the brand-name company is going to win the patent case more than half the time, as the presumption of patent validity suggests, there is no harm in having it pay money to delay entry that would not have occurred in any event and may actually occur sooner by virtue of the settlement.

But, respond the plaintiffs' bar, the FTC,[14] some scholars,[15] and some courts[16] – most prominently the 6th Circuit,[17] the question is not whether the generic would have won the patent case or *why* it might settle. Instead, the question is what do we think about the payments being made as part of the *terms* of settlement? To put it another way: "Is it bad to have settlements in which brand-name companies pay generics large amounts of money in exchange for an agreement not to compete as opposed to settling on a time for market entry?"

By asking this different question, this side comes to the different answer that these settlements are bad. Moreover, even within the confines of the Eleventh Circuit's approach, there is room for a "yes" answer to this question, a federal district court judge recently found in granting summary judgment to plaintiffs on remand from the Eleventh Circuit's *Valley Drug* decision[18]: "While [Abbott and Geneva] could have structured their Agreement in a *less restrictive way* that reasonably implemented Abbott's patent protections, they instead agreed to a restraint that *surpassed that which the patent would have allowed.*"[19]

In a particular version of this view, a patent settlement could be anticompetitive regardless of whether the brand-name company was more likely than not to win the patent case. This could be true because we call the unadjudicated patent right "probabilistic," i.e., until the brand-name company wins, it only has a chance of winning and, therefore, also has a chance of losing that it resolves by buying off a competitor.[20] Or it could be true because we do not care, i.e., given that the case is settling, buying off a competitor is either inherently or empirically an anticompetitive way of settling because it shares monopoly profits between the participants without resulting in competition.[21]

Although we would not agree with all the analysis on this side, the second question is the correct one in our view, and we favor *per se* treatment of these settlements or, at least, a bright-line rule presuming the anticompetitive nature of settlements in which the pioneer pays the generic to stay out of the market. Still, we believe that understanding the miscommunication may offer both sides of the debate a way out of the impasse.

I. HOW DO "REVERSE-PAYMENT" SETTLEMENTS COME ABOUT?[22]

A. The Hatch-Waxman Act and the Marketing of Generic Drugs

A brief synopsis of the Hatch-Waxman Act and its procedures is in order. No drug company may sell a prescription drug in the United States until it has applied for and received approval from the Food and Drug Administration ("FDA").[23] To secure FDA approval, a drug company must file a New Drug Application ("NDA"), including reports and information that demonstrate the drug is safe and effective for its proposed use(s).[24] New drugs that are approved and marketed through the NDA-approval process are called "pioneer" or "brand-name" drugs.[25] In 1984, concerned that the NDA process was cumbersome and delayed entry of relatively inexpensive generic drugs into the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act ("Hatch-Waxman").[26]

The Act established an abbreviated process to obtain FDA approval for generic versions of previously approved pioneer drugs.[27] Five years after the FDA has approved a new drug, a generic pharmaceutical company may seek approval to market a generic version of the drug by filing an Abbreviated New Drug Application ("ANDA"). To secure FDA approval of an ANDA, the generic must demonstrate that the proposed drug is the bioequivalent of the corresponding brand-name drug.[28] Hatch-Waxman, in order to protect the patent rights of the pioneer

Continued on next page

Continued from page 5

manufacturer, also requires the ANDA filer to make one of four certifications concerning patents listed with the FDA for the brand-name drug. Most pertinently for our issue, in a Paragraph IV Certification, the generic manufacturer attests that the listed patent "is invalid . . . or will not be infringed" by the generic drug.[29]

Moreover, if the generic files an ANDA IV, it must provide notice to the patent holder of the certification, including a statement of the factual and legal basis for its opinion that the patent is invalid or will not be infringed.[30] If the pioneer company brings a patent infringement suit against the generic within 45 days of receiving notice of the Paragraph IV Certification, the FDA delays approval of the ANDA until the earlier of (1) 30 months after the pioneer's receipt of the notice *or* (2) issuance of a court decision relating to the ANDA holding the patent invalid or uninfringed.[31]

The first ANDA filer enjoys a 180-day exclusivity period during which other generic drug makers are barred from competing in the market for the drug at issue; the exclusivity period commences when the first filer begins selling its product or the pioneer's patent is held to be invalid or uninfringed.[32] Accordingly, prior to the enactment of the Medicare Reform Act, any agreement between the pioneer and the first generic to delay the latter's entry into the market served to keep other generic competitors out as well, as long as the generic agreed to defend and/or not to waive its exclusivity rights.

B. "Reverse-Payment" Settlements

Not all Hatch-Waxman settlements are controversial. The attention of the FTC and private antitrust litigators – and the focus of this article, much case law, and the voluminous commentary noted earlier – has been drawn to settlements that (1) include a "reverse-payment" *and* (2) either condition the payment upon the generic company not competing, or bar the generic company from competing, for some period.

In setting forth this scenario, we need to stress two points. *First*, it is not the settlements themselves that raise antitrust concerns, but the combination of these two provisions. It is theoretically possible that there could be other settlements that violate the antitrust laws.[33] But, as a practical matter, it makes sense to have a working assumption that, if the brand-name company is *not* making a substantial payment to the generic in exchange for the generic's agreement not to compete for a period of time, the two are actually bargaining at arm's-length over the terms of competition.

Similarly, if the brand-name company wants, for some reason, to pay the generic *without* restricting the generic's entry into the market, that may be a management problem but it is not especially an antitrust problem. The concern in Hatch-Waxman settlements is not that generic companies receive funding; it is that they are agreeing not to compete in exchange for the funding. The combination of the "reverse-payment" element and the foreclosed competition raises a point of discussion because of the potential for the brand-name company's inducing the generic not to bargain at arm's-length over the terms of competition, but instead to bargain over how to divide up the monopoly rent that the brand-name company obtains from the lack of competition.

Second, in the real world, the fact scenario in which a Hatch-Waxman settlement is likely to give rise to private antitrust litigation is somewhat extreme. The cases that arise, at least in private antitrust litigation, usually involve blockbuster drugs with hundreds of millions of dollars of annual sales. If the brand-name drug is only marginally successful, it is not likely that the generic will want to pick the patent fight in the first place. Even if the generic goes ahead with the ANDA IV filing in such a case, the brand-name company has little reason to pay substantial money to generics to preserve the right to sell marginal product. And if the monopoly rent is small, the private plaintiffs' bar does not have much incentive to bring an antitrust case in an effort to disgorge it.[34]

Moreover, the cases that give rise to antitrust litigation are more likely to involve some fair grounds for dispute over the patent's validity or applicability. Granted, Hatch-Waxman established a system in which generic companies appear to have an incentive to challenge patents because they can do so without risking damages or incurring the costs and uncertainties associated with marketing the drug. The system, then, may be expected (inappropriately, we argue, when reverse payments can be sought) to encourage ANDA IV filings that might not otherwise be made. Nevertheless, generic companies who file ANDA IV applications cannot be assumed to be picking frivolous patent fights.[35] By applying to the FDA for permission to market their drugs, they invite a lawsuit for patent infringement.[36] They risk substantial litigation costs, the costs and effort of preparing their drugs for market, and potentially extensive delays until they can market their products, if the courts fail to vindicate their patent positions. Moreover, weak patent challenges are less likely to lead to a reverse-payment settlement. The weaker the case, the more likely it is to fail on early motion and the

Continued on next page

Continued from page 6

less likely to exact a premium in settlement from the pioneer.[37]

In short, although in theory you might have a case involving a marginal product and a brand-name company that has a 99.9 percent chance of winning the patent case, in practice, the cases can be expected to involve far more dollars and significantly closer patent disputes.

C. Recent Illustrations from the Case Law

Two recent "reverse-payment" Hatch-Waxman patent cases respectively involve somewhat weaker and somewhat stronger facts for analyzing the antitrust claim.

1. K-Dur 20

At issue in the *Schering-Plough* litigation was Schering-Plough Corporation's brand-name drug "K-Dur 20," an extended-release potassium chloride medicine, used in the treatment of high blood pressure and congestive heart disease.[38] Schering-Plough's patent, due to expire in September 2006, claimed the pills' extended-release coating; the active ingredient, potassium chloride, was commonly used and unpatentable.[39]

In August 1995, Upsher-Smith Laboratories filed an ANDA IV to market a generic version of K-Dur 20. Schering-Plough sued Upsher for patent infringement in December 1995; the earliest that Upsher could market its drug, upon FDA approval, was December 1998. In June 1997, on the eve of trial, Schering-Plough and Upsher settled and agreed that the earliest entry date for Upsher's generic would be September 1, 2001. Schering-Plough also agreed to pay Upsher $60 million plus other consideration to license three Upsher products.[40]

In March 2001, the FTC filed an administrative complaint against Schering-Plough, Upsher, and a third generic company[41]; the FTC's Administrative Law Judge ("ALJ") found that the agreements were lawful settlements of patent lawsuits and dismissed the complaint.[42] In December 2003, the full Commission reversed the ALJ's decision, concluding that the payments in the settlements were a *quid pro quo* for delayed entry of the generics and thus harmful to competition and consumers in violation of the antitrust laws. Schering-Plough and Upsher timely petitioned the Eleventh Circuit for review.[43] In addition to the proceedings before the FTC, reviewed by the Eleventh Circuit, private antitrust litigation arising from the Schering-Plough's agreements with Upsher and ESI has been consolidated in the New Jersey District Court.[44]

2. Hytrin

Abbott Laboratories manufactures Hytrin, a "very successful" brand-name drug used to treat hypertension and enlarged prostrate.[45] The active ingredient in Hytrin is a form of terazosin hydrochloride, for which Abbott holds a number of patents.[46] In 1996, Geneva Pharmaceuticals filed several ANDA IVs based on Hytrin[47] and Abbott filed a patent infringement suit, asserting that Geneva's proposed product infringed one of its patents.[48] In April 1998, the companies entered into an agreement, in which Geneva agreed not to market a generic terazosin hydrochloride drug until either Abbott's '532 patent expired in 2000, another company introduced a generic terazosin hydrochloride drug, or Geneva obtained a final court judgment, from which no appeal could be taken, that Geneva's terazosin products did not infringe the '207 patent or the patent was invalid. Geneva also agreed not to transfer or sell its rights to the 180-exclusivity period under its ANDAs and to support Abbott in any efforts to extend the 30-month stay of FDA approval of Geneva's ANDA. In return, Abbott agreed to pay Geneva $4.5 million/month until either someone else brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court on its infringement claim.[49]

In September 1998, the Northern District of Illinois held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent; the decision was affirmed by the Federal Circuit Court of Appeals in July 1999.[50] In December 2000, the Southern District of Florida granted summary judgment to class action and individual antitrust plaintiffs in their suit against Abbott, Geneva, and Zenith, finding that the agreements at issue constituted geographic market allocation agreements between horizontal competitors and hence were per se unlawful under Section 1 of the Sherman Act.[51] In *Valley Drug*, the Eleventh Circuit reversed and remanded for consideration of the agreements under its three-part test. On remand, the district court held that the "appellate-stay" provision[52] of the agreement exceeded the scope of the '207 patent and was per se a violation of federal antitrust law.[53]

II. WHAT ARE THE PROBLEMS WITH "REVERSE-PAYMENT" SETTLEMENTS?

There are two questions discussed at the outset of this article: (1) the "*settlement vs. litigation*" question,

Continued on next page

Continued from page 7

concerning whether the parties should be settling as opposed to litigating; and (2) the "*what settlement*" question, concerning how they are settling compared to other settlements. Both questions raise potential antitrust problems. The problems involved, however, are often [frequently] confused. The first – whether the settlement is worse than litigation – is a closer one; the second – whether this particular settlement is worse than others that might have happened – is really pretty clear in theory, even if there are arguments for why it is trickier in practice.

A. The Settlement vs. Litigation Question

The closer question is the one that the Eleventh Circuit focuses on: When, if ever, do reverse-payment Hatch-Waxman patent settlements violate the antitrust laws?[54] On this issue, there are some strong competing considerations. It is indisputable that patents accord certain rights, both temporal and practical, and confer legal and economic advantages on the nation. It is also indisputable that, in general, settlements of litigated disputes provide advantages to litigants, the courts, and society in general.[55]

If, as the side asking this question argues, some settlements would not happen but for the reverse-payment,[56] society loses this benefit. And when you are comparing a world with patent rights that are being litigated to one in which patent rights are settled, it is not easy to sort out the extent to which the lack of competition is a function of the settlement (and therefore infirm) as opposed to the patent itself (a lack of competition we tolerate or even encourage for other reasons).

Some commentators suggest that, because of risk aversion, there are circumstances in which a settlement, even with reverse payments, might be better than the expected result in litigation.[57] The Eleventh Circuit even goes so far as to suggest that "[b]y restricting settlement options, which would effectively increase the cost of patent enforcement," a *per se* rule barring reverse payment settlements "would impair the incentives for disclosure and innovation."[58] Others maintain that reverse-payment settlements might actually further competition by providing cash-strapped generics with the money to launch more-effective competition when the period of exclusion ends.[59]

Various commentators, Judge Posner,[60] and the Eleventh Circuit[61] have also challenged the premise that reverse-payment settlements are a big deal. They argue that the awkward appearance of having a patent holder pay the generic it is suing is merely a function of the artificial Hatch-Waxman setting in which a generic is able to pick a patent fight without already having infringed and run up damages. In this argument, there is no difference between having a brand-name company with a $0 potential recovery agree to pay the generic $500 million than there is having a patent holder in another case with a $1 billion potential recovery agree to accept "only" $500 million in settlement.

We believe these arguments are, to varying degrees, overstated or misapplied.

1. Reverse-payment settlements protect weak patent positions.

Society's interest in protecting patents does not connote an equally strong interest in protecting weaknesses in patent positions. Patent holders may need some room to be mistaken about patent positions without automatically facing antitrust liability, as some argue.[62] But it seems to go overboard to grant brand-name companies the right to use patent disputes as an occasion to pay a competitor not to compete whenever the brand-name company has a patent argument that is "merely" a losing one and not completely frivolous.[63]

You do not have to agree that patent rights are "probabilistic" to recognize the risk in allowing litigation settlements to overstate the strength of a patent position. Suppose a brand-name company has ten patents, each with a 50/50 chance of being upheld and enforced. All right, in light of the presumption of validity, make it 60/40, make it 70/30. No one would contend that it is frivolous or a "sham" for a patent holder to assert an infringement claim with a 50, 60 or 70 percent chance of success. Yet, it is only in five cases, or six or seven, that the brand should win; in five, four or three, it should lose. If the law permits the brand-name company to settle all ten of these cases by paying the generic company some of its monopoly rent to stave off a patent challenge, there is no competition in *any* of the ten cases. This seems wrong.

The Eleventh Circuit's standard, requiring the trial court to look at "the extent to which the agreements exceed" the scope of the patent,[64] seems to recognize the problem, but not to address this form of it. Taken literally, this standard deals with a situation in which brand-name and generic companies use the occasion of a patent dispute to eliminate competition in a way that is *broader* than the patent does. But it does not seem to address the problem that a settlement may eliminate competition in a way that is *stronger* than the patent justifies. This is an especial risk in the real world with large monopoly rents attending

Continued on next page

Continued from page 8

blockbuster drugs and some presumed merit in the generic company's patent position. Getting three to five out of ten cases wrong can mean that those who purchase drugs are paying hundreds of millions or even billions of dollars more than they would if the drug companies either litigated the cases to conclusion or settled on terms that traded at arm's-length on competition rather than dollars.

Perhaps we are reading the opinion too literally. The Eleventh Circuit recognizes the possibility of "circumstances under which the unreasonableness of a settlement agreement regarding a subsequently-invalidated or unenforceable patent would be sufficiently apparent that antitrust liability would not undermine the encouragement of genuine invention and disclosure."[65] Indeed, when *Valley Drug* came back for remand in *Terazosin II*, Judge Seitz focused on the concern that the settlement agreement there barred Geneva's entry into the market beyond resolution of the patent suit in the district court "without any determination of whether Abbott was likely to succeed on the merits of any appeal," i.e., without any assessment of the strength or weakness of Abbott's patent position.[66] The *Valley Drug* court also cited to case law extending the sham patent principles of *Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.*[67] to circumstances where the patentee knew the patent was invalid,[68] and limits its holding to circumstances in which the antitrust plaintiff had "demonstrated nothing more than subsequent invalidity."[69]

Nonetheless, the Eleventh Circuit's conclusion – that a payment from the brand-name to the generic company not to compete is not *per se* anticompetitive, even in a case in which the patent is subsequently determined to be invalid – seems to add a kind of supra-anticompetitive property to the patent. If even an invalid or unenforceable patent affords antitrust immunity for paying a competitor not to compete, we are accepting error in more than five cases out of ten.

2. Reverse-payment settlements cannot be expected to encourage innovation.

The premise that drives this willingness to accept a high rate of error is unproven and seems counterintuitive. The Eleventh Circuit is concerned that preventing patent holders from settling Hatch-Waxman cases by paying their competitors will "impair the incentives for disclosure and innovation."[70] But this seems remote. There is no reason to believe that a brand-name company that is willing to go to all the expense and risk of developing and testing a drug (and then enjoy at least a five to seven-and-a-half year period of monopoly sales before the first generic can hit the market) is not going to do so based upon the fear that *if* the drug is approved by the FDA, and *if* the brand-name company obtains a patent, and *if* it is challenged by a generic someday, and *if* the brand-name company decides to settle the litigation by paying the generic not to compete, and *if* the generic is interested in that settlement, and *if* the brand-name pays so much as to reflect a genuine weakness in the patent position, it might then face antitrust liability. Moreover, as discussed in more detail in Section IV below, the long-run effect of barring reverse-payment settlement is more likely to support disclosure and innovation by reducing the risk of extortion through litigation.

3. Reverse-payment settlements do not seem to be "necessary" to settle patent litigation, or necessarily desirable even if they were.

The contention that reverse-payment settlements are "necessary" in Hatch-Waxman litigation is a more sophisticated, and potentially troubling, argument. But it has several weaknesses. To explain this point requires a brief explanation of the argument itself.

Marc Schildkraut, for example, argues that reverse payments can close the gap in a situation where the benefits to the brand-name company of exclusivity are greater than the benefits of entry to the generic company. He uses the example of a situation where the patent holder and the generic are a year apart in their negotiations over the time when the generic can enter the market and "[t]o the patent holder, [a] year is worth, say, $120 million in monopoly profits beyond the competitive profits available after entry. To the alleged infringer, it is worth $10 million (in competitive profits)."[71] Schildkraut then posits situations in which the parties, therefore, would never reach an agreement on time without money because each day of movement costs the patent holder more than the generic gains.[72] He similarly uses examples of situations in which the brand-name company is risk-averse, but the generic overly-optimistic; in these circumstances, he argues, the time-of-entry numbers do not overlap and the pioneer's and the generic's differing expectations about money may allow them to reach agreement.[73]

This analysis is intriguing, but seems overstated. Even assuming that these particular situations occur in the real world, it is not clear that they would exist in a world in which reverse-payment settlements were illegal. A change in the rules may well change the result. If, for example, the rule were that reverse-payment settlements (or those involving a certain level of such payments) were *per se* illegal, generics whose primary interest was in the reverse

Continued on next page

Continued from page 9

payment rather than in competition would likely not file ANDAs for their products in the first place. Accordingly, those cases that were brought would be ones in which the ability to compete would have significant value to the generic.

Moreover, because a high proportion of civil cases settle and patent litigation involves some of the most imaginative professionals in our legal firmament, it is not clear that eliminating one avenue for agreement would lead to despair of all others. As a practical matter, commercial litigators often face this dilemma in settlement negotiations. Litigation – be it trademark disputes, tortious interference, or breach of contract claims – can always be settled on anticompetitive terms. How often in negotiations do we approach that moment when we say, out loud or to ourselves, "We could do this, it would settle the case and serve our client's interests, but... we really can't?" Agreements not to compete are quite frequently "win-win" agreements for those who agree to them and, therefore, could close many gaps in settlement negotiations. Yet, somehow, cases settle without them.

Indeed, Hatch-Waxman patent disputes do settle without reverse-payments. An FTC Report published in early 2005 concluded that "[s]ettlements after 1999 do not appear to include a payment from the brand-name company to the generic manufacturer in exchange for the generic's agreement not to market its product."[74] If several years of cases can be resolved without reverse payments, how "essential" can they be?

Moreover, even if reverse payments were somehow "necessary" to settle these cases, the benefits of having them settle may still not outweigh the detriment of agreements not to compete. In *Valley Drug*, for example, the Eleventh Circuit recognized that settlements that go beyond the scope of patent protection may be *per se* illegal, even if they do help close the gap between the parties.[75] It may be readily apparent that a patent settlement overreaches when the agreement not to compete extends beyond the four corners of the patent,[76] but it is difficult to see why, in principle, "closing the gap" is any better excuse for permitting settlements that alter the strength of the patent position in a way that litigation would not. Regardless of the terms that are restricting competition more than litigation would, it would not be surprising to see the parties swear after the fact on a stack of F.3d's that these terms were the *only* ones on which they could possibly have agreed given the circumstances.

However, most problematically, Schildkraut's example illustrates the very problem it purports to solve. Why is it that a year to the patent holder is worth $120 million in monopoly profits beyond the competitive profits available after entry but only $10 million (in competitive profits) to the alleged infringer? It is probably not simply because the generic is going to sell less product. Probably, it is, in part, because generic drugs have lower margins *from which consumers benefit when the generic company enters the market*. Clearly, consumers do not benefit from these lower margins when the pioneer and the generic agree to use the monopoly rent to pay for a year less of competition. Reverse-payment agreements are such "win-win" settlements for Hatch-Waxman litigants and are so useful for closing gaps because it is the rest of us who pay for them.

The interests of the private parties to these settlements simply do not conform to the interest that society has in competitive balance. Patents may be socially and economically beneficial; settlements may be good; competition may be good, but the parties with the greatest interest in the patents and the settlement do not necessarily share the same fervent interest in competition as they do in the other two.[77]

4. *Reverse-payment settlements are an inefficient way to fund competition.*

The argument that we should allow reverse-payment settlements so that generic companies can use brand-name companies to fund the generic's eventual competition seems especially strained. Even if we assumed that generic drug companies are all cash-strapped (which is, of course, untrue), companies generally do not look to their competitors as essential sources of funding for their operations. If generics have a product to sell and need cash to do it, they ought to take their business plans to venture capitalists, stockholders, bondholders or private lenders, like other businesses do. In any event, it is difficult to see why we would want to encourage generics to pick patent fights in order to pursue the sales of drugs that they cannot afford to market and/or demonstrate are worth funding. And, in the case of the type of blockbuster drugs that give rise to these issues, the inability to fund competition seems like a very remote concern.

5. *Reverse-payment settlements are not a benign "oddity" of Hatch-Waxman.*

The argument that the "reverse-payment" feature of "reverse-payment" settlements is merely an oddity of Hatch-Waxman is more misleading than it is helpful. Yes, when

Continued on next page

Continued from page 10

people compromise, they generally accept less than their highest hopes; and if the highest hope is zero, the compromise becomes negative. But, as noted above,[78] what makes these Hatch-Waxman settlements a concern is not merely that the payment goes in an apparently odd direction, but *also* the fact that the generic who receives the money is being paid not to compete. Although it would be difficult to demonstrate empirically, most patent settlements probably do not have as their tag line – "I will accept only X, if you agree never to compete." They usually say, "I will accept X amount of dollars for now, and then you will pay Y dollars to license."

Even if the tag line were that the generic is agreeing not to compete, the issue is more complex than it might appear. If the conventional patent plaintiff with a guaranteed $1 billion patent claim agreed to accept a mere $500 million in exchange for an agreement to have the alleged infringer agree not to compete, that would be a pay off. However, if the patent claim were *guaranteed* to be worth $1 billion, the case is not one with a weak patent position; the alleged infringer never had the right to compete in the first place and, thus, objectively, was *not* being paid not to compete. This is different than the Hatch-Waxman situation, because there we know that the patent holder is entitled to receive $0 *win or lose*.

Accordingly, to have a situation in which the patent holder is not guaranteed to win, requires adding a level of uncertainty to the hypothetical. It would involve a decision-tree situation something like this: Suppose the patent holder has, say, a 50 percent chance of success that would produce $1 billion, but nonetheless agreed to accept significantly less than $500 million ($1 billion x .5 probability of it occurring) (say $250 million) in exchange for an agreement that barred the alleged infringer from competing for some period of time.

The problem in this analysis is that, although we can *say* all this for purposes of a hypothetical, in the real world of non-Hatch-Waxman settlements, there is so much uncertainty that, absent very extreme facts, what we say is probably not worth the paper it is printed on. Not only is the 50 percent chance of success (a) objectively uncertain; (b) not necessarily equal to the honest, but subjective, perceptions of the parties; and (c) subject to the parties' (potentially unequal) level of risk-aversion, the $1 billion in *damages* is usually even more difficult to pin down on all of these scales. Moreover, large sums of money like this may also be subject to a diminishing marginal return to money. Even a reasonably large company might prefer to guarantee $250 million rather than incur even a mathematically justified risk in order to obtain $500 million, not merely because it is averse to the risk, but because it cares more about the first $250 million it receives than the next $250 million. Thus, although in theory, you could ask the same question in the non-Hatch-Waxman settlement – what is (the reduction in) money paying for? – in practice, the non-Hatch-Waxman setting is far more likely to present non-competition-related answers to that question.

When we are examining whether to have a *per se* rule, the issue of "how sure we are that this is anticompetitive" is not merely a footnote to a pristine theoretical analysis – it is the central question. A *per se* rule is warranted when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output."[79] In the case of reverse payments in exchange for delayed (or non-) entry of generic competition into pharmaceutical markets, the commentators are straining to come up with circumstances in which the settlement would *not* be anticompetitive. In the case of reductions in amounts potentially recovered from non-Hatch-Waxman patent claims, we have to strain to figure out when we can be sure the settlement *would be* anticompetitive.

In short, although there are certainly arguments to be made on both sides of the question of whether reverse-payment settlements are better or worse than litigation, on the whole, they are weaker than they might appear.

B. The "What Settlement?" Question.

Although the anti-reverse payment settlement side of this debate has made a number of these points at various times, the main focus of the competing analysis is not on explaining why it would be better to continue the litigation rather than settle on these terms. Instead, the approach is, in varying degrees, to take the fact of settlement as a given, and then to focus on its terms. This makes the answer to the question easier: If we assume that the case is going to settle and then focus on why the settlement included reverse payments, paying money to the generic company seems to do a lot less for competition than agreeing to the generic company's obtaining its consideration by entering the market sooner. As one judge, considering the same agreements at issue in *Schering-Plough*, explained: "Plaintiffs can sustain a claim of anticompetitive conduct simply by alleging facts which show that the outcome of the settlement agreements would have been more pro-competitive absent the cash payments from Schering to Upsher and ESI."[80]

Continued on next page

Continued from page 11

The problem becomes more glaring if the amount of the payment is large. Judge Seitz, for example, was troubled by the size of the reverse-payments, which, she observed, "exceeded Geneva's [the generic's] total revenues for 1997," the year before the settlement agreement.[81] This, in turn, raised a red flag as to whether Abbott and Geneva could have reasonably implemented Abbott's patent protections in a "less restrictive way."[82]

In *Schering-Plough*, the Eleventh Circuit's reaction to the FTC's decision was scathing on the facts, and especially frustrating to antitrust writers because, in significant measure, it rests on a factual determination that just ruins a good hypothetical. In the settlement, Schering-Plough, the brand-name company, received additional consideration in the form of cross-licenses for several of the generic company's drugs, principally Upsher's cholesterol drug, Niacor. The FTC's ALJ concluded that the cross-licenses had value. However, as noted above, the full Commission reversed, concluding that they did not. The Eleventh Circuit held that the FTC was wrong to reject the ALJ's findings.[83] If Schering-Plough actually did obtain independent value for its payment, this was not a "reverse-payment" settlement at all; it was a settlement that included a purchase agreement, and the compromise on when the generic would enter the market was presumably reached at arm's-length.

But the Eleventh Circuit did not stop with the facts. And when it turned to the theory, its discussion was mostly "often" to the FTC's "orphan." To the FTC, a reverse payment was a red-flag, presumed to be bad because parties could always be expected to trade money for time of competition. To the Eleventh Circuit, the reason for the reverse payment was not a theoretical question, but a factual one – the court critiqued the FTC for relying on an expert's "rather amorphous 'incentive' theory despite its purported lack of empirical foundation."[84]

Although the Eleventh Circuit cited to "facts" (mainly the *post hoc* explanations of those who settled about why they could not settle in any other way), the court largely relied on theories of its own. First, it declared that "[w]ithout any evidence to the contrary, there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude those who infringe on its product."[85] Then, it explained that, "[r]everse payments are a natural by-product of the Hatch-Waxman process."[86] And in a theoretical discussion about what might happen, it reasoned that, under Hatch-Waxman, generics have significant settlement leverage that alleged infringers do not normally have in patent litigation. They risk litigation costs,[87] but not the multiple damages normally at stake in a paten infringement actions.[88] Moreover, litigation costs "pale[] ir comparison to the immense volume of generic sales anc profits."[89] On the other hand, the litigation could cost the patent holder its patent,[90] with substantial losses in revenue and profits, especially in the face of competition from the victorious generic and possibly other manufacturers.

"Ultimately," the Eleventh Circuit concluded, "the consideration paid to Schering by Upsher and ESI was arguably less than if Schering's patent had been invalidated, which would have resulted in the generic entry of potassium chloride supplements."[91] That is why "[a] conceivable compromise . . . directs the consideration from the patent owner to the challengers."[92]

The problem is that none of this theory really answers the facts. True, Hatch-Waxman settlements are different. True, they involve different plusses and minuses on the parties' respective sides. And this explains why a generic may, in a Hatch-Waxman situation, be able to command a better settlement than would an alleged infringer in a non-Hatch-Waxman situation facing large potential damages. But it does not explain why the settlement needs to take the form of money, or refute the FTC's point – that the payment of money raises a red flag pointing to the likelihood that, without the money, the settlement would have resulted in the generic's competing sooner. Nor does it deal with the more basic problem – that the focus of the antitrust laws is not on the benefits that agreements confer on the potential competitors who enter them, but on the effect their obtaining these benefits has on consumers who are supposed to benefit from competition.[93]

III. A *PER SE* OR BRIGHT-LINE RULE BARRING REVERSE-PAYMENT HATCH-WAXMAN SETTLEMENTS WOULD BENEFIT ALL SIDES OF THE ISSUE

As noted above, a *per se* rule is warranted when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output."[94] When this is the case, no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on competition.[95] The classic examples that the Supreme Court has identified as subject to the *per se* rule include naked, horizontal restraints pertaining to prices or the allocation of territories.[96]

Continued on next page

Continued from page 12

Bright-line rules are similar.[97] Although bright-line rules may be over- or under-inclusive, they have the great advantage of clarity and simplicity. As Judge Posner explains in a different context, "[a] rule singles out one or a few facts and makes it or them legally determinative" as distinct from a "standard" which "allows a more open-ended inquiry."[98] The problem with confusing the two, Judge Posner warns, is that we are liable to fall into the fallacy of "confusing a rule with its rationale," which leads us often into "potentially costly, time-consuming and uncertain inquiry" into a dispute whose resolution ought really to be straightforward.[99]

Whether we are talking *per se* or bright-line rule, a rule barring significantly large reverse payments responds effectively to both the "litigation versus settlement" problem and the "what settlement" problem. As noted above, it is easy to see how a non-payment settlement including an agreement on time of market entry helps with the "what settlement" concern. The significant risk in Hatch-Waxman settlements is that the powerful force of patent-infringement settlement-bargaining will be directed to finding a solution that is very good for the parties themselves, but not at all good for the rest of us. Not only is there a temptation to agree on the "win-win" of sharing the consumer's money; the transfer of the money – especially a lot of money – is a pretty good indication *ex post facto* that the parties have yielded to it.

A system in which these settlements cannot take the form of money beyond cost of defense aligns the interests of generic companies with those of consumers. Barred from sharing in the brand-name company's monopoly profits, the generic's interests and incentives shift to forcing more competition and gaining revenues by selling product. The agreement is truly at arm's-length and, therefore, can be presumed to have fairly balanced the patent holder's interests in protection and the concerns of competition, with weakness in the patent position genuinely resulting in competition rather than mere payment.

Perhaps more tellingly, however, a bright-line rule against reverse-payment Hatch-Waxman settlements also seems to do a much better job of dealing with the "litigation versus settlement" problem than does the Eleventh Circuit's rule. We believe that the effects of a *per se* rule on disclosure, innovation, the ability to reach the best results in settling litigation and the need to clear dockets of patent cases would be positive, not negative. Under the current system, generic companies have an incentive to file ANDA IVs announcing an intention to challenge the patents for blockbuster drugs in order to receive money in reverse-payment settlements. If such settlements were barred, generic companies would be more likely to challenge patents when they genuinely were willing and able to compete. Surely, brand-name companies, given the option, would opt not to get involved in the patent litigation in the first place rather than have the privilege of settling the litigation by paying off a potential competitor.

Moreover, a *per se* rule strengthens the self-selection that already exists in some measure when generic companies decide to file ANDA IVs. Assume that the two major motivations that animate the decision to file an ANDA IV are: (1) weakness in the brand-name company's patent position; and (2) the amount of money the pioneer drug makes. In a system where the generic company can hope to be paid off rather than to compete, the relevant number for the amount of money the drug makes is, logically, the amount it makes *for the brand-name company*, who may now share some of this monopoly rent in settlement. In a system where that option is gone, the relevant figure would seem to be the (lower) amount of money the drug makes *for the generic* after competition has brought down price. The less money available to drive the decision to file an ANDA IV, the more the decision can be expected to be driven by weakness in the patent position, and the more closely we approach the situation where the brand-name company, with ten 50/50 patent positions, is sued on the five losing ones and not on the five winning ones.

Obviously, this is theoretical and imperfect. But it is, ironically, a "free-market" solution that, as many such solutions do, better approaches the result we should want than do arrays of uncertain judge-made standards.

---

2 In Section II below, we discuss briefly but in more detail the basic Hatch-Waxman scheme and describe some of the settlements that have attracted the attention of the FTC and the courts.

3 Recent published decisions include: *Schering-Plough Corp. v. FTC*, No. 04-10688, 2005 WL 528439 (11th Cir. Mar. 8, 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *In re: Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003); *In re: Terazosin Hydrochloride Antitrust Litigation*, 352 F.Supp.2d 1279 (S.D. Fla. 2005) ("*Terazosin II*"); *In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517 (D. N.J. 2004); *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp.2d 986 (N.D. Ill. 2003); *In re Tamoxifen Citrate Antitrust Litigation*, 277 F.Supp.2d 121 (E.D. N.Y. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F.Supp.2d 188, 250 (E.D. N.Y. 2003) ("*Cipro II*"); *In re: Terazosin Hydrochloride Antitrust Litigation*, 164 F.Supp.2d 1340 (S.D. Fla. 2000) ("*Terazosin I*"), *rev'd sub nom., Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

Continued on next page

Continued from page 13

4 Some recent articles on this issue include: Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004); Thomas F. Cotter, Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship, 71 ANTITRUST L.J. 1069 (2004); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004); Keith Leffler and Christofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33 (2004); Merril Hirsh, *Are False Positives Really So Negative? A Response to Kevin McDonald*, ANTITRUST, Summer 2003, at 83; Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probalistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68; Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).

5 As one scholar recently observed, "Much ink has been spilled on the topic of reverse-payment settlement agreements and their antitrust implications . . . and yet the legality of reverse payments remains very much a live, and hotly contested, issue." Cotter, *Antitrust Implications of Patent Settlements*, 71 ANTITRUST L.J. at 1069-70.

6 This should surprise no one. These cases arise at the intersection of intellectual property and antitrust law, as courts and commentators have observed, and what you ask and what answer you find satisfactory depends, in part, on where you are standing. *See, e.g., In the Matter of Schering-Plough Corp., Upsher-Smith Laboratories, Inc., and American Home Products Corp.*, Docket No. 9297, Final Order and Opinion of the Commission (Dec. 8, 2003) ("*Schering-Plough [FTC]*"), *overturned on appeal, Schering-Plough v. FTC*, No. 04-106588, 2005 WL 528439 (11th Cir. Mar. 8, 2005), available on the FTC website at http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf and http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf, respectively (noting that this "challenging case raises important issues at the intersection of patent law and antitrust law"); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probalistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68 (same).

7 *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004); McDonald, *Hatch-Waxman Patent Settlements and Antitrust*, ANTITRUST, Spring 2003, at 68.

8 *See Schering-Plough Corp. v. FTC*, No. 04-10688, 2005 WL 528439, *17 (11th Cir. Mar. 8, 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 1:00-MDL-1383 (DGT) (E.D. N.Y. Mar. 31, 2005) ("*Cipro III*"). As this article went to press, only the slip opinion was available.

9 *See Schering-Plough*, 2005 WL 528439 at *17 (rejecting *per se* treatment of "reverse-payment" Hatch-Waxman settlements "[g]iven the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements"); *Valley Drug*, 344 F.3d at 1309 (reasoning that "[t]o hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally"); *Cipro III, slip. op.* at 49 (rejecting "plaintiffs' assertion that [brand-name] Bayer's payment [of $398 million] to [generic] Barr is anti-competitive because, without it, Bayer and Barr would have agreed on an earlier entry date for Barr or would have otherwise fashioned a more pro-competitive agreement" because it "ignores the fact that, if defendants were within their rights (more specifically, the patent right) in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable").

10 *See* Kevin D. McDonald, *Patent Settlements and Payments That Flow The "Wrong" Way: The Early History of a Bad Idea*, ANTITRUST HEALTH CARE CHRONICLE, Winter 2002, at 12 (explaining that "if the settlement precludes no more generic competition than the patent itself, then the *direction* of payment flow tells us nothing about reduced competition"); Schildkraut, *Patent-Splitting Settlements*, 71 ANTITRUST L.J. at 1034 (arguing that "reverse payments are not necessarily anticompetitive" because there are "many circumstance where a reverse payment is necessary to resolve a patent litigation and that resolution is better for consumers than continued litigation").

11 *See* Schildkraut, *Patent-Splitting Settlements*, 71 ANTITRUST L.J. at 1033 (concluding that "there really is no such thing as a 'reverse payment' in the context of a settlement of a patent case . . . [because] it is likely that consideration is moving from the patent holder to the alleged infringer in most settlements of patent disputes," based on the difference between the money payments by the alleged infringer to the patent holder and the value of the patent in the market).

12 In *Valley Drug*, the Eleventh Circuit suggested that antitrust liability might attach to a Hatch-Waxman settlement "when the antitrust claimant proves that the patentee knew that the patent was invalid." *See Valley Drug*, 344 F.3d at 1308-09. Liability in that circumstance, the court reasoned, "would not undermine the encouragement of genuine invention and disclosure" in the way the court concluded a *per se* rule would. *Id.*

13 *See Schering-Plough*, at 20, citing *Valley Drug*, 344 F.3d at 1312.

14 *See In the Matter of Schering-Plough Corp., Upsher-Smith Laboratories, Inc., and American Home Products Corp.*, Docket No. 9297, Final Order and Opinion of the Commission (Dec. 8, 2003) ("*Schering-Plough [FTC]*"), *overturned on appeal, Schering-Plough v. FTC*, No. 04-106588, 2005 WL 528439 (11th Cir. Mar. 8, 2005), available on the FTC website at http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf and http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf, respectively.

15 *See, inter alia*, Keith Leffler and Christofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33 (2004); Merril Hirsh, *Are False Positives Really So Negative? A Response to Kevin McDonald*, ANTITRUST, Summer 2003, at 83; Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).

16 *See, e.g., In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517, 531-532 (D.N.J. 2004) (the question to be resolved is not patent invalidity or infringement, but "whether the settlement agreements . . . constitute anti-competitive conduct").

17 *See In re: Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003) ("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").

18 *See In re: Terazosin Hydrochloride Antitrust Litigation*, 352 F.Supp.2d 1279, 1318-19 (S.D. Fla. 2005) ("*Terazosin II*") (holding that the disputed "appellate-stay provision evidences a 'naked restraint of trade' subject to *per se* treatment"). Although not ruling on Judge Seitz's decision, the Eleventh Circuit noted her application of *per se* analysis and distinguished the agreements in *Valley Drug* on their facts from the agreements at issue in *Schering-Plough*. *See Schering-Plough*, at 19, n.14.

19 *Terazosin II*, 352 F.Supp.2d at 1317, emphasis added. (For a discussion of the facts in the *Terazosin* litigation, *see* Section II.C.2 below.) Earlier in her opinion, Judge Seitz discussed the "guidance" she found in Hovenkamp's three-part analysis of Hatch-Waxman settlements (as well as the "absence of an articulated analytic framework from the Eleventh Circuit"). *Id.* at 1295, citing Hovenkamp, *et. al., Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. at 1727 (urging courts examining such settlements to determine "(1) that the parties did have a bona fide [intellectual property] dispute; (2) that the settlement is a reasonable accommodation; and (3) that the settlement is

Continued on next page

Continued from page 14

not more anticompetitive than a likely outcome of the litigation"). Keeping in mind the Eleventh Circuit's *Valley Drug* test and relying on Hovenkamp's analytical approach, Judge Seitz articulated her own three-part test to evaluate whether the Abbott-Geneva agreement "was a reasonable implementation of the exclusionary potential of the '207 patent." *Id.*, citing *Valley Drug*, 344 F.3d at 1312. *First*, "the exclusionary scope of the '207 patent" must be examined in order to determine "the extent of the protections afforded to Abbott." *Second*, the court must evaluate "the likely outcomes" of the underlying patent litigation, including the likelihood of Abbott's obtaining injunctive relief barring Geneva from the market pending appeal of the patent validity issue. *Lastly*, the court must determine whether the settlement represented "a reasonable implementation of the protections afforded by the '207 patent, in light of the applicable law, the then-pending litigation, and the general policy justifications supporting settlements of intellectual property disputes." *Id.* at 1295-96. Although Judge Seitz could not adopt the FTC's and Sixth Circuit's analysis, it seems clear that she was sympathetic to it, relying as she did on Hovenkamp's approach, which closely parallels that analysis.

[20] *See, e.g.*, Keith Leffler and Christofer Leffler, *In Response to Kevin McDonald: The Probabilistic Nature of Patent Rights*, 17 ANTITRUST, Summer 2003, at 77. Although we clearly differ with Kevin McDonald's approach to Hatch-Waxman settlements, we do not entirely disagree with his critique of the "probabilistic" theory of patent rights. *See* Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 71 (critiquing the notion of "probabalistic" patent rights as a "semantic game" that could be played to "redefine any other form of property," for example, considering a deed to land as "only a 'right to ask a court to bar trespassers" or title to a car as 'only a right to ask a court' for a judgment in conversion").

[21] *See Cardizem CD*, 332 F.3d at 907-908 (noting that pioneer Hoechst Marion Rousel ("HMR") paid generic Andrx almost $90 million to stay off the market for 11 months and explaining that there was "simply no escaping the conclusion that the Agreement [between pioneer and generic] . . . was, at its core, a horizontal agreement to eliminate competition in the market for [HMR's] Cardizem CD throughout the United States, a classic example of a *per se* illegal restraint of trade"); *Schering-Plough [FTC]*, at 26 (reasoning that "[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").

[22] We take the point that the term "reverse payments," is viewed by some as loaded. It is, however, less pejorative than other terms, e.g., "exit" or "exclusion payments." More importantly, as explained below, our point is that they do *not* work out the same way as situations in which the alleged infringer pays the patent holder plaintiff, albeit less than what the plaintiff might have hoped to achieve in damages.

[23] *See, generally*, the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et. seq.*

[24] *See Valley Drug*, 344 F.3d at 1296, citing 21 U.S.C. § 355(a); *see also Terazosin II*, 352 F.Supp.2d at 1287.

[25] *See Terazosin II*, 352 F.Supp.2d at 1287.

[26] *Id.*, citing 21 U.S.C. § 355; *see also Cipro II*, 261 F.Supp.2d at 191-92.

[27] Hatch-Waxman also permitted the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was awaiting FDA approval. *See Valley Drug*, 344 F.3d at 1296, citing 35 U.S.C. § 156.

[28] *See Terazosin II*, 352 F.Supp.2d at 1288; *Cipro II*, 261 F.Supp.2d at 192-93, citing 21 U.S.C. § 355(j)(2)(A)(iv).

[29] *See Terazosin II*, 352 F.Supp.2d at 1288; *Cipro II*, 261 F.Supp.2d at 192-93, citing 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.94(a)(12)(A)(4). In this article, we refer to an ANDA that is filed with a Paragraph IV certification as an "ANDA IV."

[30] *See Terazosin II*, 352 F.Supp.2d at 1288; *Cipro II*, 261 F.Supp.2d at 192-93, citing 21 U.S.C. § 355(j)(2)(B).

[31] *See Valley Drug*, 344 F.3d at 1297, citing 21 U.S.C. § 355(j)(5)(B)(iii), 21 U.S.C. § 355 (j)(5)(B)(iii)(I); *see also Terazosin II*, 355 F.Supp.2d at 1288-89. If, on the other hand, the court finds the patent valid and infringed, the approval date is set for a date on or after the patent's expiration. *See Valley Drug*, 344 F.3d at 1297, citing 21 U.S.C. § 355(j)(5)(B)(iii)(II) and 35 U.S.C. § 271(e)(4)(A).

[32] Approval of an ANDA IV is automatically delayed if another ANDA IV was previously filed based on the same brand-name drug. *See Valley Drug*, 344 F.3d at 1297, citing 21 U.S.C. § 355(j)(5)(B)(iv). Prior to January 1, 2004, the effective date of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Reform Act"), the delay lasted until 180 days after the earlier of (1) the first commercial marketing of a generic under the previous ANDA or (2) the date a court hearing the infringement action brought against the previous filer held the patent invalid or uninfringed. *Id.* at 1297-98, citing 21 U.S.C. § 355(j)(5)(B)(iv). The Medicare Reform Act makes the 180-day exclusivity period contingent on the first ANDA filer marketing its drug by the earlier of 75 days after FDA approval or 30 months after the date of the ANDA filing. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I). Accordingly, there is now less incentive for a pioneer to condition settlement with a first ANDA filer on the generic's agreeing not to waive and/or to defend its 180-exclusivity period. On the other hand, there is greater incentive to settle individually and *seriatim* with subsequent generic ANDA filers.

[33] For example, imagine a situation where a clearly invalid or unenforceable patent is used as the excuse for a settlement that bars the generic from entering until the day before the patent would have expired any way; or a license deal made under such onerous royalty terms that it constitutes a ruse to bar competition. Such settlements obviously could benefit the brand company by avoiding competition it would otherwise face, but unless there are special circumstances (such as logrolling in which one company benefits from one deal while another benefits from a second), it is not obvious what the generic company's incentive is to agree to them without money changing hands.

[34] In July 2002, the FTC issued a study of Hatch-Waxman patent litigation and settlements from 1992-2002 entitled *Generic Drug Entry Prior to Patent Expiration: An FTC Study* ("2002 FTC Study"). [The 2002 FTC Study may be found on the Commission's website at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.] The study noted the prominence in the Hatch-Waxman process of "blockbuster" drugs, which it defined as drugs that appeared in the top 20 ranked by annual gross sales during one of the years covered in the study. Mentioned by name were such widely-prescribed drugs as Cardizem CD, Cipro, Claritin, Neurontin, Paxil, Pepcid, Prozac, Xanax, Zantac, Zocor, and Zoloft. *See* 2002 FTC Study at ii.

[35] Judge Trager concedes in *Cipro III* that "the patents most likely to be the subject of exclusion [or reverse] payments would be precisely those patents that have the most questionable validity," but then discounts this admittedly "well-taken . . . point" by suggesting that the strategy of buying off generic competitors only works for the first competitor but not to ward off subsequent challenges. *See Cipro III, slip op.* at 45-46. Judge Trager's confidence seems ill-founded. The published case law and the logic we discuss here suggest that brand-name companies have ample incentive, resources and will to reach reverse-payment with several generics at the same time, particularly when high-margin, blockbuster drugs are at stake and their patent position is suspect. *See, e.g., Schering-Plough*, 2005 WL 528439 at *1-3 (discussing successive settlements reached in 1997 between pioneer Schering-Plough and generic challengers Upsher and ESI); *Valley Drug*, 344 F.3d at 1298-1300 (describing nearly simultaneous settlements between brand-name Abbott and generics Zenith and Geneva).

[36] To some extent, brand-name companies can be expected to refrain from wholly-frivolous patent defenses. But they are almost certain to take up the invitation to file lawsuits in the types of cases that give rise to reverse-payment disputes. Few companies can be expected to concede without a fight that their patents on blockbuster drugs afford no protection. And

Continued on next page

Continued from page 15

Hatch-Waxman provides brand-name companies the powerful incentive of a potential 30-month delay in competition for filing a complaint. The 2002 FTC Study involving all drugs (even those that are not blockbuster) found that brand-name companies sued the first generic applicant 72 percent of the time, i.e. regarding 75 out of 104 possible drugs. *See* 2002 FTC Study at 14-15.

[37] The relative strength of the generics' patent positions and the weakness of the pioneers' is suggested by the fact that generics prevailed in 73 percent of the cases in which a court resolved the patent dispute, while the brand-name companies prevailed 27 percent of the time. *Id.* at 16.

[38] *See Schering-Plough*, 2005 WL 528439 at *1.

[39] *Id.*

[40] Most prominently, an Upsher drug called Niacor, a sustained-release niacin product used to reduce cholesterol. *Id.* at *1-2.

[41] In its complaint, the FTC also named ESI Lederle Inc. ("ESI"), a division of American Home Products, another generic manufacturer with which Schering-Plough had settled patent litigation involving K-Dur 20. Before the trial by the ALJ or subsequent proceedings, American Home Products settled with the FTC and was not a party to the petition for review to the Eleventh Circuit. *Id.* at *3, n.9.

[42] *Id.* at *3.

[43] *Id.* at *4.

[44] On September 29, 2004, the court denied Schering-Plough, Upsher, and ESI's motions to dismiss the complaint and for judgment on the pleadings as to most of the claims, including plaintiffs' federal antitrust claims. *See In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517, 551-552 (D. N.J. 2004).

[45] *See Valley Drug*, 344 F.3d at 1298. In 1998, according to the FTC, Hytrin generated $540 million in sales, accounting for more than 20 percent of Abbott's net sales of pharmaceutical products in the United States. *See Terazosin I*, 164 F.Supp.2d at 1343.

[46] *See Valley Drug*, 344 F.3d at 1298.

[47] Another company, Zenith Goldline Pharmaceuticals ("Zenith"), filed an ANDA in 1994 for a terazosin hydrochloride drug subject to Abbott's Patent No. 4,215,532 (the "'532" patent) and was subsequently involved in litigation with Abbott. In 1998, Abbott reached a settlement agreement with Zenith, under which Zenith agreed not to sell any generic terazosin hydrochloride product unless another generic came into the market first or until the '432 patent expired in 2000. In return, Abbott agreed to pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter until March 1, 2000. *Id.* at 1300 and n.13. After the district court granted partial summary judgment to plaintiffs in *Terazosin I*, Zenith came to a tentative settlement of the antitrust litigation and was not a party to the appeal of that decision to the Eleventh Circuit. *Id.* at 1296, n.1.

[48] *Id.* at 1299. Abbott's Patent, No. 5,504,207 (the "'207 patent"), claimed a method of preparing anhydrous terazosin hydrochloride and was due to expire in October 2014. *Id.* at 1299, n.10.

[49] *Id.* at 1300.

[50] *Id.* at 1301. Abbott's petition for certiorari was denied in January 2000. However, these events did not terminate Abbott's agreement with Geneva; the companies apparently terminated the agreement in August 1999 on their own in response to an FTC investigation. *Id.*

[51] *Id.* at 1301-02.

[52] On remand from the *Valley Drug* decision, plaintiffs focused their challenge to the Abbott-Geneva settlement agreement on the prohibition of Geneva's marketing its generic terazosin hydrochloride products until the conclusion of the appeals in the patent infringement litigation. *See Terazosin II*, 352 F.Supp.2d at 1294-95.

[53] *Id.* at 1307-10, 1312-15.

[54] *See Schering-Plough*, 2005 WL 528439 at *6 (explaining that "[i]n the context of patent litigation, . . . the anticompetitive effect [of a pioneer-generic settlement agreement] may be no more broad than the patent's own exclusionary power"); *Valley Drug*, 344 F.3d at 1305 (stating that "[t]o the extent that [the generic drug companies] agreed not to market admittedly infringing products before the [pioneer's] patent expired or was held invalid, the market allocation characterization [by which the district court held the agreement a *per se* antitrust violation] is inappropriate").

[55] *See, e.g., Schering-Plough*, 2005 WL 528439 at *14.

[56] *See, e.g.*, Schildkraut, *Patent-Splitting Settlements*, 71 ANTITRUST L. J. at 1061-65.

[57] *Id.* at 1061-62. Schildkraut poses the hypothetical of two companies which, in the year 2000, negotiate the resolution of a dispute over a patent that expires in 2010. He posits that, if the patentholder has a 50 percent chance of prevailing, the mean expected outcome of litigation is that the alleged infringer will enter the market in 2005. However, a risk-averse patent holder might permit entry in 2004 rather than risking losing more years of exclusivity and then, in exchange for making a reverse payment, might still get to a settlement of entry somewhere between 2004 and 2005 that represents a better result than the one expected in litigation.

[58] *See Valley Drug*, 344 F.3d at 1308.

[59] This argument tends to be asserted a fair amount on ABA panels. Schildrkraut makes the more sophisticated points that a "cash-strapped" patent infringer or generic may be specially motivated to litigate and to demand reverse payments in patent litigation settlements and that settlement with such a generic "is impossible without a reverse payment." *See* Schildkraut, *Patent-Splitting Settlements*, 71 ANTITRUST L.J. at 1063.

[60] *See Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp.2d 986, 994 (N.D. Ill. 2003) (opinion by Seventh Circuit Judge Posner sitting by designation, arguing, in *dicta*, that a prohibition on reverse payments would "reduce the incentive to challenge patents by reducing the challengers' settlement options should he be sued for infringement, so might well be thought anticompetitive").

[61] *See Valley Drug*, 344 F.3d at 1309 (stating that the court "cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements").

[62] *See, e.g., Asahi*, 289 F.Supp.2d at 992 (cautioning against the inhibiting effect on patent settlements of third parties' "haul[ing] the parties to the settlement over the hot coals of antitrust litigation").

[63] Even the Eleventh Circuit acknowledges this point: "It may be that the size of the payment to refrain from competing . . . raises the suspicion that the parties lacked faith in the validity of the patent, particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim . . ." *Valley Drug*, 344 F.3d at 1309-10.

[64] *See Schering-Plough*, 2005 WL 528439 at *7; *Valley Drug*, 344 F.3d at 1312.

[65] *See Valley Drug*, 344 F.3d at 1308.

[66] *See Terazosin II*, 352 F.Supp.2d at 1317. Moreover, Judge Seitz was plainly skeptical that Abbott and Geneva were not well aware of the weakness of Abbott's patent position. *Id.* at 1306 (explaining that the "focus of analysis . . . is not whether the [patent] litigation was frivolous and baseless, but rather on whether, upon Geneva's assertion of 'substantial questions' regarding the validity of the '207 patent, Abbott was able to demonstrate that Geneva's arguments were substantially without merit" and concluding that "Abbott's challenge to Geneva's 'on-sale bar' argument was weak and unlikely to result in a District Court finding that the '207 patent was valid").

[67] 382 U.S. 172 (1965).

[68] *See Valley Drug*, 344 F.3d at 1308-09, citing *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 994-96 (9th Cir. 1979); *Loctite Corp. v. Ultraseal, Ltd.*,

Continued on next page

Continued from page 16

http://www.ftc.gov/os/2004/01/040106pharmrules.pdf. In early 2005, the FTC's Bureau of Competition published a report on the Commission's website summarizing the number and type of agreements received during Fiscal Year 2004, ending September 30, 2004. That report may be found at http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf. The FTC's statistics are concededly limited. The Bureau of Competition indicates that it does not have settlements of litigation that were entered into between June 2002 and January 2004. Nevertheless, its report gives some indication that reverse-payment settlements do not occur all that frequently.

[75] *See Valley Drug*, 344 F.3d at 1312 (holding that, on remand, provisions of the settlement agreements "found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probably anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act"); *id.* at 1313 (noting that some provisions may be "so obviously anticompetitive that they can be condemned as illegal on the evidence so far adduced . . .").

[76] This may not always be true. The scope of a patent is itself an issue potentially subject to dispute.

As Judge Seitz commented in *Terazosin II*, "It is well known that 'parties to an intellectual property dispute have a strong incentive to enter into agreements that maximize their own interests but disserve the public's interest with respect to either competition or innovation.'" *Terazosin II*, 352 F.Supp.2d at 1308-09, quoting Hovenkamp, *et. al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. at 1722.

[78] *Supra*, Section III.

[79] *See Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1, 19-20 (1979).

[80] *In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517, 532 (D. N.J. 2004). This question is also at the heart of the FTC's Final Order and Opinion in *Schering-Plough [FTC]*:"The issue is whether these unconditional payments [by Schering-Plough to Upsher] were likely to have anticompetitive effects because they delayed entry beyond the dates that would have been agreed upon in the absence of the payments." *Schering-Plough [FTC]*, Opinion at 7.

[81] *See Terazosin II*, 352 F.Supp.2d at 1317.

[82] *Id.*

[83] *Id.* at *11 ("To borrow from the Commission's own words, we think its conclusion that Niacor was not worth $60 million, and that settlement payment was to keep Upsher off the market is 'not supported by law or logic'"); *id.* at *12 ("We think that this record [of the proceedings by the FTC's ALJ] consistently demonstrates the factors that Schering considered, and there is nothing to undermine the clear findings of the ALJ that this evidence was reliable").

[84] *Id.* at *11.

[85] *Id.* at *9.

[86] *Id.* at *16 (quoting *Cipro II*, 261 F.Supp.2d at 251).

[87] *Id.* at *15.

[88] *See Cipro II*, 261 F.Supp.2d at 208 ("the new Hatch-Waxman scheme . . . allows a generic manufacturer to seek entry into a market without incurring damages for infringement").

[89] *See Schering-Plough*, 2005 WL 528439 at *15.

[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] Nor is it entirely fair. As noted in Section II.A.2 above, in *Valley Drug*, the Eleventh Circuit relied on an assumption that preventing reverse-payment settlements would impede research and development. This assumption was no more based in empirical evidence, and probably even more difficult to test, than the FTC's assumption that parties inclined to settle would find a different way to do it. The truth is that all of these discussions – our own included – rely a fair amount on armchair theorizing.

[94] *See BMI*, 441 U.S. at 19-20.

[95] *See NCAA v. Board of Regents*, 468 U.S. 85, 100 (1984).

[96] *See Cardizem CD*, 332 F.3d at 907 (citing *NCAA*, 468 U.S. at 100) ("[h]orizontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal per se' approach because the probability that these practices are anticompetitive is so high").

[97] Actually, Judge Posner considers all rules to be bright-line and the term "*per se* rule" therefore redundant. *See* Richard A. Posner, Antitrust Law 39 (2d ed. 2001).

[98] *Id.*

[99] *See Level 3 Communications, Inc. v. Federal Ins. Co.*, 168 F.3d 956, 958 (7th Cir. 1999) (applying this logic in interpreting an insurance policy). ■

Published in Antitrust Health Care Chronicle, Volume 19, No. 2, Summer 2005.
© 2005 by the American Bar Association. Reproduced with permission. All rights reserved.
This information or any portion thereof may not be copied or disseminated in any form or by any means or stored in an electronic database or retrieval system without the express written consent of the American Bar Association.

OFFICE OF
THE COMMISSIONER

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

February 8, 2007

The Honorable Patrick Leahy
Chairman
Judiciary Committee
United States Senate
Washington, D.C. 20510

Dear Senator Leahy:

I am pleased to respond to your questions following the recent hearing on "Paying off Generics To Prevent Competition with Brand Name Drugs: Should it be Prohibited."[1] You forwarded the following comments and questions, which I have attempted to answer below. In addition, there were certain questions posed to me at the hearing to which I am also responding.

Written Questions from Senator Kohl

Q: At the hearing you were asked questions about a variety of approaches to solve the problem of reverse payment patent settlements – settlements in which the brand name drug manufacturer pays the generic company in return for a promise by the generic company to keep its generic drugs off the market. You were asked about my legislation, the Preserve Access to Affordable Generics Act (S. 316), which imposes a bright line rule banning these settlements, as well as other approaches proposed by other Senators which would examine these settlements on a case by case basis. Which approach do you believe will best solve the problem to competition posed by these settlements? Do you agree with me that the bright line rule of S. 316 is the best way to ensure a competitive pharmaceutical market?

A: I believe that the bright line approach is the most effective way to protect consumers and competition. On one hand, the harm caused by these agreements is substantial and, absent a bright-line ban, difficult to prevent; on the other hand, history shows that when deprived of the ability to use exclusion payments, brand-name and generic drug companies often reach procompetitive settlements. A bright-line rule will have little or no effect on procompetitive settlements, while eliminating a substantial number of extremely harmful settlements.

---

[1] The written testimony submitted for the January 17, 2007 hearing reflects the views of the Federal Trade Commission ("FTC" or "Commission"). However, my responses to these post-hearing questions reflect my own views and do not necessarily reflect the views of the Commission or of any other Commissioner.

Absent a legal prohibition, it will nearly always be in both the brand's and generic's interests to settle their litigation with the brand paying the generic to delay entry for as long as possible. As far as I know, no one has disputed the existence of these powerful incentives. Indeed, even the *Tamoxifen* court – despite blessing such settlements – understood that they created a windfall for the companies at the expense of consumers. 466 F.3d 187, 208 (2d Cir. 2006).

There is an urgent need for Congress to adopt a clear rule that will stop the use of exclusion payments. Under the current case by case approach, recent court decisions have: (1) viewed exclusion payments as a "natural by-product" of the Hatch-Waxman framework; (2) given overriding weight to benefits of settlement; and (3) assumed that – absent fraud or a sham lawsuit – drug patent holders are entitled to pay a generic firm not to compete as long as the exclusion does not exceed the nominal scope of the patent. Unless Congress adopts a clear standard that rejects the lenient treatment of exclusion payments, it is difficult to see how to stop the upsurge in drug patent settlements with payments to the generic and restraints on generic entry. Consequently, the proposal that settlements in Hatch-Waxman patent infringement cases be reviewed and approved by the judge in the patent case – whether under the antitrust laws or some general public interest standard – seems unlikely to protect consumers.

S. 316 provides a clear standard that directly addresses the fundamental problem: brand-name drug firms compensating a generic challenger to accept a settlement with an entry date that the generic firm would not accept based on the strength of the patent alone. S. 316 would essentially take payments to the generic out of the settlement negotiation. It would return the industry to the conditions prevailing during 2000-2004, when companies settled their patent cases, but did so without exclusionary payments.

Questions from Senator Feinstein

Q: Your testimony and the FTC's prepared statement expressed support for the intent of Senator Kohl's proposed legislation. What changes, if any, would you propose to the bill?

A: First, I suggest that the Committee add a provision to address the "bottleneck" problem described in the Commission's testimony. The operation of the Hatch-Waxman Act's 180-day exclusivity creates the potential for a settlement between a brand-name company and a first generic filer to create a bottleneck that prevents *any* generic competition, whether or not there has been an exclusion payment. A subsequent generic filer that faces a bottleneck but has not been sued, or has been offered a covenant not to sue, has no mechanism to relieve that bottleneck. The bottleneck thus postpones consumer access to a lower-priced generic version of the drug, a result that is contrary to the goals of the Hatch-Waxman Act.

Second, there are some technical changes that could clarify what types of arrangements fall within the scope of the ban. For example, it may be helpful to clarify, either in the law or in the legislative history, that the provision allowing settlements that do no more than grant the right to

market the ANDA product includes a settlement in which a generic that has already launched its product agrees to exit the market and the brand agrees to waive any possible damage claims for past sales. In addition, the bill could clarify that it does not preclude settlements where the value given is the right to sell the ANDA product before expiration of a non-patent statutory exclusivity period (such as the exclusivity granted for testing of drugs for pediatric use).

Finally, the legislative process often results in fine-tuning of even very thoughtful initial proposals. As this bill moves through the Senate, we want to work with your Committee.

Q: The Eleventh Circuit held in the Schering-Plough case that there was no antitrust violation when a settlement between a name brand pharmaceutical company and a generic manufacturer prevented the generic company from marketing the competing generic product – because the settlement did not stifle any competition beyond what the patent already prohibited. To reach this conclusion, the court relied on a presumption that patents are valid.

To reach a conclusion that such a settlement is inherently anticompetitive, do we have to assume that the patent is ***not*** *valid?*

If yes, why should we start from an assumption that the patent in question is not valid?

A: No, the conclusion that exclusion payment settlements harm consumers does not rest on any assumption that the brand name drug company's patent is invalid or not infringed. Indeed, it does not rest on any assumptions or legal presumptions about the likely outcome of the parties' patent dispute. Rather, it is premised on the critical fact that, at the time of the agreement, the outcome of the patent case was uncertain, but the brand company "bought" additional protection beyond that uncertainty.

This approach is in keeping with two well-established antitrust principles. First, the competitive effects of an agreement are to be assessed as of the time it was entered. *See, e.g.*, XI Herbert Hovenkamp, ANTITRUST LAW ¶ 1901, at pp. 185-86 (1998). Second, as the Commission's written statement discusses, antitrust law protects potential, as well as actual, competition. Thus, a payment to induce a potential competitor not to compete is a harm recognized by the antitrust laws. The published economic literature on the topic likewise treats an alleged infringer as a potential competitor. *See e.g.* Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 Rand. J. Econ. 391, 395 (2003).

The Commission's written statement draws an analogy to a scenario in which the brand-name drug firm pays a generic company to withdraw its application for FDA approval. Such conduct is harmful to consumers and warrants condemnation, even though we do not know whether the particular application would have been approved, or whether the generic would have succeeded in manufacturing and marketing its product.

Put another way, if you play blackjack in Las Vegas, and then find out the game was fixed, you

have been cheated, even though you cannot prove that you would have won in an honest game. You were deprived of the opportunity of a fair chance.

Consumers are likewise harmed if they lose the prospect of early generic entry that a "fair game" would provide – that is, arms-length negotiations between brand and generic companies, without the distorting effects of payments to induce the generic to agree not to compete. Eliminating such payments will preserve the generic's incentive to seek early entry.

Follow-up to Question Posed by Chairman Leahy at the January 17, 2007 Hearing

Q: Why did the Department of Justice oppose the FTC's petition for certiorari in the Schering case?

A: The Department's brief to the Supreme Court agreed that the appropriate treatment of exclusion payment settlements is an important issue that warrants the Court's attention. However, among other reasons, the Department concluded that certain aspects of the 11th Circuit's opinion meant the case was not a good vehicle for the Court to resolve the issues.

I do not know whether the increase in these settlements would affect the Department's position on the issue of exclusion payment settlements. But, the urgency of the issue has become even clearer. The concerns about the likely impact of the 11th Circuit's ruling expressed at the time of the Commission's petition may have been seen as merely theoretical. The evidence released in the report on settlements filed in 2006 – 14 out of 28 settlements and 9 out of 11 settlements with first filers – shows that pay-for-delay tactics are an all too common practice.

Follow-up to Question Posed by Senator Hatch at the January 17, 2007 Hearing

Q: Would it be sufficient to remove the ability of parties to a settlement to benefit from the barrier to entry arising from the 180-day exclusivity or is an outright prohibition on "reverse payments" necessary?

A: The 180-day exclusivity rules certainly create an incentive for delayed-entry settlements with the first generic applicant, because the first filer's exclusivity creates, as a practical matter, an insurmountable barrier to entry by later applicants. Certain changes to the rules governing the 180-day exclusivity could reduce the current incentives that make it so attractive for brand-name companies to pay substantial sums to the first generic applicant to settle. Such changes, however, by themselves would not eliminate the incentives for drug companies to use exclusion payments to settle.

The incentives to settle with exclusion payments exist wholly apart from the exclusivity period. Those incentives arise from the unique competitive dynamic that exists between branded and generic drugs (stemming in large part from state substitution laws). When lower-priced, generic entry occurs, there is a rapid and dramatic loss to the branded firm that far exceeds what the

generic entrant earns. Consumers reap the savings. Consequently, both brand and generic firms are better off if they share profits and avoid competition.

Although one might expect that, absent the 180-day exclusivity barrier, brand-name firms could not successfully use exclusion payments – on the theory that it would become too expensive for brand-name drug firms to pay off multiple generic applicants – that is not the case. The absence of the exclusivity period would mean the total expected profits of all generic firms likely would be significantly lower than the profits of the first generic entrant, and therefore, so would the level of payment needed to secure agreement to a deferred entry date. In other words, it likely would cost a brand less to pay five generic companies (none of whom has the exclusivity) than pay one filer with the exclusivity.

Even if the law were changed so that settlement by the first filer caused the 180-day exclusivity right to pass to the next generic applicant, and a settling first filer with final FDA approval was prohibited from entering until expiration of the 180-day period – which you suggested in your remarks – the difference between the brand's lost profits and individual generic's profits are so great that the brand would be able to pay off many generic filers before it became unprofitable for the brand to make these payments. Moreover, many products – separate and apart from the patent – are difficult to manufacture or must meet specific regulations. As a result, those products will only have very limited generic entry in any event, meaning the brand may only have to pay-off two or three generic firms.

Nevertheless, it is important to fix both the exclusion payment and bottleneck problems.

Again, I appreciate your concerns about preserving competition in the marketplace and the need to evaluate the role of exclusion payments on competition in the pharmaceutical industries. Thank you for this opportunity to respond to the Committee's questions.

Sincerely,

Jon Leibowitz by MBK

Jon Leibowitz
Commissioner

PhRMA

Billy Tauzin
PRESIDENT AND CHIEF EXECUTIVE OFFICER

February 12, 2007

The Honorable Patrick Leahy
Chairman
Committee on the Judiciary
United States Senate
224 Dirksen Senate Office Building
Washington, DC 20510

ATTENTION: Nikole Burroughs, Hearing Clerk

Dear Mr. Chairman:

Thank you for the opportunity to testify before your Committee at the hearing on "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it be Prohibited?"

Enclosed are responses to the written questions submitted by Committee members.

Sincerely,

Billy Tauzin

Enclosures

Pharmaceutical Research and Manufacturers of America
950 F Street, NW, Washington, DC 20004 • Tel: 202-835-3420 • FAX: 202-715-7052

Answers to Questions Posed to Billy Tauzin after Senate Judiciary Committee Hearing: "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?" (held January 17, 2007)

Senator Kohl's Questions for Billy Tauzin

Q. "At the hearing, you testified that 'I ask you not to shoot the good, while you are trying to kill the bad and ugly.' With respect to pharmaceutical patent settlements, please describe which settlements, in your view, fall in the 'bad' and 'ugly' categories, and which fall within the 'good' category?"

A. My reference to "good", "bad" or "ugly" settlements was not directed at a particular set of facts. Instead, it was meant to convey that each patent settlement should be evaluated individually to determine whether it is likely to harm competition and consumers.

On one hand, a "bad" settlement is one that, taking all relevant facts and circumstances into account, unreasonably restrains competition. Patent settlements in the pharmaceutical industry and other industries have the potential to harm consumers by restricting competition beyond the patent's scope in terms of duration or product range.

On the other hand, a "good" settlement does not restrict competition beyond the scope of the relevant patents. These settlements do not harm consumers, but instead typically benefit them by allowing the accused infringer to enter the market before the patent expires. They also allow innovator and generic companies to avoid the high cost of protracted patent litigation.[1] These settlements advance the federal public policy favoring resolution of disputes by settlements.[2] They also advance the policy encouraging innovation through the reward of patents that can be enforced.

Antitrust law already provides a methodology for federal courts and antitrust agencies to distinguish between "good" and "bad" patent settlements. This kind of analysis can and should be done under existing antitrust standards, and certainly the Federal Trade Commission and the Antitrust Division of the Department of Justice have the opportunity to perform this analysis in the first instance when a pharmaceutical patent settlement agreement (or description of the agreement) is filed with the agencies pursuant to provisions of the Medicare Modernization Act ("MMA").[3] The key is that the analysis should include a case-by-case evaluation of the particular settlement in relation to the situations of the parties and the scope of the patent at issue.

---

[1] *Blonder-Tongue Labs, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 334 (1971) ("[P]atent litigation is a very costly process.").

[2] *See, e.g., McDermott, Inc. v. AmClyde & River Don Castings Ltd.*, 511 U.S. 202, 215 (1994) ("[P]ublic policy wisely encourages settlements.").

[3] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, § 1112, 117 Stat. 2461-64 (2003).

Senator Feinstein's Questions for Billy Tauzin

Q. You argue that it is important for the makers of name-brand pharmaceuticals to retain the ability to enter into pro-competitive settlements.

- ***In what way do you believe that Senator Kohl's proposed legislation would prohibit pro-competitive settlements?***

A. S.316 appears to prohibit any patent settlement in which the innovator company transfers "anything of value" to the generic and the innovator and generic agree on a date when the generic will enter the market (even if that date is before the patent's expiration date). This broad prohibition would chill all settlements – in fact, it appears to cover almost any settlement agreement because a generic challenger logically would only settle in exchange for something of value and all settlements transfer, at a minimum, the value inherent in the release of the claims and defenses.[4] For example, it would even cover settlements involving certain transactions that the FTC has opined should not be banned, such as the waiver of patent infringement damages against a generic for entry that has already occurred.[5]

This chill on settlements would have significant adverse consequences for brand and generic companies and ultimately for consumers. Fewer options for settlement would raise the cost of patent enforcement (and patent challenges) by forcing both sides to incur additional litigation costs. It also could reduce generic manufacturers' incentives to challenge patents in the first place by reducing their options in litigation against patent holders.

A blanket prohibition on the exchange of "anything of value" also would foreclose the ability of innovators and generics to exchange assets that may or may not be involved in the litigation. This would put a straight jacket on the settlement negotiations because parties that have very different views of the merits of the patent case and different risk exposure in a given case will lose the ability to license unrelated technology or look for other ancillary business arrangements that could facilitate the parties' efforts to reach and structure a mutually acceptable – and pro-competitive – settlement.[6] Not only would the bill make settlements less likely, but it also would make them less efficient. It also would harm consumers because "Hatch-Waxman settlements . . . which result in the patentee's purchase of a license for some of the

---

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

[5] *See* Prepared Statement of the Federal Trade Commission before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution, January 17, 2007, at 22-23.

[6] The per se ban on payment of "anything of value" to the accused infringer contemplated in S. 316 also would appear to foreclose a settlement in which the patentee pays an amount equal to or less than expected future attorneys' fees and litigation costs. For example, assume that enforcement of a patent through trial and appeal will cost the innovator at least $5 million. In this situation, the innovator should be able to pay $3 million to settle (and thereby avoid additional litigation costs). Indeed, the Federal Trade Commission has issued consent orders allowing patent holders to settle in this manner. *See In re Schering-Plough Corp.*, No. 9297, Opinion of the Commission at 37, www.ftc.gov (Dec. 18, 2003) (citing FTC consent orders expressly allowing settlement payment for litigation costs).

alleged infringer's other products may benefit the public by introducing a new rival into the market, facilitating competitive production and encouraging further innovation."[7]

- ***Is a settlement that prohibits or postpones a competitor's developing or marketing a competing product ever pro-competitive?***

A. Yes, if that settlement is within the patent's scope, and particularly if it allows the generic product to enter the market before the expiration of the patent. Critics of recent brand-generic patent settlements have characterized those settlements as agreements to postpone generic entry and have portrayed business transactions between the brand and the generic that accompany the settlements as "payments for delay." But it is important to remember that, as Bruce Downey of Barr Laboratories explained in his testimony before the Committee, the innovator's patent – not the consideration exchanged as part of a settlement – has the greatest influence over the date of the generic's entry.

Consistent with the antitrust laws, a patent holder may exclude others from producing a patented article or may grant limited licenses.[8] 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. Patents are a crucial factor in pharmaceutical innovation. Patents provide the minimum degree of assurance for investors to risk the capital investment necessary to fund the pharmaceutical discovery and development processes despite the uncertain chances of producing a commercially viable product.

Congress has determined that patents are legally entitled to a presumption of validity.[9] Absent a final judgment that its patent is invalid or not infringed, an innovative pharmaceutical company that has filed a patent infringement action against a generic challenger is not obligated to allow the generic company to enter the market prior to expiration of the patent. Nevertheless, federal court opinions and Federal Trade Commission reports demonstrate that many patent settlements between innovative and generic companies allow the generics to bring their allegedly infringing products to market well before patent expiration.[10] The settlements also may include additional terms or ancillary agreements that facilitate compromise of the dispute over the patented product and often promote competition on other products.[11]

These types of settlements, allowing for enforcement of patents within their scope, do not harm competition. To the contrary, the settlements allow the parties to avoid the costs and uncertainty of litigation and bring generic products to market sooner

---

[7] *Schering-Plough*, 402 F.3d at 1075.
[8] *See, e.g., Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940).
[9] 35 U.S.C. § 282.
[10] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193-96 (2d Cir. 2006); 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 Fiscal Year 2006* (Jan. 2007), at 6, www.ftc.gov.
[11] *See, e.g., Schering-Plough*, 402 F.3d at 1059-61 (discussing settlements in which assets were exchanged).

than if the innovator had succeeded in enforcing its patent through a trial and final judgment. Consumers benefit from this result.

Q. ***In your prepared statement and your testimony, you seemed to oppose Senator Kohl's legislation on the grounds that it would prohibit all settlements in which a brand-name company gives a thing of value to a generic drug manufacturer. Senator Kohl's bill, however, is not that broad: it would only bar settlements that involve both a payment of something of value to the generic and an agreement by the generic to delay the development or marketing of the generic product.***

- ***How would you propose modifying the bill to make it more narrowly targeted at only the settlements that are anticompetitive?***

Antitrust law disfavors per se rules. They are applied only in limited circumstances where conduct is so obviously pernicious that it automatically works against consumers' interests whenever it occurs, even without a case-specific analysis of its competitive impact.[12] The majority of courts that have examined patent settlements involving some transfer of value from the innovative to the generic pharmaceutical company have determined that it would be inappropriate to apply a per se rule to ban all of these settlements.[13] Even the Federal Trade Commission, in its opinion in the *Schering-Plough* case, declined to apply a per se rule.[14] First and foremost, any legislation addressing brand-generic patent settlements should likewise reject a per se ban on a whole category of settlements. As demonstrated in my testimony and in that of Mr. Downey of Barr Laboratories, a per se ban would chill all settlements and likely would have the unintended consequence of decreasing the number of Paragraph IV filings by generic companies (because generics would know that settlement options would be strictly limited and litigating the case through trial may be the only alternative).

The proposed legislation exacerbates the overbreadth of this per se ban by applying it to any patent settlement in which the innovator company transfers "anything of value" to the generic. As noted in my testimony and in response to another of Senator Feinstein's questions, the phrase "anything of value" encompasses nearly all settlement agreements. The following are just a few examples of circumstances where pro-competitive agreements that allow generic entry prior to patent expiration would be swept up in the per se ban against the transfer of "anything of value": (1) when the value that a patentee pays to the accused infringer is consideration for other goods or services unrelated to the allegedly infringing product; (2) when the payment enables the accused infringer to remain a viable competitor; (3) when the payment represents expected future attorney fees and litigation costs that would have been incurred had the parties litigated their dispute through trial and appeal; (4) when the value represents the

[12] *Texaco Inc. v. Dagher*, 126 S. Ct. 1276, 1285 (2006); Antitrust Modernization Committee, Tentative Recommendations at 1.
[13] *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 202-03, 206-07 (2nd Cir. 2005); *Schering-Plough*, 402 F.3d at 1063-65.
[14] *In re Schering-Plough Corp.*, No. 9297, Opinion of the Commission at 14, 86 (Dec. 18, 2003), www.ftc.gov.

waiver of patent infringement damages against a generic for entry that has already occurred.

PhRMA believes that existing antitrust law, combined with the federal antitrust agencies' ability to review all innovator-generic patent settlement agreements under the MMA, safeguards consumers' interests. If Congress is concerned that these safeguards do not sufficiently deter anticompetitive settlements, it could change the filing requirements specified in MMA or potentially create other requirements that will enhance opportunities for judicial and/or agency review of individual settlements. But a case-by-case examination of each settlement compared to the scope of the patent should be the central component of any statutory requirements.

Senator Schumer's Questions for Billy Tauzin

Q. Congressman Tauzin and Mr. Downey, you have each stated that you oppose the legislation before us today. Do you believe that there are any anti-competitive patent settlements?

A. It is possible that a patentee and an accused infringer could structure a patent settlement in such a way as to restrict competition beyond what the innovator's patent lawfully could exclude. An example might be a settlement in which the parties to the patent litigation agree to restrict competition in products that are not alleged to be infringing. The innovator and accused infringer might benefit from that type of settlement, but such profit would come at the expense of competition and consumers. Antitrust agencies and courts have the authority to evaluate and condemn such settlements under existing antitrust laws. The MMA's filing requirements provide additional tools for evaluating patent settlements in the pharmaceutical industry.

Q. [Question for Mr. Tauzin and Mr. Downey] The brand company Cephalon negotiated agreements with four generic companies, including Mr. Downey's company, regarding the sleep medication Provigil. The generic companies agreed to stay off the market until October 2011 in exchange for a total of $136 million in payments. Cephalon paid $136 million in order to save six years worth of revenues for a drug that makes $500 million a year. Can you tell me how the consumer benefited from this settlement?

A. As President and CEO of PhRMA, I did not testify on behalf on any particular company, but rather offered a broad perspective on the importance of innovation and patents in the life sciences industry and on the need for public policies that foster innovation. In addition, it would be inappropriate for me to offer any opinion on specific settlements involving PhRMA's member companies. Having said that, it seems to me that the assumptions underlying this question may not be consistent with public reports about the settlements. Specifically, Cephalon has disclosed in its SEC filings that its various agreements with generic drug companies provide for the license to Cephalon of important intellectual property. Cephalon also has stated publicly that the referenced amounts are in exchange for these license grants. Cephalon's public statements

also disclose that the patent covering their product modafinil actually runs until 2014, and that the terms of these settlements allow for generic competition to begin a full three years before patent expiration. Generally, settlements that allow early generic entry may result in substantial savings for consumers because without these settlements competition might well not have occurred until the patent expired.

Response of Michael Wroblewski to Questions Submitted by Senator Dianne Feinstein Following the January 17, 2007 Senate Judiciary Committee Hearing: "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?"

Question: The Eleventh Circuit held in the *Schering-Plough* case that there was no antitrust violation when a settlement between a name-brand pharmaceutical company and a generic manufacturer prevented the generic company from marketing the competing generic product – because the settlement did not stifle any competition beyond what the patent already prohibited. To reach this conclusion, the court relied on a presumption that patents are valid.

> • *To reach a conclusion that such a settlement is inherently anticompetitive, do we have to assume that the patent is* ***not*** *valid?*

Answer: No. It is unnecessary for the plaintiff to offer proof on the underlying merits of the patent dispute, in order to establish whether the agreement is illegal. *Tamoxifen Citrate Antitrust Litigation*, 429 F.3d 370, 388 (2d. Cir. 2005). In determining whether an agreement is unlawful (and not whether there is consumer harm), courts must assess the agreement at the time it was made to determine whether it was "unreasonable," *i.e.*, whether it likely delayed generic entry beyond the date that would have been provided in a differently crafted settlement. The law distinguishes between a determination of whether an agreement is anticompetitive and whether consumers have been harmed by the agreement after the fact. It is in this latter determination in which patent validity or infringement would be at issue.

In the *Tamoxifen* case, the court dismissed an antitrust challenge to an agreement that settled a patent dispute between a brand and generic company, with terms that included a reverse payment from the brand to the generic company. In return, the generic company agreed not to market its own version of the Tamoxifen drug prior to the expiration of the patent, but instead took a license to sell product manufactured by the pioneer. In that case, however, the validity of the brand company's patent was the crucial issue in the underlying patent dispute and, subsequent to the settlement in question, the brand company's patent was successfully defended in litigation with three other generic challengers. In a private action for damages, after the fact, the *Tamoxifen* court had good reason to believe that the settlement did not ultimately cause consumer harm.

The simple logic behind distinguishing between legality and damages can be illustrated in another context. If, for example, a firm entered into an agreement with a would-be new entrant in which the new entrant agreed to delay or forgo introduction of its new product, it would be no defense for the firm already in the market to argue that the new product *might* not have succeeded in the market. Similarly, the existence of such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition, by guaranteeing that the new product will not be introduced.

• *If yes, why should we start from an assumption that the patent in question is not valid?*

Answer:

Not applicable, see answer above.

Response of Michael Wroblewski, Consumers Union to Senator Kohl's Follow-up Questions from Hearing on "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?"

Question 1: Do you have an estimate of how much consumers are paying as a result of these "reverse payment" patent settlements which have the effect of keeping generic competition off the market?

Answer: Consumers Union does not have a dollar amount of consumer harm because of these "reverse payment" settlements because identity of the drug products is not publicly known.

Consumer Reports has estimated that individual consumers can save hundreds of dollars per year if they fill their prescriptions with generic drugs for just one class of drugs. For example, consumers who need medicine to lower their cholesterol could save up to $1,800 per year.[1] This amount varies depending upon the identity and number of prescription drugs a consumer takes.

Question 2: In your view, are there any circumstances in which consumers are benefited by a patent settlement in which a generic firm agrees to keep its drug off the market in return for a cash payment from a brand name manufacturer?

Answer: No, I can think of almost no circumstances in which in the long run consumers benefit from these payments. If Congress believes that there are such circumstances, the legislation could be amended so that the settling parties could petition the FTC for approval of patent settlement agreements containing reverse payments.

Brand and generic companies argue that settlements with reverse payments permit generic entry prior to patent expiration, in some cases several years in advance of patent expiration. *See* Testimony of Bruce L. Downey at 2, Senate Committee on the Judiciary Hearing, "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?" (Jan. 17, 2007). I believe two reasons undermine this argument.

First, absent the reverse payment, the parties could find another basis on which to settle the case. For example, depending upon the strength of the patent, the parties could negotiate an earlier generic entry date (*i.e.,* a brand company with a weak patent case may be willing to negotiate an earlier entry date than it would if it also made a reverse payment to the generic company). Indeed, the FTC data for FY 2004 and 2005 (when it was thought to be illegal to use reverse payments) showed that brand and generic companies found ways to settle patent litigation, just not with a reverse payment.

---

[1] "New Generic Statins Mean Big Savings for Consumers Needing Cholesterol Reduction, Consumers Union Best Buy Drugs (June 22, 2006), available at http://www.consumersunion.org/pub/core_health_care/003557.html.

Second, if the brand and generic companies cannot agree on a settlement without a reverse payment, the public interest in speeding market entry for generic drugs favors a court decision in the patent litigation case. The FTC 2002 Generic Drug Study shows that generic companies won 73% of their patent challenges in those cases in which a court ruled on patent validity or infringement. Even if the generic success rate were lower (*e.g.*, 50%), generic entry is likely to occur earlier than when the brand and generic companies privately decide when generic entry should occur.

Question 3: The FTC reports that in the year after the two court decisions allowing these "reverse payment" patent settlements, half of all patent settlements contained terms in which the brand name company paid the generic money in return for the generic's agreement to keep its drug off the market. The year before the court decision, no patent settlements contained such terms. Doesn't this data show that such "reverse payment" settlements are likely to become increasingly common unless our legislation is enacted?

Answer: Yes, the FTC's FY 2006 data show that unless your legislation is enacted, there will continue to be settlements that keep generic drugs off the market. Indeed, the FTC's recent data shows history repeating itself. Prior to the FTC's legal challenges to these types of agreements, there were a substantial number of agreements with reverse payments. The FTC's 2002 Generic Drug Study showed that of the 20 final settlements between brand name and generic companies between 1992 and 2002, nine contained reverse payments. FTC Generic Drug Study at 28 (Table 3-1). The delay of generic entry ranged from 4 months to 10 years. The 9 brand-name drugs subject to these agreements had annual sales, in the year the agreement was made, that ranged from less than $100 million to over $1 billion. As your question notes, these types of agreements have reappeared.

Jan-16-07 01:48pm From-BARR LABS DC OFFICE 2026383386 T-594 P.002/011 F-186

SUBMISSIONS FOR THE RECORD

TESTIMONY OF

BRUCE L. DOWNEY

CHAIRMAN AND CEO, BARR PHARMACEUTICALS, INC.

"Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?"

BEFORE THE

JUDICIARY COMMITTEE
U.S. SENATE, CONGRESS OF THE UNITED STATES

JANUARY 17, 2007

* * * * *

Chairman Leahy, Ranking Member Specter, and members of the Committee, my name is Bruce Downey and I am the Chairman and Chief Executive Officer of Barr Pharmaceuticals, a leading generic pharmaceutical company.

I want to thank you for convening this hearing and for allowing me to express my Company's views on issues so vital to the continued success of the generic pharmaceutical industry – an industry that saves consumers and taxpayers literally billions of dollars each year in prescription drugs costs. Indeed, no other industry has made, or continues to make, a greater contribution to affordable health care than the generic pharmaceutical industry.

INTRODUCTION

Barr has always been deeply committed to providing the public with affordable generic drug products, and to do so as expeditiously as possible under the circumstances. Barr has long championed legislative measures that would expedite generic market entry. Similarly, Barr has steadfastly fought against measures that would impede the progress made by the 1984 Hatch-Waxman Amendments and the 2003 Medicare Modernization Act ("MMA").

The proposed legislation, which would stifle a generic company's ability to resolve patent disputes is one such measure. The simple fact is that, in some instances, litigation settlements turn out to be the means by which consumers gain

Jan-16-07 01:48pm From-BARR LABS DC OFFICE 2026383386 T-594 P.004/011 F-186

access to generic drugs before patent expiration. Indeed, patent litigation settlements are the sole means by which the public can be *guaranteed* generic access prior to patent expiration

The courts have recognized that parties to a legitimate dispute concerning the scope or validity of a patent can reach a settlement that involves consideration other than (or in addition to) a grant of early market entry to the patent challenger, and that such settlements do not implicate the antitrust laws, unless the settlement itself extends the scope or duration of the patent. Hence, patent holders in all industries can and often do enter into patent litigation settlements that involve an explicit or implicit flow of consideration from the patent holder to the patent challenger without subjecting themselves to antitrust risk.

The proposed legislation would not change this rule for most industries. It would allow patent holders and challengers in the automotive or computer fields to continue to settle their cases without requiring the patent holder and challenger to litigate rather than accept consideration in settlement. However, it would adopt a special rule that patent holders and challengers in the pharmaceutical industry alone would be restricted, in that the only settlements they could lawfully entertain would be those in which the patent holder grants early entry as the only consideration for the settlement.

Because the proposed legislation would effectively undermine the rights of inventors in the pharmaceutical arena, it will discourage innovation at a time when it is most needed. It will also discourage vigorous challenges of patents, because generic companies will lack the flexibility to settle some cases once they are filed. In sum, I am concerned that the legislation would discourage pro-competitive patent settlements, discourage patent challenges, and ultimately reduce, not increase, consumer benefits.

On the other hand, there is a potential issue with regard to pharmaceutical patent settlements that could be addressed by legislation. One protection that consumers typically have when patent disputes are settled is that other competitors may still litigate the validity of the disputed patent. When Congress enacted the MMA, it included a provision that was intended to permit ANDA applicants to bring a declaratory judgment action against the patent holder when the patent holder failed to sue the ANDA applicant. This provision would have ensured that all ANDA applicants would have the opportunity to litigate the merits of the patent with respect to their products. Unfortunately, the Federal Circuit has adopted a narrow interpretation of the provision that prevents ANDA applicants from bringing a declaratory judgment action in many circumstances. This may mean that an innovator can settle a patent suit with the first ANDA applicant, decline to initiate litigation against other generics that have filed ANDAs, and effectively

prevent future patent challenges. Barr is ready to work with Congress to draft legislation that would address this problem related to innovator-generic settlement, without undercutting the important incentives to challenge innovator patents.

DISCUSSION

A. Generic Companies Have Been Able To Achieve Combination Settlements That Significantly Advance Competitive Entry.

Litigation settlements that guarantee generic market entry prior to patent expiration are inherently pro-consumer. The settlements with which I am most familiar have, in fact, guaranteed that a lower-priced drug product could enter the market a total of nearly 28 years prior to patent expiration. My company, Barr, was able to settle our litigation over the Cipro patent and secure early generic entry when *four* subsequent challengers all *lost* their cases.[1] Thus, with the benefit of hindsight, if Barr had not settled, it is pretty clear there would have been *no* benefit to consumers -- we would have lost. Allowing us to settle on terms to which Barr and the patent holder could agree thus secured a pro-competitive result. Similarly, we settled our patent litigation regarding tamoxifen to introduce a competing product years before patent expiration, despite the fact that the patent was later upheld in subsequent litigation. In short, these settlements all provided value to the

[1] *See Bayer AG v. Schein Pharms., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001) (rejecting validity challenges by Mylan and Schein on summary judgment), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002); *Bayer AG v. Carlsbad Tech., Inc.*, No. 01CV0867-B (S.D. Cal. June 7, 2002 and August 7, 2002) (rejecting Carlsbad's validity challenge after bench trial); *Bayer AG v. Ranbaxy Labs, Inc.*, C.A. No. 98-4464 (D.N.J. Oct. 29, 1999) (dismissing as moot Ranbaxy's challenge).

consumer that *would not have been achieved* if the generics had proceeded to litigate and lose.

Barr's settlements and those of most other generic companies of which I am aware have included a significant advance in the date of launch of the generic product, as compared to the expiration of the patent. Generic companies are strongly motivated to achieve early entry into a patent protected market, because it enables them to sell a product with much higher margins than most generic products. Generic companies also want to obtain that entry sooner rather than later, because the value of early entry diminishes over time due to uncertainty over future market conditions.

Brand companies are obviously reluctant to grant immediate early entry, as it is the most expensive form of settlement consideration they can offer. A grant of early entry is tantamount to the branded company losing the litigation on the date of early entry, or the generic company winning the case on the date of early entry. Even if the branded company receives a royalty from the generic company, it still incurs a significant loss, as the royalty on lower-priced generic products will be substantially lower than the branded company's profits on the branded drug. However, branded companies are usually willing to allow early entry at a later point in time, as it allows them the opportunity to replace the lost profits with sales of other products in development.

Consideration in addition to early entry can be useful in bridging the gap between the generic company's proposed entry date and the branded company's proposed entry date. A branded company that is dead set against an earlier entry date may nevertheless be willing to provide economic value other than early entry in order to persuade the generic company to accept a later entry date. When this occurs, consumers win, because they obtain the market advantage of guaranteed early entry that may well not occur if the case were litigated to its final conclusion. The public, without question, benefits from the pre-patent expiration marketing of more affordable drug products.

B. The Proposed Legislation Will Discourage Pro-Consumer Settlements And Discourage Hatch-Waxman Patent Challenges.

Restricting the allowable settlement consideration will discourage pro-competitive settlements. The proposal seems to assume that the settlement of Hatch-Waxman litigation for money or other consideration "harms" consumers, because in the absence of such consideration, the brand-name company would settle by permitting the generic drug company to introduce its competing product even earlier. That conclusion is wrong. The proposed legislation would in fact harm the public by chilling patent challenges animated by the Hatch-Waxman Act.

Contrary to the proposal's easy assumption that a monetary settlement could always be converted into a time period of early entry, other consideration will often be essential to allowing the parties to a patent dispute to reach agreement.

First, the parties will often be unable to agree upon an acceptable entry date because the brand-name drug company and the generic challenger have substantially different perspectives on the relative risks of the litigation. In order to agree to settle on an entry date alone, the parties would need to have similar views on the outcome of the litigation. If both parties believe they are likely to prevail – as can often be the case – then the generic company will insist on an early entry date to which the branded company simply will not agree. Again, early entry is tantamount to a victory for the patent challenger and a defeat for the patent holder. In contrast, parties may be able to settle litigation that they both believe they are likely to win if their settlements can include consideration other than the entry date alone.

Second, the parties may have different perspectives on future market conditions. The branded company may believe that its product will continue to grow, such that it will be providing significant future value with its proposed entry date. The generic company may believe that the product's future is less certain. These differences in perception about the value of entry on a certain date could well prevent the parties from being able to settle a case when the date of entry is the only permissible consideration. The ability to include other consideration as part of an overall settlement provides the ability to bridge that gap. Once again, consumers unambiguously benefit when the parties settle on a date-certain entry

that is earlier than the expiration of the patent. That it may take additional consideration to get the case resolved is not a reason to discourage such settlements. In short, while the parties may be able to agree upon some form of license in most cases, a rule requiring that all settlements take the form of a "time only" license would make settlements less likely.

C. Because This Bill Would Make Settlements Less Likely, It Would Decrease The Number Of Challenges.

In rendering settlement less likely, this proposal would inevitably raise the costs and risks of bringing patent challenges, thereby reducing the number of patent challenges a generic company can effectively mount. Generic companies may have many ANDA challenges at any one time. In deciding whether to challenge a patent, the generic challenger must consider the potential gains from the challenge – including the possible settlement alternatives – against the risk of recovering nothing. The 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.

To be sure, the generic company cannot know what kind of settlement it would obtain in deciding whether to file an ANDA statement, but like any other litigant, it does count on the possibility of settlement in budgeting its litigation costs. 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.

The ability to settle a patent challenge on flexible terms has a pro-competitive effect because it increases the number of patent challenges by decreasing barriers to entry, *i.e.*, the costs of bringing a patent challenge. In contrast, the proposed rule prohibiting a settlement for other consideration could be anticompetitive because it would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement.

In sum, parties in Hatch-Waxman cases would not always "get to yes" if forced to negotiate over a "time only" term of entry, rather than over both flexible license terms and other consideration. The proposed bill therefore would undermine the incentives Congress has carefully created to promote generic competition.

CONCLUSION

Thank you, Mr. Chairman, Ranking Member Specter, and Members of the Committee, for giving me the opportunity to explain our views and concerns about these important topics. We look forward to continuing to assist Congress in this area.

Statement of U. S. Senator Russell D. Feingold
Senate Committee on the Judiciary
Hearing on "Paying Off Generics to Prevent Competition
with Brand Name Drugs: Should it Be Prohibited?"
January 17, 2006

Mr. Chairman, thank you very much for holding this hearing. This is a very important issue for U.S. consumers of prescription drugs, and this hearing goes to the integrity of our antitrust laws and the Hatch-Waxman Act. It is important, however, that we remember that this is not just a typical antitrust matter; the stakes here are particularly high. These consumers are Americans suffering from illness and disease, and they seek to buy prescription drugs that might ease that suffering and cure those diseases.

Americans are paying some of the highest prices in the world for their drugs while, at the same time, the pharmaceutical industry is enjoying some of the highest profits of any industry in the world. There is mounting evidence that drug companies are attempting to deprive consumers of the option of less expensive generic drugs by paying their generic competitors to not compete. As Federal Trade Commissioner Leibowitz tells us in his testimony, these settlement agreements restrict competition at the expense of consumers and federal and state government entities that pay for prescription drugs.

I am deeply concerned at the possibility of settlements where both the brand-name and the generic drug companies agree to enjoy the artificially inflated profits that monopolies generate since that profit comes at the expense of the consumer. The current high prescription drug prices take a particularly heavy toll on sick and low-income individuals who desperately need life-saving medicines. It is time for Congress to ensure that a truly competitive marketplace for prescription drugs is in place -- one that will help bring down the skyrocketing prices in this country.

I hope today's testimony will help us parse out the complicated incentives that lead both brand-name pharmaceutical companies and those generic drug companies that are supposed to be their competitors to agree to reverse payments. I am also intrigued at the prospect that a legislative fix might actually strengthen patent protections and increase judicial efficiency by eliminating incentives for unmerited patent challenges, mounted only in the hopes of gaining a share in profits. I am certain that today's hearing will help us evaluate how best to legislate in a manner that strengthens the unique framework Congress has constructed to deal with pharmaceutical patent disputes and, in the process, save consumers and taxpayers millions of dollars.

I congratulate Senator Kohl for the excellent work he has done with the "Preserve Access to Affordable Generics Act," and I am pleased to be an original cosponsor, along with Chairman Leahy and Senators Grassley and Schumer. I am heartened to see that the Federal Trade Commission believes that we are on the right path with this legislation.

Our goal is to craft legislation that both protects American people from drug costs that are artificially inflated because of anti-competitive incentives and also respects the importance of strong protection of patent rights.

I thank you again, Mr. Chairman, for holding a hearing on this important issue.

SENATOR GRASSLEY'S OPENING STATEMENT FOR SENATE JUDICIARY COMMITTEE HEARING, "PAYING OFF GENERICS TO PREVENT COMPETITION WITH BRAND NAME DRUGS: SHOULD IT BE PROHIBITED?" (JANUARY 17, 2007)

Chairman Leahy, I'm pleased that you're holding this hearing today. We should be doing all that we can to see that the American consumer has access to lower priced drugs as soon as possible. Recently, there has been a dramatic increase in sweetheart deals between brand name and generic pharmaceutical manufacturers that delay the entry of less costly medicines in the marketplace. The Federal Trade Commission took the position that these settlement agreements violate antitrust law and the intent behind the Hatch-Waxman law. But the courts came to the conclusion that there wasn't a problem.

Well, I agree with the FTC that these agreements aren't competitive. I agree with the FTC that these kinds of arrangements only end up keeping drug costs high for consumers. Furthermore, these kinds of deals threaten the long term sustainability of federal healthcare programs, such as Medicare and Medicaid.

So I joined Senator Kohl, Chairman Leahy, and several other of my Senate colleagues in introducing legislation that would ban these kinds of agreements. I know that a number of folks have concerns with the way that the bill is drafted, and I'm certainly open to looking at possible modifications to the language. However, I firmly believe that we need to pass legislation to put a stop to these agreements that only harm consumers.

I urge the Commission to continue looking for anti-competitive agreements in the drug industry and taking aggressive action to protect the American public. I commend the FTC for its hard work in this area. Mr. Chairman, I look forward to hearing the testimony today, and to working with you to ensure that prescription drug competition is not hampered by these abusive deals.

Testimony of Merril Hirsh

Before the Senate Judiciary Committee

January 17, 2007

"Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?"

Introduction

My name is Merril Hirsh. I am a partner in the Washington, D.C. office of the law firm of Ross, Dixon & Bell, LLP and I want to thank the Committee and its staff for affording me the opportunity to comment on the proposed Preserve Access to Affordable Generics Act. Although, on this issue, my law firm has generally represented the interests of companies who pay the costs of drugs through self-insurance, the views I express today are my own and not necessarily those of either my firm or any of its clients. In fact, my firm represents both plaintiffs and defendants in various types of litigation and I hope that whatever thoughts I can convey to the committee reflect the experience of having been on both sides of litigation.

I believe that a bright line rule preventing reverse payment settlements is the simplest, most efficient and fairest solution to the patent lawsuit issue raised by the Hatch-Waxman Act and promotes the central purposes of the Hatch-Waxman Act to foster both drug innovation and reasonable prices. If reverse payment settlements are permitted, brand and generic drug companies face a powerful – indeed, in some cases, overwhelming – incentive to use the huge monopoly rent earned by the exclusive rights to sell some of the most profitable drugs in history to buy off competition and to avoid challenges to weak patent positions. The proposed legislation would instead create an incentive to achieve a result that fairly reflects the power of the patent position. In fact, there is an irony in this process: the very argument that is most commonly used as a reason to refrain from external antitrust involvement in the marketplace – the fear that the action of the lawmaker, regulator or judge to impose a rule upon a market will, itself, defeat the incentives a free market provides for efficiency – cuts strongly in favor of a bright line rule here, rather than one that relies on case-by-case judgments.

My testimony has three parts. First, although I know that the Committee is familiar with the issue, I will outline briefly the problem of "reverse payments", the situation in which it has commonly arisen and comment on what the issue does *not* involve. Second, I will discuss the competing arguments often made in favor of either generally permitting reverse payments or some kind of fine analysis on a case-by-case basis. Finally, I will discuss the benefits of a bright line solution to the problem and the draft legislation that is before the Committee. For the Committee's convenience, I have also attached an article I published with a colleague that discusses these issues in more detail. "I Didn't Say Orphan Often: The Benefits of a Bright Line Rule Barring Brand to Generic Payments in Hatch-Waxman Patent Settlement," ANTITRUST HEALTH CARE CHRONICLE, v. 19, No. 2, Summer 2005 (reprinted by permission of the American Bar Association).[1]

I. THE PROBLEM – WHAT IT IS AND WHAT IT IS NOT

The issue the proposed legislation would address is not whether brand companies can obtain the benefit of patent protection. They can. It is not whether generic companies can challenge patents as being invalid or argue that a generic alternative they would like to sell does not infringe patents. They can do that. It is not about whether the brand companies can bring and pursue non-sham lawsuits to defend their patent position. They can do that. It is not about whether brand and generic companies can settle their disputes over the validity or applicability of patents to potential generic competition. They can do that too. The issue involves whether their settlement can take the form of a payment from the brand company to the generic in exchange for an agreement not to compete. Although sometimes discussion about this issue assumes that

[1] This article footnotes references for a number of the points I make here. Accordingly, I will not burden this testimony with additional footnotes, and add only those references that post-date the article.

situation is really similar to other patent settings, it arises because of the special concerns Congress sought to address in the sale of pharmaceuticals.

No drug company may sell a prescription drug in the United States until it has applied for and received approval from the Food and Drug Administration ("FDA"). To secure FDA approval for a new drug, a drug company must file a New Drug Application ("NDA"), including reports and information that demonstrate the drug is safe and effective for its proposed use(s). New drugs that are approved and marketed through the NDA-approval process are called "pioneer" or "brand-name" drugs. In 1984, concerned that the NDA process was cumbersome and delayed entry of relatively inexpensive generic drugs into the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.

The Act created incentives for generic companies to bring down prices for blockbuster drugs. The Act established an abbreviated process to obtain FDA approval for generic versions of previously-approved pioneer drugs. Five years after the FDA has approved a new drug, a generic pharmaceutical company may seek approval to market a generic version of the drug by filing an Abbreviated New Drug Application ("ANDA"). To secure FDA approval of an ANDA, the generic company must show only that the proposed drug is bioequivalent to the corresponding brand drug – it need not do all the testing that creates long delays in bringing drugs to market.

But Hatch-Waxman did not just stop with abbreviating the process of FDA approval for generic drugs. It also created a new way of teeing up patent disputes that makes it easier for generic manufacturers to raise genuine challenges. Hatch-Waxman requires the ANDA filer to make one of four certifications concerning patents listed with the FDA for the brand-name drug.

In a Paragraph IV Certification (which is the primary one that gives rise to the problem the proposed legislation addresses), the generic manufacturer attests that the listed patent "is invalid . . . or will not be infringed" by the generic drug (an "ANDA-IV" certification).

If the generic company files an ANDA-IV certification, it must provide notice to the patent holder of the certification, including a statement of the factual and legal basis for its opinion that the patent is invalid or will not be infringed. The mere filing constitutes a statutory act of infringement, such that the brand company may file an infringement action even though the generic product has not entered the market. If the pioneer (brand) company brings a patent infringement suit against the generic within 45 days of receiving notice of the Paragraph IV Certification, the FDA must delay approving the ANDA until the earlier of (1) 30 months after the brand company's receipt of the notice; or (2) issuance of a court decision relating to the ANDA holding the patent invalid or uninfringed. The effect of this system is that generic drug companies can raise patent challenges without actually going through the cost of marketing the competing drug or bearing the risk of having to disgorge profits in a patent infringement lawsuit.

To provide an even greater incentive for generic companies to create competition for drugs, the Act also provided that the first generic company to file an ANDA enjoys a 180-day exclusivity period. During this period, other generic drug makers are barred from competing in the market for the drug at issue.

Since Congress passed Hatch-Waxman, a major issue running through both the case law and Congress' amendments has been how to make sure that drug companies use its provisions, as Congress intended, to promote competition, rather than to preserve the high prices that come from monopolies. In discussing this issue, I want to make clear: people can properly be concerned about how this process works without criticizing the desire of drug companies to earn

profits. In our economy, in general, we expect companies to want to earn profits. And most of the time, that benefits people. The process of fulfilling the vision of Hatch-Waxman has required closing the loopholes that incentivize companies to earn those profits by *avoiding* competition, rather than engaging in it.

In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Reform Act"), Congress closed some of those loopholes. For example, as originally enacted, Hatch-Waxman allowed the first-filing generic companies to obtain a 180-day exclusivity that ran from the earlier of (1) the first commercial marketing of a generic under the previous ANDA or (2) the date a court hearing the infringement action brought against the previous filer held the patent invalid or uninfringed. The problem was that this created a great incentive for the brand company to settle an infringement action by paying the first generic filer for an agreement *never* to market a generic product. This was a kind of double-whammy. If the generic company *never* marketed the product, and a court *never* reached the question of whether the patent was invalid or uninfringed, the 180-day period would never begin to run and, therefore, never expire. Accordingly, by settling with the first ANDA filer, a brand company could prevent *any* other generic company from marketing a competing product until the patent expired.

This result obviously defeated the goals of the Hatch-Waxman Act. Congress enacted Hatch-Waxman to encourage generics to compete with brand companies by *marketing* generic drugs, *not* to encourage generic companies to sell the right to prevent competition by *refusing* to market them. And in the Medicare Reform Act, Congress closed this loophole. That Act makes the 180-day exclusivity period contingent on the first ANDA filer *marketing* its drug by the earlier of 75 days after FDA approval or 30 months after the date of the ANDA filing. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I). Accordingly, there is now less incentive for a pioneer to condition

settlement with a first ANDA filer on the generic's agreeing not to waive and/or to defend its 180-day exclusivity period.

In the currently proposed legislation, Congress has the chance to close another loophole that defeats the fundamental purpose of the Hatch-Waxman Act. Even with the Medicare Reform Act, there is still an incentive to use the Hatch-Waxman process to achieve effectively the same result. Unless either Congress, the regulators or the courts stop the practice, a brand company still has a huge incentive to pay the first-filer (and if necessary subsequent filers) to resolve patent disputes not by determining the terms of competition, but by delaying it.

To explain the problem, it is important to note three things. First, not all Hatch-Waxman settlements are bad. The concern that this proposed legislation would address involves those settlements that *both* (1) include a "reverse-payment" (a payment going *from* the patent holder *to* the generic company that the patent holder claims will infringe); *and* (2) obtain an agreement from the generic company not to compete,. These two conditions are important because Hatch-Waxman involves a situation in which the brand company starts out by receiving a monopoly profit. If the brand company can settle its lawsuit by sharing some of that monopoly profit with the generic company, it is incentivized to do that, because effectively consumers then fund the settlement.

If the brand and generic companies are prevented from settling by reverse payment, their negotiation looks a lot different. They need to negotiate *not* between themselves over how to share the monopoly profit, but at arm's-length over *when* the generic can enter to market. Put another way – if the brand company cannot pay the generic to stay out, the generic's incentive is generally to come in.

Second, Hatch-Waxman settlements generally arise when a lot of money is at stake. Hatch-Waxman has its greatest relevance when we are talking about blockbuster drugs involving hundreds of millions or even more than a billion dollars of annual sales. In 2000, generic companies used Hatch-Waxman to challenge *nine* of the ten best-selling drugs of 2000, prior to the expiration of their patent. *See* C. Scott Hemphill Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1567 n.52 (2006) ("Paying for Delay") (citing other sources). Those drugs were household names: Celebrex, Claritin, Lipitor, Paxil, Prevacid, Prilosec, Prozac, Zocor and Zoloft. *Id.*

Not only are generic companies most likely to challenge blockbuster drugs, it is those drugs that are most likely to lead to reverse payment settlements. The more money there is to preserve, the more incentive there is find a way to preserve it.

Third, the numbers are so large that even a little delay matters. In rough numbers, just to illustrate the order of magnitude, if a drug promotes revenue of $1 billion a year, and full generic competition would reduce that price by 50 percent (most estimates place it at more than that), delaying full competition by a mere six months could convert to revenue of $250 million ($1 billion/year x 1/2 year x 50 percent). (The market for these types of drugs tends to be inelastic – companies do not generally increase sales for blockbuster drugs by lowering prices).

With numbers like this, it is easy to see why the Medicare Reform Act only solves part of the problem. True, under the law as it now stands, a brand company cannot exclude all the generics by paying money to the first-filing generic. But if allowed to settle the patent dispute by paying the generic not to compete, the brand company can (1) eliminate from competition the *only* generic company that has the incentive of a 180-day period of exclusivity; (2) delay competition for additional months, *or years*, in a situation where even short periods of time

matter; and (3) if necessary, reserve the right to enter into similar (probably smaller) settlements with other generics if they, subsequently, mount a patent challenge.

A good example of this comes from the words of the CEO of Cephalon. This CEO was interviewed after his company settled patent challenges by paying reverse payment settlements to each of several generic companies. By settling, Cephalon avoided a ruling on the generic companies' argument that Cephalon's patent for Provigil, a drug for sleep disorders, was invalid, and that their generic substitutes did not infringe the patent in any event. As the CEO explained:

> A lot of [Wall Street's enthusiasm for Cephalon's stock] is a result of 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.***

Philadelphia Business Journal, March 20, 2006 (emphasis added).

This process of paying to avoid patent challenges leads to two results that defeat the fundamental purpose of the Hatch-Waxman Act of encouraging generic competition where that competition is possible. *First*, instead of encouraging generics to make ANDA-IV certifications when they have good patent challenges, it encourages generics to challenge patents almost regardless of their strength. The more sales a drug has, the better the chance that a brand company will pay off the generic to drop its lawsuit.

Second and worse, the incentive to settle cases with reverse payments means that the weakness of the brand company's patent position translates into a better split for the generic company, *instead of* lower prices for consumers. Going back to the example of the brand company with the $1 billion drug facing a 50 percent price reduction if there is full competition, the brand and generic companies essentially have two choices – they can litigate to the end, and, through competition, divide up a pie that much smaller. Or they agree not to compete and instead divide up the extra money the consumers are paying. If that agreement is legal, the

incentive to take the money rather than to compete is obvious and, in certain circumstances, overwhelming.

Outlawing the reverse-payment settlement creates incentives that are more consistent with the goals the Hatch-Waxman Act was designed to foster. Barred from bringing lawsuits in the hope of generating a payoff, the proposed legislation would incentivize generic companies to use the Hatch-Waxman process to challenge patents only when the generic companies believe those patents are weak and the companies truly plan to compete in the event they win. Barred from settling by sharing the monopoly profits paid by consumers, brand and generic companies are forced to negotiate at arm's-length over when a generic company can enter the market, with the generic company incentivized by its own business interest to benefit consumers by having the competition start as soon as possible.

Moreover, it is only a bright-line rule that clearly obtains these benefits. If reverse payment settlements might or might not be legal depending upon circumstances, brand and generic companies have an incentive – if only because of the delay it occasions – to attempt to use money between them to by delay in competition for blockbuster drugs.

II. WHAT ABOUT THE ARGUMENTS ON THE OTHER SIDE?

Those who have defended reverse payment settlements in court, and those courts that have upheld those settlements against antitrust challenge, have made a number of arguments. I believe these arguments are unpersuasive and will explain why. But even if these arguments were more persuasive than they are, there is a difference between the arguments a court might consider persuasive in deciding whether existing antitrust law bars certain conduct and the arguments this Committee and Congress must consider in deciding how to fulfill the goals of Hatch-Waxman.

Even courts that have upheld the use of reverse-payment settlements against antitrust challenge are troubled by the practice. They recognize the risk of a payoff being used to avoid competition. But they are concerned about the proper standard to be used *generally, as a matter of antitrust law*, to assess the lawfulness of conduct alleged to be anticompetitive.

For example, a significant concern that courts have is that, in general, settlements are considered to be good and continued litigation, bad. In general, this is true. But it is not true about the Hatch-Waxman Act. The Hatch-Waxman Act actually encourages litigation – it sees, in a particular situation, an advantage to having generic companies challenge weak patent positions in the hopes of generating competition of enormous benefit to consumers. Under Hatch-Waxman, it is *not* better to have cases settle *on terms that do not generate the competition Hatch-Waxman was designed to foster* than it is to litigate them. *See* Paying for Delay, 81 N.Y.U. L. Rev. at 1616. Litigating the patent cases to conclusion, or settling them at arm's-length by agreeing on when the generic company can enter the market, serves the purposes of the Hatch-Waxman Act. Reverse payment settlements defeat those purposes with no benefit to consumers.

Antitrust law is flexible and largely judge-made. But a judge is still not a policy-maker. A court may decide that a private settlement does a disservice to consumers; even an extreme disservice. But that does not mean that the court feels authorized by existing law to correct the problem. It is Congress that makes our policy judgments.

With that general comment, I would like to address briefly the main arguments made in court cases in defense of reverse-payment settlements:

Reverse payment settlements do not "protect" patent rights or innovation.

It is true that society has an interest in protecting patents. Patent protections spur innovation that, in turn, ultimately benefits competition and consumers. But this interest in

protecting patents does not mean that there is an interest in protecting a "right" to avoid patent challenges through reverse payments.

To begin with, society is not as interested in protecting weak patent positions as it is in protecting patents. In fact, "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.'" *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 58 (1973). Suppose a brand company has ten patents, and it believes that each of them has an 60 percent chance of being upheld and enforced. If the brand and generic companies litigate the case to conclusion, the brand company expects that it would face competition for four out of those ten drugs. And that competition would come at lower prices that could save consumers billions of dollars. If the law permits the brand-name company to settle all ten of these cases by paying the generic company some of its monopoly profit to stave off a patent challenge, there is no competition in *any* of the ten cases. That is not "good" for society. It thwarts competition and the innovation that it spurs.

Moreover, the connection between the terms under which someone can settle an eventual patent case, and the incentive to develop drugs is incredibly remote. There is no reason to believe that a brand company that is willing to go to all the expense and risk of developing and testing a drug (and then enjoy at least a five to seven-and-a-half year period of monopoly sales before the first generic can hit the market) is not going to do so based upon the fear that *if* the drug is approved by the FDA, and *if* the brand-name company obtains a patent, and *if* it is challenged by a generic company someday, it will, at that point, be unable to settle the litigation by paying off the generic company.

In any event, our desire to protect patent interests is ill-served by a system that encourages parties to pick patent fights in the hopes of being paid off. A system that eliminates the incentive to obtain payoffs limits patent challenges to those that have merit in circumstances where the generic company genuinely expects to compete. This change *protects* strong patent positions.

A rule against reverse payments does not prevent desirable settlements.

As I discussed above, the fact that settlements, in general, are good things, does not mean that we should permit settlements that defeat the purposes of the statute. Under the Hatch-Waxman Act, bringing serious patent challenges can be a good thing; and settling them without obtaining competition is not.

But even if settlements were always a "good thing," this still would not justify the use of reverse payment settlements. To begin with, eliminating reverse payments does not prevent brand and generic companies from settling. They can settle. They just have to negotiate over when the generic company comes into the market, instead of how to divide a monopoly profit.

There is theoretical discussion about circumstances in which it might be conceivable that a brand and generic company cannot come to terms without having the brand company make a payment to the generic. As the attached article explains in more detail, there are a number of responses to this argument, but the most basic response is that this discussion really is theoretical. When the FTC initially took the position that settlements involving substantial reverse payments were presumptively anticompetitive, and the Sixth Circuit in the *Cardizem* case rejected one such settlement, brand and generic companies settled cases without reverse payments. An FTC Report published in early 2005 concluded that "[s]ettlements after 1999 do not appear to include a payment from the brand-name company to the generic manufacturer in

exchange for the generic's agreement not to market its product." *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 (2005) (available http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf).

Then, in 2005 and 2006, coinciding with the decision against the FTC's position by the Eleventh Circuit in *Schering-Plough*, and what was then the lower court decision upholding a reverse-payment settlement in *Tamoxifen*, brand and generic companies reversed course and entered into a number of new reverse payment settlements. *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 (2006) (available http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrept.pdf); Paying for Delay, 81 N.Y.U. L. Rev. at 1571, n.71 (citing other sources).

If several years of cases can be resolved without reverse payments only to have reverse payment settlements return after the legal winds change, reverse payments must not be "essential." Brand and generic companies will enter them if they can. As history has demonstrated, if they cannot, they will resolve their disputes in a different way.

Moreover, much as it may be good to settle some cases, it is better for the brand company, for the generic company and the courts *not* to have weak cases brought *in the first place*. To tout the benefits of settlement misses the genuine cost of leaving in place a system that encourages generic companies to file ANDAs in the hopes of receiving a reverse payment settlement from the brand company in the resulting litigation. Fewer lawsuits is better than more settlements.

Preventing reverse payment settlements in Hatch-Waxman cases does not create a slippery slope.

Another group of arguments maintain that the word "reverse payment" is a misnomer. These arguments assert that all that is happening is that the unusual structure of Hatch-Waxman (in permitting patent suits before there is any actual infringement giving rise to damages) merely makes apparent a trade-off that occurs in all patent litigation. The theory is that every time a patent holder settles a case with an alleged infringer and, in the process accepts less than 100 percent of its potential damages in settlement it is in effect making a reverse payment equal to the difference between its settlement and its highest hopes. Then, the argument goes on to assert, establishing a rule that bars reverse payments in the unusual Hatch-Waxman setting, will, like falling down a slippery slope, lead to a bar on all settlements.

As the attached article explains this comparison is not really apt for a number of reasons. Patent settlements do not all involve agreements by the defendant not to compete. And, even if they did, there is a significant difference between having parties compromise off their highest hopes in litigation, and the Hatch-Waxman settlement in which money changes hands in order to settle a dispute in which both parties' expectation is that they will receive $0 – ***win or lose***.

But even if the comparison were apt, the slippery slope argument would not be. Congress passed Hatch-Waxman because it recognized that the drug approval process created unique competitive issues that necessitated a unique system for encouraging and resolving patent disputes. It does not have to legislate all cases when it legislates pharmaceutical cases.

Reverse-Payment settlements are an inefficient way to fund competition.

Finally, some argue that reverse-payment settlements are competitive because they provide money that generic companies can then use to fund other competition. But the truth is that if generics require funding they can obtain it through the ways other companies obtain

funding – take out loans, find venture capital, issue bonds, sell stock. There is no reason why we should want to encourage generics to pick patent fights in order to pursue the sales of drugs that they cannot afford to market and/or cannot demonstrate are worth funding.

III. WHY DO WE NEED A BRIGHT LINE?

Usually, when lawyers make arguments against bright-line tests in antitrust litigation, the most common argument involves a fear of false positives. The theory goes that antitrust law is based in a paradox: the premise of antitrust law is that fair competition and the market will lead to the best result; but enforcing fair competition requires judges or regulators or lawmakers to impose rules that are *not* decided by the market.

Whether this theory is correct or not, in the case of reverse-payment settlements under the Hatch-Waxman Act, the theory cuts dramatically in the opposite direction. A case-by-case resolution of the viability of reverse-payment settlements is certainly better than a result that routinely approves them regardless of how anticompetitive they are. But it is a remedy devised by judges or regulators or lawmakers, not by the market.

As I have tried to explain, the issue of reverse-payment settlements is one of incentives. If we create an overwhelming incentive for brand companies to pay off generics who challenge patents, we can expect to produce litigation and payoffs, but not competition. If we create an incentive for generic companies to negotiate the earliest time to begin competition, we harness the market remedy of arm's-length negotiation to achieve a result where generic companies bring fewer lawsuits; bring better lawsuits; and resolve them in ways that reflect a market judgment about the strength of the patent in litigation. This result does not, by itself, overcome all the obstacles to fulfilling the laudable purpose of the Hatch-Waxman Act. But it is a large step forward. I strongly urge passage of the proposed legislation.

Statement of Senator Patrick Leahy
Senate Judiciary Committee
Hearing On "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?"
January 17, 2007

This hearing is a continuation of a longstanding, bipartisan effort by several members of this Committee to provide consumers more choices and lower-cost medicines. My focus is on making lower-cost generic medicines available to our seniors and families. Existing law is being misused by some brand-name and generic drug companies. The fact that we have scheduled this hearing so early in this new Congress is a sign that solving this problem will be the high priority for this Committee that it deserves to be, and that consumers want it to be.

We will examine the harmful effects of a type of collusion that limits consumer choices and that keeps consumer prices artificially high. Rarely do we have such a clear-cut opportunity to remove impediments that prevent competition and keep the marketplace from working as they should, to benefit consumers.

The basics of this issue are very simple: Congress never intended for brand-name drug companies to be able to pay off generic companies NOT to produce generic medicines. That would be a shame, harmful to consumers, and a crime.

In fact, the history and text of the Hatch-Waxman laws make it clear that the OPPOSITE of delay was the goal.

It is no secret that prescription drug prices are rising and are a source of considerable concern to many Americans, especially senior citizens and working families. In a marketplace free of manipulation, generic drug prices can be as much as 80 percent lower than the comparable brand name version.

In June of last year I sponsored a bill, introduced by Senator Kohl, and also sponsored by Senators Grassley, Schumer, Feingold and Johnson, which would have stopped these payoffs to delay access to generic medicines. Working with Senators Kohl and Grassley and with many others, we will try to enact a new version of that bill.

It is unfortunate that we even have to do this. However, as I said in June, there are still some companies driven by greed that may be keeping low-cost, life-saving generic drugs off the marketplace, off pharmacy shelves, and out of the hands of consumers, by carefully crafted anti-competitive agreements.

Since some of these deals used to be done in secret, I am glad that because of a bill that was reported out of this Committee, Congress is now aware of this problem. In 2001, I worked with Chairman Hatch and later with Senator Grassley to make sure that our law enforcement agencies – the Federal Trade Commission and the Department of Justice – at least were made aware of these secret, and potentially criminal, deals.

The New York Times and others published major investigative stories on how the manufacturer of a hypertension drug to help prevent strokes and heart attacks -- Cardizem CD -- had made deals to pay a potential generic competitor $10 million every three months to stop it from developing a generic version of Cardizem. This led to my introduction of S. 754 – the Drug Competition Act -- which was reported out of this Committee and was finally passed as part of the Medicare Modernization Act Amendments with significant assistance from Senator Grassley.

The concept of that law is simple: It requires that if a brand-name company and a generic firm enter into an agreement that is related to the sale of either the brand named drug or its generic version, then both companies must file copies of any agreements with the FTC and the DOJ so those agencies can enforce the law. Incidentally, once the Cardizem deal was exposed and challenged, the U.S. Circuit Court held that the "the horizontal market allocation agreement . . . [was] *per se* illegal under the Sherman Act."

Today, Commissioner Leibowitz will testify about what the FTC has found regarding these deals between brand-name companies and generic companies and the harm done to the public.

I will once again strongly support a legislative effort by Senators Kohl and Grassley to allow the FTC to do its job. Two subsequent Circuit Court decisions have undermined the Cardizem approach and relied on the general rule favoring settlements between private litigants - Even though private corporate litigants have duties to their share holders, not consumers, to

maximize profits. The problem -- with respect to deals not to compete -- is that the interests of millions of senior citizens, millions of children, and millions of others – are not taken into account. Those cases ignore the decision in *Associated General* in which the U. S. Supreme Court noted that "the Sherman Act was enacted to assure our customers the benefits of price competition . . . ." Note the focus is on consumers, not on whether private companies should be able to make back-room deals that harm consumers as part of a settlement of a lawsuit.

Our bipartisan bill will solve that problem by making payments by brand-name companies, to delay introduction of a generic drug, unlawful. My initial position is to follow this bright-line approach to avoid endless litigation and set forth a clear standard. I will be interested in hearing from others on possible solutions, so long as the interest of the public in accessing these life-saving medicines is paramount. That has been, and will continue to be, my top priority.

# # # # #

PREPARED STATEMENT OF THE FEDERAL TRADE COMMISSION

Before the

COMMITTEE ON THE JUDICIARY

of the

UNITED STATES SENATE

on

ANTICOMPETITIVE PATENT SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY: THE BENEFITS OF A LEGISLATIVE SOLUTION

January 17, 2007

Summary

Chairman Leahy, Ranking Member Specter, and Members of the Committee, I am Jon Leibowitz, Commissioner of the Federal Trade Commission. I appreciate the opportunity to appear before you today to testify on behalf of the Commission regarding anticompetitive agreements between branded and generic drug firms.[1]

Prescription drugs represent a substantial component of health care spending. Protection of competition in the pharmaceutical sector has been and continues to be among the FTC's highest priorities. In that regard, the agency has directed significant efforts at antitrust challenges to what have come to be called "exclusion payment settlements" (or, by some, "reverse payments"), a term used to describe settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon the patent challenge and delay entering the market. Such settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years.

Recent court decisions, however, have made it more difficult to bring antitrust cases to stop exclusion payment settlements, and the impact of those court rulings is becoming evident in the marketplace. These developments threaten substantial harm to consumers and others who pay for prescription drugs. For that reason, the Commission supports legislation to prohibit these anticompetitive settlements and strongly supports the intent of the legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer, including the objective to adopt a bright-line approach to addressing exclusion payments.

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

[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 Commissioner.

cost. To speed market entry of generic drugs, and to ensure that the benefits of pharmaceutical innovation would continue, in 1984 Congress passed the Hatch-Waxman Act.[2] Hatch-Waxman established a regulatory framework that sought to balance two fundamental objectives: maintaining incentives for continued innovation by research-based pharmaceutical companies and encouraging market entry by generic drug manufacturers.[3] One of the key steps Congress took 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. The Act likewise encourages brand name drug companies to file infringement suits at an early stage.

Almost six years ago, this Committee held a hearing to examine the implications of some settlements reached under this patent challenge process that Hatch-Waxman established. At that time, the Committee was considering a bill introduced by Senators Leahy and Grassley to facilitate antitrust enforcement by requiring that all such settlements be filed with the FTC and the Department of Justice. Thanks to this filing requirement, which Congress enacted in 2003 as part of a package of reforms to Hatch-Waxman, the FTC staff is able to review all settlements of patent cases brought under the Act.

Despite this important enforcement tool, however, the prospects for effective antitrust enforcement against anticompetitive agreements between branded and generic pharmaceutical manufacturers are substantially less encouraging today than they were in 2001. Two appellate

---

[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)).

[3] *See infra* Section I.A. The Act also was intended to encourage pharmaceutical innovation through patent term extensions.

court decisions handed down in 2005 took an extremely lenient view of exclusion payment settlements.

Pharmaceutical companies are responding to this change in the legal landscape. Although 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 to 2004, the recent court decisions have triggered a disturbing new trend. The staff's analysis of settlements filed during the fiscal year ending in September 2006 found that half of all of the final patent settlements (14 of 28) 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. 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 exclusion payment settlements are highly profitable for brand-name and generic firms. If such payments are lawful, companies have compelling incentives to use them.

The implications of these developments for consumers, and for others who pay for prescription drugs, are serious. Although it is well known that the use of generic drugs – which are priced 20 to 80 percent or more below than the price of the branded drug[4] – 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. Generic competition following successful patent challenges involving just four major brand-name drugs is estimated to have

[4] *See infra* note 14.

saved consumers more than $9 billion.[5] The cost savings that result from generic entry after successful patent challenges are lost, however, if branded drug firms are permitted to pay a generic applicant to defer entry.

Advances in the pharmaceutical industry bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs than with alternative means, such as surgery. 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 Hatch-Waxman framework. But the court decisions allowing exclusion payments grant holders of drug patents the ability to buy more protection from competition than congressionally-granted patent rights afford. These rulings disrupt the careful balance between patent protections and encouraging generic entry that Congress sought to achieve in the Hatch-Waxman Act.

The increased costs resulting from anticompetitive agreements that delay generic competition harm all those who pay for prescription drugs: individual consumers; the federal government, which spends substantial sums under the new Medicare Part D program; state governments trying to provide access to health care with limited public funds; and American businesses striving to compete in a global economy.

The Commission's perspective on the important issue highlighted by this hearing is informed by extensive experience in examining competition in the pharmaceutical industry. The agency has undertaken numerous investigations and antitrust enforcement actions affecting both

[5] *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://commerce.senate.gov/hearings/042302jaegar.pdf>.

brand-name and generic drug manufacturers,[6] empirical studies and economic analyses of the pharmaceutical industry,[7] assessments of competitive issues in matters before the United States Food and Drug Administration ("FDA") regarding Hatch-Waxman implementation,[8] testimony before Congress,[9] and amicus briefs in the courts.[10] The Commission's 2002 report entitled

---

[6] *See, e.g., 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. 5, 2002) (consent order as to American Home Products); *FTC v. Perrigo and Alpharma*, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004) (stipulated judgment); *Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (Apr. 14, 2003) (consent order); *Biovail Corp. and Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 20, 2002) (consent order); *Biovail Corp.*, Dkt. No. C-4060 (Oct. 4, 2002) (consent order); *Abbott Labs.*, Dkt. No. C-3945 (May 26, 2000) (consent order); *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 26, 2000) (consent order); *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (Apr. 2, 2001) (consent order); *FTC v. Mylan Labs., Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999).

[7] *See, e.g.*, Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Aug. 2005), *available at* <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>; Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Oct. 2003), *available at* <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>; David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), *available at* <http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf>; Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999), *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

[8] *Response to Citizen Petition by Ivax Pharmaceuticals, Inc.* (Apr. 5, 2005), *available at* <www.ftc.gov/os/2005/04/050407ltrivaxpharm.pdf> (recommending that FDA deny Ivax's request that the FDA prohibit delisting of patents from the Orange Book); Comment of the Federal Trade Commission, *FDA: Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed* (Dec. 23, 2002) ("30-Month Stay Comment"), *available at* <http://www.ftc.gov/be/v030002.pdf> (recommending modifications to FDA proposed rule on patent listing requirements and providing suggestions to the proposed patent declaration); Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission, *FDA: Citizen Petition* (Mar. 2, 2000), *available at* <http://www.ftc.gov/be/v000005.pdf> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission, *FDA: 180-DayGeneric Drug Exclusivity for Abbreviated New Drug Applications*,(Nov. 4, 1999) ("Marketing Exclusivity Comment"), *available at* <http://www.ftc.gov/be/v990016.htm> (recommending that the FDA's Proposed Rule on 180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent litigation settlement agreements).

[9] Testimony of the Federal Trade Commission before the Special Committee on Aging, United States Senate, *Barriers to Generic Entry* (July 20, 2006), *available at* <*http*://www.ftc.gov/os/2006/07/P052103BarriersstoGenericEntryTestimonySenate07202006.pdf>; Testimony of the Federal Trade Commission before the Committee on Judiciary, United States Senate, *Competition in the Pharmaceutical Industry* (June 17, 2003), *available at* <http:/www.ftc.gov/os/2003/06/030617pharmtestimony.htm>; Testimony of the Federal Trade Commission before

"Generic Drug Entry Prior to Patent Expiration" ("Generic Drug Study") was based on a detailed examination of experience under the Hatch-Waxman Act and recommended a number of the reforms that Congress adopted in 2003.[11] The FTC staff's ongoing review of drug company patent settlements and other agreements filed pursuant to the mandate in the 2003 reforms has enabled the Commission to provide Congress and the public with annual reports on the types of patent settlements being undertaken.[12]

Today's testimony reviews the role of generic drugs in the pharmaceutical industry and the regulatory framework that governs their introduction, and then discusses the economics of exclusion payment settlements and their impact on consumers, the court rulings and industry response, and some issues relating to a legislative remedy to the exclusion payment problem.

---

the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives, *Competition in the U.S. Pharmaceutical Industry* (Oct. 9, 2002), *available at* <http://www.ftc.gov/os/2002/10/generictestimony021009.pdf>; Testimony of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, *Competition in the Pharmaceutical Industry* (Apr. 23, 2002), *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; Testimony of the Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001), *available at* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

[10] *See, e.g.*, Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *In re Tamoxifen Litigation*, (2d Cir. Nov. 30, 2005) ((No. 03-7641), *available at* <http://www.ftc.gov/os/2005/12/051202amicustamoxifen.pdf>: Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *Teva Pharm. v. Pfizer Inc.*, (Fed. Cir. Feb. 5, 2005) (03CV-10167), *available at* <http://www.ftc.gov/ogc/briefs/050208teva.pdf>.

[11] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (hereinafter "Generic Drug Study").

[12] 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>; 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 2004: A Report by the Bureau of Competition* (Jan. 2005), *available at* <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

The testimony also briefly describes how brand-name drug firms can effectively block generic entry by settling with the first generic applicant and declining to sue subsequent applicants.

I. The Benefits of Generic Competition

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a price that is 70 to 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.[13] Subsequent generic entrants may enter at even lower prices – discounted as much as 80 percent or more off the price of the brand name drug – and prompt the earlier generic entrants to reduce their prices. As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of a lower-priced generic product.[14]

A. Statutory Background

Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.[15] The Act allows for accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing, among other things, that the new drug is "bioequivalent" to an approved drug.[16]

---

[13] *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"); *see generally* David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

[14] CBO Study, xiii.

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

[16] 21 U.S.C. § 355(j).

A brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA") that, among other things, demonstrates the drug product's safety and efficacy. At the time the NDA is filed, the NDA filer also must provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[17] Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."[18]

The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "Paragraph IV certification");[19] and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed.

To encourage generic drug manufacturers to challenge questionable patents, the Hatch-Waxman Act provides that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA

[17] 21 U.S.C. § 355(b)(1).

[18] *Id.* § 355(j)(7)(A).

[19] *Id.* § 355(j)(2)(A)(vii)(IV).

may not approve a potential competitor's ANDA.[20] Although a first-filer can forfeit its exclusivity under certain conditions,[21] ordinarily it will be entitled to 180 days of exclusivity beginning on the date of the first commercial marketing of the generic drug product.[22] Even if the first filer substantially delays marketing its product, under the prevailing interpretation of the Hatch-Waxman Act, a later ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired.[23]

B. Consumer Savings from Challenges to Drug Patents

Experience has borne out the efficacy of the Hatch-Waxman process and the correctness of its premises: that many patents, if challenged, will not stand in the way of generic entry, and that successful challenges can yield enormous benefits to consumers. The Commission studied all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products.[24] Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration (see chart).[25]

---

[20] *Id.* § 355(j)(5)(B)(iv).

[21] *Id.* § 355(j)(5)(D)

[22] *Id.*

[23] *See id.* § 355(j)(5)(B)(iv).

[24] *Generic Drug Study*, at 19-20.

[25] *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).

Examples of Generic Entry Prior to Patent Expiration from Successful Patent Challenges

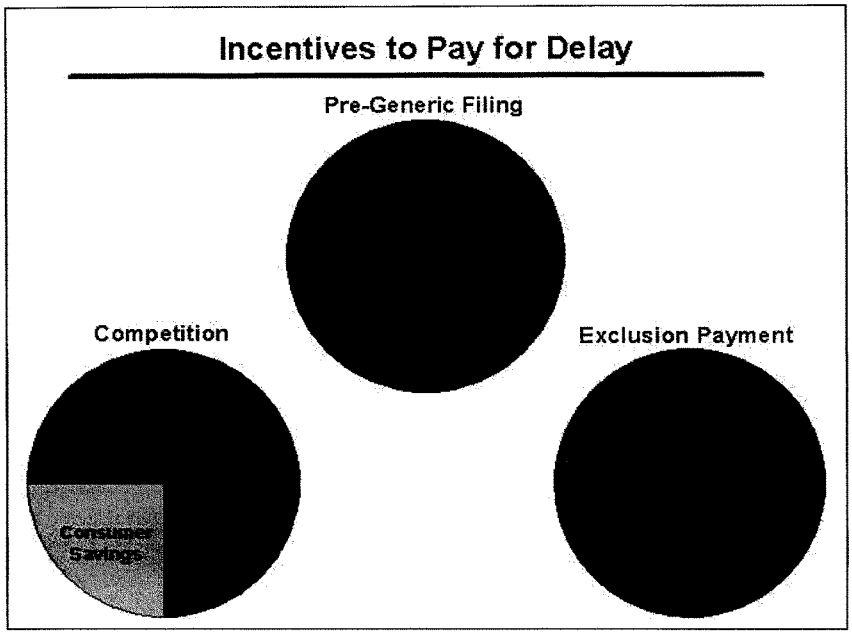
Drug	First Generic Entrant	Generic Entry Date	Annual Brand Sales Prior to Generic Entry	Expiration Date of Last Patent
Zantac	Granutec	1997	$1.6 billion	2002
Taxol	Baker Norton	2000	$1.6 billion	2013
Prozac	Barr	2001	$2.5 billion	2004
Prilosec	Kudco	2002	$3.7 billion	2018
Paxil	Apotex	2003	$2.2 billion	2017

II. The Economics of Exclusion Payment Settlements and the Role of Antitrust Enforcement

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 to settle the patent dispute and agree 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.



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 the

generic company would have prevailed in the lawsuit (as noted, the FTC's Generic Drug Study found generic challengers enjoyed a success rate in excess of 70 percent), or because the parties would have negotiated a settlement with an earlier entry date absent the payment. Instead, consumers pay higher prices because such early generic entry is delayed.

Several years ago, this Committee recognized the threat that such agreements pose, and, to promote effective antitrust enforcement, Congress amended the Hatch-Waxman Act in 2003 to require brand-name companies and generic applicants to file patent settlement agreements with the Commission and the Department of Justice. As the Senate Report explained, those amendments sought in part to stamp out the "abuse" of Hatch-Waxman law resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."[26]

The Commission has challenged patent settlements in which brand-name and generic companies have eliminated the potential competition between them and shared the resulting profits.[27] All settlements include some form of consideration flowing between the parties; it is the type of consideration that matters in the antitrust analysis. Some types of consideration, such as an early entry date, a royalty to the patent-holder, or compromising on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition. But the

---

[26] S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

[27] *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>. 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&o.htm>. The consent order in *Hoechst/Andrx* is *available at* <http://www.ftc.gov/os/2001/05/hoechstdo.htm>. *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm. *Bristol-Myers Squibb Co.*, Dkt. No. C-4076, *available at* <http://www.ftc.gov/os/caselist/c4076.htm>.

sharing of profits achieved by eliminating competition is at the core of the what Section 1 of the Sherman Act proscribes.

Initially, the Commission's enforcement efforts in this area appeared be a significant deterrent to anticompetitive behavior. In the late 1990s, the Commission learned of exclusion payments arising in Hatch-Waxman patent litigation and began to investigate.[28] Public reports of those investigations began to appear in 1999, and the Commission brought a number of enforcement actions beginning in 2000. For several years, such agreements essentially stopped. The Commission is not aware of any pharmaceutical settlement between a brand-name manufacturer and a generic filer that included both a payment to the generic company and an agreement by the generic company to defer marketing its product between 2000 and the end of 2004.

During the same period, however, patent settlements did not disappear. To the contrary, 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.[29] Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases.

---

[28] The Commission ultimately determined that, in the seven years between 1992 and 1999, there were fourteen final settlements between brand-name manufacturers and the generic first-filer, and that eight of those settlements included a payment from the brand name drug company to the generic drug applicant in exchange for the generic company's agreement not to market its product. 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>.

[29] We lack data for the approximately three year period between the end of the Generic Drug Study and the beginning of the MMA reporting period. It is quite likely that there are additional settlements that occurred during this period for which we do not have information.

III. The Current Threat to Consumers from Exclusion Payment Settlements

In 2005, two appellate courts adopted a permissive – and, respectfully, in our view, incorrect – position on exclusion payment settlements.[30] After years of active antitrust enforcement, including the Sixth Circuit's decision in the *Cardizem* case holding a challenged exclusion payment arrangement unlawful,[31] these two rulings have prompted a resurgence of 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.

In the *Schering* case,[32] the Eleventh Circuit vacated a decision in which the Commission found two patent settlements violated the FTC Act. Schering-Plough Corporation ("Schering"), the manufacturer of a brand-name drug called "K-Dur 20," settled patent litigation with two manufacturers of generic counterparts, Upsher-Smith Laboratories, Inc. ("Upsher") and American Home Products Corporation ("AHP"). The two generic manufacturers agreed to forbear marketing their generic drugs until specified dates in exchange for guaranteed cash payments totaling $60 million to Upsher and $15 million to AHP. A full trial was held before an administrative law judge, and the Commission reviewed the entire record *de novo*. The Commission concluded that in each settlement, Schering had paid its generic competitors to accept the settlement and that the settlements provided Schering with more protection from competition than a settlement without a payment or simply proceeding with litigation. As a

---

[30] *Schering-Plough Corp. v. F.T.C.*, 403 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting).

[31] *In re Cardizem Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

[32] *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 American Home Products).

result of these agreements, Schering continued to enjoy supracompetitive profits from K-Dur 20 for several more years, at the expense of consumers.

The court of appeals set aside the Commission's decision.[33] The court purported to assess whether the agreement exceeded the exclusionary potential of Schering's patent. In so doing, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and [AHP] from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent,"[34] and noted that there was no allegation that the patent claim was a "sham."[35] In particular, the court ruled that a payment by the patent holder, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger agreed to a later entry date in return for such payment, even if there was no other plausible explanation for the payment.[36]

The Commission sought Supreme Court review. Thirty-six states, AARP, and a patent policy think tank supported the Commission's petition. The Solicitor General filed a brief in opposition, acknowledging the importance of the issues presented, but arguing that the case was not the right vehicle for the Court to address them. In June 2006, the Supreme Court declined to review the Eleventh Circuit's ruling.

The impact of the Eleventh Circuit's decision – in the courts and in the pharmaceutical industry – has been evident. Other courts have understood that decision to require only an inquiry into the nominal reach of the patent, and not (as some have suggested) a direct

[33] *Schering*, 402 F.3d at 1058.

[34] *Id.* at 1066-67.

[35] *Id.* at 1068.

[36] *Id.* at 1076.

assessment of the likelihood that the patent holder could successfully effect exclusion through patent litigation.[37] A divided panel of the Second Circuit, ruling on an antitrust challenge to a patent settlement involving the anti-cancer drug Tamoxifen, followed the Eleventh Circuit's holding.[38] The plaintiffs in the *Tamoxifen* case have asked the Supreme Court to review the Second Circuit's ruling, and their petition for certiorari is pending.

The response of pharmaceutical companies to these developments in the courts is reflected in the changing nature of patents settlements since the *Schering* decision. One investment analyst report described the Eleventh Circuit's *Schering* decision as having "opened a Pandora's box of settlements."[39] After a five-year hiatus in payments to generics following the initiation of Commission enforcement actions aimed at exclusion payment settlements, pharmaceutical companies have once again started entering into settlement agreements that include both compensation in various forms to generic challengers and restrictions on generic market entry.[40] By the end of fiscal year 2005, the year of the Eleventh Circuit's decision in *Schering*, there were three such settlements. In fiscal year 2006 – the *Tamoxifen* ruling came early that year – there were significantly more:

---

[37] *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005), *appeal docketed*, No. 05-2851 (2d Cir. June 7, 2005) ("Cipro") (the ruling below "is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a post hoc analysis of the patent's validity").

[38] *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) , *amended*, 466 F.3d 187 (Aug 10, 2006), *petition for cert. filed*, http://www.supremecourtus.gov/docket/06-830.htm (Dec. 13, 2006) (No. 06-830).

[39] 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).

[40] 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>.

- Fifty percent (14 of 28) of the 2006 final settlement agreements between brand-name and generic companies included both an agreement to defer generic entry and some form of payment from the brand-name firm to the generic challenger.

- The findings concerning settlements with first generic filers – that is, settlements that can serve to block FDA approval of later applicants – are even more striking. More than 80 percent (9 of 11) of the settlements with first generic filers involved a payment to the generic challenger and a restriction on generic entry.

  One of the two first filer settlements that did not follow the trend involved a case in which the patent was due to expire within the year. In that case, the generic abandoned the patent challenge without compensation. The other settlement is currently being investigated by FTC staff.

- The compensation conveyed to the generic firm under the settlements takes various forms, and frequently includes agreements involving a product other than the one at issue in the patent litigation.

- Notably, so-called "side deals," such as purchasing rights to unrelated products and co-promotion arrangements, were observed in settlements that restrained generic entry, but virtually never in settlements that did not.[41] This pattern indicates that such "side agreements" may be serving as a vehicle to compensate a generic challenger for its agreement to a later entry date than the generic firm would otherwise accept.

The economic implications of the courts of appeals' rulings are substantial. Americans spent $200.7 billion on prescription drugs in 2005.[42] Many of the top-selling prescription drugs in the U.S. – including such blockbusters as ulcer drug Nexium, the anti-psychotic Seroquel, and cancer treatment Gemzar – are currently the subject of patent challenges by generic firms seeking to enter the market under the provisions of the Hatch-Waxman Act. The prospect of consumer benefit from such challenges is enormous, to the extent that they lead to early, non-infringing

[41] This pattern was observed in the FTC staff's review of Hatch-Waxman settlements from 1993 through 2000, which were collected in the Generic Drug Study, as well as all the settlements filed under the MMA. There were two exceptions to the observation that side deals do not occur in settlements that do not explicitly restrict entry. One of these settlement is under investigation.

[42] *See* Aaron Catlin, et al., *National Health Spending in 2005*, 26 HEALTH AFFAIRS 142, Jan./Feb. 2007, *available at* <http://content.healthaffairs.org/cgi/content/full/26/1/142>.

generic entry. 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.[43] Under the courts of appeals' rulings, however, the parties in such cases have the strong economic incentive, discussed above, to enter into anticompetitive settlements that deprive consumers of the benefit of low-cost, non-infringing generic drugs.

Where a patent holder makes a payment to a challenger to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed – *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition.[44] Some who disagree with the Commission's position argue that, rather than treat the outcome of the patent suit as uncertain (as it often is), antitrust analysis must presume the patent is valid and infringed unless patent litigation proves otherwise. This argument, however, ignores both the law and the facts. The antitrust laws prohibit paying a potential competitor to stay out of the market, even if its entry is uncertain. Indeed, the position that antitrust law would bar a brand name drug firm from paying a generic filer to withdraw its application for FDA approval should be uncontroversial, even though the potential generic competitor's application might not be approved. The suggestion that generic entry before the end of a patent term is too uncertain to be of competitive concern is likewise untenable. It is contradicted both by the Hatch-Waxman framework, which encourages

[43] *See supra* note 6.

[44] For example, for a hypothetical patent infringement claim with a 50% chance of success, with 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years of competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward. The appellate courts' approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee's claims.

patent challenges, and by the empirical evidence that generic applicants have enjoyed a nearly 75 percent success rate in patent litigation initiated under Hatch-Waxman.[45] Finally, the argument that prohibiting exclusion payments will prevent legitimate settlements is contradicted by experience during the period from 2000 through 2004. Patent settlements – using means other than exclusion payments – continued to occur. And patent settlements will continue if Congress enacts legislation that prohibits anticompetitive payments in settlements of Hatch-Waxman patent cases.

In sum, the majority opinion in *Tamoxifen* and the court of appeals ruling in *Schering*, take an extremely lenient view of exclusion payment settlements. Given that the brand-name and generic company are both better off avoiding the possibility of competition and sharing the resulting profits, there can be little doubt that, should those rulings become the controlling law, we will see more exclusion payment settlements and less generic competition. Although the Commission will continue to be vigilant in this area, litigating another case to conclusion will take years, the outcome of such litigation is uncertain given the *Schering* and *Tamoxifen* decisions, and in any event such litigation will provide little relief for those harmed in the interim. The cost to consumers, employers, and government programs will be substantial.

Prozac provides a telling example. In the course of patent litigation, the brand name company, asked if it would pay the generic challenger $200 million to drop the patent challenge, rejected the idea, stating that such a settlement would violate the antitrust laws.[46] The generic ultimately won that patent litigation, and consumers – and federal and state governments – saved

[45] *Generic Drug Study* at 19-20.

[46] 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>.

over two billion dollars.[47] Under the legal standard articulated in the *Schering* and *Tamoxifen* cases, however, the proposed settlement would have been legal, generic entry would not have occurred, and consumers would have had to pay higher prices until the patent expired.

IV. Addressing Anticompetitive Hatch-Waxman Settlements through Legislation

The Commission strongly supports a legislative remedy for the problem of exclusion payment settlements between branded pharmaceutical firms and would-be generic entrants. Congressional action on this issue is warranted for several reasons. First, the threat that such 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.

Second, the problem is prevalent. Because exclusion payment settlements are so profitable for both branded and generic firms, if they are legal they would threaten to eliminate most pre-patent-expiration generic competition. The settlements filed with the FTC in 2006 demonstrate that it is now common for settlements of Hatch-Waxman patent litigation to involve compensation to the generic drug applicant and an agreement by the generic to stay off the market, typically for several years.

Third, the problem of exclusion payment patent settlements has arisen in – and, to our knowledge, only in – the context of the special statutory framework that Congress created with the Hatch-Waxman Act. 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

[47] Stephanie Kirchgaessner & Patti Waldmeir, *supra* note 41.

drugs to market and maintaining incentives for new drug development. Legislative action concerning exclusion payment settlements can be tailored to the special circumstances of pharmaceutical patent settlements and help to ensure that this unique framework works as Congress intends.

Fourth, the reasoning underlying the recent 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. Indeed, the Eleventh Circuit's *Schering* opinion emphasized that its decision was based on "policy."[48] As the court saw it, the Hatch-Waxman framework Congress created gave generic firms "considerable leverage in patent litigation," and could therefore "cost Schering its patent."[49] Congress, however, is the body with constitutional 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 Congress address the use of exclusion payments in drug patent settlements.

Finally, a legislative remedy offers the prospect of a relatively swift solution to this important issue. While the Commission's enforcement activities are continuing, we recognize the time and uncertainty involved in litigation challenges to anticompetitive settlements. Legislation could provide a speedier and more comprehensive way to address this pressing concern.

---

[48] 402 F.3d at 1076.

[49] *Id.* at 1074.

For these reasons, the Commission strongly supports the intent behind the bipartisan legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer." We would welcome the opportunity to work with the Committee as it considers the bill.

Certain principles may be useful to consider in crafting the precise form and scope of a legislative remedy. A law must be broad enough to prevent evasion or other anticompetitive practices that could render the legislation ineffective, but it should avoid unwarranted deterrence of settlement. The fundamental concern underlying exclusion payment settlements is the sharing of profits 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.

In addition, it is important that the law encompass all arrangements that are part of the settlement, even if not part of a written settlement agreement. That is, it should be clear that substance, not form, governs in assessing what transactions are actually part of the parties' settlement agreement.

At the same time, settlement avenues should not be unduly limited. All settlements provide some value to the generic, even if it is nothing more than termination of the litigation. And settlements in which the value received by the generic amounts to nothing more than the right to sell a generic version of the branded drug the innovator firm is seeking to protect – whether it be the right to sell the generic drug product before patent expiration, a waiver of the brand's market exclusivity based on testing of a drug for pediatric use, or a waiver of patent infringement damages against a generic for entry that has already occurred – are unlikely to

involve a sharing of profits preserved by avoiding competition. Legislation should preserve such settlement options.

Finally, a statutory bar on exclusion payment settlements should include meaningful remedies. Delaying generic competition to a blockbuster drug can be enormously profitable for the brand-name-drug seller. Remedies should take into account the economic realities of the pharmaceutical industry.

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

Hatch-Waxman patent settlements present an additional issue that warrants a legislative remedy. The operation of the Hatch-Waxman Act's 180-day exclusivity creates the potential for a settlement between a brand-name company and a first generic filer to generate a bottleneck that prevents *any* generic competition. When they enter into an agreement for the generic to delay market entry, whether with or without an accompanying payment, the agreement does not trigger the running of the exclusivity period. Although Hatch-Waxman was designed to provide a mechanism to eliminate the bottleneck when the later filer can get a court ruling that it does not infringe, forcing the first filer to "use or lose" its exclusivity period, court decisions have prevented generic firms from using this mechanism. Consequently, the exclusivity creates a bottleneck that prevents any subsequent generic applicant from entering the market until after the first generic enters and the period runs.[50]

[50] *See* Generic Drug Study at vii-xi, 57-58, 62-63.

A subsequent generic can relieve the bottleneck only by obtaining a court decision that the patent supporting the 180-day exclusivity period is invalid or not infringed.[51] That decision acts as a forfeiture event that forces the first filer to either use or lose its exclusivity period within 75 days.[52] A problem arises if the brand-name company does not sue the subsequent generic filer on every patent supporting the exclusivity, thereby eliminating the possibility that the generic company will obtain a favorable court decision on every patent and relieve the bottleneck. Having settled with the first challenger, perhaps for delayed entry, a brand-name company can preempt all subsequent generic challenges and the chance of any earlier generic entry by declining to sue subsequent filers.

A brand name drug firm has a significant incentive to use this strategy, and a trend by brand-name companies to do so is increasingly evident.[53] Some generic companies facing this scenario have attempted to bring declaratory judgment actions of non-infringement and invalidity, but these efforts have been unsuccessful thus far because the courts have dismissed those actions for lack of a Constitutionally-required "case or controversy."[54] However, even if a

---

[51] The decision must be "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorai) has been or can be taken that the patent is invalid or not infringed." Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(a)(1), Pub. L. No. 108-173, 117 Stat. 2066, 2457 ("MMA") (amending 21 U.S.C. § 355(j)(5)(B)(iv)).

[52] The other forfeiture events established by the Medicare Modernization Act are a court-entered settlement that the patents are invalid or not infringed, or withdrawal of the patents from the Orange Book by the brand company. MMA, § 1102(a)(1), Pub. L. No. 108-173, 117 Stat. At 2457(amending 21 U.S.C. § 355(j)(5)(B)(iv)). Both require action by the brand company.

[53] *See, e.g.*, *Teva Pharms. USA, Inc., v. FDA*, 2005 WL 2692489 (D.D.C. Oct. 21, 2005); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp.2d 187 (S.D.N.Y. 2005); *Glaxo Group Ltd. v. Dr. Reddy's Labs, Ltd.*, 325 F. Supp.2d 502 (D.N.J. 2004); *Mutual Pharm. Co. v. Pfizer, Inc.*, 307 F. Supp.2d 88 (D.D.C. 2004).

[54] *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005). The Supreme Court recently examined the availability of declaratory judgment jurisdiction in patent cases in *Medimmune, Inc. v. Genetech, Inc.*, No. 05-068 (U.S.S.Ct. Jan. 9, 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. Although the Supreme Court criticized language in *Teva v.*

generic company could bring that declaratory judgment action, the brand company could still prevent an adjudicated court decision on the patent merits by granting the generic a covenant not to sue. 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.[55]

As a result, a subsequent generic filer that faces a bottleneck but has not been sued, or has been offered a covenant not to sue, has no mechanism to relieve that bottleneck. Even if the subsequent filer has a strong case for noninfringement, the bottleneck postpones consumer access to any lower-priced generic version of the drug. In such circumstances, it is contrary to the Hatch-Waxman Act's purposes of encouraging meritorious patent challenges and promoting generic entry to delay market entry by later applicants when the brand-name manufacturer and first generic applicant are involved in protracted litigation or have settled their litigation without resolving the issues of validity or infringement.

There is a potential legislative remedy, however. The Commission recommends that Congress pass legislation making dismissal of a declaratory judgment action of non-infringement or invalidity for lack of a case or controversy, when brought by a generic applicant, a forfeiture event for the 180-day exclusivity period.[56] The brand's submission of a covenant not to sue the generic applicant should also constitute a forfeiture event. These provisions will give a generic applicant that has raised strong non-infringement or invalidity arguments that a brand company does not wish to litigate a mechanism for removing the bottleneck.

Pfizer, the effect of this decision on declaratory judgment jurisprudence in the Hatch-Waxman context awaits further development in the courts.

[55] *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).

[56] The Commission made a similar recommendation in its 2002 Generic Drug Study at x-xi.

Conclusion

Thank you for this opportunity to share the Commission's views. The Commission looks forward to working with the Committee, as it has in the past, to protect competition in this critical sector of the economy.

Prepared Statement of Billy Tauzin

President and Chief Executive Officer

Pharmaceutical Research and Manufacturers of America

Senate Committee on the Judiciary Hearing: *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?*

January 17, 2007

Chairman Leahy, Ranking Member Specter, and Members of the Committee:

Thank you for the invitation to participate in today's hearing on pharmaceutical companies' settlements of patent disputes. My name is Billy Tauzin and I am the President and Chief Executive Officer of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to developing medicines that allow patients to lead longer, healthier, and more productive lives. Our member companies invested more than $39 billion in 2005 discovering and developing new medicines. PhRMA companies are leading the way in the search for new and better treatments for patients.

As most of you know, I have a very personal reason to be deeply grateful to the thousands of men and women who work every day to bring these new medicines to patients. Because I too have been a patient. Just about three years ago, I was diagnosed with cancer, and I left Congress to battle that disease. Today, with support from family and friends and the help of some amazing doctors and nurses, I am now a cancer survivor. I also know that I would not be here now without the help of the innovative medicines made by America's research-based biopharmaceutical companies. Because of those medicines, I am cancer free and living a healthy, full life.

Ten years ago – even five years ago – that might not have been true. Some of the medicines that helped save my life would still have been in the development process then. It took the efforts of innovative pharmaceutical companies willing to risk money, time, resources and manpower to get these medicines all the way through the regulatory approval process and into the hands of physicians and patients. And because of these efforts, patients like me everywhere are better off.

In order to foster these much-needed medical breakthroughs, we must continue to pursue public policies that provide for strong patents – patents that allow pharmaceutical companies and their investors an opportunity to recoup and secure the benefits of their significant investments. This testimony will address the importance of patents to 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.

Courts and experts have stated unequivocally that settlement of litigation should be encouraged and that settlement of patent litigation can benefit consumers. Blanket prohibitions on certain types of settlements could force both sides to spend valuable resources litigating their patent dispute to judgment. Statistics show that innovators will win a significant number of those cases, and a win by the patent holder means the generic likely would not be able to enter the market before the patent expires. In addition, both innovators and generics 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.

A total ban on settlements in which the brand company gives something of value to the generic 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 Modernization Act, Congress gave the FTC and the Department of Justice the authority and ability to evaluate patent settlement agreements between brand and generic companies before the generic is due to come on the market. This approach will give 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 or secure 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 – think of life without the plow, the steam engine, the jet engine, the laptop computer, the wireless phone or fiber optic cable, to name a few. 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]

Patents are given due respect in the law. By Congressional enactment, an issued patent is afforded the presumption of validity.[2] In the antitrust context, courts have held that the antitrust laws should be interpreted not to supplant the

[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] 35 U.S.C. § 282.

patent right.[3] 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."[4] Consistent with the antitrust laws, a patent holder may exclude others from producing a patented article, or may grant limited licenses.[5] Generally, only when a restriction on use goes "outside the scope of the patent grant" are the antitrust laws implicated.[6]

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. Strong intellectual property protection is essential for the preservation and growth of the research-based pharmaceutical industry. It takes on average 10-15 years and more than $800 million, according to the Tufts Center for the Study of Drug Development, to bring a new medicine to consumers.[7] Let's take Gleevec®, for example, the breakthrough treatment for chronic myeloid leukemia that won PhRMA's Discover's Award in 2004: researchers spent two years isolating the molecule that would become Gleevec and devoted another eight years to safety testing and development before they were ready to try the drug in patients. Early clinical trials showed great promise; the innovator moved quickly to expand clinical trials to include more patients; and the drug was granted "fast-track" designation to receive accelerated FDA review. And even with all this promise and focus, Gleevec still took more than 11 years to get from the laboratory through FDA approval.

And of course, there are no guarantees. While investors may love the success stories like Gleevec, it is clear that market success for a particular medicine depends on many factors beyond the manufacturer's and investors' control, including for example, demand for a particular drug therapy and competition from other brand drugs. Consider these odds:

- Only one in 5,000 to 10,000 compounds eventually reach patients.
- Only two out of every ten compounds that enter clinical testing reach the market.
- Only three out of every ten drugs that reach the market ever earn back enough money to match or exceed the average R&D cost of getting them to the marketplace.

Given these odds, it's easy to see why patents are a crucial factor in innovation. Patents provide the minimum degree of assurance for investors to risk the capital necessary to fund the pharmaceutical discovery process despite the uncertain

---

[3] *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*.").
[4] *Atari Games Corp. v. Nintendo, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990).
[5] *See, e.g., Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940).
[6] *Monsanto v. McFarland*, 302 F.3d 1291, 1298 (Fed. Cir. 2002).
[7] *See, e.g.*, J.A. DiMasi, "New Drug Development in the United States from 1963 to 1999", *Clinical Pharmacology & Therapeutics*, 69 (2001): 5, 286-96.

chances of producing a commercially viable product. Simply put, scientific advances made in recent years would have been impossible without a system of intellectual property laws to provide the structure, stability and opportunity for recouping investment.

II. Congress Has Attempted To Strike a Balance Between Policies That Foster Innovation and Those That Promote the Availability of Generic Pharmaceuticals

Even as we discuss the critical role of patents in pharmaceutical innovation, it is important to recognize that pharmaceutical products effectively receive a shorter period of useful patent life than other types of products. To better understand this, first consider the basics about patents in other industries. 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. Recent statistics from the Patent and Trademark Office demonstrate that it takes about two and a half years, on average, from the date a patent application is filed until a patent is issued.[8] Thus, patent holders that do not have to obtain FDA approval of their products may receive about 17.5 years of effective patent life, or time on the market before the patent expires.[9]

By comparison, pharmaceutical companies are required to obtain FDA approval before they can market their products. Let's say that it takes, as one peer-reviewed study indicates, 14.2 years to proceed through the phases of drug development from early discovery, to pre-clinical work, to clinical trials, to FDA review, and finally, to FDA approval.[10] 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")[11] strove to balance the interests of innovative and generic companies and granted innovators products marketing exclusivity for limited periods and restored some of their effective patent time lost during the clinical research and FDA regulatory review of the product. Still, research demonstrates

[8] *See* The United States Patent and Trademark Office, "Frequently Asked Questions About Patents," (accessed January 15, 2007) http://www.uspto.gov/web/offices/pac/doc/general/faq.htm
[9] *See* U.S. Patent And Trademark Office, Performance and Accountability Report Fiscal Year 2006 - Management's Discussion and Analysis, http://www.uspto.gov/web/offices/com/annual/2006/3020100_patentperfrm.html
[10] J.A. DiMasi, "New Drug Development in the United States from 1963 to 1999," *Clinical Pharmacology & Therapeutics*, 69 (2001): 5, 286-296.
[11] 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.

that the average period of effective life for new medicines, even with patent term restoration granted under the Hatch-Waxman Act, is between 11 and 12 years.[12] And there are examples where the time of useful patent life is even less – for instance, Orudis®, a medicine used to treat pain, fever and inflammation, was approved by FDA with only 5 years remaining before its patent was set to expire. In short, pharmaceutical companies typically have less time than innovators in other industries under their patents to recoup their investments.

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. 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.[13] In fact, the average length of time before a first-in-class drug got its first direct competitor dropped from 8.2 years in the 1970s to 1.8 years in 1995.[14]

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 innovator's patent and exclusivity periods have expired.[15] 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).[16] 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 for a generic version of a drug prior to the expiration date of the innovators' patents, provided it certifies that the patents are invalid or will not be infringed by the manufacture,

---

[12] H.G. Grabowski and J. Vernon, "Longer Patents for Increased Generic Competition in the U.S. – The Waxman-Hatch Acts After One Decade," *Pharmacoeconomics* 10, suppl. 2 (1996): 110-123.

[13] DiMasi JA, Paquette C. The Economics of Follow-On Drug Research and Development: Trends in Entry Rates and the Timing of Development, *Pharamacoeconomics* 2004, 22, suppl. 2, 1-13.

[14] Op. Cit.

[15] 21 U.S.C. 355(j).

[16] 35 U.S.C. 271(e)(1).

use, or sale of the generic drug.[17] 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 almost 60 percent today.[18] 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.[19] Prior to Hatch-Waxman, only 35 percent of top-selling innovator medicines had generic competition after their patents expired.[20] Today, many more innovator medicines face such competition.[21] In addition, there are increasing examples of generic competition before patent expiration. And in most cases, sales of innovator medicines drop by as much as 90 percent or more within weeks after a generic copy enters the market.[22]

III. Public Policy Favors Settlements of Expensive, Burdensome Patent Infringement Litigation

In this climate of 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 to the Committee that patent litigation among brand and generic pharmaceutical companies is both common and costly.[23]

Numerous courts have recognized that "public policy wisely encourages settlements."[24] Courts and experts likewise have stated unequivocally that

---

[17] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
[18] Generic Pharmaceutical Association, "Statistics" (accessed January 15, 2007) http://www.gphaonline.org/Content/Navigation Menu/AboutGenerics/Statistics.default.htm
[19] 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").
[20] 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 (May 1986), 195-198).
[21] 1998 CBO Report.
[22] Javed Sayed, "Indian firms' U.S. generic market scope looks bleak," The Economic Times: November 15, 2005.
[23] The Paragraph Four Report, Frequently Asked Questions, accessed on January 15, 2007 <http://www.paragraphfour.com/forums/index.php?showtopic=14> .
[24] *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994).

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.[25] The Sixth Circuit has said "[t]he importance of encouraging settlement of patent-infringement litigation ... cannot be overstated."[26] 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.[27]

It is basically a truism that patent litigation is complex, lengthy and extremely expensive for all concerned. U.S. patent litigation overall has been estimated to cost about $1 billion annually.[28] Another study found that the median expense for patent litigation with more than $25 million dollars at risk is $4.5 million.[29] The costs of patent litigation in the pharmaceutical industry likewise are significant. In fact, at the administrative hearing in the Schering-Plough – FTC case, one expert witness estimated that for every dollar spent on pharmaceutical research and development, about 27 cents is spent on patent litigation.[30] And it is not uncommon for a patent dispute to last several years.[31] As these figures illustrate, settlements allow both litigants and the court system to conserve resources that can then be put to more efficient use.

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, heretofore unknown facts uncovered during discovery, unpredictable juries, and even lawyer competence. 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 affecting its bottom line.

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

---

[25] *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056, 1072 (11th Cir. 2005).
[26] *Schlegal Mfg. Co. v. U.S.M. Corp.*, 525 F.2d 775, 783 (6th Cir. 1975)
[27] Settlements Resolving Intellectual Property Disputes, 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046, at 265-66 (1999).
[28] Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale J. Reg. 359, 380 (1999).
[29] Am. Intellectual Prop. Law Ass'n, Report of the Economic Survey 2005, at 22 (2005).
[30] Opening Brief of Schering-Plough Corp., 2004 WL 3557974, at 48 (11th Cir. June 1, 2004).
[31] 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.").

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

A law that would ban patent settlements just because the brand company transfers something of value to the generic (as proposed in legislation introduced in the 109th Congress, S. 3582) 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. 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.

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 recoups 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 is not exposed to any infringement damages as a result of the Hatch-Waxman statutory scheme.[32]

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.

[32] *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").

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 to settle. For example, the innovator may be less willing to settle precisely because of the value of the marketing 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.[33]

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.[34]

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."[35]

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

[33] *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.").
[34] *See, e.g., Schering-Plough*, 402 F.3d at 1059-61 (discussing settlements in which assets were exchanged).
[35] *Schering-Plough*, 402 F.3d at 1075.

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.[36]

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. In its *amicus* brief, the United States 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."[37] 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 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.

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 can only afford to make these investments because

---

[36] *Schering-Plough*, 402 F.3d at 1076.

[37] Brief for the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (filed May 17, 2006).

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.

This effect on innovators has been recognized by the courts and has been one of the key drivers in their refusal to accept a rule that would effectively prohibit all 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."[38]

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 medicines.[39] 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.[40] 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.[41]

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."[42] Moreover, limits on settlement will limit a generic's ability to gain access to technology or other assets in the pioneer'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 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.

---

[38] *Schering-Plough*, 402 F.3d at 1075.
[39] http://www.innovation.org/index.cfm/ImpactofInnovation/Controlling_Healthcare_Costs (accessed January 15, 2007).
[40] F. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, National Bureau of Economic Research Working Paper, No. 8996 (Cambridge, MA, NBER June 2002).
[41] 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).
[42] *Asahi Glass Co. v. Pentech Pharm.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

Finally, fewer settlements mean that litigants will spend more time and money litigating. By spending more time and money on litigation, the litigants will have to make corresponding cuts in their other expenditures, including expenditures invested in new drug development.

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

The question then is what is 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 all settlements involving payments by 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.

Questions relating to the antitrust validity of settlements that include payments from innovator to generic are currently working their way through the courts. The United States filed a brief before the Supreme Court in *Schering-Plough* expressing the correct view that this issue is important and there is room for debate, but that consideration by the Supreme Court was premature.[43] As the brief explained, the courts' views on this issue are still emerging. As more cases work their way through the courts, a more defined body of antitrust law will emerge addressing this question and perhaps solving the debate. At the least, these opinions will further enhance understanding of this complex subject.

We urge the Committee 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

[43] Brief for the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (filed May 17, 2006).

and, in turn, severe consequences for consumers...."[44]

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."[45] This kind of analysis can only be done on a case-by-case basis.

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. A total ban on an entire category of settlements is unnecessary – that kind of blanket rule is overbroad and would chill all settlements, even those that 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 Committee 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 Committee and others in Congress as you address these and other important policy issues relating to innovation and access to medicines.

---

[44] *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d at 256.
[45] R. Hewitt Pate, Assistant Attorney General, Antitrust Division, Address to the American Intellectual Property Law Association, January 24, 2003.

PhRMA

Billy Tauzin

President and Chief Executive Officer

Billy Tauzin was named president and chief executive officer of the Pharmaceutical Research and Manufacturers of America (PhRMA) in January 2005 and immediately took up two of the most important causes of his career: To help ensure patients everywhere continue to have access to the miracles of medicines, and to ensure that innovative biopharmaceutical research thrives, improving and saving lives everywhere.

He knows firsthand what patients face as they search for hope, treatment and cures having recently battled cancer himself. This unique insight guides his leadership as PhRMA president where he is helping to develop solutions to America's health care challenges so patients now and in the future have the medicines they need.

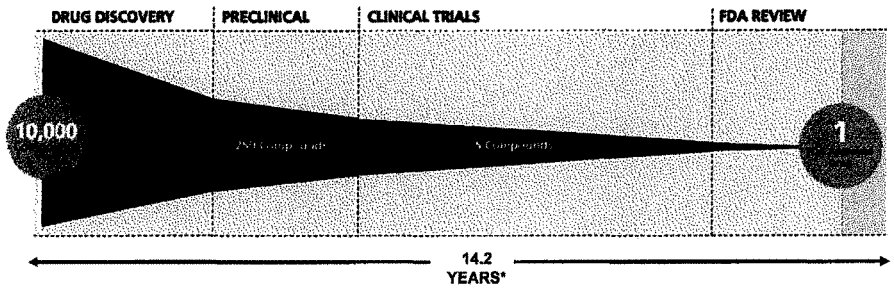
Throughout a long and distinguished public service career, including 13 terms representing the people of the 3rd Congressional District of Louisiana, Billy Tauzin exhibited a class and leadership style that made him a standout among our nation's elected officials. As a Member of Congress, he was called "knowledgeable and eloquent" by the *Almanac of American Politics* and "one of the House's savviest members" by *National Journal* Magazine.

Billy Tauzin began his public service career in the Louisiana State Legislature where he served in a variety of distinguished posts such as Chairman of the House Natural Resources Committee and Chief Administration Floor Leader. He was chosen twice as one of Louisiana's "Ten Best Legislators."

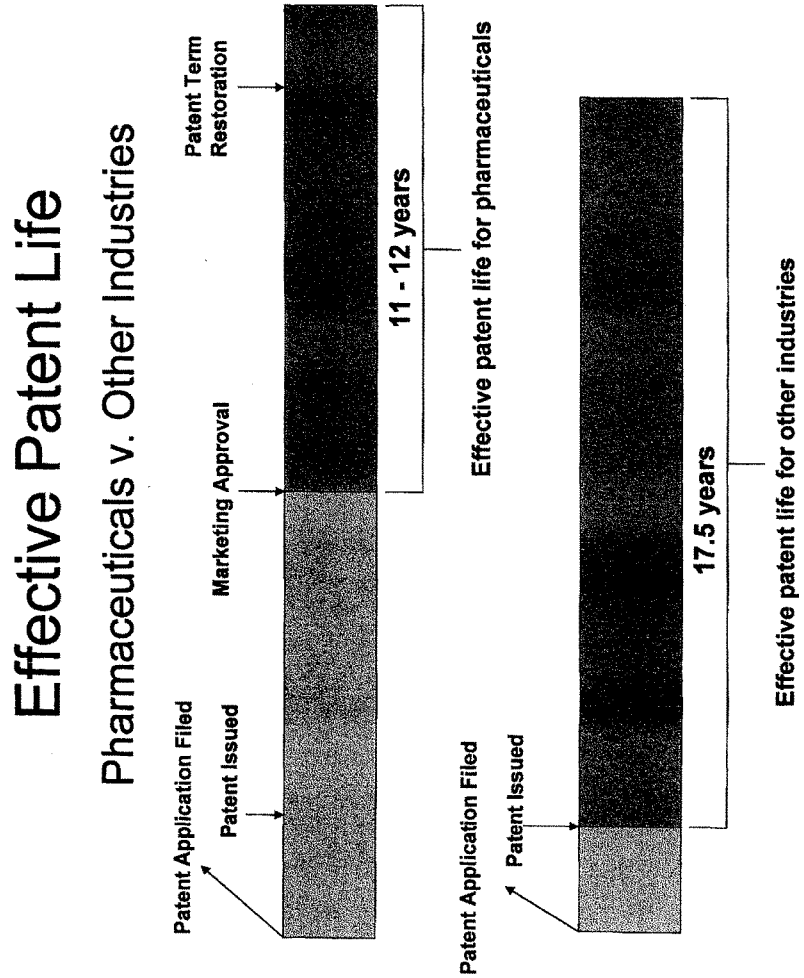
He was first elected to the U.S. House in 1980 as a Democrat. Because his conservative views increasingly led him to vote with GOP House members despite his Democratic affiliation, he switched parties in 1995. In 1998, he joined with House Majority Leader Dick Armey to propose a revamping of the tax code.

While in Congress, he held several leadership positions, beginning with his chairmanship of a Merchant Marine Subcommittee, which oversaw legislation related to the Exxon Valdez oil spill in Alaska. In September 1995 he was named Deputy Majority Whip; he is the first American to have been part of the leadership of both parties in the House. In an effort to promote a spirit of bipartisan cooperation on Capitol Hill, he co-founded and served as Co-Chairman of the Mainstream Conservative Alliance, better known as Republican "Blue Dogs."

Drug Discovery Process



*J.A. DiMasi, "New Drug Development in the United States from 1963 to 1999," *Clinical Pharmacology & Therapeutics*, 69 (2001): 5, 286-296.


Effective Patent Life
Pharmaceuticals v. Other Industries
Patent Application Filed
Patent Issued
Marketing Approval
Patent Term Restoration
11 - 12 years
Effective patent life for pharmaceuticals
Patent Application Filed
Patent Issued
17.5 years
Effective patent life for other industries

United States Senate Committee on the Judiciary
"Paying Off Generics to Prevent Competition with Brand Name Drugs:
Should it Be Prohibited?"

January 17, 2007

Statement of Michael Wroblewski
Project Director, Consumer Education and Outreach
Consumers Union, the Non-Profit Publisher of *Consumer Reports*

Mr. Chairman, Members of the Committee:

Thank you for the invitation to testify today. Consumers Union is the independent non-profit publisher of *Consumer Reports*. Consumers Union investigates and reports extensively on the issues surrounding the costs, safety, and effectiveness of prescription drugs so that we can provide consumers with expert, non-biased advice to help them manage their health.[1]

In answer to the question that motivated this hearing, "Whether paying off generics to prevent competition with brand-name drugs should be prohibited?" Consumers Union responds with an emphatic "Yes!" Consumers Union strongly supports prompt Congressional action to create a bright line rule to end the use of patent settlements that include compensation from brand-name companies to generic drug

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with expert and independent information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports* and ConsumerReports.org, its other publications and from noncommercial contributions, grants and fees. Consumers Union's products have a combined paid circulation of approximately 7.3 million consumers. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and ConsumerReports.org regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

applicants in order to restrict generic market entry.[2] These types of settlements should be declared "unfair methods of competition."[3]

These settlements restrict generic competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years. These settlements also jeopardize the health of millions of Americans who have difficulty obtaining safe and effective medicines at affordable prices. In light of the recent increased use of these agreements,[4] we urge prompt Congressional action to end this practice.

This testimony first discusses why generic drugs are critical to affordable health care today and how Consumers Union is educating its readers and the public about the substantial benefits of generic drugs. The testimony then explains how the dynamics of generic drug competition create powerful incentives for brand-name and generic companies to settle patent litigation in a way that harms consumers. The Hatch-Waxman Act (the Act),[5] which governs the approval of generic drugs, exacerbates these incentives. The testimony highlights why continued reliance on the courts to provide consumers with timely relief is misplaced. The testimony also describes Consumers Union's support of

---

[2] This compensation can take the form of a cash payment. These types of payments were highlighted by the Federal Trade Commission's enforcement actions involving Hytrin, Platinol, and Taxol. *See Abbott Labs.*, Dkt. No. C-3945 (May 26, 2002) (consent order); *Geneva Pharms., Inc.*, Dkt No. C-3946 (May 22, 2000) (consent order); *Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (Apr. 13, 2003) (consent order). It also could be in the form of the brand-name company agreeing not to launch an "authorized generic drug" prior to expiration of the brand-name drug company's patents claiming the brand-drug product.

[3] Consumers Union supports S. 3582, the "Preserve Access to Affordable Generic Act," introduced in the 109th Congress by Senators Kohl, Leahy, Grassley, and Schumer.

[4] *See* Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate, "Barriers to Generic Entry," (July 20, 2006) at 16-17, ([i]n the current fiscal year, we have seen significantly more settlements with payments and a restriction on entry-- seven of ten agreements between brand-name and generic companies included a payment from the brand-name to the generic company and an agreement to defer generic entry.") ("FTC Aging Committee Statement"), *available at* http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf.

[5] 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)).

several other legislative changes to speed generic entry, including: (a) breaking the bottleneck that can occur when generic applicants cannot obtain decisions on the merits concerning patent infringement, (b) clarifying the law to provide for the development of generic versions of complex molecular biologic medicines, (c) clearing the backlog of generic applications at the FDA, and (d) eliminating the abuse of citizen petitions in the generic drug approval process.

I. Generic Drugs Can Help Dampen High Health Care Costs Now

Health care costs continue to surge at double or triple the rate of general inflation, in part due to the high cost and rate of inflation of brand-name prescription drugs.[6] Generic drugs can dampen health inflation by providing equally safe and effective medicine at a far lower price—often prices up to 70 percent or less of the brand name drug.[7]

New generic drug entry in 2006 illustrates the substantial savings that generic drugs can have on health-care spending. During 2006, the cholesterol-lowering drugs Zocor and Pravachol, the antidepressants Zoloft and Wellbutrin, and the nasal spray Flonase all went generic. Employers, governments, and patients paid $9.4 billion for these drugs in 2005 (the year before generic entry). Because generic drugs can be up to 70% less expensive than brand-name drug price, there is a potential annual savings of $6.6 billion on those five drugs alone.[8] This year and in 2008, several brand-drugs are

[6] *See* Aaron Catlin, et al., "National Health Spending in 2005: The Slowdown Continues," 26 *Health Affairs* 142, 144, Exhibit 2 (Jan./Feb. 2007) (prescription drugs expenditures increased 13.1% in 2003, 8.6% in 2004, and 5.8% in 2005).

[7] David Reiffen and Michael Ward, "Generic Drug Industry Dynamic," 87 *Review of Econ. & Stat.* 37 (2005).

[8] Rachel Brand, Popular Drugs are Getting Cheaper," *The Detroit News* (Dec. 6, 2006), *available at* http://www.detnews.com/apps/pbcs.dll/article?AID=/20061206/LIFESTYLE03/612060326/1040.

expected to go generic, including blockbuster drugs with over $1 billion in annual sales such as Prevacid (used to treat heartburn), Imitrex (to treat migraine headaches), Zyrtex (to treat allergies), and Effexor (to treat depression).[9] The consumer savings once generic versions of these drugs are available will be immense.

Consumer Reports strongly encourages the use of generics as a way for consumers to save money while obtaining quality health care. We have made a major organizational commitment to educate consumers about generic drugs and to help consumers obtain reliable, easy-to-understand advice about the safest, most effective, and lowest cost prescription drugs available. In December 2004, Consumers Union launched *Consumer Reports Best Buy Drugs*℠, a free public education project.[10] Attached to this testimony are two sample *Best Buy Drugs* summary reports on prescription drugs to reduce cholesterol and to relieve heartburn. We currently provide information for 16 different classes of medicine, and we plan to expand to additional classes in the near future.

The goals of *Best Buy Drugs* are to:

- improve the quality of care by ensuring people get the safest, most effective drugs with the least side effects;
- improve access by helping consumers choose drugs that are most affordable (taking into account effectiveness, side effects, safety, and price); and
- help consumers and taxpayers by reducing the cost of health insurance, consumers' out-of-pocket expenses, and Medicare and Medicaid.

---

[9] FDA, Approved Drug Products with Therapeutic Equivalence Evaluations (Electronic Orange Book) - *via on-line resources* FDC Reports, *The Pink Sheet (*2004-2005).

[10] *Consumer Reports Best Buy Drugs*℠ is funded by grants from the Engelberg Foundation and the National Library of Medicine. In addition, Consumers Union makes a large in-kind contribution to support this project.

We estimate that a consumer who switches from a highly advertised, high-priced brand name drug to a Best Buy Drug can often save between $1,000 and $2,000 a year. Approximately 100,000 *Consumer Reports Best Buy Drugs*℠ reports are downloaded each month, including about 20,000 in Spanish. In addition to our Web site www.CRBestBuyDrugs.org, we distribute print versions of our reports in five states with the help of pharmacists, senior organizations, doctors, and libraries. The *Best Buy Drugs* website also provides additional information describing how *Best Buy Drugs* operates and the rigorous evidence-based review that is used to derive the "Best Buy Drug" in each class of medicine.

Consumer Reports also has been active in reporting on the consumer benefits of generic drugs. Most recent, *Consumer Reports* published a report in its November 2006 issue that explained how cash prices for generic drugs vary widely at different types of pharmacies. The report concluded that for five highly prescribed generic drugs (fluoxetine, lisinopril, lovastatin, metformin, and warfarin), median prices at mass merchant and online pharmacies were approximately 20 to 50 percent less expensive than prices at supermarket and drug chain pharmacies.[11] We urged our readers to shop around for the best deals.

II. The Dynamics of Generic Drug Competition Create Powerful Incentives for Brand-Name and Generic Companies to Settle Patent Litigation in A Way that Thwarts the Objectives of the Hatch-Waxman Act.

The economics surrounding generic entry create powerful incentives for brand-name and generic companies to enter into these types of patent settlements. These incentives are created because the total profits available to the brand-name company prior

[11] *Consumer Reports* (Nov. 2006) at 58-59.

to generic entry *exceed* the total profits of *both* the brand-name and generic applicant after generic entry.[12] As a result, the brand-name company has a powerful economic incentive to pay the generic applicant something more than it would earn by entry with its generic product, because the sum the brand-name company pays will still be less than it would lose if the generic applicant did enter the market. Likewise, the generic applicant who is sued for patent infringement can earn more by entering into a settlement in which it agrees to defer market entry than it could earn by winning its patent challenge and competing in the market. In short, when these payments are allowed, the generic company may obtain more by settlement than it could have obtained by outright victory in the patent case.

A. The Hatch-Waxman Act Exacerbates the Incentive to Settle Patent Litigation with Compensation Paid to the Generic Applicant.

When Congress enacted the Hatch-Waxman Act, it represented a compromise between making available more low-cost generic drugs, while at the same time restoring patent life lost due to the length of FDA brand-name drug approval process.[13] To accomplish this goal, Congress created a number of industry-specific incentives to speed generic entry. In order to see how these incentives work, and their effects on the dynamic of patent settlements, it is necessary to understand three unique features of the Act: a paragraph IV certification, the 30-month stay period, and the 180-day marketing exclusivity provision.

---

[12] *See* Robert Kneuper, "Four Economic Principles Underlying the FTC's Position Against Reverse Payments in Patent Settlement Agreements," *The Antitrust Source* (Jan. 2006) at 2, *available* athttp://www.abanet.org/antitrust/at-source/06/01/Jan06-Kneuper1=26f.pdf.

[13] H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984).

The Act establishes a procedure for accelerated FDA approval of generic drugs through the use of an "Abbreviated New Drug Application" (ANDA). The Act requires a generic applicant to show that its generic drug is "bioequivalent" to the brand-name drug. The generic drug manufacturer does not have to replicate the costly safety and efficacy tests for its drug; rather, the Act permits the generic company to rely on the safety and efficacy tests of the brand-name drug product.

One of the most important features of this application process is if the generic applicant seeks prompt approval of its generic drug, it must certify that its generic drug product does not infringe on the patents claiming the brand-name drug product, or that patents claiming the brand-name drug product are invalid.[14] The Act names this a "paragraph IV" certification.

A generic applicant that makes a paragraph IV certification must notify the patent holder. If the patent holder does not bring an infringement action against the generic applicant within 45 days, the FDA may approve the ANDA, assuming the other regulatory requirements are met. Alternatively, if the brand-name company brings an infringement action during the 45-day period after notification, the patent owner is entitled to an automatic stay of FDA approval of the ANDA for 30 months (the 30-month stay). This process provides the brand-name company and the generic applicant an opportunity to litigate patent issues before the generic drug has entered the market and incurred any damage exposure.

---

[14] The Act also creates a way for a generic applicant to obtain approval at the expiration of any patent claiming the brand-name drug product (a "paragraph III" certification). The relevant statutory and regulatory framework for the ANDA approval process has been described in *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. at 676-78; *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1063-65, 46 USPQ2d 1385 (D.C. Cir. 1998); and *Bristol-Myers Squibb Company v. Royce Laboratories, Inc.*, 69 F.3d at 1131-32, 1135.

The Act provides that the generic applicant to file the first ANDA containing a paragraph IV certification (the "first filer") for a particular brand-name drug is entitled to 180-days of marketing exclusivity. During this period, the Food and Drug Administration may not approve a subsequently filed ANDA for the same brand-name drug product. The 180-day period starts once the first filed generic applicant begins commercial marketing of its generic drug product. The real effect of this exclusivity period is that the FDA is prohibited from approving any subsequently filed ANDA for the same brand-drug product until the first filer's 180-day period of marketing exclusivity expires. The 180-day exclusivity period is an important incentive Congress provided to would-be generic entrants to encourage them to challenge weak or questionable patents claiming brand-name drug products or to design around a brand-name drug's patent.

This regulatory structure exacerbates the economic incentives underlying patent settlements between brand-name companies and generic applicants discussed above. A settlement between the brand-name company and the first filer will avoid the brand-name company's lost profit potential. In addition, the 180-day marketing exclusivity provision blocks entry by subsequently filed generics until 180 days after the first filer actually begins commercial marketing. Unfortunately for consumers, the first filer has a powerful incentive to accept a settlement because it will not only get the brand name company's compensation, but it retains its 180-day marketing exclusivity when it does enter at a later date. Although both the brand-name company and the generic company are better off with the settlement, consumers lose the possibility of an earlier generic entry, either because the generic company would have prevailed in the lawsuit or the parties would have negotiated a settlement with an earlier entry date but no payment.

B. These Settlements Are Contrary to the Purpose of the Hatch-Waxman Act.

The irony, of course, is that the purpose of the ANDA application process was to speed the entry of generic drugs. This policy was reaffirmed in 2003 when Congress amended the Hatch-Waxman Act in the Medicare Modernization Act. As the Senate Report explained, those amendments sought in part to stamp out the "abuse" of the Hatch-Waxman Act resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."[15] Indeed, Senator Hatch, one of the Act's co-authors, stated during the debate over these amendments that "[a]s a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these types of reverse payment collusive arrangements appalling. I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition."[16]

C. Experience Shows that Brand-Name Companies and Generic Applicants Do Not Need to Use Payments for Delay to Settle Patent Litigation.

As noted above, the FTC has reported that these types of patent settlements reappeared in 2005, after a six year hiatus.[17] Two observations can be made from this fact. First, the FTC reported that in 1999 its investigations into the legality of these types

[15] S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

[16] *See* Statement of Sen. Orrin Hatch, Senate Floor Debates on S. 812, *Cong. Rec.* at S7567 (July 30, 2002).

[17] 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. *See also* FTC Aging Committee Statement at 16-17.

of settlement agreements became public. The result of this public knowledge was that brand-name and generic companies stopped entering into patent settlement agreements with these terms. Second, brand-name and generic companies continued to settle patent disputes during this period (roughly from 1999 to 2005), when many industry participants believed it to be anticompetitive to enter into these types of patents settlements. This fact undermines any contention now that these payments are necessary to settle patent litigation.

III. The Courts are Unlikely to Provide Timely Relief to Consumers.

We encourage Congress to act now to end the use of these types of settlement agreements because it is unlikely the federal courts will provide consumers relief in a timely manner. Two recent appellate court decisions have taken a lenient view of these types of patent settlements, with one of the courts rejecting the reasoned antitrust analysis of these settlements put forth by the FTC.[18] Both courts have, in essence, held that these settlements are legal unless the patent was obtained by fraud or that the infringement suit itself was a sham. These courts relied on the presumptive validity of a patent to support the conclusion that any settlement which does not exceed the exclusionary scope of a patent also must be valid. The upshot of these court rulings is that a patent holder can pay whatever it takes to buy off a potential challenger during the life of the patent. In one sense, court approval of these types of payments will convert Hatch-Waxman into a vehicle for facilitating the collection of "greenmail" by generic applicants.[19]

---

[18] *Schering-Plough Corp. v. F.T.C.*, 403 F.3d 1056 (11th Cir. 2005) (cert. denied); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

[19] *See* Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III, Address Before the ABA Spring Meeting (Mar. 29, 2006), at 26, *available at* http://www.hhlaw.com/files/News/05ac8357-7511-43c9-a927-2c7e96a0ecde/Presentation/NewsAttachment/fd869e0b-b58a-451d-ad8d-2e110dbb796b/LearyABASpringMeetingSpeech.pdf.

These rulings are based on two faulty premises. First these courts seem to require that unless the patent can be proved to be invalid or not infringed, a court cannot declare a settlement illegal. This test, as the FTC discussed in its *Schering* opinion, may be good in theory but, it is nearly impossible to make work from a practical point of view.[20]

The second faulty premise is that these courts have elevated the generally held principle that public policy favors settlements above the statutory mechanisms that Congress put in place to encourage generic applicants to challenge weak patents and, hence, speed generic entry. This reasoning also lacks an appreciation of the view, as recently articulated by the U.S. Department of Justice Antitrust Division, that public policy also strongly favors ridding the economy of invalid patents, which impede efficient licensing, hinder competition, and undermine incentives for innovation.[21]

Indeed, the industry experience under Hatch-Waxman between 1992 and 2000 shows that Congress struck the right balance when it established these incentives. During this period, generic challengers that had used paragraph IV certifications won their patent challenges in 73% of the cases.[22] Indeed, these challenges have resulted in generic entry earlier than what otherwise would have occurred absent the generic challenge. These patent challenges and subsequent generic entry have yielded enormous benefits to consumers.

---

[20] *See Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (F.T.C.) (Commission Decision and Final Order) at 33-35 (the FTC's opinion discussing the practical and public policy limitations on the usefulness of a "mini patent trial" within the conduct of an antirust case).

[21] Brief for the United States As Amicus Curiae Supporting Petitioner, *MedImmune, Inc. v. Genentech, Inc., et al.*, No. 05-608 (May 2006) at 2, *available at* http://www.usdoj.gov/osg/briefs/2005/3mer/1ami/2005-0608.mer.ami.pdf.

[22] Federal Trade Commission, Generic *Drug Study Prior to Patent Expiration: An FTC Study* (July 2002) at vi, *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

Although the FTC remains vigilant in searching for appropriate ways to take enforcement action against these types of patent settlements,[23] administrative law enforcement actions and appeals take several years to complete. During this time, consumers will be denied access to affordable drugs.

IV. Other Legislative Suggestions to Help Speed Generic Entry.

Congress also may wish to consider four specific actions so that consumers have access to safe and effective generic medicines in a timely manner. First, we urge Congress to address a way to break the bottleneck that occurs if the brand-name company does not sue a subsequent generic applicant. Under current law, there is no way to trigger a forfeiture of the first-filer's 180-day period, even through a subsequently filed generic drug application is ready to be approved. To address this issue, Consumers Union supports the FTC's recommendation for Congress to clarify that dismissal of a court action brought by a generic applicant seeking a declaratory judgment on patent infringement or invalidity constitutes a forfeiture event for the 180-day exclusivity period.[24]

Second, there is no clear law providing for the development of generic versions of complex molecular biologic medicines. These new products are the most expensive medicines on the market—some costing as much as $100,000 to $250,000 for a course of treatment. Consumers Union believes that biogenerics could provide some savings and can be provided safely, thus helping some of our most severely ill patients.[25] Existing

---

[23] FTC Aging Committee Statement at 5.

[24] *Id.* at 24.

[25] Tsao, Amy. "Seeking a Prescription for Biogenerics." Business Week. October 24, 2003.

FDA law should be clarified to allow the U.S. to do what the Europeans are doing: bringing some relief to consumers.[26]

Third, we urge Congress to provide the FDA with sufficient resources to eliminate the backlogs in the approval of generics.[27] In a memo to Consumers Union last autumn, the FDA reported that an unduplicated count of pending generic applications showed a backlog of 394 drugs pending more than 180 days—drugs which could help lower costs to consumers if they were approved.

Fourth, we urge Congress to stop the use of phony citizens petitions to delay generic entry. According to the FDA, only 3 of 42 petitions answered between 2001 and 2005 raised issues that merited changes in the agency's policies about a drug. For example, Flonase, a commonly used prescription allergy medication, went off-patent in May 2004. But GlaxoSmithKline stretched its monopoly window by almost two years with citizen petitions and a legal challenge to the use of generics.[28] We recommend Congress end this abuse.

Respectfully Submitted,

Michael Wroblewski
Project Director, Consumer Education and Outreach
Consumers Union
101 Truman Avenue
Yonkers, New York 10703
mwroblewski@consumer.org

---

[26] *See* Statement of Jim Guest before the Senate Committee on Health, Education, Labor and Pensions on S. 3807, the Enhancing Drug Safety and Innovation Act of 2006 (Nov. 16, 2006) at 20, *available at* http://help.senate.gov/Hearings/2006_11_16/Guest.pdf.

[27] *Id.* at 19.

[28] *Consumer Reports* (Nov. 2006) at 5.

Consumer Reports
BEST BUY DRUGS
PROVEN • EFFECTIVE • AFFORDABLE
www.CRBestBuyDrugs.org

Drugs to Treat Heartburn, Ulcers, and Stomach Acid Reflux:

The Proton Pump Inhibitors

Comparing Effectiveness, Safety, and Price

IF YOU SUFFER from heartburn, ulcers or gastroesophageal reflux disease (GERD, more commonly known as acid reflux), you may need treatment with a proton pump inhibitor, or PPI. Five medicines in this class are available. One is a nonprescription drug. PPIs range in cost from around $25 to more than $200 a month.

To help you and your doctor choose a PPI, *Consumer Reports* has evaluated the drugs in this category based on their effectiveness, safety, and cost. This 2-page brief is a summary of an in-depth report you can access on the Internet at **www.CRBestBuyDrugs.org.** You can also learn about other drugs we've analyzed on this free Web site. Our independent evaluations are based on scientific reviews conducted by the Oregon Health and Science University-based Drug Effectiveness Review Project. Grants from the Engelberg Foundation and National Library of Medicine help fund *Consumer Reports Best Buy Drugs.*

Do You Need a PPI?

Almost everyone has heartburn once in a while. Periodic bouts can be treated effectively and safely with over-the-counter antacids and acid reducers such as Alka Selzer, Maalox, Rolaids, Tums, cimetidine (Tagamet) or ranitidine (Zantac). But if you have heartburn or acid reflux more than once a week and your symptoms are not relieved by these over-the-counter medicines, **you may need a PPI. GERD can be dangerous. If left untreated, it can cause erosion of the lining of the esophagus.**

Comparative Effectiveness of PPIs[1]

Generic Name with Dose per Day	Brand Name	Complete Symptom Relief (% of Patients)	Esophageal Healing at 8 Weeks (% of Patients)	Relapse Prevention (% of Patients)
Esomeprazole 40mg	Nexium	60-70%	92%	93%
Lansoprazole 30mg	Prevacid	60-70%	87%	NA
Omeprazole 20mg	Prilosec	60-70%	86%	86%
Pantoprazole 20mg	Protonix	60-70%	91%	86%
Rabeprazole 20mg	Aciphex	60-70%	91%	NA

(1) Effectiveness data presented for those PPI dosage strengths that have been studied and compared to date.

Our Recommendations

You can save money – in some cases $200 a month or more – if you need to take a PPI and your doctor prescribes one of the more expensive ones. That's because all five of the PPIs are quite similar in effectiveness and safety.

Talk to your doctor about other medicines that may relieve your heartburn symptoms, either before you require a PPI or in combination with a PPI. Also talk with your doctor about the role that dietary and lifestyle changes can play in alleviating symptoms – such as eating smaller meals, weight loss and avoiding alcohol.

- If you have no health insurance for prescription drugs, we have chosen **Prilosec OTC 20mg (omeprazole)** as the *Consumer Reports Best Buy Drug.* This proven medicine is sold over-the-counter, without a prescription, and costs 50 to 80 cents a day. It is as effective for most people as the more expensive PPIs.
- If you have drug coverage, find out if your health **plan provides a discount coupon for Prilosec OTC. If not, talk with you doctor about choosing the PPI** that has the lowest out-of-pocket cost, or co-pay, under your insurance plan.
- If you are one of the 15% of people with GERD who have moderate to severe erosions in your esophagus, **you may need a higher dose of a PPI.**

SAFETY NOTE: PPIs interact with some other medicines, such as blood thinners and anti-anxiety drugs. Tell your doctor about all the drugs you are taking before you take a PPI. People aged 65 and over, and people with chronic medical conditions, who take a PPI should get vaccinated against pneumonia and get a flu shot every year.

See the cost comparison table on page 2. This information was last updated in November 2004. Go to **www.CRBestBuyDrugs.org** for the latest news and information on the drug classes we examine.

© *Consumers Union 2005*

PPI Cost Comparison

Generic Name with Dose per Day	Brand Name[1]	Average Monthly Cost[2]
Esomeprazole 20mg	Nexium	$171
Esomeprazole 40mg	Nexium	$165
Lansoprazole 15mg delayed release lingual tablets	Prevacid	$133
Lansoprazole 30mg delayed release lingual tablets	Prevacid	$126
Lansoprazole 15mg sustained release tablets	Prevacid	$164
Lansoprazole 30mg sustained release tablets	Prevacid	$169
Lansoprazole 30mg enteric coated capsules	Prevacid	$159
Lansoprazole 15mg delayed release suspension packets	Prevacid	$172
Lansoprazole 30mg delayed release suspension packets	Prevacid	$162
Omeprazole 20mg	**Prilosec OTC[3]**	**$24**
Omeprazole 10mg sustained release capsules	Prilosec	$133
Omeprazole 20mg sustained release capsules	Prilosec	$154
Omeprazole 40mg sustained release capsules	Prilosec	$245
Omeprazole 10mg sustained release capsules	Generic	$120
Omeprazole 20mg sustained release capsules	Generic	$119
Pantoprazole 20mg delayed release tablets	Protonix	$145
Pantoprazole 40mg delayed release tablets	Protonix	$136
Rabeprazole 20mg	Aciphex	$165

UNDERSTANDING GENERICS: A generic drug is one that is sold under its generic name. In this table, only omeprazole is available as a generic. It is also sold under its brand name, Prilosec. A nonprescription version, Prilosec OTC, is also available. The remaining PPIs are sold only as brand name drugs, though their generic or chemical names are also given in the first column.

(1) "Generic" indicates drug sold by generic name, omeprazole.
(2) Prices reflect nationwide retail average for September 2004, rounded to nearest dollar; data provided by NDCHealth, a health care information company.
(3) This is a nonprescription (over-the-counter) version of omeprazole.

Consumer Reports
BEST BUY DRUGS
PROVEN • EFFECTIVE • AFFORDABLE

www.CRBestBuyDrugs.org

Treating Elevated Cholesterol and Heart Disease

The Statins

Comparing Effectiveness, Safety, and Price

If you have high cholesterol or are at risk of heart attack or stroke, your doctor may prescribe a "statin" – the most widely used type of cholesterol-lowering drug. There are six statins. Three are now available as less expensive generics – lovastatin, pravastatin and simvastatin. One new combination drug – Vytorin – combines simvastatin with another type of cholesterol-lowering drug.

To help you and your doctor choose the statin that is right for you, *Consumers Reports* has evaluated the drugs in this category based on their effectiveness, safety, and cost. This 2-page brief is a summary of an 18-page report you can access on the Internet at www.CRBestBuyDrugs.org. You can also learn about other drugs we've analyzed on this free Web site. Our independent evaluations are based on scientific reviews conducted by the Oregon Health and Science University-based Drug Effectiveness Review Project. Grants from the Engelberg Foundation and National Library of Medicine help fund *Consumer Reports Best Buy Drugs.*

DO YOU NEED A STATIN?

If your cholesterol is only marginally elevated and you're not at risk for heart disease, heart attack, or stroke, dietary and lifestyle changes may be enough to lower your "bad" (LDL, or Low Density Lipoprotein) cholesterol to a healthy level. So you might try that before taking a medicine. But if your LDL is too high and/or you are already at risk for heart disease and stroke (for example, if you smoke, have diabetes, or have coronary artery disease), your doctor is likely to prescribe a statin.

Latest advice on LDL cholesterol reduction

Risk level and criteria*	Reduce LDL to:
Low - No current heart disease - No or only one risk factor	- Below 160mg/dl - Below 130mg/dl is better
Moderate - No current heart disease - Two risk factors	- Below 130mg/dl - Below 100mg/dl is better
Moderate High - Two or more risk factors	- Below 130mg/dl - Below 100mg/dl is better
High - Known heart disease - Diabetes - Multiple Risk Factors	- Below 100mg/dl - Below 70mg/dl is better

* In addition to having an elevated LDL and/or low HDL, the most important risk factors for heart disease, heart attack and stroke are cigarette smoking and having diabetes or high blood pressure. Other risk factors include being overweight, getting little or no exercise; having elevated triglycerides or C-reactive protein levels, and having a family history of heart disease.

Our Recommendations

Statins are highly effective and generally safe medicines. In people at risk for heart disease or who have heart disease, they substantially lower the chances of a heart attack, stroke, and death.

The statins differ in their ability to reduce cholesterol and there is stronger evidence for some when it comes to reducing your risk of heart attack or death from heart disease or stroke. The statins also vary widely in cost – from about $30 a month to $170 a month. (See page 2)

Taking the evidence for effectiveness, safety, and cost into account, we have chosen four statins as *Consumer Reports Best Buy Drugs:*

- *Generic lovastatin* – if you need to lower "bad" (LDL) cholesterol by less than 30%
- *Generic pravastatin* – if you need to lower LDL cholesterol by less than 30%
- *Generic simvastatin* – for some people who need less than 30% LDL reduction; for people who need 30% or greater LDL reduction and/or have heart disease or diabetes; and for some people who have had a heart attack or have acute coronary syndrome (chest pain and signs of coronary artery disease)
- ***Atorvastatin (Lipitor)*** – for some people who have had a heart attack or have acute coronary syndrome; use for two years

Lovastatin is much less expensive than the other statins. Pravastatin and simvastatin have only recently become available as generics. Their cost will decline in the fall of 2006 and in early 2007. Lipitor is not available as a generic and is more expensive than the three generics.

Most people who need a statin should take the lowest dose that reduces their LDL cholesterol to an acceptable level. High doses of statins pose greater risk of muscle and liver problems. But some people – such as those who have had heart attacks – may need higher doses.

No matter what dose you take, if you have muscle aches and pains when taking a statin, contact your doctor immediately. Also, ask your doctor about splitting your statin pills. This can save you money.

This information was last updated in July 2006.

© Consumers Union 2006

Statins – Comparative Effectiveness and Cost[1]

Generic Name And Dose Per Day	Brand Name[2]	Average Monthly Cost[3]	Average Expected LDL Reduction	Reduces the Risk of Heart Attack?[4]	Mortality Reduction?
Atorvastatin				Yes	Yes
Atorvastatin 10mg	Lipitor	$90	34-38%		
Atorvastatin 20mg	Lipitor	$129	42-46%		
Atorvastatin 40mg	Lipitor	$129	47-51%		
Atorvastatin 80mg	Lipitor	$128	46-54%		
Ezetimibe/simvastatin				Yes[5]	Yes[5]
Ezetimibe/simvastatin 10mg/10mg	Vytorin	$105	45%		
Ezetimibe/simvastatin 10mg/20mg	Vytorin	$104	52%		
Fluvastatin				Likely	Likely[6]
Fluvastatin 20mg	Lescol	$77	22%		
Fluvastatin 40mg	Lescol	$75	25%		
Lovastatin				Yes	Likely[6]
Lovastatin 10mg	Generic	$32	21%		
Lovastatin 20mg	Generic	$36	24-27%		
Lovastatin 40mg	Generic	$56	31%		
Lovastatin 10mg	Mevacor	$43	21%		
Lovastatin 20mg	Mevacor	$81	24-27%		
Lovastatin 20mg longacting	Altoprev	$99	30%	Yes[7]	Likely[7]
Lovastatin 40mg longacting	Altoprev	$108	36%		
Pravastatin[8]				Yes	Yes
Pravastatin 10mg	Pravachol	$120	18-23%		
Pravastatin 20mg	Pravachol	$114	20-25%		
Pravastatin 40mg	Pravachol	$168	26-34%		
Rosuvastatin				Likely	Likely
Rosuvastatin 10mg	Crestor	$106	43-50%		
Rosuvastatin 20mg	Crestor	$105	52-55%		
Simvastatin[8]					
Simvastatin 10mg	Zocor	$98	26-33%		
Simvastatin 20mg	Zocor	$169	30-40%		
Simvastatin 40mg	Zocor	$170	35-45%	Yes	

UNDERSTANDING GENERICS: A generic is a copy of a brand drug whose patent has expired. For example, in this table lovastatin is the generic version of the brand name drug Mevacor. As explained on page 1, generic pravastatin and simvastatin only recently became available so we don't yet have the monthly costs for those two drugs. The prices given in this table are for the brand versions, Pravachol and Zocor. Generic drugs are less expensive. If you are prescribed a brand name drug that is available as a generic, ask your doctor or pharmacist why.

(1) Because of space limitations this table does not contain all dosage forms. For a full list, please see the full 18-page statin report at www.CRBestBuyDrugs.org.
(2) "Generic" indicates drug sold by generic name.
(3) Prices reflect nationwide retail average for April 2006, rounded to nearest dollar; information derived by *Consumer Reports Best Buy Drugs* from data provided by Wolters Kluwer Health, Pharmaceutical Audit Suite
(4) Nonfatal and fatal heart attack plus deaths attributed to heart disease.
(5) The combination of these two drugs has not been proven but simvastatin has. The benefit is assumed for the combination.
(6) Lovastatin has not been proven to reduce deaths, but the evidence strongly points in that direction.
(7) Based on the results for shorter-acting versions of the drugs.
(8) A generic version of pravastatin became available in April 2006. A generic version of simvastatin became available in June 2006. Future updates of our statin report and this brief will include the monthly costs for these medicines.

STAT W2 0706