PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2007

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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H.R. 1902, PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2007

WEDNESDAY, MAY 2, 2007

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

The subcommittee met, pursuant to call, at 3 p.m. in room 2123, Rayburn House Office Building, Hon. Bobby L. Rush (chairman) presiding.

Present: Representatives Butterfield, Barrow, Hill, Gonzalez, Matheson, Dingell, Stearns, Pitts, Bono, Burgess, and Blackburn.

Staff present: Angela Davis, Valerie Baron, Consuela Washington, Christian Fjeld, Judith Bailey, Shannon Weinberg, Brian McCullough, Will Carty, and Matthew Johnson.

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

Mr. RUSH. The Subcommittee on Commerce, Trade and Consumer Protection will come to order. We are convening this hearing to discuss H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007.

I will recognize myself for 5 minutes for an opening statement, and then we will proceed with the ranking member Mr. Stearns. And as Members come in, then they will be recognized for opening statements also.

Today's hearing focuses on an alarming practice in the pharmaceutical industry that is costing American consumers billions of dollars. Brand name drug companies are paying generic drug companies to stay out of the marketplace. Consequently, they are denying consumers the considerable savings they should otherwise receive from generic competition in their prescription drug costs. This practice of pay for delay is known as exclusion payment or reverse consideration, and they are features in legal settlements between brand name and generic drug companies in their patent disputes.

It is worth noting from the outset that these exclusion payments are unique to the U.S. pharmaceutical industry. In the commercial world, outside of drugs, patent disputes are settled by the accused infringer paying a royalty fee to the patent holder in order to legally market a product. Exclusion payments in the pharmaceutical world turned this concept on its head. The patent holder or the brand name drug company is paying the accused patent infringer, the generic, to stay off the market.

It is no accident that these types of anticompetitive, anticonsumer agreements are prevalent in the pharmaceutical industry, but absent everywhere else. The unique regulatory framework of the groundbreaking Hatch-Waxman Act set the table for drug companies to game the system and thwart the law's intent.

By design Hatch-Waxman is supposed to strike a balance. Brand name drug companies retain incentives for innovation, but generic challenges are encouraged to aggressively challenge weak patents and bring their products to market.

The first generic company to successfully challenge a brand name's patent and bring its product to market is rewarded with a 180-day period of exclusivity in which only that generic company is allowed to compete with the brand name company. As such, it is easy to see why the brand name and generic companies would settle their dispute. The brand name and generic companies can simply stop competing with each other, take the savings that consumers will receive from their competition, and divide it up among themselves. It is easy money.

In response to these unique anticonsumer agreements, Chairman Waxman and I have introduced a bill to crack down on exclusion payments and ensure that the purpose of Hatch-Waxman is fulfilled. H.R. 1902, the Protecting Consumer Access to Generic Drugs Act, creates a bright line solution and bans reverse consideration agreements in drug patent settlements. This is the legislative approach recommended by the Federal Trade Commission.

I want to emphasize that this bill does not in any way affect any other kind of legal settlement. So the complaint that the Rush-Waxman bill somehow squashes the ability of brand name and generic drug companies to settle their disputes is simply not true. Our bill zeroes in on a very specific type of legal settlement that is completely unique to the pharmaceutical industry. Moreover, we are addressing a problem that is not trivial and is costing the consumers and Government programs billions upon billions of dollars.

Let me note here that since the FTC started challenging these anticonsumer practices, every single commissioner, 11 in all, Republican, Democrat and Independent, have supported these enforcement efforts. Under this bill drug companies are still free to settle their disputes like all other companies do. The bill provides exceptions to the ban and authorizes the FTC to promulgate interpretive rules and additional carve-outs if the Commission believes that such exemptions serve consumer interest. As such, this is in no way a radical bill, and we are attempting to legislate with a scalpel and not a meat ax.

Lastly, let me briefly address the issue of the regulatory bottleneck. Currently under Hatch-Waxman a generic company can park its 180-day exclusivity and effectively preclude other generic companies from seeking approval from the FDA and entering the market. The Rush-Waxman bill deals with this bottleneck provision as part of a larger solution to the anticompetitive nature of reverse consideration legal settlements. However, I have pledged to work with my colleague and friend Chairman Pallone of the Health Subcommittee to address effectively this issue since it technically falls under the Health Subcommittee's jurisdiction.

While I believe that clearing the regulatory bottleneck is an important part of the overall solution, I want to work constructively with Chairman Pallone to ensure that we craft a careful and thoughtful piece of legislation.

Lastly, I want to welcome our guests who are appearing before us today. As chairman of the subcommittee, I intend for this hearing to serve as a serious policy discussion and as a first step toward correcting a market failure that is costing American consumers billions of dollars in prescription drug calls.

Thank you.

And now I'll recognize the ranking member of the subcommittee Mr. Stearns.

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

Mr. STEARNS. Thank you, Mr. Chairman. And it is nice that we are here to discuss this bill. And I understand the Federal Trade Commission, Mr. Leibowitz, is endorsing this idea. He has endorsed the bill, so to speak.

I think the intent of the legislation, I think, as ranking member and my colleagues on this side would say that we support that intent to bring generic drugs to market sooner, benefiting our customers with greater choices and lower prices. But between the cup and the lip, there are some things that we think are some problems. And I do have some concern, Mr. Chairman, about this bill, and I thought I would just outline these two concerns.

These two pieces of legislation in concert will create disincentives for generic pharmaceutical companies to challenge brand drug patents. There is a strong incentive built into the Hatch-Waxman Act. That incentive was designed for a reason. The generic pharmaceutical companies needed strong encouragement to take on the financial burden of litigating a patent challenge. We know how expensive that is.

Litigation on patent challenges can last for years, and legal fees reach into the millions of dollars for both parties. For a generic pharmaceutical company it is an impossible financial burden without a mechanism to ensure that they can recoup their investment if there is a successful patent challenge.

In 1984, our colleagues wisely devised a 180-day marketing exclusivity period for the first patent challenger. Now, this 180-day period is a carrot for generic pharmaceutical companies to challenge brand drugs. The first patent challenger will be the only generic pharmaceutical product on the market for 6 months, an opportunity to recoup legal costs and an award of sorts for being the first company to put its neck out there.

My colleagues, without this carrot, fewer generic pharmaceutical companies would be willing to bring a patent challenge, opting instead to wait until a brand drug's patent expires. This legislation will effectively nullify, in our opinion, that carrot. By triggering the countdown clock to a forfeiture of this 180 days by just a dismissal of a frivolous or meritless lawsuit by another generic pharmaceutical company, a first filer will be forced to launch their product at risk or lose a 180-day exclusivity period, which is their assurance for recouping their legal fees.

If a generic pharmaceutical company launches their product prior to a court's determination that their challenge is successful or prior to a settlement with a brand pharmaceutical company permitting prepatent expiration marketing, then the generic pharmaceutical company is liable for triple damages for patent infringement. This would simply be too much risk for a publicly traded generic pharmaceutical company to challenge a patent without a guarantee for a return on their investment.

The second part of this legislation bans cash or other compensation in settlements. I will admit such trades sound bad, but if we dig deeper, we find that these settlements are actually beneficial to consumers. Bear with me. Brand companies are not keeping generic companies off the market altogether. They are actually giving up some of their guaranteed monopoly time under their patent and bringing generic drugs to market much sooner than would otherwise occur. Just because money or other compensation is involved does not make the deal anticonsumer. Patent litigation is expensive. The outcomes are often uncertain, and the odds for success or failure are about even when you consider whether a generic drug launched results. Without additional compensation a generic pharmaceutical company would not settle for anything less than an immediate launch of their product in order to recoup their investment. However, brand drug companies have no reason to give an immediate launch date and would prefer to litigate to the end, delaying even further a launch of a generic drug.

To interfere in private litigants' ability to settle is dangerous territory. Obviously we want to balance this interest with the consumer's best interest, but Congress has done that. Both the FTC and the Department of Justice have tools that challenge suspect settlements in court. The courts have reviewed so many settlements and have refused, refused, to throw out so many settlements sends a clear signal that we should not look at drug patent settlements as anticompetitive on their face. Furthermore, our goal should be to encourage settlements in any area of the law, not force cases to the bitter end, wasting not only limited judicial resources, but also wasting precious dollars in legal fees that could otherwise be used for research and development of new treatments and drugs.

So I look forward to hearing from our distinguished panel of witnesses, and I thank you, Mr. Chairman, for holding this hearing.

Mr. RUSH. Thank you.

I now recognize the chairman of the full committee Mr. Dingell.

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

Mr. DINGELL. Mr. Chairman, I begin by commending you and our colleague Mr. Waxman for introducing H.R. 1902 upon which we are having hearings today. Legislation is sorely needed. Consumers no longer receive full benefits that Congress intended when it passed the Hatch-Waxman Act in 1984. It appears that in instances drug companies may be making deals that thwart the goals of Hatch-Waxman and cost consumers billions of dollars in savings which the Congress intended that they should have.

When Congress passed this legislation, it appreciated the growing importance of pharmaceuticals for treating a host of physical and mental conditions. The statute struck a careful balance between drug innovation and drug affordability.

Mr. Chairman, there is more in my statement that I ask be put in the record by extension of remarks. I simply observe this is good legislation. Your leadership is of great value in this matter. I look forward to working with you to see to it this becomes law at an early time. And I thank you for your leadership again, Mr. Chairman.

I yield back the balance of my time.

[The prepared statement of Mr. Dingell follows:]

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

Let me begin by commending Chairmen Rush and Waxman for introducing H.R. 1902, the Protecting Consumer Access to Generic Drugs Act of 2007. It is sorely needed. Consumers no longer receive the full benefits that Congress intended when it passed the Hatch-Waxman Act in 1984. It appears that, in certain instances, drug companies may be making deals that thwart the goals of Hatch-Waxman and cost consumers billions of dollars in intended savings.

When Congress passed Hatch-Waxman, it appreciated the growing importance of pharmaceuticals treating a host of physical and mental conditions. The statute struck a careful balance between drug innovation and drug affordability.

On the one hand, it extended the patent protection for pharmaceuticals to encourage "branded" manufacturers to research and develop new drugs, given the lengthy Food and Drug Administration approval process. On the other hand, it crafted incentives to induce generic manufacturers to enter the market sooner to make lower-cost alternatives available to consumers. Among those incentives, the legislation encouraged generic companies to challenge potentially dubious patents and withstand infringement litigation by a branded company.

The legislation has been successful. Consumers Union estimates that in 2006 the appearance on the market of new generic drugs as alternatives to just five "blockbuster" drugs saved consumers over $6 billion.

For some years now, however, we have learned that instead of continuing litigation, some generic entrants are accepting cash payments and other transfers of value to settle and stay out of the market. These settlements, called "exclusionary payments" or "reverse payments," are a sweetheart deal for both brandeds and generics. Generics get paid even when they bring no product to the market. The brandeds pay less to the generics than the revenues they would lose when competing against a lower-cost rival.

These settlements are bad deals for consumers. Drug companies are essentially pocketing the savings that Hatch-Waxman intended for consumers.

Let's focus on some of the consumers left behind by these deals.

One is the taxpayer. Through programs such as Medicare and Medicaid, the Government spends billions on drugs every year. In 2006, Government expenditures for prescription drugs were estimated to be $68 billion. By 2016, these estimates rise to more than $200 billion.

Other consumers include employer heath plans sponsored by U.S. industry. Government and industry would save enormous sums if more generics were made available earlier in the marketplace, as the Hatch-Waxman Act had intended.

H.R. 1902 endeavors to fix this problem. It will prevent exclusionary payments and restore Hatch-Waxman's goal of putting generic drugs on the market more quickly.

Chairman Rush, I look forward to working with you as this legislation moves through the committee and the Congress.

Mr. RUSH. Thank you, Mr. Chairman.

We now recognize the gentleman from Texas Mr. Gonzalez.

Mr. GONZALEZ. Waive opening.

Mr. RUSH. The Chair now recognizes the gentleman from Georgia Mr. Barrow.

Mr. BARROW. And I waive the opportunity to make an opening.

Mr. RUSH. Mr. Matheson is now recognized.

Mr. MATHESON. I waive opening.

Mr. RUSH. Now we will recognize the gentle lady from Tennessee Mrs. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. I want to thank you and our ranking member for holding today's hearing so that we can continue to explore the merits of H.R. 1902, the Protecting Consumer Access to Generic Drugs Act of 2007. The American people have greater access to lifesaving, low-cost prescription drugs today than at any other time in our modern history, and though my colleagues share strong opinions and may disagree on many issues surrounding prescription drugs, I truly think we can all agree that generic drug access is a net positive for our constituents and the consumers. And given the title of the legislation under consideration today and the fact that they are all cosponsors of H.R. 1902, I am sure that my colleagues on the other side of the aisle believe they are doing just that.

What I want to point out is that sometimes the devil is in the details, Mr. Chairman, and I want to make certain that this committee acts deliberately before amending the landmark Hatch-Waxman Act patent dispute amendments of 1984. After all, the Hatch-Waxman Act amendments are largely responsible for the proliferation of generic pharmaceuticals in the marketplace. And without them many of our constituents would not enjoy the benefits of competition that are available to them today.

These considerations guide my thinking with respect to the bill, and I do not take them lightly. That is not to say, however, that the relative proliferation of out-of-court settlements and patent disputes between generic and brand name pharmaceutical companies does not warrant attention. Far from it. The American people do have a right to understand why a patent holder, in this case the drug companies, would pay a settlement fee to a potential patent infringer, in this case a generic manufacturer, during a patent dispute. Such reverse payments, if you will, might defy logic to a casual observer given the fact they do not happen in any other American industry, something that is unique to the pharmaceutical industry. It might even appear that such settlements allow large drug companies to game the system or prevent generic drugs from coming to the market.

If that is the case, as several of today's witnesses will suggest, the American people have a right to gripe. Yet my experience teaches me to remain cautious before jumping to such conclusions, Mr. Chairman, and I look forward to the expert testimony of our witnesses and their shedding some light on the situation.

Thank you. And I yield back.

Mr. RUSH. I want to thank the gentle lady.

It is the rule of this subcommittee that a nonmember will have an opportunity to testify before this committee after all members of the subcommittee have testified.

And now it is my honored privilege to recognize the co sponsor of this bill and the Waxman of the original Hatch-Waxman Act, none other than our colleague from California Mr. Waxman, for an opening statement for 5 minutes. And I want to commend him on his unparalleled leadership in this particular endeavor.

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

Mr. WAXMAN. Thank you very much, Mr. Chairman, and my colleagues. I want to thank you for holding this very important hearing. In 1984, when we drafted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman law, we were trying to benefit consumers by lowering drug prices, and we did this by creating competition where there was none and ending the permanent monopolies that drug companies had enjoyed until that point.

By almost any measure this law worked. It worked very well. It promoted competition, lowered drug prices. In fact, generic drugs, when they are available, lower drug prices by as much as 90 percent.

But there is evidence that the law could function more effectively for consumers. The fact is that in 2005 we still spent 10 times as much on brand name drugs, $229.5 billion, over the $22 billion we spent on generics. This simply illustrates we can do more to get generics on the market faster.

The Federal Trade Commission, and I thank them very much for their excellent work, they highlighted a significant cause of this problem. In recent years generic and brand name companies have increasingly been entering into patent settlement agreements that the FTC believes have an anticompetitive effect. These settlement arrangements now frequently include agreements under which the brand companies pay the generic firms to keep their product off the market.

Well, this averts the objectives of the law. One of the unique aspects of Hatch-Waxman is that it was intended not only to speed up generic drug approval, but to speed up resolution of patent disputes. Rather than wait until after approval to litigate patent infringement actions, Hatch-Waxman encourages patent challenges to begin before approval. The law also provides incentives for generic companies to undertake this protracted litigation.

We gave the first generic company to challenge the brands patents 180 days of exclusive marketing. Our goal, our whole reason for this, was to hasten generic market entry for the benefit of the consumers. By rewarding generic companies to challenge patents that had no business blocking market entry either because they were invalid or not infringed, consumers could have access to low-cost generic drugs at the earliest possible moment.

Anticompetitive settlements turned this fundamental goal of Hatch-Waxman on its head. We established an abbreviated regulated pathway to encourage generics to enter the market as soon as possible, not to authorize the companies to use that regulatory pathway as a means for sharing the brands' monopoly profits.

The impact of these settlements is that they are contracts between two parties, generic and brand companies, to share the profits that are entirely paid by a third party. And the third party are the consumers, the insurance companies, the Government, and they pay those profits in the form of higher drug prices, yet consumers have no say in the terms of these contracts. As long as consumers bear the full cost of the later marketing date, there is little incentive for the parties to negotiate an earlier date. And economics is sometimes referred to as the moral hazard, an agreement in which parties are motivated to spend more money as long as it is someone else's money. Some courts have erroneously concluded that these agreements were condoned by Hatch-Waxman. They say that since the law created a situation in which generic firms could extract the settlement payments in exchange for delayed entry, that this was somehow the intent.

Well, those courts are sorely mistaken. The use of Hatch-Waxman to prevent generic competition was very obviously not the intent of the law. As a result of their misunderstanding of the underlying intent of the law and the Supreme Court's refusal to look at this issue, Congress is now in a position in which we need to act to prevent the continued erosion of the principles of the law.

I recognize we need to proceed with care. Some patent settlement agreements can provide benefits across the board. Settlements can allow the parties involved to avoid expensive protracted litigation. But it strikes me as a much more prudent thing to do to pass this legislation. If the Federal Trade Commission decides that other exceptions to this bright line test need to be made to enhance competition and benefit consumers, then FTC can implement those changes through rulemaking. In effect, the bill is designed to rid us of the bad settlements and leave us with the good. And I look forward to the testimony of the witnesses today, and I hope we can move expeditiously on this legislation.

Thank you very much, Mr. Chairman and my colleagues.

Mr. RUSH. Thank you very much. This concludes opening statements. Any other statements for the record as well as the text of H.R. 1902 will be accepted at this time.

[The prepared statement of Mr. Butterfield and H.R. 1902 follows:]

OPENING STATEMENT
CONGRESSMAN G. K. BUTTERFIELD
SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION
COMMITTEE ON ENERGY AND COMMERCE
H.R. 1902 – PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2007
MAY 2, 2007

Mr. Chairman, access to affordable drugs is one of the most critical problems facing our healthcare system today. I represent the 15th poorest district in the United States, where a growing number of my constituents are facing the tough choice of whether to use a portion of their fixed income to purchase food or their prescription medication. This is a choice that no human being should have to make.

Rising prescription drug costs remain a major challenge for consumers, especially older Americans. Generic drugs play an essential role by providing less

expensive medication as an option. Consumers want lower-cost options for drugs, and in a recent AARP survey of people ages 45 and up, 84 percent said generic drugs are important for controlling drug costs. Most also said they usually choose generic over brand names when generics are available. Twenty-four percent reported not being able to afford a prescription drug when no generic was available.

I understand the intent of this bill. That is why I am an original cosponsor or H.R. 1902 – the Protecting Consumer Access to Generic Drugs Act of 2007. This bill provides improved access to generic drugs for consumers which are often priced 70 to 80 percent below the competing brand name drugs. In 2005,

consumers paid $9.4 billion for five high-profile brand name drugs. In 2006, these name brand drugs had competing generic drugs hit the market. If the consumers chose to purchase the generic drugs, the annual cost would be $6.6 billion, a total savings of nearly $3 billon. A 2002 study by the Schneider Institute for Health Policy at Brandeis University in Waltham, Massachusetts, concluded that if Medicare increased the rate of generic usage to that of similar high-performing private sector health plans, its 40 million beneficiaries could see potential savings of $14 billion.

H.R. 1902 prohibits "reverse consideration" or "exclusion payments" from taking place between brand

name and generic drug manufacturers. These sweetheart deals that delay the entry of low cost drugs in the marketplace not only hurt consumers, they also threaten the sustainability of federal health care programs, such as Medicare and Medicaid. H.R. 1902 ensures that the FTC has the ability to look out for the American public, not the profits of drug companies.

I look forward to the successful passage of H.R. 1902 so that Americans can have full access to more affordable prescription drugs. No American should be forced to choose between adequate and essential healthcare and nutrition. It is a travesty if we allow this awful trend to continue.

I

110TH CONGRESS
1ST SESSION

H. R. 1902

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 17, 2007

Mr. RUSH (for himself, Mr. WAXMAN, Mr. MARKEY, Mr. BUTTERFIELD, Mr. DOYLE, Ms. SCHAKOWSKY, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Protecting Consumer Access to Generic Drugs Act of 2007".

1 **SEC. 2. UNFAIR AND DECEPTIVE ACTS AND PRACTICES RE-**
2 **LATED TO NEW DRUG APPLICATIONS.**

3 (a) CONDUCT PROHIBITED.—It shall be unlawful for
4 any person to directly or indirectly be a party to any
5 agreement resolving or settling a patent infringement
6 claim in which—

7 (1) an ANDA filer receives anything of value;
8 and

9 (2) the ANDA filer agrees not to research, de-
10 velop, manufacture, market, or sell, for any period
11 of time, the drug that is to be manufactured under
12 the ANDA involved and is the subject of the patent
13 infringement claim.

14 (b) EXCEPTIONS.—Notwithstanding subsection
15 (a)(1), subsection (a) does not prohibit a resolution or set-
16 tlement of a patent infringement claim in which the value
17 received by the ANDA filer includes no more than—

18 (1) the right to market the drug that is to be
19 manufactured under the ANDA involved and is the
20 subject of the patent infringement claim, before the
21 expiration of—

22 (A) the patent that is the basis for the pat-
23 ent infringement claim; or

24 (B) any other statutory exclusivity that
25 would prevent the marketing of such drug; and

1 (2) the waiver of a patent infringement claim
2 for damages based on prior marketing of such drug.
3 (c) ENFORCEMENT.—A violation of subsection (a)
4 shall be treated as an unfair and deceptive act or practice
5 and an unfair method of competition in or affecting inter-
6 state commerce prohibited under section 5 of the Federal
7 Trade Commission Act (15 U.S.C. 45). The Federal Trade
8 Commission shall enforce this Act in the same manner,
9 by the same means, and with the same jurisdiction as
10 though all applicable terms and provisions of the Federal
11 Trade Commission Act were incorporated into and made
12 a part of this Act.
13 (d) DEFINITIONS.—In this section:
14 (1) AGREEMENT.—The term "agreement"
15 means anything that would constitute an agreement
16 for purposes of section 5 of the Federal Trade Com-
17 mission Act (15 U.S.C. 45).
18 (2) AGREEMENT RESOLVING OR SETTLING.—
19 The term "agreement resolving or settling", in ref-
20 erence to a patent infringement claim, includes any
21 agreement that is contingent upon, provides a con-
22 tingent condition for, or is otherwise related to the
23 resolution or settlement of the claim.
24 (3) ANDA.—The term "ANDA" means an ab-
25 breviated new drug application for the approval of a

1 new drug under section 505(j) of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 355(j)).
3 (4) ANDA FILER.—The term "ANDA filer"
4 means a party that has filed an ANDA with the
5 Food and Drug Administration.
6 (5) PATENT INFRINGEMENT.—The term "pat-
7 ent infringement" means infringement of any patent
8 or of any filed patent application, extension,
9 reissuance, renewal, division, continuation, continu-
10 ation in part, reexamination, patent term restora-
11 tion, patent of addition, or extension thereof.
12 (6) PATENT INFRINGEMENT CLAIM.—The term
13 "patent infringement claim" means any allegation
14 made to an ANDA filer, whether or not included in
15 a complaint filed with a court of law, that its ANDA
16 or drug to be manufactured under such ANDA may
17 infringe any patent.
18 **SEC. 3. FTC RULEMAKING.**
19 The Federal Trade Commission may, by rule promul-
20 gated under section 553 of title 5, United States Code,
21 exempt certain agreements described in section 2 if the
22 Commission finds such agreements to be in furtherance
23 of market competition and for the benefit of consumers.
24 Consistent with the authority of the Commission, such
25 rules may include interpretive rules and general state-

1 ments of policy with respect to the practices prohibited
2 under section 2.

3 **SEC. 4. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD**
4 **UNDER THE FFDCA.**

5 Section 505(j)(5)(D)(i) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)) is amend-
7 ed—

8 (1) in subclause (I)(bb)—

9 (A) by redesignating subitem (CC) as
10 subitem (EE); and

11 (B) by inserting after subitem (BB) the
12 following:

13 "(CC) In a declaratory
14 judgment action described in
15 subitem (AA), a court dis-
16 misses the action for lack of
17 subject matter jurisdiction,
18 either with or without preju-
19 dice.

20 "(DD) The applicant
21 files with the Secretary a
22 covenant by the patent
23 owner that the patent owner
24 will not sue the applicant for

1 infringement with respect to
2 the patent."; and
3 (2) in subclause (V), by inserting "section 2 of
4 the Protecting Consumer Access to Generic Drugs
5 Act of 2007 or" after "that the agreement has vio-
6 lated".

7 **SEC. 5. NOTICE AND CERTIFICATION OF AGREEMENTS.**

8 (a) NOTICE OF ALL AGREEMENTS.—Section
9 1112(c)(2) of the Medicare Prescription Drug, Improve-
10 ment, and Modernization Act of 2003 (21 U.S.C. 3155
11 note) is amended by—
12 (1) striking "the Commission the" and insert-
13 ing "the Commission (1) the"; and
14 (2) inserting before the period at the end the
15 following: "; and (2) a description of the subject
16 matter of any other agreement the parties enter into
17 within 30 days of an entering into an agreement
18 covered by subsection (a) or (b)".
19 (b) CERTIFICATION OF AGREEMENTS.—Section 1112
20 of such Act is amended by adding at the end the following:
21 "(d) CERTIFICATION.—The Chief Executive Officer
22 or the company official responsible for negotiating any
23 agreement required to be filed under subsection (a), (b),
24 or (c) shall execute and file with the Assistant Attorney
25 General and the Commission a certification as follows: 'I

1 declare under penalty of perjury that the following is true
2 and correct: The materials filed with the Federal Trade
3 Commission and the Department of Justice under section
4 1112 of subtitle B of title XI of the Medicare Prescription
5 Drug, Improvement, and Modernization Act of 2003, with
6 respect to the agreement referenced in this certification:
7 (1) represent the complete, final, and exclusive agreement
8 between the parties; (2) include any ancillary agreements
9 that are contingent upon, provide a contingent condition
10 for, or are otherwise related to, the referenced agreement;
11 and (3) include written descriptions of any oral agree-
12 ments, representations, commitments, or promises be-
13 tween the parties that are responsive to subsection (a) or
14 (b) of such section 1112 and have not been reduced to
15 writing.'.''.

○

Mr. RUSH. And now the subcommittee will hear from the first panel. And the first panel is the Honorable Jon Leibowitz. He is a Commissioner of the Federal Trade Commission. Commissioner Leibowitz will testify on behalf of the FTC, which favors a strong legislative response to exclusion payment agreements. The Commission has been very aggressive in pursuing legal action against these agreements, and Commissioner Leibowitz will inform the subcommittee on why they are anticompetitive and bad for consumers.

Before we hear testimony from the Commissioner, I will ask for unanimous consent to allow Commissioner Leibowitz to testify for 8 minutes instead of the usual and customary 5 minutes. Without objection, so approved.

Welcome, Commissioner.

STATEMENT OF JON LEIBOWITZ, COMMISSIONER, FEDERAL TRADE COMMISSION

Mr. LEIBOWITZ. Thank you, Chairman Rush; thank you, Chairman Waxman, Ranking Member Stearns, members of the subcommittee, so much for inviting the FTC to testify here on this lovely afternoon.

Simply put, we believe H.R. 1902 is a fundamentally sound approach to eliminate the pay-for-delay settlement tactics employed by the pharmaceutical industry that could cost American consumers and the Federal Government billions of dollars annually. Obviously the Federal Government is a major purchaser of drugs.

But let me start with the usual disclaimer. The written statement we submitted today represents the views of the Commission. My oral testimony does not necessarily reflect the views of any other Commissioner. And I ask unanimous consent to put the Commission's written statement into the record. And I thank you for the 8 minutes. I won't use all of it.

There is particular urgency to pharmaceutical competition issues today. Recent appellate decisions are making it difficult, as Chairman Waxman pointed out, to challenge so-called exclusion payments and reverse payments; that is patent settlements in which the brand name drug firm pays the generic 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 will continue to rise.

Indeed, in the past year we have seen a dramatic increase in the types of deals, from none in fiscal year 2004 to more than a dozen in fiscal year 2006. These increased costs will burden individual consumers, they will burden American businesses, and they will burden the Federal Government, which, with a new Medicare Part D program, paid an estimated $68 billion or 32 percent of the Nation's $215 billion in annual drug purchases last year.

Now, when Congress enacted the Hatch-Waxman statute in 1984, and we heard from one of the authors, this committee promoted speedy introduction of generics by encouraging challenges of invalid or narrow patents on branded drugs by providing additional protections for innovator firms. This statutory framework ensured that our pioneer drug companies remain the envy of the world, and they are, while also delivering enormous consumer savings.

Generic entry prior to patent expiration has played an instrumental role in allowing Americans to find and to get the medicines that they need. The first generic usually enters the market at a 20 to 30 percent discount off the brand price. When other generic companies enter, the price can drop by 80 percent or more. Indeed, according to the Generic Pharmaceutical Association's own study, generic competition following successful patent challenges to just four, Prozac, Zantac, Taxol and Platinol, is estimated to save consumers more than $9 billion alone. All those savings could be lost, however, if brands are given a green light to pay generics to sit it out until the patent expires. As you pointed out, Chairman Rush, it can be easy money.

Sadly, the incentives to enter into these pay-for-delay deals 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 by competing. So it is a win-win deal for the companies, but it is a lose-lose profit for consumers who are left holding the bill.

Over the past decade a unanimous Commission, six Republicans, four Democrats and one Independent—and by the way, in response to your very good point, Mrs. Blackburn, a bipartisan companion bill to this legislation came out of the Senate Judiciary Committee by unanimous consent. Chuck Grassley is one of the cosponsors. A bipartisan Federal Trade Commission has made stopping these harmful settlements a priority.

In 2000 and 2001, the Commission obtained two major consent decrees preventing anticompetitive payments from brands to generics, and our actions stopped this conduct cold. The Commission set forth rules that everyone understood. If you settled a case by paying off a generic, we would not let you get away with it. And there were dozens of settlements between 2000 and 2005, as you can see from the chart—well, I'll go to the chart later—but no exclusion payments.

Recent court decisions, though, have changed this dynamic. In 2003, the Commission ruled 5 to 0 that a 1997 settlement involving a payment from Schering-Plough, the brand, to Upsher-Smith, the generic, violated the antitrust laws. The case involved a drug widely used by older Americans. The Eleventh Circuit reversed us in 2005. Later that year, the Second Circuit, in a 2 to 1 decision in the tamoxifen case, issued a similar holding. These decisions essentially allow a patent holder to compensate a generic, except under very limited circumstances.

As a result, the exclusion payment problem is almost certainly growing. And, Mr. Chairman, how do we know this to be true? Well, thanks to the reporting requirement that this committee included in a 2003 Medicare Monitorization Act, and presumably you did so because you were troubled by these agreements, the FTC now reviews each and every Hatch-Waxman settlement. And tellingly, here's 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 contain both a payment from the brand and an agreement to defer generic entry, but data from fiscal year 2006, which reflects agreements after the Schering and tamoxifen

decisions, is far more disturbing. Half of all the 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. And almost all the settlements with first filers, I think it is 9 out of 11, you can see the charts better than I can, involve similar restrictions.

As you know, Mr. Chairman, these settlements with first filers can create a bottleneck that may make it impossible for other generics to enter.

In sum, just before Schering and tamoxifen, there were no reverse payments. Now it is becoming the new way of doing business.

Mr. Chairman, it is not hard to predict what will happen if nothing changes. 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. Now, from our perspective we are going to be vigilant in looking for ways to challenge anticompetitive deals. It is public knowledge that we are looking to bring a case or cases that will create a clear split in the circuits. And we are hopeful that the Supreme Court will review the tamoxifen decision, which is a cert petition before the Supreme Court now. But the Court only takes a handful of cert petitions annually, and a litigation strategy could take years. A legislative approach could provide a swifter and cleaner solution.

For that reason we strongly support legislation to prohibit these anticompetitive payments. Both your approach, Chairman Rush and Chairman Waxman, and the bipartisan measure reported out of the Senate Judiciary Committee would ensure that consumers continue to have access to low-price generics. But we also recognize that these issues are complex, so we want to work with you and other interested parties as the bill moves forward.

Mr. Chairman, we do have great respect for the pharmaceutical industry. Brand firms pursue hundreds of drug candidates for each one that comes to market, and these companies have brought enormous health benefits to consumers. And for their part, generic companies have produced low-cost drugs and really pushed the brands to innovate even further. But we do not and we cannot support settlements when brands and generics resolve their disputes at the expense of consumers and at the expense of the American taxpayers.

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

Mr. RUSH. Thank you, Commissioner.

[The prepared statement of Mr. Leibowitz follows:]

**PREPARED STATEMENT OF THE
FEDERAL TRADE COMMISSION**

Before the

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

on

**PROTECTING CONSUMER ACCESS TO GENERIC DRUGS:
THE BENEFITS OF A LEGISLATIVE SOLUTION TO ANTICOMPETITIVE PATENT
SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY**

May 2, 2007

Summary

Chairman Rush, Ranking Member Stearns, and Members of the Subcommittee, I am Jon Leibowitz, Commissioner of the Federal Trade Commission. Thank you for the opportunity to testify on behalf of the Commission about an issue of great importance to consumers: the need to prevent anticompetitive agreements between branded and generic drug firms.[1]

Protection of competition in the pharmaceutical sector has been and continues to be among the FTC's highest priorities. As part of these efforts, the agency has brought 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 commends your efforts to prohibit these anticompetitive settlements.[2] We believe the bill introduced by Chairman Rush, Chairman Dingell, Chairman Waxman, and other members of the Committee, H.R. 1902, represents a fundamentally sound approach to eliminating the exclusion payment problem. We look forward to continuing to work with you to ensure that the legislation effectively bars anticompetitive

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[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.

[2] Legislation for this purpose has been introduced in the Senate as well as the House. The Senate Judiciary Committee favorably reported S. 316, a bi-partisan measure, on February 27, 2007.

agreements but allows exceptions for those agreements that do not harm competition. In addition, we are pleased that the bill also addresses the "bottleneck" problem (described below), which allows the brand company to use its settlement with the first generic filer to prevent subsequent generic companies from entering the market and competing as well.

Generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically-identical alternatives to brand-name drugs at a significantly reduced cost. 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.[3] 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.[4] 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.

In the late 1990s, the Commission began to bring antitrust challenges to some settlements reached under this patent challenge process that Hatch-Waxman established. To facilitate antitrust enforcement, in 2003 Congress enacted a requirement that all such settlements be filed

[3] 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)).

[4] *See infra* Section I.A. The Act also was intended to encourage pharmaceutical innovation through patent term extensions.

with the FTC and the Department of Justice. Because of this filing requirement, 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 court decisions handed down in 2005 took an extremely lenient view of exclusion payment settlements.[5]

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 through 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

[5] *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); *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).

are priced 20 to 80 percent or more below the price of the branded drug[6] – 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 saved consumers more than $9 billion.[7] 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. So are the savings to the federal government. In 2006, the federal government was projected to have accounted for 32% of the $214 billion spent on prescription drugs, and the federal government share is expected to rise to 42 percent by 2016.[8]

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

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[6] *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").

[7] *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>.

[8] Centers for Medicare and Medicaid Services, Office of the Actuary, Table 11, *National Health Expenditures Projections 2006-2016* (2007), *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf.

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, 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 brand-name and generic drug manufacturers,[9] empirical studies and economic analyses of the pharmaceutical industry,[10] assessments of competitive issues in matters before the United States Food and Drug Administration ("FDA") regarding Hatch-Waxman implementation,[11] testimony

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[9] *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).

[10] *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>.

[11] *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*

before Congress,[12] and amicus briefs in the courts.[13] The Commission's 2002 report entitled "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.[14] The FTC staff's ongoing review of drug company patent settlements and other agreements filed pursuant to the mandate in the 2003 reforms has

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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).

[12] 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/P052103BarrierstoGenericEntryTestimonySenate07202006.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 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>.

[13] *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>.

[14] 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").

enabled the Commission to provide Congress and the public with annual reports on the types of patent settlements being undertaken.[15]

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 the reasons for a legislative remedy to the exclusion payment problem. The testimony also describes another strategy that brand-name drug firms can use to effectively block generic entry – by settling with the first generic applicant and declining to sue subsequent applicants – and the desirability of a legislative solution.

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.[16] 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

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[15] 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>.

[16] *See* CBO Study; *see generally* David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

to 80 percent of branded sales within the first full year after launch of a lower-priced generic product.[17]

A. Statutory Background

Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.[18] 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.[19]

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.[20] 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."[21]

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

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[17] CBO Study, xiii.

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

[19] 21 U.S.C. § 355(j).

[20] 21 U.S.C. § 355(b)(1).

[21] *Id.* § 355(j)(7)(A).

the generic product (known as a "Paragraph IV certification");[22] 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 may not approve a potential competitor's ANDA.[23] Although a first-filer can forfeit its exclusivity under certain conditions,[24] ordinarily it will be entitled to 180 days of exclusivity beginning on the date of the first commercial marketing of the generic drug product.[25] 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.[26]

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

[22] *Id.* § 355(j)(2)(A)(vii)(IV).

[23] *Id.* § 355(j)(5)(B)(iv).

[24] *Id.* § 355(j)(5)(D)

[25] *Id.*

[26] *See id.* § 355(j)(5)(B)(iv).

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

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.[27] Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration (see chart).[28]

[27] *Generic Drug Study*, at 19-20.

[28] *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).

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. In other words, these settlements are harmful because the parties are resolving their dispute at the expense of consumers. Although both the brand-name companies and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry, which may occur either because 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."[29]

III. Commission Challenges to Exclusion Payment Settlements

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.[30] 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 sharing of profits achieved by eliminating competition is at the core of the what Section 1 of the Sherman Act proscribes.

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[29] S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

[30] *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>.

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.[31] 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.[32] Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases.

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[31] 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>.

[32] 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.

IV. 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.[33] After years of active antitrust enforcement, including the Sixth Circuit's decision in the *Cardizem* case holding a challenged exclusion payment arrangement unlawful,[34] 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,[35] 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

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[33] *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).

[34] *In re Cardizem Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

[35] *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.[36] 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,"[37] and noted that there was no allegation that the patent claim was a "sham."[38] 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.[39]

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

[36] *Schering*, 402 F.3d at 1058.

[37] *Id.* at 1066-67.

[38] *Id.* at 1068.

[39] *Id.* at 1076.

assessment of the likelihood that the patent holder could successfully exclude the generic through patent litigation.[40] 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.[41] 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.[42]

The response of pharmaceutical companies to these developments in the courts is reflected in the changing nature of patent 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."[43] 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.[44] 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:

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[40] *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").

[41] *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).

[42] The Court has invited the Solicitor General to submit a brief expressing the views of the United States.

[43] 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).

[44] 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 FY 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.[45]

- 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, we have observed so-called "side deals," such as purchasing rights to unrelated products and co-promotion arrangements, in settlements that restrained generic entry, but virtually never in settlements that did not.[46] 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.[47] Many of the top-selling prescription drugs in the U.S. – including such blockbusters as the ulcer drug Nexium, the anti-psychotic Seroquel, and the 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-

[45] 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.

[46] 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 settlements is under investigation. In the other, the generic was on the market at the time of the agreement; the generic company acquired the brand product, thus eliminating independent competition between the brand and generic; and the generic company continues to sell both the brand and generic version of the product.

[47] *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>.

infringing 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.[48] Under the courts of appeals' lenient 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.[49] 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.[50] 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

[48] *See supra* note 9.

[49] 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.

[50] *See, e.g.*, Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, 17 ANTITRUST ABA 68 (2003).

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 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.[51] 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 entry. 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,

[51] *Generic Drug Study* at 19-20.

rejected the idea, stating that such a settlement would violate the antitrust laws.[52] The generic ultimately won that patent litigation, and consumers – and federal and state governments – saved over two billion dollars.[53] 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.

V. Addressing Anticompetitive Hatch-Waxman Settlements through Legislation

The Commission believes that H.R. 1902 is a fundamentally sound approach to solving 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 considered 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.

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[52] 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>.

[53] Stephanie Kirchgaessner & Patti Waldmeir, *supra* note 43.

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 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."[54] 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."[55] 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.

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[54] 402 F.3d at 1076.

[55] *Id.* at 1074.

Legislation could provide a speedier and more comprehensive way to address this pressing concern.

As the Commission has said elsewhere, certain principles are important in crafting the precise form and scope of a legislative remedy. 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. At the same time, legislation should be designed to avoid unwarranted deterrence of settlements that present no competitive problem.

H.R. 1902 provides two mechanisms to prevent settlement avenues from being unduly limited. First, it contains express exclusions from the general prohibition on settlements in which the generic firm receives something of value and agrees to refrain from selling its product. When the value received by the generic applicant 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 – the settlement is unlikely to involve a sharing of profits preserved by avoiding competition. The bill properly exempts such settlements. We look forward to working with you to ensure that, if other exemptions are warranted, they are included in the legislation. It may be appropriate, for example, to include some form of exemption related to reasonable costs of litigation.

Second, the bill provides flexibility by authorizing the FTC to adopt rules to exempt certain agreements from the general prohibition. With this authority, the Commission can ensure that the law remains flexible and keeps pace with changes in patent settlement terms: by continuing to review the diverse ways in which value is being transferred, the Commission can identify those exchanges that are not harmful to competition and consumers, and exempt them from the prohibition.

In sum, H.R. 1902 offers a straightforward means to quickly combat conduct that is costly to consumers, provides drug companies with certainty about what conduct is prohibited, and provides flexibility to protect procompetitive arrangements. We would welcome the opportunity to work with the Subcommittee as it continues to consider the bill.

VI. 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.[56] 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

[56] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(a)(2), Pub. L. No. 108-173, 117 Stat. 2066, 2457 ("MMA") (amending 21 U.S.C. § 355(j)(5)(B)(iv)) makes settlement of patent litigation a forfeiture event only if "a court signs a settlement order or consent decree that enters a final judgment that includes a finding the patent is invalid or not infringed." If the parties request and the court enters a settlement order that does not include such a finding, as is usually the case in this context, the settlement will not constitute a forfeiture event.

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.[57]

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.[58] That decision acts as a forfeiture event that forces the first filer to either use or lose its exclusivity period within 75 days.[59] 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.[60] Generic companies facing this scenario that have attempted to bring declaratory judgment actions of non-infringement and invalidity have so far been unsuccessful, because the courts have dismissed those actions for lack of a

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[57] *See* Generic Drug Study at vii-xi, 57-58, 62-63.

[58] 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." MMA, § 1102(a)(2), Pub. L. No. 108-173, 117 Stat. 2066, 2457 ("MMA") (amending 21 U.S.C. § 355(j)(5)(B)(iv)).

[59] 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)21), 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.

[60] *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).

Constitutionally-required "case or controversy."[61] Although recent developments in the case law governing the availability of declaratory judgment actions in patent cases suggest that branded drug firms will no longer be able to avoid a declaratory judgment action merely by failing to sue the generic applicant,[62] these developments will not cure the bottleneck problem. That is because the brand company can still have the generic's declaratory judgment action dismissed, and thereby prevent an adjudicated court decision on the patent merits, by granting the generic a covenant not to sue.[63] 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.[64]

As a result, a subsequent generic filer that faces a bottleneck but has been given 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

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[61] *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005).

[62] The Supreme Court recently examined the availability of declaratory judgment jurisdiction in patent cases in *Medimmune, Inc. v. Genetech, Inc.*, 127 S.C. 764 (2007). The Court held that the case or controversy requirement did not require a patent licensee to breach its license agreement before seeking a declaratory judgment that the underlying patent is invalid or not infringed. In *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 2007 WL 942201 (Fed. Cir. Mar. 30, 2007) the Court of Appeals for the Federal Circuit followed the analysis in *MedImmune* and held that an ANDA applicant could bring a declaratory judgment action challenging patents listed in the Orange Book where the brand company had sued on some but not all of the listed patents. The Federal Circuit has not yet addressed the question of whether an ANDA applicant can bring a declaratory judgment action when the brand company has not sued for infringement of any listed patent.

[63] *See, e.g.*, *Merck & Co. v. Apotex, Inc.*, No. 06-230 (D. Del. Apr. 10, 2007) (order dismissing claims of patent noninfringement and invalidity brought by ANDA applicant for lack of subject matter jurisdiction based on brand company's granting a covenant not to sue); *see also* http://www.orangebookblog.com/2007/04/index.html (describing arguments and holding in *Merck v. Apotex*).

[64] *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).

are involved in protracted litigation or have settled their litigation without resolving the issues of validity or infringement.

H.R. 1902, however, would make dismissal of a generic applicant's declaratory judgment action of non-infringement or invalidity for lack of subject matter jurisdiction a forfeiture event for the 180-day exclusivity period.[65] The brand's grant of a covenant not to sue the generic applicant and the generic's filing of the covenant with the FDA would also constitute a forfeiture event, so that a generic in possession of a covenant need not file an unnecessary declaratory judgment action in order to obtain a dismissal. 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.

Conclusion

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

[65] The Commission made a similar recommendation in its 2002 Generic Drug Study at x-xi.

Mr. RUSH. The Chair recognizes himself for 5 minutes of questioning.

Commissioner, in your testimony on behalf of the Commission, you stated that the FTC believes the Rush-Waxman bill is a fundamentally sound approach to solving the problem of exclusion payment settlements. Can you please tell the committee why the Commission prefers our approach as opposed to the approach suggested by the pharmaceutical industry, which proposes a solution in which the FTC and courts review settlements on a case-by-case basis?

Mr. LEIBOWITZ. Well, I would make this point, Mr. Chairman. We think your approach is fundamentally sound. That is a bright line approach to the reverse payment problem and a solution to the bottleneck problem, because during the period of 2000 to 2005, when everyone believed that these payments were illegal, we still saw plenty of settlements, dozens of settlements actually, but we didn't see any anticompetitive settlements. A bright line approach will allow settlements to continue. And you saw settlements in 2006. Some were ones that weren't troubling to us; others were problematic. About half of each. But it will also make the potentially anticompetitive settlements migrate towards the nonanticompetitive side.

And with the approach I have seen different drafts of different proposals from the generic industry. Most of them take a case-by-case approach. Some of them take a sort of Hart-Scott-Rodino prereview approach. And as I heard one of the members of this committee say, the devil is in the details. We do want to solve a problem, but some of the drafts we have seen might not reverse, for example, the Schering decision. And if you are not changing the substantive standard in a case-by-case approach, then you are really not going to solve the problem. There are going to be more and more of these deals, consumers are going to be harmed, and those deals will push entry out, of course, back to almost the expiration of the patent.

Mr. RUSH. You know that after the FTC began cracking down on exclusion payments, they disappeared, and a drug company settled their patent disputes, just like the rest of the commercial sector, without these exclusion settlements, payments. You just noted that. Then when the courts intervened and invalidated the Commission's enforcement efforts, settlements with exclusion payments came back to life and now are accelerating in their frequency.

Is there a reason that we only see these types of settlement in the drug industry, and why don't we see these type of settlements in other commercial sectors of our economy?

Mr. LEIBOWITZ. Well, I think we only see these reverse payments or these exclusion payments in Hatch-Waxman settlements. And we only see side-bar deals, which we are very concerned about, because it is not always a straight cash payment. Sometimes it is a payment that is refraining from introducing an authorized generic, sometimes it is a side-bar deal.

Why do we see them only in Hatch-Waxman deals? Well, I think it is the economics of the industry. When the first generic comes in, prices go down by 20 or 30 percent. When multiple generics come in, sometimes as early as 6 months after the first generic, certainly if you will solve the bottleneck problem with your legisla-

tion, prices can go down by 80 percent. So there is a giant sweet spot in which the brand can pay the generic, the generic can receive more compensation by not competing than by competing, and the brand will make more money by keeping its monopoly rent essentially. So it is a win-win deal for the companies; it is a losing proposition for consumers.

Mr. RUSH. My final question on this round is if we don't pass this bill, how will the FTC be able to act and protect consumers against these anticompetitive agreements?

Mr. LEIBOWITZ. Well, look, if the legislation doesn't pass, we are still going to keep at it. This is a bipartisan priority for the Commission. It has been, as you pointed out. Since 1999, we have had 11 Commissioners, 6 Republicans, 4 Democrats and 1 Independent, and we are all committed to doing this. So it is public knowledge we have investigations going on. We are hoping the Court takes it, the tamoxifen case, to reverse Schering and tamoxifen in the Second Circuit. But what is going to happen is that companies are going to migrate to the more lenient standard. So there will be more and more of these deals, and they are going to push out the entry date of the first generic in the market. And so instead of having entry, as the GPHA said, long before patent expiration, you are going to have entry at the end of the patent or 6 months before, which will give the first generic 6 months of exclusivity, and you won't have all those benefits that Hatch-Waxman intended.

It turns Hatch-Waxman on its head. It really does. And consumers will be the ones who pay, and the taxpayers as well, because obviously the Federal Government pays a third of all prescription drug costs. So if somehow the current lenient standard isn't modified, and we think your bill is a fundamentally sound approach for doing so, we are all going to pay more.

Mr. RUSH. I thank you.

The Chair now recognizes Ranking Member Stearns.

Mr. STEARNS. Thank you, Mr. Chairman.

Mr. Leibowitz, I am just coming at this as an outsider just looking at it. Do all the Commissioners agree with you, or are you pretty much the strongest proponent of this bill?

Mr. LEIBOWITZ. No. You know, unlike, say, the FCC, when the FTC submits testimony, all of the Commissioners vote on it, all of us have a hand in writing it.

Mr. STEARNS. So the chairwoman has signed off on it?

Mr. LEIBOWITZ. Yes, she has. And I think what we say is we fundamentally support the approach of this legislation.

Mr. STEARNS. When you look at this just as an outsider, it looks like the free market is working in its own way. You don't think it is working right, so you want the Government to step in with mandates. Is that a fair way to put it?

Mr. LEIBOWITZ. I wouldn't characterize it exactly that way, Mr. Stearns. Look, Hatch-Waxman has been a wonderful statute. It gave the brands patent term restoration. It gave them something. It gave the generics early entry. It has given consumers enormous benefits, as I think Mrs. Blackburn said.

Mr. STEARNS. But you have been arguing here, and the chairman mentioned it, too, that you don't seem to have the tools. I mentioned in my opening statement the Federal Trade Commission, the

Department of Justice, I thought had the tools. And according to your reports and settlements, there has been over 50 settlements filed with the FTC in the last 3 years. Your testimony noted that a large number of them have side agreements. Yet of these 50 settlements, the FTC has not filed legal challenges against any of them. And private plaintiffs have brought suits against only two of the settlements.

The question is why has the FTC not challenged any of these settlements, and particularly in light of the fact that Commissioner Tom Roche suggested the FTC could successfully challenge these settlements under the standards in the Schering case? Why should the law be changed if you can't litigate changes under the Schering standard?

Mr. LEIBOWITZ. There are several good questions embedded in that one question. Let me see if I can answer some of them. If I miss one, you can come back and ask me again.

Mr. STEARNS. You got two there.

Mr. LEIBOWITZ. Let me start with Commissioner Rosch. Commissioner Rosch supports a legislative approach of fixing this problem. Commissioner Rosch believes that Schering and tamoxifen were wrongly decided and should be reversed.

Mr. STEARNS. It is fair to say he indicated the FTC could successfully challenge that, is our understanding; he has said that publicly?

Mr. LEIBOWITZ. He has said that, and I will put the Rosch statement into the record if there is no objection.

Mr. STEARNS. Sure.

Mr. LEIBOWITZ. Yes. And I think we all agree that we have investigations going on now. You want to make sure you get your investigations right. We don't believe we are entirely precluded from bringing a case. And, in fact, Mr. Stearns, as you may know, one of the reasons why the bright line test is a good one is it will bring some certainty to this rule. In the Eleventh Circuit the rule is very lenient; fraud, sham, or beyond the actual scope of the patent, that is the end of the patent.

Mr. STEARNS. But the Department of Justice hasn't filed anything, have they?

Mr. LEIBOWITZ. Let me get to the Department of Justice. You are asking all really good questions.

Mr. STEARNS. I know. And the problem is I have only 5 minutes, so if I interrupt you, it is not because I am being impolite.

Mr. LEIBOWITZ. In the Sixth Circuit they have a rule of per se illegality. All these reverse payments are per se illegal, as these kind of deals would be if they were outside of the Hatch-Waxman context. The Justice Department in the Schering case, the Justice Department in the Schering case did not support the FTC's position.

Now, I have a lot of respect for the Solicitor General. We worked together on the Senate Judiciary Committee. He is a wonderful, decent, incredibly bright person. I think that at the time of Schering, I think part of the reason why the Justice Department didn't support our petition was because we said this was a problem that was we couldn't show that it was anything but theoretical. In other words, we thought there would be more reverse payments. Since

then, as you can see from our settlement report in fiscal year 2006, and again it was your committee that gave us these settlement agreements to review, we can see that it is not just a theoretical concern, because after Schering and tamoxifen, half of the deals we have seen, 14 out of 28, now have a payment from the brand to the generic and deferred generic entry. And even more important, because of the bottleneck problem, 9 out of 11——

Mr. STEARNS. But isn't it true that you say it is difficult for the FTC to litigate this case because of the Court's decision in a case like Schering? But there seems to be several courts that have ruled similarly. Why shouldn't we rely on their decisions?

Mr. LEIBOWITZ. Again, you want certainty in the law.

Mr. STEARNS. Can you ever get permanent certainty in the law?

Mr. LEIBOWITZ. Well, Hatch-Waxman is a law that people have tried to undo certainly from time to time.

Mr. STEARNS. Well, the mandate from the Federal Government is permanent certainty, and I agree with that.

Mr. LEIBOWITZ. I would sort of look at Chairman Rush's bill and Chairman Waxman's bill.

Mr. STEARNS. One other thing. You indicated the money lost, the extra money that is going to come from the prescription drug benefit part D. But actually that has come down, the cost has come down.

Mr. RUSH. The gentleman's time is up.

Mr. LEIBOWITZ. Well, my understanding is that prescription drug costs, the rate of increase went down in 2005. It may well go up in 2006. And, of course, with the new Medicare Part D program, which started in 2006, the Federal Government's costs are obviously going to go up.

Mr. RUSH. The Chair recognizes the gentleman from Texas Mr. Gonzalez.

Mr. GONZALEZ. Thank you very much, Mr. Chairman.

Welcome, Commissioner. I guess one of your observations was this reverse exclusionary payment settlement under the present guise and interpretation by courts and such is perfectly legal. We understand that, and that is why we are attempting to address it legally through legislation. Only because something is legal does not necessarily make it right or best practice.

Mr. LEIBOWITZ. Well, I think that is absolutely true. And again, it is legal in the Eleventh Circuit. It is legal by a 2-to–1 decision in the Second Circuit. It is per se legal in the Sixth Circuit.

And I just want to be read something that Senator Hatch said on the Senate Floor in 2002 about these reverse payments. He called these types of deals, reverse payments, collusive arrangements, appalling. And, of course, we heard from one of the authors of Hatch-Waxman. This is the coauthor, and he is very, very concerned, because I testified on the Senate side about the bottleneck problem.

And so I think you are absolutely right, Mr. Gonzalez. It is permissible under certain circuits' interpretations. And, of course, if it is permissible, businesses are going to want to do it. They have a responsibility to their shareholders. And you will see, these are really good businessmen, and these are really good lawyers, and they are doing what is in the best interest of their shareholders.

That is why we believe that either through Supreme Court reversing those bad decisions or through the bright line approach and the solution to the bottleneck that this bill entails you can solve this problem.

Mr. GONZALEZ. Commissioner, you earlier alluded to the resulting lack of savings that would be realized by the introduction of generics in the competition. This is anticompetitive. If you don't get the generics out there, you said there is obviously some cost to the consumer. But you pointed out something that is of great importance to us up here, and that is a third of the cost of the drugs is borne by the United States Government, Medicare and Medicaid. Can you put a dollar figure on that?

Mr. LEIBOWITZ. Yes. I put a dollar figure in my oral statement. I think it is $68 billion, or 32 percent of the $214 billion spent in annual drug purchases last year by Americans. That adds up to about $800 per American citizen or per American citizen or resident, $800 per American, and about $230 paid by taxpayers, by the Federal Government. And then that percentage is expected to go up, I think it is in our written statement, considerably in coming years, the amount that is paid by the Federal Government, and the overall amount that Americans will pay.

Mr. GONZALEZ. And one last question, because I think when we enter these debates, and it comes to patents and patent litigation, and we start making distinctions between the type of patent being held, is it in the telecommunications or is it pharmaceutical, and it seems to me that when we get into the pharmaceuticals, there are different factors and considerations, and some will advance the argument that it is so unique, the factors and the elements in that business sector is so unique, that you need special arrangements, or the laws should treat them differently.

Is there anything so unique in that particular industry or entity, business arrangement, business model, that should take it out of the norm and have a situation as we have presently?

Mr. LEIBOWITZ. Well, I guess I would say this. Hatch-Waxman, it is unique in the sense that when the first generic enters, the price goes down considerably. When other generics enter, and it is anticipated by Hatch-Waxman by this committee's product that you will have early generic entry, pricing can go down by 80 or 90 percent. And so I think the fact that you have passed this law, and there was a congressional intent to it, meaning that it should be part of what you think about along with the antitrust laws, and along with the patent laws, too, which have a presumption of validity as this legislation moves along—but, yes, it is a unique industry. It is an industry that has done wonderful things for consumers. The generics have brought down prices for consumers, but you are going to see no more early generic entry if these lenient rules continue to apply. And again lenient rules in two circuits, per se rule against in another.

Mr. GONZALEZ. Thank you very much, Commissioner.

Mr. RUSH. The Chair wanted to remind the Member that he has an additional 3 minutes because he waived his opening statement. Do you want to yield?

Mr. GONZALEZ. I guess one last point, and that is you always hear, and I think there is some validity to this, that when it comes

to the pharmaceutical companies, that is a tremendous investment that they make in the research, in the development and the trials and so on. And I have to appreciate that. But should we go ahead and attempt to fix what we perceive as a shortcoming in Hatch-Waxman? Does it really impact that particular industry in the innovation, in bringing new products to the market and, again, being able to protect that investment?

Mr. LEIBOWITZ. Look, I would say in some tangential way—well, I agree with you, the innovator firms, the brands, they look at hundreds of different, maybe thousands of different chemical compounds before they bring one to market. And when they have to pull a product—and Pfizer had to pull a cholesterol drug, Torcetrapib; they lost $18 billion in market capitalization in a single day. But that is not an excuse for violating the antitrust laws, or for doing something that we all believe should be illegal, or for turning Hatch-Waxman on its head. So I agree with your thoughts.

Mr. GONZALEZ. Thank you very much.

I yield back.

Mr. RUSH. The Chair recognizes now the gentle lady from Tennessee Mrs. Blackburn for 5 minutes.

Mrs. BLACKBURN. Thank you Mr. Chairman.

Commissioner, I am not a lawyer. Usually I say thankfully I am not. When we get into hearings like this, and when I am working with my creative community in Tennessee, all of my song writers, my auto engineers, a lot of our biotech innovators, I find myself always wishing I knew a little bit more about these issues. And as my colleague was just talking about, there are two sides to this coin. And I think that those of us who are passionate about being certain that we meet the needs of our constituents, when it comes to health care, looking at drugs getting to the marketplace, we realize the desire that is there. When we look at innovators and their right to take an idea and a concept and take it through R&D, and take it through commercialization, and move it to the marketplace, and then to be fairly and justly compensated, we realize the need for that also.

And you all have argued, the Commission has argued that the recent court decisions do make it difficult to bring the antitrust cases to stop these exclusion payment settlements and that the settlements are uncompetitive, all the things that we have talked about. And we are looking at, tying back into Mr. Gonzalez's question, you know, people are concerned about this having a chilling effect. What is it going to do? What is it going to do long term? Especially when we are tying back into the hearing we had this morning with our Health Subcommittee and looking at the biosimilars and the new products that are there and that can be coming to the market. It is a concern shared by a lot of our manufacturers.

So let us talk about the discrepancy in the claims. Don't the generic manufacturers have an incentive to make sure that they can sell their product to the public? Let us talk just a little bit more about that. And before you begin, because I am going to let you just talk for the rest of the time, I want you to touch on the difference in your opinion and the Department of Justice statement and why they have argued back against the position that you all hold.

And, Mr. Chairman, if you would, I think that for the sake of debate, and I have that DoJ argument with me. I would love for us to submit that into the record for the sake of discussion as we move forward on the bill, and then I will yield to our guest to answer the question.

Mr. RUSH. So ordered.

Mr. LEIBOWITZ. Well, I mean, you make a very important point, Congresswoman. We have issued two reports on patents in the last 3 years for our intellectual property. We issued one last month. We believe strongly in the importance of intellectual property. I worked at the Motion Picture Association for 4 years, and we worked very much with the music industry to protect intellectual property.

But a patent is an absolute. A patent is a presumption. And what we have found in these deals, this is the Commission's position, is that you are buying extra protection. And the incentives, because of Hatch-Waxman, because of its uniqueness, are so great, there is this giant sweet spot where the brand can pay the generic. The generic makes more money by not competing before the patent expires. And again, the generic can only get into the market if it is not infringing on the brand's patents or if the brand's patent isn't valid.

But here what you are doing is you are buying extra protection with these lenient court decisions, because the court decisions are out there. But it means that a brand will pay the generic. The generic will earn more by not competing before the patent expires or maybe 6 months, or by not coming in before the patent expires. Because of the bottleneck problem, nobody else can jump in in front. And that is a problem for consumers; that is a problem for the Federal Government which pays for so much of the prescription drugs in America.

Now, as to the DoJ position in Schering, we found by a 5-nothing, 5 to 0, that Schering had violated the antitrust laws by paying a generic $60 million in a side deal for a license. They never used the license. We thought it was a fig leaf for the anticompetitive payment.

The Eleventh Circuit reversed us. And we appealed to the Supreme Court, because we have the authority. I think the FCC is one of the other agencies that can do that, too. The Supreme Court asked the Solicitor General for his opinion. And again, Paul Clement, the Solicitor General, is a brilliant, wonderful, decent guy and a former colleague of mine, and I admire him enormously.

The brief will speak for itself, and we put it in the record.

I think the Justice Department was concerned about a couple of things. One is they were concerned that the ruling wouldn't be cabined off only to Hatch-Waxman, which we know is unique. The pharmaceutical in this is really unique because it is under Hatch-Waxman. That is, of course, not a problem with the bright line approach of the Rush bill, of the Kohl-Grassley-Leahy-Schumer bill in the Senate, because it would only apply to Hatch-Waxman.

And the other reason, and I am speculating a little bit here, the other reason I think is at the time of Schering, it was before our 2006 report, and so what we said was a problem was only a theoretical problem. They sort of acknowledged at some level in the

brief that it was a problem, but we could only show it was theoretical.

Now, if you look at first filers in fiscal year 2006, which goes through, I think, the end of October 2006, 9 out of 11 times when there is a first filer, the brand has been able to pay the filer, there has been a delay in generic entry, and that leaves all the other generic companies lining up behind them for a later entry date. They can't get in until 180 days after the first filer does.

If you look at all the deals, 14 out of 28. So now we believe there is a very real problem. And the Supreme Court has actually asked the Solicitor General for his opinion about whether it takes cert on the tamoxifen decision. And obviously we are having discussions with the Solicitor General, his staff and the Antitrust Division.

Mr. RUSH. The gentle lady's time is up.

We will now recognize the gentleman from Texas Mr. Burgess.

Mr. BURGESS. Mr. Leibowitz, I am having a little bit of trouble understanding the concept of bottlenecking. Can you explain that to me in simple declaratory sentences with a subject and verb?

Mr. LEIBOWITZ. I will try my best. You can ask me a couple of times.

What basically happens is the first generic to enter has 180 days' exclusivity. But sometimes a brand and a generic will settle for a later entry date, possibly because there is a reverse payment, possibly because both the brand and the generic think there is a 50 percent chance of the generic winning, and so they split the difference. If there is 10 years left, it is a 5-year delay.

Mr. BURGESS. So that is a business arrangement that they make between themselves?

Mr. LEIBOWITZ. It is a business arrangement they make between themselves. Now, if there is a reverse payment involved, we would be concerned about it.

Mr. BURGESS. But the business arrangement itself is legitimate?

Mr. LEIBOWITZ. It may or may not be. It depends on the nature of the business arrangement. But to explain the bottleneck problem, let's say the first generic is entering 5 years later. Well, maybe the first generic didn't have the best case against the brand. Maybe the first generic's product infringes, but the other generics who filed a little bit later, maybe they have a product that is less likely to infringe or a better product, and they have to wait. Under current interpretations of the law and FDA rule, they have to wait until the first generic goes to market.

Now, Hatch-Waxman has a forfeiture provision that says if the first generic doesn't come in for a period of time, if it comes in on a much later entry date, other generics can force the first generic either to use it or lose it. But that forfeiture provision hasn't worked because of a glitch in the law, and so it has created a bottleneck. It really allows the first generic to park its exclusivity, and everybody else is in a bottleneck behind that first generic.

So there are different approaches for solving this. We think Chairman Rush's approach is a good one. I know that Dr. Sherman, the CEO of Apotex who is testifying on the next panel, has a slightly different approach, and we want to think a little bit about his concerns as well. But that is basically it.

Mr. BURGESS. Just in layman's terms, what is the solution proposed by the bill before us today?

Mr. LEIBOWITZ. The solution in the bill would allow generics, if they receive a covenant not to sue from the brand, they would treat your covenant not to sue as a forfeiture event and would allow them to go to court to get a declaratory judgment action. And if it is dismissed for lack of subject matter jurisdiction, that would also be a forfeiture event.

Right now under the current law, to make that a forfeiture event, you would need probably to litigate that case to the end. And this would basically say if it is dismissed for lack of subject matter jurisdiction, it would be a forfeiture event. And what would really happen as a practical matter, because I think that is what you are interested in, is companies, the brands, would then litigate, I believe, against the second generics. And so they would litigate, and they decide whether the second generic had a valid or an invalid claim.

Mr. BURGESS. And that would be a streamlined process over what we see today?

Mr. LEIBOWITZ. It would be a streamlined process over what we see today. Yes. I don't know that this is entirely a statute that involves lots of streamlining. And, in fact, the tamoxifen case which is now pending on circuit before the Supreme Court, patent cases started on that—it is now an antitrust case—in 1987. So we are talking 20 years. It is like the Bleak House of pharmaceutical litigation, and so part of the reason why a bright line approach is a good approach is it solves the problem quickly.

Mr. BURGESS. Let me ask you this. We have been in another hearing about similar drugs all morning, so forgive me if I wander from the jurisdiction over which we preside in this committee. But just in general, on generic drugs—and you talked about 70 to 80 percent savings that are available to consumers by going to a generic drug. But at some point with a drug that has been out there for a while, and all the research and development costs have been recouped, and all the costs of this expensive litigation have presumably been recouped or written off somewhere, at some point it is just the cost of manufacture that is borne for things that have been out there for a long time. I am thinking about things like Phenergan. I am thinking about things like erythromicin and penicillin.

Has the FTC looked at the amount of markup that some of those generics—you know, we talk about the percentage markup on a brand name, but over the cost of production, over the cost of manufacturing, which may be pennies or tenths of pennies——

Mr. LEIBOWITZ. And the cost of research, of course.

Mr. BURGESS. Well, the research is now gone. It has all been recovered. Is there anything that you or your office does to look at—is the price too high for what we are paying for generics that have been around for a long time?

Mr. LEIBOWITZ. Well, I would say this. We are mostly an enforcement agency, so if we see collusive arrangements even after patent expiration between a branded and generic, we actually have one case pending now. But have we looked at the mark——

Mr. BURGESS. What case is that?

Mr. LEIBOWITZ. That is the Warner Chilcott-Barr case settled with Warner and Chilcott, not with Barr.

Mr. BURGESS. Would you make that information available?

Mr. LEIBOWITZ. Absolutely. We don't look at the markups. We are an enforcement agency, we are not really a regulatory agency. But I will try to get you some information, Congressman. I am happy to do that.

Mr. RUSH. The Chair recognizes the gentle lady from California Mrs. Bono for 5 minutes.

Mrs. BONO. Thank you, Mr. Chairman. I appreciate very much the spirit of this bill before us today. I think it is a very important issue, and I appreciate our panelists being here. But I have good news. I don't have any questions, so I will yield back.

Mr. LEIBOWITZ. Thank you. I want to continue to work with you on spyware matters.

Mr. RUSH. Mr. Pitts is recognized for 5 minutes.

Mr. PITTS. No questions.

Mr. RUSH. Mrs. Blackburn.

Mrs. BLACKBURN. Thank you. Mr. Leibowitz, I have to tell you, sitting here making some notes and listening to you, I feel like as you are using the terms well, speculation of this and the theoretical problems of this, I have a feeling you are the thought police kind of going on me here just a little bit. I mentioned my industry in Tennessee. And in light of that, can you give me any examples with any other industry where the Congress has specified that there should be certain industry-specific settlement practices that are per se illegal?

Is there anywhere else that this is happening?

Mr. LEIBOWITZ. The courts have certainly said that there are certain settlements or certain deals are per se illegal. You can't pay your competitor to stay out of the market, right, outside of this. But in terms of industries, let me get back to you. I don't know that there is again, but again——

Mrs. BLACKBURN. What we would like to know, and one of the things that concerns me, is we look at intellectual property, and as we look at making certain that intellectual property is a private property right, and as we look at patent law, what I want you to do is give me any example—as I said, I am not a lawyer. I am not an intellectual property lawyer.

Mr. LEIBOWITZ. To your credit.

Mrs. BLACKBURN. Yes, I do believe it is to my credit. But if there is some other industry that is doing this, where Congress is coming in and saying, all right, this is the settlement practices, and then if there is not another industry where this is standard practice, then I would like to hear from you why we should make an exception and apply that only to pharmaceuticals. So that would be my two-pronged question for you, if you will, sir.

Mr. LEIBOWITZ. All right. As to the first prong, the courts have declared a lot of types of agreements per se illegal, and they have declared reverse payments per se illegal in the Sixth Circuit. That is the Cardizem decision. So the courts are sort of split about this.

The second question, could you just give me the second question one more time? I want to make sure I have it right.

Mrs. BLACKBURN. If you can tell us why we should make an exception for this industry. And there again you are talking about the courts are split on this, and that is where I feel like we are kind of morphing over in here into more or less a thought police. And I am just not real comfortable. The more I have listened, the less comfortable I have gotten. How about that?

Mr. LEIBOWITZ. We don't want to police them in any way. Again, here is why. And maybe I just haven't done a good job of explaining it. Because of the unique nature of this industry, because there is such a giant sweet spot between the brands' revenues and profits, if there is no one competing with it, and the brands' revenues of generics are entered—particularly multiple generics—there is a huge incentive here that you don't see in other industries. Maybe it is because you don't see in other industries for the brand to pay the generic some form of compensation to stay out of the market. The generic can make more by taking this payment of some sort, by taking the payment, than it would by competing. That is not what we want in America. That is not what we want under Hatch-Waxman.

And so that is why I think—and what you see—and because these lenient rules that a couple of courts have come up with, they are allowed to do it legally. So they should do it. I shouldn't say they should do it; so they have an incentive to do it. They have to represent their shareholders. They are good business people.

Mrs. BLACKBURN. I appreciate that, and the last time the Federal Government, and I think the only time the Federal Government, has jumped into an industry and said, let us help you out with this, we are going to set in Federal statute the maximum that you can earn, it was for song writers. And we are still trying to straighten this out, Mr. Leibowitz. And I know you are very familiar with that industry.

So what you need to do is say, this isn't going to lead us down that road, so that we look at losing an industry like we are looking at losing a lot of our creative community right now.

Mr. LEIBOWITZ. Let me say this. And I think that is so important, and creators need to be paid value—you need to maintain those incentives for creators, music, movies, of patent holders.

But having said that, we do believe in this industry, and calving off only to this industry, right, that the incentives are so much that a permissive rule encourages those deals to happen. They harm consumers. And that is why we support a legislative approach or a court overturning of the permissive rules.

So thank you. Those are good questions. We will continue to have this discussion, I hope.

Mr. RUSH. I want to point out to the gentle lady from Tennessee that no other industry is governed by a law like Hatch-Waxman. And this is the congressional will that has been in effect for some time now, and this practice is certainly absent in all other sectors of our economy. So I just wanted to point that out to her.

Thank you so much, Commissioner.

Mr. RUSH. And now we will proceed with our next panel.

I want to recognize and welcome all the witnesses for panel 2. I want to recognize specifically Dr. Bernard Sherman, who is is CEO of Apotex, Incorporated, and Apotex is a generic pharma-

ceutical company that opposes legal settlements with exclusion payments. Dr. Sherman will testify why his company is successful without these agreements and how reverse consideration legal settlements are anticompetitive and bad for consumers.

Our next witness is Mr. C. Scott Hemphill, J.D., an associate professor of law at the Columbia University Law School. Professor Hemphill has devoted considerable academic work to the issue of exclusion payments and agreements and will testify in favor of the bill. He will explain how the regulatory structure of Hatch-Waxman gives rise to such agreements and how they are anticompetitive.

It is worth noting to my Republican friends that Professor Hemphill is a former clerk to Judge Richard Posner and Justice Antonin Scalia, so he should have a lot of street credibility with our conservative friends.

The next witness will be Mr. Phillip Proger. He is a J.D., a partner in Jones Day. Mr. Proger is a prominent expert on intellectual property law and will provide his insights on the issue of reverse consideration legal settlements and drug patents disputes. He will testify that the problem of reverse payments is overstated, and that the FTC and the courts are already well equipped to handle any potential problems through the antitrust laws.

Michael Wroblewski, J.D., is a project director for the Consumer Education and Outreach Division of the Consumers Union. Of course, Consumers Union is one of the Nation's most prominent consumer advocacy groups. Mr. Wroblewski will testify that these agreements adversely affect consumers and should be banned. Consumers Union, as an organization, supports this bill.

Finally, our witness is Mr. Theodore Whitehouse, who is also a distinguished juris doctor. He is a partner in the firm of Willkie Farr & Gallagher LLP, representing Teva Pharmaceuticals. Teva is the Nation's largest generic drug company, and Mr. Whitehouse will present the generic industry's side of this particular issue. While Teva believes that there is room for reform, Mr. Whitehouse will assert that certain legal settlements will reverse consideration provisions unnecessary and beneficial to consumers.

I want to welcome all of our witnesses, and we will recognize now Mr. Sherman for 5 minutes.

STATEMENT OF BARRY SHERMAN, CHIEF EXECUTIVE OFFICER, APOTEX, INC.

Mr. SHERMAN. Thank you, Mr. Chairman, Ranking Member Stearns and Members of the committee. Thank you for the opportunity to testify.

Apotex is very much opposed to anticompetitive settlements, and therefore we are generally in favor of the bill as proposed, but we have to add a big caveat to that, and that is we believe that there are problems more fundamental than the reverse payments, and that focusing solely on reverse payments without taking into account the more essential problem is likely to not accomplish very much. And I would like to try to explain.

The fundamental problem that, as far as we can see, with the settlements is that the settler retains the Hatch-Waxman exclusivity and continues to block market access from all others who would

continue the patent battle and would bring the products to market much earlier. It is a fundamental problem that needs to be addressed.

And indeed that is also what distinguishes this industry from all others. That question was asked of the previous witness. And I think the real answer is that this industry is different because here the alleged infringer has the power to stop all others from entering the market, and by settling with one, the first to file the patent keeps everybody out of the market for the entire patent life essentially.

Apotex operates on the principle that it has a duty to always work and fight for the earliest possible market entry. That is a commitment we make to our customers, and it is something we honor. We do not enter anticompetitive settlements.

Indeed we find it frustrating that so many times our ability to bring products to market is obstructed by the very Hatch-Waxman provisions that are intended to give us an incentive. And there is one fundamental problem, and that is that the incentives don't necessarily go to the right people. What happened is the Hatch-Waxman provisions, the regime was intended to give a reward to the first person to file with a Paragraph IV certification and to win the litigation and bring the product to market. That made sense. But the courts have determined that the exclusivity is earned merely by being the first to file, which means that someone could be first to file, earn the exclusivity, and do nothing else, not win, not even litigate, and even enter into a settlement where it agrees not to litigate, and it agrees to delay market entry for years, and yet it still keeps that exclusivity it has not earned.

The exclusivity was given as a reward because litigation is expensive, and to earn it the first to file is supposed to litigate to win and to bring early entry, not to settle and collude to delay market entry.

The effect of this exclusivity going only to the first to file regardless of whether or not he wins has two implications. Number 1 is the reward is going to someone who hasn't earned it, but even worse is the flip side. That exclusivity prevents someone else from coming to market who would litigate and win. And this is not just a theoretical problem, it is a real, practical problem.

And there have been examples. There is one very big example. Just last month in the case of amlodipine, which is a blockbuster product, Apotex won and defeated the patent in the court of appeals last month, but was unable to launch because it was not first to file. Instead the first to file, another generic firm, launched and is making hundreds of millions of dollars not earned by it, but we earn nothing as a result of our investment.

And one may say, so what; Apotex is not getting the reward that it earned. But the practical problem is we can't keep doing it. Generic applicants were not first to file—as happened in this case—can't litigate, can't afford to litigate to bring about market entry if there is no reward at the end of the day, and if all they will get is legal costs with no benefit.

This is the fundamental problem, and it is very easily fixed. All that needs to be done is provide shared exclusivity to the person that is first to win and to break the patent monopoly. There is al-

ready a concept of shared exclusivity. If several people are first to file on the same day, they should share exclusivity even if they don't do anything to earn it. There is no reason exclusivity can't also be shared by being the person who actually earns it by being the first to litigate and to win. And that is an essential fix that we think is needed to resolve the problem.

I also want to comment on the bottleneck provisions in this bill. As you have heard, someone who is not first to file can be stuck in a bottleneck where it can't trigger an exclusivity because it isn't sued by the patentee. And the bill proposes to fix that by having exclusivity forfeited if there is a judgment stopping a DJ, declaratory judgment, action from proceeding for lack of jurisdiction or a covenant not to sue.

Mr. RUSH. Dr. Sherman, would you please bring your testimony to a conclusion?

Mr. SHERMAN. Yes, I will.

The problem with that is that it will only replace one bottleneck with another because the result will be that the patentees will now sue everybody and put them in the same position that we were in with respect to amlodipine. The second filer won't be able to afford to litigate because if it wins, it still can't come to market unless it is a provision of this bill that anyone who settles loses the exclusivity.

Mr. RUSH. Thank you so very much.

[The prepared statement of Mr. Sherman follows:]

Testimony of Dr. Bernard C. Sherman, Ph.D, P. Eng.
CEO of Apotex Inc.
Hearing on HR 1902, The Protecting Consumer Access to Generic Drugs Act of 2007
Subcommittee on Commerce, Trade, and Consumer Protection
Energy and Commerce Committee
US House of Representatives

May 2, 2007

Introduction

Chairman Rush, Ranking Member Stearns, Members of the Subcommittee, thank you very much for the opportunity to testify before you on anti-competitive patent settlements between brand and generic pharmaceutical companies. My name is Bernard Sherman. I am the CEO and Chairman of Apotex Inc. Apotex is the largest Canadian pharmaceutical manufacturer. We are also one of the largest generic drug manufacturers in the world. In the United States, we are the 7th largest generic drug manufacturer measured by sales. Our U.S headquarters is located in Weston, Florida. We also have a distribution center in Indianapolis, Indiana.

Apotex is pleased to testify today in support of HR 1902. Apotex shares your view that settlements in which brand and generic pharmaceutical manufacturers thwart consumer access to generic drugs through collusive agreements should be unlawful. Such settlements are the antithesis of what was intended by Congress in the Hatch-Waxman provisions. Apotex applauds you for your introduction of this legislation and your leadership on this important consumer issue. We hope you find the recommendations we will put forward today, which we recognize fall under the jurisdiction of the Energy and Commerce Committee's Health Subcommittee, helpful as you and your colleagues in both subcommittees continue your work to ensure consumers have timely access to quality, affordable generic medicines.

At Apotex, we believe generic companies should endeavor to bring generics to market at the earliest possible time, and that the legislative and regulatory framework should facilitate, not obstruct, early generic entry. Our record in advocating for such a public policy framework, from our support for a district court trigger for exclusivity rather than an appellate trigger, our pursuit of declaratory judgment actions, our efforts in the courts to vacate anti-competitive settlements, our pursuit of infringement verdicts even where there is no guaranteed benefit to us, and our opposition to patent settlements, is unique and unmatched among generic manufacturers.

As one example, about 5 weeks ago, Apotex succeeded in invalidating Pfizer's patent for amlodipine besylate, sold by Pfizer as Norvasc®. Apotex undertook this battle despite the fact Mylan, and not Apotex, was the first to file with a paragraph iv certification. The result of our investment, our work and our victory was that Mylan, and not Apotex was

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then immediately able to launch a generic amlodipine product. As a consequence, consumers are now saving hundreds of millions of dollars, Mylan is garnering hundreds of millions of dollars of profits that rightfully should have gone to Apotex, while Apotex receives no benefit whatsoever, and is left only with a large loss on the investment in the litigation. This is a perverse outcome of a system that rewards only the first to file, even if the first to file does not litigate and win, and ignores the needs of a subsequent filer who is prepared to fight to win. It is this flaw in the system that is the root of the settlement problem.

As another example, Apotex has sued to invalidate the settlement agreements between Cephalon and four generic first-filers. Under the settlement agreements, the generics have agreed to abandon the patent challenge and defer launch until shortly before patent expiry. Apotex is prepared to carry on the patent challenge, just as it did for amlodipine, but again will get nothing in return, because of two anticompetitive aspects of settlements. The first is that the first filers will continue to hold the180 Hatch-Waxman exclusivity, despite the fact that they have settled. Thus, even if Apotex wins, it will still be unable to sell. The second is that the settlements invariably contain a "poison pill" provision, whereby market entry of the first filers will be accelerated if a subsequent filer, such as Apotex, continues to litigate and wins. This means that, if Apotex continues to litigate and wins, the result will again be that Apotex will continue to be held off the market, while the first filers, who agreed not to launch for years, will be able to launch and thus take all of the benefit properly earned by Apotex, again leaving Apotex with nothing but costs.

Apotex very much wants to continue to fight for the interests of consumers, as intended by the Hatch-Waxman provisions. However, it should be clear that we will be unable to continue to do what is right, unless Congress addresses the essential problems. Two things are sorely needed:

1. An amendment that gives shared (if not sole) exclusivity to a generic challenger who, although not first to file with a paragraph iv certification, is first to succeed in addressing the listed patents.
2. Amendments to stop settlement agreements from denying any benefit to a subsequent filer who continues to fight. Specifically:
    - i) a generic first filer who enters into any settlement agreement should immediately forfeit its exclusivity; and
    - ii) a generic first filer who agrees to defer launch should not be permitted to then accelerate launch as a result of a win by a subsequent filer who continues to litigate.

Having first filer settlements result in the forfeiture of exclusivity is crucial to ensuring that the system functions the way Congress originally intended. Allowing first filers to preserve exclusivity when they settle for market entry only months before patent expiry will result in a system in which every early generic entry will forever be capped at only months before patent expiry. There is no doubt, Mr. Chairman, that, if permitted to get

away with it, the first-filer and brand company will ALWAYS settle for generic entry only slightly before patent expiry, maintaining almost all of the life of every monopoly, even when the patents are clearly invalid and or not infringed. Consumers are much better off with a system that allows for the possibility of generic entry years rather than just months earlier. Indeed, Congress' intent in passing the Hatch-Waxman regime was to create a framework under which generics were incentivized – for the benefit of consumers – to break, not preserve, patents that are invalid or not infringed.

I would also emphasize, Mr. Chairman,that we are not proposing that settlements be barred. We do not think they should be. If a first filer thinks slightly earlier generic entry is a good deal, it should take that deal. But it should not be permitted to stand in the way of another generic who thinks it can get to market even earlier, and is willing to take up the patent fight. Otherwise, benefits that might have been won for consumers will never be realized.

Mr. Chairman, Apotex commends you for including in HR 1902 a provision that would correct the declaratory judgment problem -- a key loophole that contributes to the "bottleneck" problem. These bottlenecks arise when first to file generic companies conspire with their brand counterparts to block the market and delay generic competition.

The inability of subsequent generic filers to get a declaratory judgment ("DJ") helps to sustain the monopoly. Current law requires subsequent filers to successfully litigate the same universe of patents to which the first filer has certified. To ensure that market entry remains indefinitely blocked, brand companies simply do not sue subsequent generic filers. The only avenue left for a subsequent filer is to pursue a DJ action. Unfortunately, the courts have routinely dismissed efforts to get a DJ, on the basis that the generic lacks standing to sue. It appeared that the decision of the Supreme Court in the MedImune case might resolve this problem. However, patentees have come up with a new gimmick. In addition to not suing, they now give covenants not to sue.

As an example, Apotex has been seeking a DJ to trigger the exclusivity on alendronate, sold by Merck under the tradename Fosamax®. Merck responded with a covenant not to sue, and despite the Supreme Court's decision in MedImune, the District Court has again held that Apotex' motion for a DJ is not justiciable because of the covenant not to sue. The situation is preposterous. A covenant not to sue has no meaning, because Apotex' market access will remain blocked by the exclusivity that Apotex cannot trigger.

HR 1902 corrects the DJ problem by making both the dismissal of a DJ action for lack of subject matter jurisdiction and the execution of a covenant not to sue triggering events for the first filer's exclusivity.

Apotex strongly supports the enactment of this provision. However, we must caution that even this provision will be ineffective, unless the problem of anti-competitive settlements is adequately addressed. If and when your proposed provision to fix the DJ problem is enacted, the result will be that the patentee will invariably sue the subsequent filer,

thereby subjecting the subsequent filer to the enormous cost of litigation. No subsequent filer will be able to justify the cost, whenever there has been a settlement wherein the first filer has agreed to delay launch, while maintaining exclusivity, as any subsequent filer who continues to litigate can get no reward. Anti-consumer patent settlements will continue unabated.

HR 1902 includes a provision that would ban so called "reverse payments" -- from a brand to a generic company settling a patent infringement case. The intuitive reaction shared by almost all is that reverse payments are unethical and wrong. However, Apotex believes that this issue is a "red herring" and that outlawing reverse payments, if not coupled with other amendments, will have no significant impact on the number of settlements or their anticompetitive impact, but will simply reduce the cost of such agreements for patentees. This can be understood from the following analysis.

A settlement typically includes a provision that the first generic applicant will be licensed to enter the market during the last year or less prior to patent expiration. The significant value for the first generic applicant is the 180 day exclusivity. Litigation is almost always uncertain as to outcome. If the generic litigates, there is a risk of losing and ending up with nothing. Hence, it is inevitable that it will ***always*** make more sense for a generic to settle for exclusivity during the last months of patent life rather than to litigate in the hope of winning and getting earlier entry. The reason that generics have been able to negotiate for "reverse payments" in addition to market entry during the last months is that the agreement is enormously valuable to the patentee. The patentee keeps the monopoly for all but the last months, so the benefit to the patentee is generally enormously greater than to the generic. The generic thus takes the position that it is not willing to settle for only a generic monopoly during the last months, and the patentee is always willing to provide a further benefit to the generic through a "reverse payment". It may appear that, if such reverse payments are made illegal, the generic company will simply demand that the patentee allow it to enter the market even earlier than the last months of patent life as a substitute for the banned payment. However, that fails to take into account that earlier entry for the generic has very little additional value, because the exclusivity will terminate and other generics will enter the market 180 days after first sale by the first generic. It follows that making reverse payments illegal is unlikely to have any substantive effect on settlements, that generics will still settle for guaranteed market entry during the last months of patent life, and the only effect, if any, will be that the cost of settling will be reduced for the patentee, with no benefit for consumers.

As mentioned earlier, in Apotex's view, it is critical to recognize that the primary anticompetitive aspects of settlements are those that eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry.

We thus urge the Subcommittee to work for legislation that includes all of the following features:

1. A provision that makes both dismissal of a DJ action for lack of jurisdiction and execution of a covenant not to sue triggering events for the first filer's exclusivity, as now proposed in HR 1902.

2. An amendment that gives shared (if not sole) exclusivity to a generic challenger who, although not first to file with a paragraph iv certification, is first to succeed in addressing the listed patents.

3. Amendments to stop settlement agreements from denying any benefit to a subsequent filer who continues to fight. Specifically:
    a. a generic first filer who enters into any settlement agreement should immediately forfeit its exclusivity; and
    b. a generic first filer who agrees to defer launch should not be permitted to then accelerate launch as a result of a win by a subsequent filer who continues to litigate.

As aforesaid, we believe that there is a fundamental flaw in a system that rewards only the first to file, regardless of whether or not the first to file continues to litigate for the earliest possible market entry, and that, conversely, denies any reward for the generic that does litigate and wins. To ensure timely consumer access to generic competition, this fundamental flaw must be fixed.

Year after year, Apotex has tirelessly litigated to bring products to market, as we believe was intended by Congress. We want to continue down that path, and urge Congress to make it possible by addressing all of these issues.

Adopting this approach will bring a swift and just end to the bottleneck problem. This approach would preserve the right of all companies to settle litigation – a right that should be preserved. What it would not allow is the continued perversion of the 180 day exclusivity period -- an award Congress intended to incentivize generic companies to open markets early, not block them.

Conclusion

Thank you very much for inviting Apotex to share our views with you and the Members of this Subcommittee on this issue. Please know that Apotex stands ready to assist you and your colleagues in this Subcommittee and the Health Subcommittee in any capacity in which you may call on us. We hope that our insight has helped and will help in arriving at legislation that will work as intended by Congress for the benefit of consumers.

Mr. RUSH. I just want that point out your solution of relating to the exclusivity period is not within the jurisdiction of this committee. It is within the jurisdiction of another subcommittee, the Health Subcommittee. Thank you so very much.

The Chair now recognizes Mr. Hemphill for 5 minutes of testimony.

STATEMENT OF C. SCOTT HEMPHILL, ASSOCIATE PROFESSOR OF LAW, COLUMBIA UNIVERSITY LAW SCHOOL, NEW YORK, NY

Mr. HEMPHILL. Chairman Rush, Ranking Member Stearns and members of the subcommittee, I am Scott Hemphill, an associate professor at Columbia Law School. My scholarship in teaching focuses upon the balance between innovation and competition established by antitrust law, intellectual property and sector-specific regulation. I welcome this opportunity to testify today about anticompetitive pay-for-delay agreements between brand name drugmakers and their generic rivals. These remarks draw upon ongoing academic research into the economic effects of these settlements and their appropriate legal treatment.

For more than 20 years, the Hatch-Waxman Act has provided a way for generic drugmakers to introduce a competing version of a brand name drug even before a patent expiration by arguing the relevant patents are invalid or not infringed. The patent litigation which often results has become the norm with respect to the most important brand name drugs. These challenges often succeed in securing early generic entry. For example, of the 10 best-selling drugs of 2000, 9 attracted challenges of which at least 4 led to early entry.

In some cases the innovator, rather than take a chance the generic firm might win the patent suit, settles litigation. The parties dismiss the suit and agree to a particular date for generic entry. The entry date is a result of a hard-fought bargain between rivals. The innovator pushes for a later entry date by arguing that if the litigation proceeds to judgment, a court is likely to hold the patent is valid and infringed. The likelier that judgment is, the later the entry date.

Now, a settlement that relies solely upon the inherent strength of the patent is properly permitted, but the situation is different when an innovator makes a payment to its rival rather than relying solely upon its prospects at trial. In that case the payment secures a later entry date than is warranted by the likely validity of the patent alone. That payment to a rival made to secure additional delay—in effect a privately arranged patent term extension—is properly prohibited.

These settlements have become a major tool of life-cycle management. It is not uncommon for settlement to account for more than one-third of the time between brand name product introduction and generic entry scheduled under the settlement. Brand name sales during the settlement period—considering just six drugs whose settlements have attracted pending antitrust suits or FTC investigations—total more than $16 billion.

The current approach to pay-for-delay settlement is not working. A case-by-case judicial evaluation has failed to identify and remedy the consumer harm. A new wave of settlements, moreover, as we

heard earlier, will make the problem worse. Even though the new settlements exchange payment for delay, they do so in ways the courts are unlikely to recognize through complex arrangements that disguise the payments by converting them to other forms.

H.R. 1902 takes an important step forward in identifying and deterring pay-for-delay settlement. The bill adopts a bright line prohibition carefully limited to those settlements that combine payment by the innovator with delay by the generic firm; whereas here, anticompetitive activity is frequent, and courts have demonstrated difficulty distinguishing if such a rule is justified.

Taken alone, this proposed rule might prohibit on occasion a competitively harmless settlement, but that in itself is no vice. In price-fixing and bid-rigging, for example, two settings that pay-for-delay settlements resemble, a ban is well justified by the severe harm to consumer welfare, notwithstanding the possibility that rule has a somewhat overinclusive effect.

The real issue is whether any procompetitive justification for settlement is sufficiently important as a practical matter so as to justify an exception in a well-defined class of cases. And here the bill places the identification of such exceptions in the hands of the entity best positioned to recognize them: the FTC. The FTC has developed a deep expertise in evaluating settlements, and thanks to the foresight of Congress, which in 2003 required drugmakers to file all such settlements with the agency, it is in an excellent position to make comprehensive evaluations of settlement practice.

To conclude, the pay-for-delay problem appears to be worsening as courts continue to permit the settlements and as settlements evolve in a way that makes effective judicial intervention unlikely. Congress has a vital role to play here in prohibiting anticompetitive settlements while maintaining agency flexibility to recognize exceptions where they are practically justified. The subcommittee is to be commended for taking up this important issue, and I look forward to your questions and further thoughts.

[The prepared statement of Mr. Hemphill follows:]

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

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

Hearing on H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007

May 2, 2007

Chairman Rush, Ranking Member Stearns, and Members of the Subcommittee, I am Scott Hemphill, an Associate Professor at Columbia Law School. My research and teaching focus upon the balance between innovation and competition established by antitrust law, intellectual property, and sector-specific regulation. I appreciate the opportunity to testify today about certain anticompetitive, "pay-for-delay" agreements between brand-name drug makers and their generic rivals. These remarks draw upon my ongoing academic research into the economic effects of these settlements and their appropriate legal treatment.[1]

I wish to make three points. First, the pay-for-delay settlement problem is large and longstanding. Second, courts have failed to provide an effective

[1] In particular, *Drug Patent Settlements Between Rivals: A Survey* (working paper 2007) [hereinafter *Survey*], *available at* http://ssrn.com/abstract=969492, which undertakes an empirical examination of settlements, with a view toward identifying a workable policy rule; and *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) [hereinafter *Paying for Delay*], which analyzes the competitive effects of certain settlements and their proper treatment under existing law.

response to the problem. And third, Congress can play a useful role in this area by passing legislation such as H.R. 1902 that prohibits settlements that combine payment with delay, while permitting exceptions to be made for settlements that can be shown not to result in consumer harm.

The pay-for-delay settlement problem

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

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

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

best-selling drugs of 2000, nine attracted pre-expiration challenges, of which at least four saw pre-expiration entry.[4]

In some cases the innovator, rather than take a chance that the generic firm might win the patent suit, settles the litigation. The parties dismiss the suit and agree to a particular date when the generic firm may enter the market. The entry date is the result of a hard-fought bargain between rivals. The innovator pushes for a later entry date by arguing that if the litigation proceeds to judgment, a court is likely to hold that the patent is valid and infringed. The likelier that judgment is, the later the entry date.

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

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[4] In 2000, the ten best sellers were Celebrex, Claritin, Glucophage, Lipitor, Paxil, Prevacid, Prilosec, Prozac, Zocor, and Zoloft. *See* Robert Pear, *Spending on Prescription Drugs Increases by Almost 19 Percent*, N.Y. TIMES, May 8, 2001, at A1. Of these, all but Glucophage attracted a pre-expiration challenge. CTR. FOR DRUG EVALUATION & RESEARCH, FDA, PARAGRAPH IV PATENT CERTIFICATIONS AS OF APRIL 23, 2007, http://www.fda.gov/cder/OGD/ppiv.htm. Of the nine challenges, Paxil, Prilosec, Prozac, and Zocor all resulted in pre-expiration entry. *See Paying for Delay*, *supra* note 1, at 1567 n.57.

The situation is different when an innovator makes a payment to its rival, rather than relying solely upon its prospects at trial. In that case the payment secures a later entry date than is warranted by the likely validity of the patent alone. That payment to a rival, made to secure additional delay—in effect, a privately-arranged patent term extension—is properly prohibited.[5] If the innovator paid a rival *after* patent expiration to abandon its effort to market a competing drug, that transaction would clearly be inappropriate. The same is true when the privately arranged extension postpones an entry date that is prior to patent expiration.

A payment to secure delayed entry undermines the existing balance between innovation and competition set by the Hatch-Waxman Act. The Act as written provides brand-name firms with important special protection for their innovative efforts, including patent term extension and a variety of nonpatent regulatory delays to generic entry. For example, if the innovator's approved drug contains a novel active ingredient, the Food and Drug Administration (FDA) must not accept any application to market a generic version for four years.[6] Once the generic application is accepted, and assuming that the innovator files a patent suit in response, the Act blocks FDA approval of the

[5] For a full analysis, see *Paying for Delay*, *supra* note 1.

[6] *See* 21 U.S.C. § 355(j)(5)(F)(ii) (Supp. III 2003). The delay is five years for ANDAs that do not contain a Paragraph IV certification. *Id.*

generic application for the first several years of the suit's pendency.[7] These provisions, taken together, can provide more than seven years of protected profits even if the patent protection is very weak.[8] A privately arranged term extension, then, is in addition to extensive protections already granted by Congress.

Pay-for-delay settlements are a longstanding issue. The very first blockbuster drug, the antiulcer medicine Zantac, had its effective patent protection extended by a pay-for-delay settlement.[9] One of the first settlements, a 1993 agreement involving the cancer drug tamoxifen, attracted an antitrust challenge that is only now, fourteen years later, pending as a petition for certiorari at the Supreme Court.[10]

Settlements are a major tool of lifecycle management. Figure 1 depicts, for selected drugs, the fraction of an innovator's exclusivity period covered by settlement. It is not uncommon for the settlement period to account for more

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

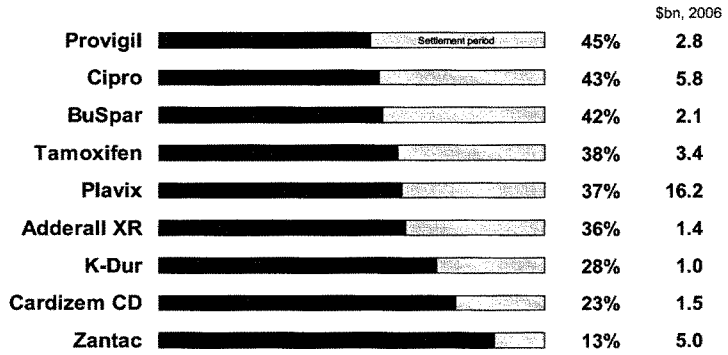
[8] If the patent case is decided before the expiration of the automatic stay, the period is shorter.

[9] For a fuller discussion, see *Survey, supra* note 1.

[10] Petition for Writ of Certiorari, *In re* Joblove, No. 06-830 (U.S. Dec. 13, 2006), 2006 WL 3694387.

than one-third of the time between brand-name product introduction and generic entry scheduled under the settlement. Percentages tell only part of the story. The dollar value is also large. Figure 1 includes an estimate of brand-name sales during the settlement period (in 2006 dollars).[11] This is the metric used by the maker of the wakefulness drug Provigil after settling four generic challenges. The firm's CEO quipped, "we were able to get six more years of patent protection. That's $4 billion in sales that no one had expected."[12]

Figure 1. Fraction of pre-entry period covered by settlement



[11] The estimates are based upon U.S. sales at the time of settlement, and assume that post-settlement sales remain constant in inflation-adjusted terms. That method underestimates the sales of some drugs—Provigil sales in 2006 exceeded sales in 2005, the benchmark year, by more than $200 million—and overestimates others. For each drug except Adderall XR, U.S. sales estimates were drawn from public sources as described in *Survey, supra* note 1. For Adderall XR, where only global sales were available, the figure in text reflects an assumption that U.S. sales were 60 percent of global sales.

The estimates do not coincide with the amount at stake for an innovator. An innovator would discount for the likelihood of success at trial and ignore that part of the settlement period where the generic firm would be unable to enter for another reason, such as the continued applicability of the stay.

[12] John George, *Hurdles Ahead for Cephalon*, PHILA. BUS. J., Mar. 17, 2006.

At least a dozen settlements have attracted pending antitrust suits or agency investigations.[13] Nine of these restrict generic entry associated with some $16 billion in sales, measured in 2006 dollars.[14] The figure excludes the sales that would have been covered by the failed Plavix settlement; that settlement, had it been fully implemented, would have restricted an additional $16 billion in sales. Not all important settlements have received antitrust scrutiny; the Zantac settlement, for example, restricted generic entry associated with about $5 billion in sales.

The settlements have occurred in two distinct waves. The first wave began in 1993 and ended in 2000 after the Federal Trade Commission (FTC) made clear its opposition to pay-for-delay settlements. The second wave began in 2005, after two appeals courts rejected antitrust liability for the settlements.[15] Figure 2 is a timeline depicting the two settlement waves, together with the two appeals court decisions, marked as solid diamonds.

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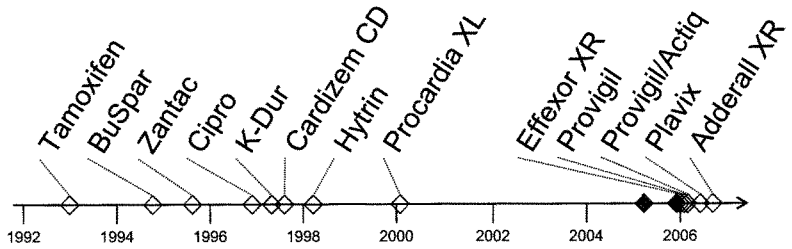
[13] The settlements are tamoxifen, Cipro, K-Dur, Hytrin, Provigil (four settlements), Actiq, Altace, Plavix, and Adderall XR. An innovator-generic agreement involving another drug, Ovcon 35, has attracted FTC and private antitrust attention, but there is no patent at issue there.

[14] The calculation omits three drugs listed in the previous footnote—Plavix (for reasons explained in the text), Altace, and Actiq. Altace, which had U.S. sales of approximately $700 million in 2003, is excluded due to the lack of clear public information about the terms of settlement. Actiq is omitted because that settlement did not directly delay entry but raises concerns in conjunction with one of the Provigil settlements.

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

Figure 2. Two waves of settlement



Evolution and the failure of judicial intervention

The new wave of settlements is a direct response to the failure of federal courts to recognize and resolve the pay-for-delay issue.[16] When private parties and the FTC have challenged the settlements on antitrust grounds, courts have failed to recognize the illegality of the settlements. That failure is likely to be compounded, moreover, by an evolution in the means by which innovators now pay for delay.

In the earliest settlements, such as the tamoxifen, BuSpar, Zantac, and Cipro settlements, payment was a relatively straightforward affair. In exchange for the generic firm's delayed entry, the brand-name firm paid cash.[17] Modern

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

[17] At least in part. Some of these early settlements also included alternative forms of payment, as explained below.

settlements also entail payment for delay, but the parties avoid a straight conveyance of cash, preferring instead to employ a variety of alternative forms of payment. Two are most important: *mispriced transfers* and *preserved exclusivity*.

Mispriced transfers are possible when the parties include more in their agreement than delay and a simple cash payment. For example, in many settlements the generic firm contributes not only delay but also something else, such as an intellectual property license. By overstating the contributed value of the generic firm, the parties can claim that the innovator's cash payment is in exchange for the contributed value, rather than for delay. The side deal thus provides a means to smuggle compensation to the generic firm.

Side deals take four principal forms, listed below, together with a few representative settlements that contain the term:[18]

- *Intellectual property and new product development.* The generic firm licenses its own intellectual property or agrees to develop new products for sale by the innovator. K-Dur, Provigil, Adderall XR.

- *Manufacturing and supply services.* The generic firm agrees to provide manufacturing services or supply product to the innovator,

[18] The settlements listed here for each provision are illustrative, not exhaustive. For listed drugs with multiple settlements, at least one settlement contains the term. For a detailed account of each settlement, see *Survey*, *supra* note 1.

or stands ready to do so upon the innovator's request. Provigil, Niaspan, Adderall XR, AndroGel.

- *Inventory*. The generic firm sells its existing stockpile of the drug. Provigil, Plavix.

- *Product promotion*. The generic firm agrees to promote the innovator's product at issue or an unrelated product. Niaspan, Adderall XR, AndroGel.

A second form of mispriced transfer is the flip side of an overpriced side deal. Rather than announcing a high price for value transferred from the generic firm to the innovator, the parties agree to a low price for value transferred from the innovator to the generic firm. The low price permits net payment from an innovator to a generic firm. Among the examples are the following:

- *Private label product*. The generic firm resells product licensed by the innovator in exchange for a fee to the innovator. Tamoxifen, Procardia XL.

- *Product lines*. The generic firm acquires the right to sell an older variant of the product at issue or an unrelated product. Effexor XR, Adderall XR.

From an outsider's perspective, it is not always possible to say with confidence whether a particular arrangement confers net compensation upon the generic firm. Public announcements of patent settlements frequently do not provide enough information—for example, by disclosing the price term of the deal—to perform an exact evaluation. The arrangements are very suspicious, however, to the extent that they tend to occur in the course of patent settlements but not otherwise. The FTC has noted, based upon observation of settlements during fiscal year 2006 and a review of settlements between 1993 and 2000, that side deals are common among settlement agreements that restrict entry but uncommon among those that do not,[19] a finding that supports the inference that the side deals are being used to confer payment.

An examination of multiple agreements also highlights a disadvantage of judicial decisionmaking, relative to agency review. Judicial decisionmaking focuses upon a single case, without examination of a larger sample of agreements. The latter is likely to provide useful insight as to the likelihood of anticompetitive activity in a particular case.

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[19] *See Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution: Hearing Before the S. Comm. on the Judiciary*, 109th Cong. 17 & n.41 (2007) (prepared statement of Federal Trade Commission), *available at* http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf; *see also* 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 3 (2007), *available at* http://www.ftc.gov/reports/mmact/MMAreport2006.pdf (explicating this point for the fiscal year 2006 data).

Courts that have evaluated mispriced transfers, moreover, have failed to recognize their significance. One appeals court examined a side deal but wrongly concluded that the payment was for intellectual property licenses, not for delay.[20] The court ignored the extensive evidence offered by the FTC, which had challenged the settlement, that the payment was actually for delay.[21] Another appeals court considered a settlement containing a private label provision but misunderstood the opportunity for compensation.[22] It is therefore unsurprising that such terms have become a routine feature of modern settlement practice.

Preserved exclusivity. A second form of compensation avoids cash altogether. An important source of generic firm profits is a special exclusivity period, potentially available to a generic firm that is first to file a pre-expiration challenge. Such a firm may enjoy a 180-day exclusive right to market a generic version in competition with the innovator, effectively creating a duopoly during

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[20] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1068–71 (11th Cir. 2005).

[21] See *In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651, Part IV (F.T.C. Dec. 8, 2003), which summarizes the evidence, including the fact that the payment was justified to the innovator's board of directors as a prerequisite to a settlement, given the generic firm's desire for cash to replace the lost income from generic entry, and that the innovator did an unusually haphazard job in assessing the value of the licenses to the firm.

[22] Indeed, the court wrongly thought that the deal *decreased* the amount of total compensation. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 215 (2d Cir. 2006). The point had been raised to the court by plaintiffs in that case. *See* Brief of Plaintiffs Appellants at 28, *available at* 2004 WL 3564422 ("As a newly-created partner with Zeneca in the tamoxifen monopoly, Barr enjoyed nine years of sales at 'branded' prices without generic competition.")

that period.[23] The exclusivity period is a valuable benefit to the generic firm worth hundreds of millions of dollars for a major drug.[24]

But exclusivity is not a sure thing, at least if the patent suit proceeds to judgment. If the first-filing generic firm loses the suit, it forfeits eligibility for exclusivity. Many settlements avoid this adverse outcome for the generic firm by preserving exclusivity, thereby insulating the generic firm from the risk of loss.[25] Settlement improves the generic firm's mere probability of enjoying exclusivity to a near certainty.[26] Preserving eligibility in this manner is a very valuable benefit conferred upon a generic firm. Indeed, the benefit is valuable even if the first-filing generic firm never actually enters the market. In the Zantac settlement, for example, the first-filing generic firm secured an additional cash payment from another generic firm by selectively waiving its entitlement to

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[23] 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003).

[24] For example, Apotex reportedly earned between $150 million and $200 million from the exclusivity period on Paxil, a blockbuster antidepressant. Comment of Apotex Corp. in Support of Citizen Petition of Mylan Pharmaceuticals, Inc. at 4, No. 2004P-0075/CP1 (F.D.A. Mar. 24, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf. That large reward, moreover, came despite competition from an additional generic firm licensed by GlaxoSmithKline, Paxil's manufacturer. *Id.*

[25] For example, Zantac, K-Dur, Procardia XL, Effexor XR, Provigil, Plavix, and Adderall XR.

[26] The generic firm is not entirely certain of enjoying exclusivity because, for example, a later-filing generic firm might win a patent suit, triggering the first filer's exclusivity period prior to the first filer's FDA approval.

exclusivity, as the FDA permits a first filer to do, thereby permitting the later filer to enter.[27]

Some settlements take a further step to preserve exclusivity, by including a commitment by the innovator not to launch an "authorized generic" product. The authorized generic issue arises when an innovator, faced with generic competition, licenses a competing, unbranded version of the drug. Competition from an authorized generic product reduces the value of the first filer's exclusivity,[28] perhaps by half. Some settlements, including the Adderall XR and Plavix settlements,[29] include an agreement not to launch an authorized generic. Such an agreement again increases the value of exclusivity. It is another means to pay for delay.

So far as I am aware, no court has considered exclusivity preservation as a form of payment. Courts are unlikely to recognize this form of payment for delay, however, given both their prior refusal to prohibit settlements even when

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[27] *See* FDA, Response to Pfizer Citizen Petition at 4-5 & n.5, No. 2004P-0227 (July 2, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0227-pdn0001.pdf (explaining availability of selective waiver).

[28] Authorized generic entry is possible during the exclusivity period because exclusivity applies only to the approval of other ANDAs, not to entrants licensed under the innovator's own New Drug Application.

[29] There are two versions of the Plavix agreement. The initial agreement included the term, and the parties disagree about whether the revised agreement included the term. See *Survey, supra* note 1, for a fuller discussion.

the innovator pays cash and their demonstrated misconception of exclusivity as it shapes generic firm incentives.[30]

It is possible that the Supreme Court might step in to repair the errors made by lower courts. But the Court's previous refusals to review similar cases,[31] though they occurred before the practical importance of the settlement issue became quite so clear, leave that outcome very much in doubt. Even if the Court does enter the fray, moreover, its focus is likely to be limited to simple cash payments. That was the focus of the appeals court opinion that has given rise to a pending petition for certiorari. There is even less reason to expect that the Court will address the variety of ways in which innovators now pay for generic delay.

A new approach to pay-for-delay settlements

The current approach to pay-for-delay settlement is not working. Case-by-case judicial evaluation of individual settlements has failed to identify and

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[30] *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 214 (2d Cir. 2006) (taking the erroneous view that later filers had an incentive similar to the first filer's eligibility for the 180-day exclusivity period); Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (taking the incorrect view that a settlement "leaves the competitive situation unchanged"). For a further explanation of these errors, see *Paying for Delay*, *supra* note 1, at 1583–86.

[31] The Court has declined to review three such petitions. *See* FTC v. Schering-Plough Corp., 126 S. Ct. 2929 (2006); Andrx Pharmaceuticals, Inc. v. Kroger Co., 543 U.S. 939 (2004); Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 543 U.S. 939 (2004).

remedy the consumer harm. And the inadequacy of judicial resolution is likely to worsen, as payment increasingly takes alternative forms.

H.R. 1902 takes an important step toward identifying and deterring pay-for-delay settlement. Section 2(a) of the bill prohibits settlements that combine a delay in generic entry with an innovator's provision to the generic firm of "anything of value" beyond a negotiated entry date. Section 3 provides a process by which the FTC can create exceptions by rulemaking to the general prohibition of section 2. Taken together, the bill adopts an across-the-board prohibition of pay-for-delay settlements, coupled with rulemaking to flexibly identify exceptions to the general rule where they are practically justified.

A general prohibition, carefully limited by statute to those settlements that include a payment by the innovator and delay by the generic firm, is superior to case-by-case judicial scrutiny. That conclusion follows from two features of pay-for-delay settlement—first, that such settlements are frequently attempted and frequently successful, hardly a surprising result, given the parties' very strong incentives to enter pay-for-delay agreements. Second, courts have a demonstrated propensity to permit settlement behavior that properly ought to be condemned. Where, as here, anticompetitive activity is frequent and courts have difficulty distinguishing it, an across-the-board rule is justified.

Taken alone, this proposed rule will prohibit on occasion a competitively harmless settlement. That by itself is no critique of the rule. In price fixing and bid rigging, for example, two settings that pay-for-delay settlements resemble, a ban is well justified by the severe harm to consumer welfare, notwithstanding the possibility that the rule has a somewhat overinclusive effect. The real issue is whether any procompetitive justification for settlement is sufficiently important as a practical matter so as to justify an exception in a well-defined class of cases.

The FTC is ideally positioned to make such determinations in the pay-for-delay context—far better, certainly, than a generalist court. The agency sees the full range of cases, in contrast to the single-case purview of a court, due to its national enforcement scope. It augments its stock of knowledge by combining the analyses of staff economists with information gleaned from civil investigatory demands of market players. Perhaps most important, the FTC has access to the terms of all newly filed agreements, thanks to the foresight of Congress in 2003, which required drug makers to file such settlements with the agency.[32]

Suppose, for example, that the settling parties wish to defend a settlement that entails both delay by the generic firm and a side deal in which the innovator

[32] *See* Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003).

pays the generic firm for certain intellectual property licenses. That settlement is prohibited under section 2 of the bill because it includes both innovator payment and generic delay, subject to the exceptions created pursuant to section 3. If the settling parties wish to argue that the side deal has an important procompetitive effect, achievable only as part of this overall settlement, the FTC is in an excellent position to evaluate the practical heft of that claim, and to identify an exception if justified. This is a useful adjunct to its existing power to challenge anticompetitive settlements.

* * *

The pay-for-delay settlement problem appears to be worsening, as courts continue to decline to prohibit the settlements and as settlements evolve in a direction that makes effective judicial intervention increasingly unlikely. Congress has a vital role to play in establishing a broad prohibition of anticompetitive settlements, while maintaining agency flexibility to recognize exceptions where they are practically justified.

Mr. RUSH. Mr. Proger. You are recognized for 5 minutes.

STATEMENT OF PHILLIP A. PROGER, PARTNER, JONES DAY, WASHINGTON, DC

Mr. PROGER. Thank you, Mr. Chairman. At the outset I would like to express my appreciation to the Chair, the ranking member and the other members of the committee for inviting me to testify.

My name is Phillip Proger. I am a practitioner specializing in antitrust law. I am here speaking for myself today. And I do have clients in this area. I have represented clients in antitrust class actions against settlements and in FTC investigations. But I am here today just speaking for myself.

H.R. 1902 addresses issues important to the welfare of the American public, and I am pleased to have an opportunity to address some of these issues. I have submitted a written statement, and I would like to address in my oral comments just one core issue, and that is, is it appropriate or necessary to supplant the antitrust laws for particular conduct in a particular industry? H.R. 1902 appears to do so.

I am concerned about the precedent that is created by doing so. In answer to the question of Congresswoman Blackburn earlier in the hearing, I have looked for an example of whether Congress has ever expressly chosen a particular practice in a particular industry to enact special legislation outlawing that practice in that industry.

Now, there are examples where Congress carves out industries for regulatory oversight, but in answer to your question, Congresswoman, I have not been able to find an example where Congress has done so. Perhaps there are, but they are few and far between as far as I can tell.

I believe that the application of the antitrust laws and the general standard of prohibiting conduct that restrains competition still is the appropriate way to address the effect on consumer welfare of drug patent settlements. The patent laws and the antitrust laws both promote consumer welfare, but in the short run, each do it differently by different means. Patent laws encourage innovation and invention by giving the patent holder an exclusionary grant for a period of time. After all, we would not be here today if the drug map had not been invented in the first place. The antitrust laws, on the other hand, referee our free markets to ensure that the American public receive the benefits of the competitive market.

Some settlements may be anticompetitive. Settlements that go beyond the scope or time of the patent raise concern under existing antitrust laws, and the courts, as Commissioner Leibowitz has pointed out, have attacked those settlements. But settlements that are within the scope of the patent, both in time and scope, pose a more difficult question.

If the settlement is within the exclusionary grant of the patent, I don't see why there is a presumption that the settlement is unlawful. Any settlement, by definition, does result in payments from one side to another. It is a settlement. It is an adjudication of risk. But there appears to be a presumption by those who believe that these settlements are a problem that the existence of a settlement means that the patent holder believes its patent is weak.

I believe that presumption is not valid. The Hatch-Waxman Act, which is laudatory, and, as I said in my written statement, is working—generic drugs are much more widely available today—does alter the balance of power in anti-drug-patent litigation. The patent holder has much to lose. The generic has comparatively little to lose. Consequently it is not surprising that even a patent holder with a valid and enforceable patent that it believes to be strong may still settle. Given the economics, even if you believe you have a virtually sure right to prevail, there is some chance that you could lose, and therefore it may make sense for you to settle.

The antitrust laws balance the laws of innovation with the laws of competition on a case-by-case basis and permit the courts and the FTC to make such an evaluation in that circumstance, not a broad, blunt rule.

Settlements that are bad for society are those that go beyond the scope of the patent. Settlements that merely split the rents given by the exclusionary grant are not necessarily anticompetitive and, in fact, may be procompetitive. Society's interest is best served by keeping the good settlements that balance the interest of patent innovation with competition and prohibiting the bad settlements that are anticompetitive.

I believe that that balance is best accomplished by a case-by-case, fact-intensive analysis that is the essence of the antitrust laws, and we are uniquely situated here to do so. The Medicare Act of 2003 requires that settlements between a drug patent holder and a generic challenger be notified to the Federal Trade Commission. The Federal Trade Commission has demonstrated that it is a vigilant and able enforcer. The threat of FTC enforcement alone is a powerful deterrent. And for those that settle, the FTC has the right to investigate and challenge the conduct.

Moreover, private plaintiffs have brought class actions against a number of settlement. Each settlement involves its own unique set of facts, own unique circumstances, own unique industry, and unique terms and conditions of the settlement.

No one rule fits all. The antitrust laws have been judicially developed for the past 117 years to deal with these type of cases, factually intensive, unique facts. The antitrust standard of outlawing only conduct that is anticompetitive is most appropriate when, as you do have here, the law has to govern factually intensive and unique conduct. A blunt instrument prohibiting virtually all settlements does not distinguish between those that harm consumer welfare and those that do not.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Proger follows:]

Testimony of Phillip A. Proger

**Before the United States House of Representatives
Subcommittee on Commerce, Trade, and Consumer Protection
of the Committee on Energy and Commerce**

May 2, 2007

Summary

In my testimony, I will address three principal questions that I believe underlie any effort to pass legislation. *First*, what is the nature and seriousness of the problem to which H.R. 1902 is addressed? *Second*, how does the proposed solution in H.R. 1902 relate to that problem? *Third*, what is the danger that unintended consequences will flow from the provisions of H.R. 1902 that could undermine its legislative intent?

I conclude (1) that reverse payments are not "reverse" and not always anticompetitive; (2) that the proposed solution is not a competitive solution at all, and is contrary to the historical role of Congress in enacting antitrust legislation and the FTC in conducting antitrust enforcement; and finally, (3) that adopting a broadly inclusive per se ban on any settlement "for value" will have unintended consequences that could actually inhibit incentives for generic entry, and may alter the balance between drug innovation and affordability that Hatch-Waxman currently embodies.

For all of these reasons, it is my view that issues raised by H.R. 1902 warrant further study. H.R. 1902 would adopt for the first time the blunt instrument of a per se antitrust rule against specific conduct in a specific industry. Such a step would be a departure for Congress, which has previously (and wisely) decreed that antitrust practices should be measured by *competitive* standards. That is, whether a given practice at a given time harms consumers by reducing output as a means of raising price. A per se ban on settlements which transfer "value" to the generic is neither needed, nor consistent with our well-developed system of antitrust jurisprudence. The FTC has demonstrated that it is an able and vigorous prosecutor in this area. Pursuant to the 2003 Medicare Act, all settlements must be notified to the FTC. Private class action plaintiffs also have challenged such settlements. Congress can be thus assured that all settlements between a patent holder and a generic challenger will be subject to complete scrutiny. The FTC and the courts can review each settlement — like any other agreement — and determine whether that agreement does in fact reduce competition.

Finally, I include in my discussion of unintended consequences a series of questions that I believe should be considered before this change is enacted.

Testimony of Phillip A. Proger

**Before the United States House of Representatives
Subcommittee on Commerce, Trade, and Consumer Protection
of the Committee on Energy and Commerce**

May 2, 2007

I. INTRODUCTION

Mr. Chairman and Members of the Committee, thank you for inviting me to express my views concerning H.R. 1902 and the issues it addresses.

I should note at the outset that, while I am a partner at Jones Day, my testimony today and my written submission are in my individual capacity, expressing the views that are my own and which do not necessarily represent the views of Jones Day, any other Jones Day partner, or any client of Jones Day. Jones Day is a large multinational law firm and it is possible that one or more Jones Day clients may have an interest in this legislation.

I commend the Chairman and Members of the Committee for its focus on this question. The American public has a critical interest in ensuring that the pharmaceutical industry continues to develop new and improved drugs at the lowest feasible cost. For a suffering patient, the invention of a new drug can be a miracle that literally saves lives just as the provision of such drugs at affordable prices may vastly improve those lives. In the Hatch-Waxman Act and elsewhere, Congress has heretofore achieved a judicious balance between the twin goals of drug innovation and drug affordability, a balance that does not permit one goal to undermine the other.

I also commend the Federal Trade Commission (FTC) for its leadership in this important area. Through both studies of industry experience and enforcement efforts, the FTC has called attention to the question of patent settlements' effect on competition.

The FTC's efforts have helped to emphasize a long-standing principle of antitrust law that settlement agreements that extend the exclusionary effect of a patent beyond that inherent in the patent grant tend to be anticompetitive. On this principle, courts have supported the FTC and those antitrust plaintiffs who echo their concerns. On the related but different question of whether so-called "reverse payments" in Hatch-Waxman settlements are anticompetitive even when the settlement is *not* beyond the scope of the patent, however, the FTC has failed to persuade those courts either (1) that the resulting effect they identify is an anticompetitive effect, or (2) that payments in settlements are always anticompetitive. That, in my view, is what has brought us together today.

In my testimony, I will address three principal questions that I believe underlie any effort to pass legislation. *First*, what is the nature and seriousness of the problem to which H.R. 1902 is addressed? *Second*, how does the proposed solution in H.R. 1902 relate to that problem? *Third*, what is the danger that unintended consequences will flow from the provisions of H.R. 1902 that could undermine its legislative intent?

I conclude (1) that reverse payments are not "reverse" and not always anticompetitive; (2) that the proposed solution is not a competitive solution at all, and is contrary to the historical role of Congress in enacting antitrust legislation and the FTC in conducting antitrust enforcement; and finally, (3) that adopting a broadly inclusive per se ban on any settlement "for value" will have unintended consequences that could actually inhibit incentives for generic entry, and may alter the balance between drug innovation and affordability that Hatch-Waxman currently embodies.

For all of these reasons, it is my view that issues raised by H.R. 1902 warrant further study. H.R. 1902 would adopt for the first time the blunt instrument of a per se antitrust rule against specific conduct in a specific industry. Such a step would be a departure for Congress, which has previously (and wisely) decreed that antitrust practices should be measured by *competitive* standards. That is, whether a given practice at a given time harms consumers by reducing output as a means of raising price. A per se ban on settlements which transfer "value" to the generic is neither needed, nor consistent with our well-developed system of antitrust jurisprudence. The FTC has demonstrated that it is an able and vigorous prosecutor in this area. Pursuant to the 2003 Medicare Act, all settlements must be notified to the FTC. Private class action plaintiffs also have challenged such settlements. Congress can be thus assured that all settlements between a patent holder and a generic challenger will be subject to complete scrutiny. The FTC and the courts can review each settlement — like any other agreement — and determine whether that agreement does in fact reduce competition.

Finally, I include in my discussion of unintended consequences a series of questions that I believe should be considered before this change is enacted.

II. WHAT IS THE NATURE AND DEGREE OF THE PROBLEM?

A. Is It A Hatch-Waxman Problem?

One of the concerns to which H.R. 1902 is addressed may be stated as follows: Unless Congress acts to place limits on the ability of ANDA litigants to settle, Hatch-Waxman's goal of ensuring generic competition will be frustrated. In my view, that concern does not warrant a special rule carving out these specific agreements from the antitrust laws.

The Hatch-Waxman Balance. As the official name of what we now call Hatch-Waxman reflects, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act),[1] facilitated market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development. In the words of the Food and Drug Administration (FDA), "[t]he two parts of the [Hatch-Waxman Amendments] were intended to provide a careful balance between promoting competition among pioneer or brand-name and generic drugs, and encouraging research and innovation," through protection of patent rights.[2] Thus, the Act attempts to balance the twin goals of improved consumer welfare through innovation and invention and through lower cost drugs resulting from generic entry.

The Act contains provisions to facilitate generic entry. *First*, the Act allows generic manufacturers to piggy-back on the brand-name manufacturer's New Drug Application (NDA), where a patent holder must demonstrate the safety and efficacy of its product,[3] by allowing a generic manufacturer to simply file an Abbreviated New Drug Application (ANDA), demonstrating that its product is bioequivalent to the brand-name

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[1] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[2] 54 Fed. Reg. 28,872 (July 10, 1989) (proposed rule); *see also* 59 Fed. Reg. 50,338 (Oct. 3, 1994) (final rule) ("Congress intended the two titles [of the Hatch-Waxman Amendments] to provide a careful balance between promoting competition among brand-name and duplicate or 'generic' drugs and encouraging research and innovation."); *Abbott Labs. Inc. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) ("Facing the classic question of the appropriate trade-off between greater incentives for the invention of new products and greater affordability of those products, Congress struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers.") (citing H.R. Rep. No. 98-857 (Pt. 1), at 14-15, *reprinted in* 1984 U.S.C.C.A.N 2647, 2648); *Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000) ("[T]he Hatch-Waxman Amendments emerged from Congress' efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.") (internal quotation marks omitted).

[3] 21 U.S.C. § 355(b).

counterpart.[4] If the generic manufacturer seeks entry before the patent expires, it has the option of submitting an ANDA IV, which certifies that the listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug."[5] *Second*, as an incentive to incur potentially substantial litigation costs, the first company to submit an ANDA IV is awarded a 180-day period of exclusive rights to market a generic formula of the pioneer drug before any other ANDA may be approved.[6]

The Act also contains provisions to encourage innovation and invention. *First*, the filing of an ANDA IV creates an automatic cause of action for patent infringement, and the applicant must notify the owner of the listed patent of the filing of its ANDA IV certification.[7] *Second*, the patent holder has 45 days to initiate a patent infringement suit against the ANDA applicant,[8] and, if it does so, the FDA's approval is automatically stayed for 30 months, unless the patent expires or is judicially determined to be invalid or not infringed before that time.[9] *Third*, the Act gives patent holders the ability to extend the life of a patent to compensate for the fact that patent exclusivity includes the time when a drug is under FDA review and thus not yet on the market.[10] Yet another provision grants an additional three years of market exclusivity when the brand can obtain an approval requiring clinical tests, such as a new dosage form.[11]

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[4] *Id.* § 355(j).

[5] *Id.* § 355(j)(2)(A)(vii); *see also* 21 C.F.R. § 314.94(a)(12)(A)(4).

[6] *Id.* § 355(j)(5)(B)(iv).

[7] *Id.* § 355(j)(2)(B).

[8] *Id.* § 355(j)(5)(B)(iii).

[9] *Id.*

[10] Congressional Budget Office (CBO), "How Increased Competition from Generic Drugs has affected Prices and Returns in the Pharmaceutical Industry," ix, xii, xiv (July 1998) (CBO).

[11] CBO, at xiv.

In striking this balance, the Act's legislative history further confirms that (1) the Hatch-Waxman Amendments were not intended to override the statutory presumption of patent validity under 35 U.S.C. § 282;[12] (2) the Amendments were not intended to legalize the marketing of infringing drugs;[13] and (3) the Amendments, including the provisions relating to the 30-months stay, were not intended to authorize infringing entry.[14] Nor is there any indication that, in establishing procedures to encourage litigation between NDA holders and ANDA filers, Congress intended to deprive such parties of the same rights to settle such litigation enjoyed by all other litigants.

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[12] *See* H.R. Rep. No. 98-857, pt. 1, at 27, *reprinted in* 1984 U.S.C.C.A.N. at 2661 ("The provisions of this bill relating to the litigation of disputes involving patent validity and infringement *are not intended to modify existing patent law* with respect to the burden of proof and the nature of the proof to be considered by the courts *in determining whether a patent is valid or infringed.*") (emphasis added); *see also id.* ("Concern has been expressed that permitting an applicant to market its drug at the conclusion of the 18 month period and possibly before the resolution of the patent infringement suit overturns the statutory presumption of a patent's validity. *On the contrary, the Committee intends that a patent would have the same statutory presumption of validity as is afforded under current law.*") (emphasis added).

[13] *See, e.g., id., reprinted in* 1984 U.S.C.C.A.N. at 2678 ("Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs. This section *does not permit the commercial sale of a patented drug* by the party using the drug to develop such information, but it does permit the commercial sale of research quantities of active ingredients to such party. . . . The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is *to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.*") (emphasis added).

[14] *See id., reprinted in* 1984 U.S.C.C.A.N. at 2679 ("In the event the patent is found to be valid and infringed, so that the act of infringement described in section 271(e)(2) has occurred, the remedies available to the court are three-fold. . . . If the infringing party has begun commercial marketing of the drug, *damages and other monetary relief and injunctive relief may be awarded for the infringement and to prevent further infringement.* In addition, the FDA would be mandated to change the effective date of the approved ANDA to the expiration date of the infringed patent.") (emphasis added); H.R. Rep. No. 98-857, pt. 2, at 9 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2693 (explaining reasons for rejection of proposed amendment to House bill replacing determinate stay of FDA approval with final decision by district court and noting that "[t]his provision was added by the Committee on Energy and Commerce to accommodate the competing concerns of the [Pharmaceutical Manufacturers Association ("PMA")] and the generic manufacturers. The PMA was willing to compromise on the provisions of title I of the bill (relating to abbreviated new drug application procedures (ANDAs)) in exchange for some *greater protection* of existing human pharmaceutical patents.") (emphasis added).

Payments are "Natural." One "natural byproduct" of Hatch-Waxman's structure and incentives is the resulting focus on reverse payments.[15] Because Hatch-Waxman gives a generic challenger the opportunity to obtain a declaratory judgment against the patent without risking liability for damages, the generic has everything to gain while the patent holder has everything to lose. As courts and commentators have explained, such cases can only be settled by the transfer of value from the patent holder to the generic challenger, who (in the words of Judge Posner) "would not settle unless he had something to show for it."[16] In cases outside the Hatch-Waxman context, on the other hand, the transfer of value to the patent challenger may take other forms than cash, because the alleged infringer is already in the market place taking sales away from the patent holder, and thus exposing itself to damages. In those cases, the transfer of value may take the form of a compromise of the infringement damages already inflicted, or restrictions on the existing infringing sales in terms of time, geography, or royalty rate. In Hatch-Waxman cases, however, none of those infringing sales have occurred, and all of the risk beyond legal fees lies with the patent holder. That is why it is "natural" for the value flowing to the challenger to take its most efficient form, cash.

But this difference is one of form only. In the words of one of the drafters of the FTC and United States Department of Justice guidelines for the enforcement of intellectual property: "Hatch-Waxman creates a context in which payments from the patent owner to the infringer become explicit rather than implicit, but it does not change

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[15] *In re Ciprofloxacin Hydrochloride Antitrust Litigation (Cipro)*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003).

[16] *Asahi Glass Co. Ltd., Inc. v. Pentech Pharms, Inc.*, 289 F.Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

the underlying nature of the payments or make them more anticompetitive than such payments in the traditional context."[17]

If there were any doubt that this is true, one should ask this question: Why are there no examples of patent settlement "pay-offs" in other industries? It makes just as much sense for a patent holder to pay a challenger to drop its case against a weak patent in other industries, so why does it not happen? The answer is that all settlements consist of transfers of value between parties based on their perceived risk of prevailing in the litigation,[18] and what each has economically at risk. Generally, economic value will flow from the party with greater risk to the party with lesser risk. Hatch-Waxman settlements are not different in economic terms, nor of greater concern in their effect on consumers.

The Success of Hatch-Waxman. The failure of Hatch-Waxman to place limits on the rights of ANDA litigants to settle has not undermined the goals of the Act.

The evidence shows that the Act's goal of facilitating generic entry has been realized. *First*, in 1984, prior to the enactment of Hatch-Waxman, the generic drug share of the U.S. prescription market was 19%. In 2006, it was 61%.[19] (*See* Appendix A.) The generic share of the prescription drug market grew steadily at a rate of roughly two percent per year from 1984 to 2006, first exceeding 50 percent in 1998. (*See* Appendix B.) Industry analysts expect further growth in the share of generic

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[17] Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 621 (2006).

[18] *See Cipro*, 261 F. Supp. 2d at 251.

[19] Deutsche Bank, "Global Pharmaceuticals – Pharmaceuticals for Beginners," at 65 (Aug. 2005); Credit Suisse, "Sector Review – What's New in Generics," at 4 (Mar. 2007).

prescriptions in the next few years as several large drugs face patent expiration.[20] *Second*, Hatch-Waxman increased the proportion of branded drugs that face generic competition. In 1983, only 35 percent of the top-selling drugs with expired patents had generic versions available, while nearly all do today.[21] *Third*, Hatch-Waxman reduced the average delay between patent expiration and generic entry from more than three years to less than three months for top-selling drugs.[22]

The growth and success of the generic drug industry has resulted in lower prices not only for blockbuster drugs, but virtually for all consumer drugs. While roughly 80 percent of drugs with sales of more than $100 million face generic competition, and do so within 50 days of their patents expiring, around 50 to 60 percent of drugs with sales in the $10 to $25 million range face generic competition 200 days after their patents expire.[23]

Some critics of reverse payments argue that Hatch-Waxman has achieved its remarkable success in increasing the availability of generic drugs *despite* its failure to limit the rights of litigants to settle. But others, including some judges, economists, antitrust experts, and those who run generic companies, disagree. They suggest, to the contrary, that the knowledge that generic challengers possess the same rights as litigants in every other industry to settle cases is a key factor in the incentive to bring

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[20] Deutsche Bank, at 65; Danske Equities, "Sector Report - Pharmaceuticals and Biotech," at 13 (Oct. 2005); Credit Suisse, at 4.

[21] Congressional Budget Office (CBO), "How Increased Competition from Generic Drugs has affected Prices and Returns in the Pharmaceutical Industry," July 1998: xii (excluding antibiotics and drugs approved before 1962).

[22] CBO, at ix.

[23] Deutsche Bank, at 65-66.

Paragraph IV challenges in the first place.[24] For precisely that reason, Judge Posner has observed, in words that directly apply to the text of H.R. 1902, that:

> "Reverse payment" patent settlements . . . are criticized and sometimes invalidated on the theory that they prevent competition. Whether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent. *A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.*[25]

In sum, both the evidence of actual generic entry and the incentives of ANDA filers signal caution.

An important question for the Committee is whether the ability of ANDA litigants to settle cases has *increased* the number of generic challenges and resulted in a net benefit to consumers. A related, and equally important question, is whether placing severe limitations on settlement rights will hurt both the generic challengers *and* patent holders. A ban on settlements may upset the delicate balance that Hatch-Waxman has heretofore maintained, which is to promote generic entry while protecting legitimate patent rights.

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[24] *Cipro*, 261 F. Supp. 2d at 256 ("The incentives created by the Hatch-Waxman Amendments have led to generic investment in product development, patent review and product challenges through litigation. Indeed, Barr has admitted that it has over ten ANDA challenges in litigation today and more than twice that number under review. To maximize these incentives, a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced.") (internal citation omitted); *see also Paying Off Generics to Prevent Competition With Brand Name Drugs: Should It Be Prohibited?, Before the S. Comm. on the Judiciary, available at* http://judiciary.senate.gov/testimony.cfm?id=2472&wit_id=5984 (testimony of Bruce L. Downey, Chairman and CEO, Barr Pharmaceuticals, Inc., Jan. 17, 2007) ("The proposed legislation [] would stifle a generic company's ability to resolve patent disputes . . . . The simple fact is that, in some instances, litigation settlements turn out to be the means by which consumers gain 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.").

[25] *Asahi Glass*, 289 F. Supp. 2d at 994 (citations omitted; emphasis added).

Our Society also benefits from new and improved drugs. The time and expense of developing new life-saving drugs continues to spiral. The estimated cost of bringing a new drug to market reportedly rose from $231 million in 1997 to $802 million in 2000. And even those who argue that the importance of patent protection to innovation is overstated recognize its continued importance in this industry. Only last week, FTC Commissioner Rosch cited an economist whose data allegedly reflected "almost no relationship [between innovation and patent protection], *except* in the pharmaceutical industry."[26]

If we agree that "patent protection is important in spurring innovation in the pharmaceutical industry,"[27] and further acknowledge Hatch-Waxman's success in achieving generic entry, we might well conclude that making a fundamental shift in the existing rights of Hatch-Waxman litigants raises all the dangers of fixing a "problem" that is not a problem at all. As discussed below, under these circumstances it would be appropriate to allow the natural evolution of the law here to continue.

B. What Is The Scope of The Problem?

The Generic "Success Rate." Those who favor severe limits of settlement rights often base their concern on the so-called generic success rate under Hatch-Waxman. Some have read the FTC's 2002 Generic Drug Study as establishing that, of all Hatch-Waxman lawsuits initiated against ANDA IV filers from 1992 and 2002, the

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[26] Remarks of J. Thomas Rosch, FTC Commissioner, Law Seminars International, Pharmaceutical Antitrust, Washington, D.C. (April 26, 2007), at 1-2 (citing F.M. Scherer, "The Political Economy of Patent Policy Reform in the United States," Working Paper 06-22, Oct. 2006, AEI-Brookings Joint Center for Regulatory Studies, at 6, *available at* http://www.aei.brookings.org/admin/authorpdfs/page.php?id=1334) (emphasis added).

[27] *Id.* at 2.

generic challenger prevailed 73% of the time.[28] But, the 2002 Study makes no such claim.[29] Indeed, the Study demonstrates that for all cases in which the patent holder sued the first ANDA IV challenger, the generic prevailed only 29.33% of the time.[30] The number for *all* ANDA IV cases (*i.e.*, against both first filers and later filers) cannot be determined precisely from the Study itself, but appears to be even lower, that is, no greater than 24.75%.[31]

The 73% figure was obtained by focusing on a much smaller universe of ANDA cases. That smaller number was derived by subtracting from all cases initiated against ANDA IV filers (1) those not yet resolved at the time of the Study, (2) those that were settled, (3) those for which the patent expired before resolution, (4) those for which the patent was withdrawn, and, finally, (5) those which duplicated the result for the same patent (*e.g.*, where the patentee won several challenges to the same patent, as in *Tamoxifen* and *Ciprofloxacin*).[32] Thus, the 73% figure derives from 29 generic victories,

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[28] *See* Petition for Writ of Certiorari, *F.T.C. v. Schering-Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688), 2005 WL 2105243 at *5 (citing Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 19-20 (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf); Brief of Amicus Curiae Federal Trade Commission in Support of Plaintiffs-Appellants, *In re Tamoxifen Citrate Antitrust Litigation,* 466 F.3d 187 (2nd Cir. 2005) (No. 03-7641), 2005 WL 3332374 at *7 n.10; *Prepared Statement of the Federal Trade Commission, Before the Special Committee on Aging of the United States Senate, on Barriers to Generic Entry, available at,* http://ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf; *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, available at,* http://ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

[29] 2002 FTC Study at 19-20.

[30] *Id.* at 14-17 (22 generic victories out of 75 cases initiated against first filers).

[31] *Id.* at 18-20 (29 generic victories out of at least 118 ANDA cases initiated, *i.e.*, 75 (p. 14) plus 43 (p. 18)).

[32] The first four of these subtractions are set forth clearly in the chart on page 15 of the FTC Study. The last subtraction, eliminating "similar outcomes" is referenced on page 19 in calculating the overall success rate.

divided by a total of 40 cases in which there were final judicial determinations of the patent claim.

Whatever their significance, the numbers in the 2002 Study involved samples too small to support a conclusion that generics have and always will have a high success rate.[33] Thus, even an accurately reported generic success rate of 24% or 29% tells us little, especially when we consider that ANDA IV litigation involves a pre-selection by generic applicants of those patents most vulnerable to challenge. Nor should any *average* success rate serve to render problematic any individual settlement involving a patent which, by its terms, excluded all generic entry and was repeatedly upheld in court. For current purposes, however, the Committee may rest easy that there is no empirical support for the view that three out of four, or even a bare majority of, patent settlements somehow deprive consumers of a generic victory.

The Court Decisions. Nor do the cases actually decided reflect any significant consumer harm. Consider first the cases in which courts rejected the view that generic drug settlements are anticompetitive. In the *Tamoxifen* and *Ciprofloxacin*[34] cases, the patents were compound patents on the drug's active ingredient that precluded, by definition, all generic competition.[35] There was no dispute that the patents, if valid, would have been infringed by the generic product. In both cases, moreover, the patent was repeatedly upheld against validity challenges after the settlement. In *Tamoxifen*,

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[33] In fact, one commentator has concluded that patent holders were winning more cases after publication of the FTC study. Gregory Glass, *Why Settle?*, Update, Sept./Oct. 2005, at 17-18 ("When settlements decreased after the FTC study, [] brand companies won 40% of the cases filed (and 53% of those cases actually tried).").

[34] I am one of the counsel for the patent holder in these cases.

[35] *See In re Tamoxifen Citrate Antitrust Litigation (Tamoxifen)*, 466 F.3d 187, 214 (2d. Cir. 2006), *pet. for cert. filed*, 75 U.S.L.W. 3333 (Dec. 13, 2006) (06-830); *Cipro*, 261 F. Supp. 2d at 197.

three generic companies filed ANDA IVs for tamoxifen and mounted challenges to the patent similar to the challenge raised originally by the first-filer. One challenge was dismissed by consent when the generic agreed that FDA approval would not be effective before the expiration of the patent,[36] and two federal courts, one appellate and one district, concluded that the patent was, in fact, valid.[37]

In *Ciprofloxacin,* moreover, the patent holder after the settlement voluntarily submitted its patent to the PTO for a successful reexamination, after which four generic companies filed ANDA IVs. One challenge was dismissed,[38] and the patent holder won the other three.[39]

And now consider the two cases — *Cardizem* and *Terazosin* — in which antitrust liability has been imposed on settlements that those courts found to go beyond the scope of the formulation patents at issue. The courts found that the "interim" settlements precluded not only infringing generics but non-infringing ones as well.[40]

Yet, in *Cardizem*, it was also shown that, as soon as the generic produced a non-infringing formulation and obtained FDA approval, the "interim" settlement agreement

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[36] *AstraZeneca UK Ltd. v. Mylan Pharms., Inc.*, No. 00-2239, slip op. at 2-3 (W.D. Pa. Nov. 30, 2000).

[37] *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 146 (Fed. Cir. 1997) (deciding that Zeneca's patent was valid); *Zeneca Ltd. v. Pharmachemie B.V.*, No. 96-12413, 2000 WL 34335805, at *15 (D. Mass. Sept. 11, 2000) (concluding that Zeneca had not engaged in inequitable conduct and that the patent was valid). *See generally Tamoxifen*, 466 F.3d at 204.

[38] *See Bayer AG v. Ranbaxy Pharms., Inc.*, No. 3:98 Civ. 4464 (D.N.J. Oct. 29, 1999) (dismissing case per stipulation).

[39] *See Bayer AG v. Schein Pharm., Inc.*, 301 F.3d 1306 (Fed. Cir. 2002). *See generally Cipro*, 261 F. Supp. 2d at 197.

[40] *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682 (E.D. Mich. 2000) (where the patent covered only a once-a-day timerelease delivery and its dissolution profile); *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000) (where the patent covered only the tablet formulation of the drug).

was terminated, allowing generic entry.[41] Thus, in announcing its Consent Decree with the parties, the FTC stated that "it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD."[42]

Similarly, on remand from the Eleventh Circuit's reversal in *Terazosin*, the District Court held again that a portion of the settlement agreement was per se illegal, that is, the portion in which the generic agreed not to enter in the period between a generic victory at trial and an affirmance of that victory on appeal.[43] (The Court's per se ruling was unrelated to the existence of reverse payments.) In a subsequent trial, however, a jury awarded zero damages to the antitrust plaintiff, concluding that the generic company would not have entered the market "at risk" while the appeal was pending.[44]

In sum, whether one agrees or disagrees with the fine points of the antitrust analysis in these decisions, it is difficult to argue as a matter of fact that they have deprived the American consumer of access to any non-infringing generic drug. As these cases illustrate, moreover, antitrust enforcement is working well.

C. Is There an Antitrust Problem?

Patent settlements can harm competition. Any settlement that excludes more competition than would the patent itself is likely to be anticompetitive, because it obtains

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[41] *Cardizem*, 105 F.Supp. 2d at 688-89.

[42] *See* www.ftc.gov/os/2001/04/hoechstanalysis.pdf.

[43] *Terazosin*, 352 F.Supp. 2d at 1319.

[44] *Kaiser Foundation Health Plan, Inc. v. Abbot Labs. & Geneva Pharmaceuticals, Inc.*, No. 2:02-cv-02443 (C.D. Cal. Apr. 6, 2006), *appeal docketed*, Nos. 06-55687, 0655748 (9th Cir. May, 8, 2006).

by agreement an exclusionary effect that even in victory the patent holder would not have obtained.

A different question is whether a settlement is anticompetitive when it excludes no competition beyond the scope of the patent. On this question, plaintiffs have been notably unsuccessful in persuading courts that the presence of payments in such settlements is, in fact or theory, anticompetitive. Courts have considered the claims that such settlements are "pay offs" to horizontal competitors to "exit" the market and thus constitute per se illegal market division. In response, courts have observed that (1) all settlements can be labeled "pay offs" to avoid litigation risk;[45] (2) all patent litigation, by its nature, seeks to "delay" entry in the form of the challenger's infringing entry;[46] (3) all patent agreements, including the most common license, would be per se illegal market division if one were to ignore the existence of the patent;[47] and (4) the antitrust law does not protect infringing entry, which in fact injures consumers.[48] For these reasons, courts have concluded that plaintiffs have focused on the wrong villain:

> If [the patent holder] Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. *The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect*, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.[49]

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[45] *See, e.g.*, *Asahi Glass*, 289 F. Supp. 2d at 994.

[46] *See, e.g.*, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003).

[47] *See, e.g.*, *Valley Drug*, 344 F.3d at 1304; XII Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW, ¶ 2040b, at 199 (1999).

[48] *See, e.g.*, *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981); *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907).

[49] *Valley Drug*, 344 F.3d at 1309 (citation omitted) (emphasis added).

Courts have further noted the plaintiffs' failure to tie the presence of payments to any real anticompetitive effect by pointing out that the same allegedly harmful effect to consumers could be accomplished by settlements with licenses, depending on their terms, even though the plaintiffs insist that licenses are competitively benign.[50] As one court observed: "Thus, outlawing exclusion-payment settlements in favor of early-entry licenses would not necessarily result in a public benefit, or satisfy plaintiffs, unless royalty rates are also constrained."[51]

In my view, the emerging consensus among these courts leads to this conclusion: If you want to challenge a patent infringement settlement, you must show that it goes beyond the scope of the patent, and you can do that in two ways: *First*, you can show that it excludes non-infringing goods without competitive justification. *Second*, you can show that the patent is so weak with respect to the alleged infringing product that it has no scope at all. That leads to the objectively baseless test of Judge Posner, which holds, in essence, that if the patentee had a colorable enough patent claim to bring the infringement action, then it had the right to settle within the exclusionary effect of the patent.[52]

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[50] *See Cipro*, 261 F. Supp. 2d at 252 ("In fact, even in the traditional context, implicit consideration flows from the patent holder to the alleged infringer. For instance, suppose a case is ready for trial and the patent holder can prove damages (infringing sales) of $100 million. The parties settle before trial with the alleged infringer paying the patent holder $40 million and agreeing to cease sales of its product. In addition to the $40 million payment to the patent holder, there is an implicit $60 million payment to the alleged infringer to cease its sales. In reality, what has occurred is the alleged infringer is permitted to keep a portion of the profits from its sales. Under plaintiffs' analysis, a settlement such as this, where the patent holder forgoes collecting all damages due, would be a per se violation. Such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation.").

[51] *Cipro*, 363 F.Supp. 2d at 538.

[52] *Asahi Glass*, 289 F. Supp. at 994.

Contrary to the complaints of some, these courts have not ruled that patent law somehow trumps antitrust law in all cases. Rather, they have recognized that patents have long-term pro competitive effects that antitrust law embraces. This makes sense. Patent law traces its roots to the Constitution itself and existed long before the antitrust laws were passed. For the past 117 years, the courts have worked to apply antitrust law to patent agreements in a manner that respects the trade-off between a patent's short-term exclusion of rivalry and its long-term enhancement of consumer welfare through innovation and invention.

III. DOES THE PROPOSED SOLUTION SPEAK TO THE PROBLEM?

Even if the problem addressed by H.R. 1902 were one of genuine competitive restraint, the solution proposed — a flat, bright-line ban on any settlement in which a generic applicant receives "anything of value" from the patent-holder — would not be a competitive solution at all. Competitive analysis in antitrust is a fact-specific, detail driven assessment of actual consequences to markets and consumer welfare. It results in a fact-finder determining whether a given practice in a specific context does or does not reduce output and thus harm competition. In this context, the bright line rule of per se liability is too blunt an instrument to address factually-complex settlements involving different types of patents and different compromise points.

In its opinion in *Schering–Plough* the FTC derided a per se ban on patent settlements with payments as unsophisticated.[53] Shortly thereafter, it informed the

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[53] In describing what it viewed as the *Cardizem* opinion's use of a per se rule, the Commission stated that it did not "believe the opinion has taken adequate account of Supreme Court decisions that mandate a more nuanced approach." *In the Matter of Schering-Plough Corporation*, No. 9297, 2003 WL 22989651, at *13, n.26 (F.T.C.) (Dec. 8, 2003). The Commission went on to hold that "we are not now prepared to say that all such payments should be viewed as per se illegal or 'inherently suspect.'" *Id.*

Supreme Court that, if the Sixth Circuit's decision in *Cardizem* were read to be a per se rule against reverse payments, that decision would be "erroneous."[54] The Committee should thus be exceedingly cautious in considering enacting such a per se ban by statute.

It is well established that the genius of antitrust law is its common law model, where the legality of particular conduct is assessed in light of the facts of the market, the industry, the product, and evolving standards of economic knowledge. Thus, one set of actions at a given time in a given market may be anticompetitive, but under different circumstances, the very same conduct may be procompetitive. As the Supreme Court has explained, "recognizing and adapting to changed circumstances and the lessons of accumulated experience" is an essential element of antitrust law.[55] Thus, the Supreme Court has repeatedly relied on and emphasized "the accepted view that Congress expected the courts to give shape to the statute's broad mandate by drawing on common-law tradition." *Id.* (emphasis added). Accordingly, the term "restraint of trade," as used in Section 1, "invokes the common law itself, and not merely the static content that the common law had assigned to the term in 1890." *Id.*

Consistent with this understanding, Congress has not traditionally decreed conduct unlawful per se. Rather, Congress has adopted competitive solutions to competitive problems, directing the courts and enforcers to focus on real-life effects of the allegedly anticompetitive conduct in evaluating its legality. Even Clayton Act

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[54] Brief for the United States as *Amicus Curiae* at 7, *Andrx Pharms. Inc. v. Kroger Co.*, 125 S. Ct. 307 (2004) (No. 03-779).

[55] *State Oil Co. v. Khan*, 522 U.S. 3, 20-21 (1997).

strictures on types of conduct (such as tying) depend on an ultimate finding of reduced competition in fact.[56]

It is arguably ironic for Congress to be adopting a per se ban on a specific industry practice when the Supreme Court has itself in recent years been moving away from strict presumptions about parties' economic behavior for antitrust purposes. The Supreme Court has increasingly eschewed the inflexibility of the per se label, which requires no inquiry into the competitive effects of the condemned practice.[57] That default approach is the rule of reason, which entails scrutinizing parties' conduct by carefully considering the possible benefits and harms to competition resulting from an alleged restraint.[58] Accordingly, the Supreme Court has rejected many of its previously adopted per se rules in recent years, including two in the last term.[59]

Regulation of safe harbors by the FTC, as provided in Section 3 of the Bill, will not help. I have always understood the FTC to think of itself as an enforcer, rather than

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[56] *See* 15 U.S.C. § 14 ("It shall be unlawful for any person engaged in commerce, in the course of such commerce, to lease or make a sale or contract for sale of goods, wares, merchandise, machinery, supplies, or other commodities, . . . where *the effect* of such lease, sale, or contract for sale or such condition, agreement, or understanding may be *to substantially lessen competition* or tend to create a monopoly in any line of commerce.") (emphasis added).

[57] *See Broadcast Music, Inc. v. CBS*, 441 U.S. 1, 7-8 (1979) ("[This] Court has held that certain agreements or practices are so plainly anticompetitive ... and so often lack ... any redeeming virtue, ... that they are conclusively presumed illegal without further examination under the rule of reason generally applied in Sherman Act cases.") (internal citations omitted). A practice historically be condemned as per se anticompetitive when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output." *Id.* at 19-20.

[58] *See, e.g., Business Elecs. v. Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988) ("Ordinarily, whether particular concerted action violates § 1 of the Sherman Act is determined through case-by-case application of the so-called rule of reason.").

[59] *See Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 47-49 (1977), *overruling United States v. Arnold, Schwinn & Co.*, 388 U.S. 365 (1967) (vertical non-price restrictions); *see also State Oil Co. v. Kahn*, 522 U.S. 3 (1997), *overruling Albrecht v. Herald Co.*, 390 U.S. 145 (1968) (maximum vertical price-fixing); *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 126 S. Ct. 1281 (2006) (presumption of market power in per se tying cases); *Texaco Inc. v. Dagher*, 126 S. Ct. 1276, 1279 (2006) (per se price-fixing in joint venture).

a regulatory agency, with respect to antitrust and unfair competition. The FTC already does, and can continue to, provide guidance through its decisions, transparency when it exercises prosecutorial discretion, speeches, and possibly enforcement guidelines. But they are called guidelines for a reason. The agencies recognize that individual facts in individual cases are what determines antitrust analysis.

Thus, if Congress perceives that settlements with payments are anticompetitive, the Congress should enact a competitive solution. If it is a patent law problem, such as there are too many drug patents (a conclusion for which I am unaware of existing support), then the House should marshal the evidence and amend the patent laws. If the problem somehow lies in Hatch-Waxman, despite its phenomenal success at introducing generic drugs, the House should marshal that evidence as well and amend Hatch-Waxman.[60] But introducing the first per se ban on a specific practice in a specific industry is, in my view, unwise.

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[60] New arguments against payments by Professor Hemphill and others are based on the existence of Hatch-Waxman. *See, e.g.*, C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006). The idea is that Hatch-Waxman creates incentives for later filers to free-ride on the efforts of the first filer. Thus, according to the critics, Hatch-Waxman changed the antitrust laws by implication, making anticompetitive a settlement that would not be anticompetitive in another industry. *Cf.* Remarks of J. Thomas Rosch, FTC Commissioner, Law Seminars International, Pharmaceutical Antitrust, Washington, D.C. (April 26, 2007), at 10 ("Thus, outside of the [Hatch-Waxman] context, I think the *Schering* and *Tamoxifen* decisions might be relatively uncontroversial."). Besides the fact that this argument would apply to all settlements with first-filers, with or without payments, there is another fundamental problem. It turns the Supreme Court's reasoning in *Verizon Communications, Inc. v. Law Offices of Curtis v. Trinko*, 540 U.S. 398, 415-16 (2004), on its head. There the Court made it clear that just because a federal regulatory scheme brought the parties together and created a federally mandated form of rivalry, that did not change the application of the antitrust laws to their behavior. There, the FCC mandate that the defendant cooperate with a competitor did not render its failure to do so, though a violation of communications law, an antitrust violation as well. *Id.* ("The Sherman Act is indeed the Magna Carta of free enterprise, but it does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."). Other statutes may impliedly *repeal* the antitrust laws, but they never impliedly supplement them.

In fact, a competitive solution to any concern with Hatch-Waxman settlements already exists, in my view, with the FTC in its customary and leading rule. The Medicare Modernization Act of 2003 gave the FTC the notification its sought of ANDA settlements, so none will slip by unnoticed. The FTC retains its power to investigate fully, to file complaints when appropriate, to adjudicate those cases before the full Commission, and to defend its decisions in the courts. Private litigants have also brought antitrust cases attacking settlements, and show no apparent lack of interest in continuing. Courts, as indicated, have found some settlements illegal, others not, and are developing a body of rules. This normal evolution and reasoned elaboration of antitrust principles in this area should be preferred. It is consistent with how Congress treats other conduct in other industries, and in the FTC we have an able prosecutor.

IV. UNINTENDED CONSEQUENCES.

Even if The House views the problem as significant and the solution as appropriate, will there be unintended consequences from the Act as drafted? One obvious concern is whether H.R. 1902 will reduce the number of ANDA IV settlements. I think the answer is clear. After the FTC made clear that it would challenge payments, the total number of Hatch-Waxman settlements dropped. However, after courts in *Valley Drug*, *Ciprofloxacin*, *Schering Plough*, and *Tamoxifen* declined to impose per se liability on such settlements and concluded that so long as they constrain no more competition than protected by the patent, settlements with payments are not suspect,

such settlements rose again sharply. Thus, a presumptive rule against payments clearly means *fewer* settlements.[61]

The proposed Bill's use of the term "Anything of Value" means that it condemns every settlement, except for a narrow exception provided in Section 2(b), because all settlements transfer value. As the Bill is written, the exchange of "value" does not even have to be causally connected to the settlement of the patent claim. Any cross-license or co-promotion agreement would be banned. Allowing the challenger to enter early as an authorized generic would also be banned. The only thing allowed is free entry with the generic described in the ANDA—*i.e.*, no license restrictions of any kind—at a date prior to expiration. That will greatly reduce settlements because the Hatch-Waxman parties value added time on entry differently. Thus if the generic insists on two more months to get another $5 million in profit, and the brand will not agree because, while willing to pay $5 million in cash, the two months would cost it $30 million, there will be

[61] The FTC Reports indicate that in 2004, there were 0 agreements with restriction on generic entry and compensation to the generic out of 14 final settlements (total of 22 agreements filed); in 2005, there were 3 agreements with restriction on generic entry and compensation to the generic of 11 final settlements (total of 20, for 16 drugs, of agreements filed); and in 2006, 14 out of 28 final settlements had restriction on generic entry and compensation to the generic (total of 45 of agreements filed). Agreements Filed with Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2006, A Report By the Bureau of Competition, Figure III. "In FY 2006, the Commission received . . . more than double the number of agreements received in each of the two previous years." *Id.* at 1.

no settlement at all.[62] Indeed, one of the vocal critics of reverse payment settlements agrees that some settlements simply cannot happen without payments.[63]

There are other crucial questions that need to be answered with empirical evidence before such a sweeping legislation is enacted, particularly given the delicate balance that Hatch-Waxman itself has struck.

For example, when you force more cases to trial, will patent holders win more often than they do now? Perhaps. The current financial incentives of Hatch-Waxman mean that it always makes sense to settle, no matter how strong your patent. If fewer cases settle, a higher percentage of strong patents may be litigated. When settlements dropped off before the 2005 court decisions, at least one empirical analysis showed that the success rate for patentees rose relative to the generics, and actually surpassed it.[64]

Will limitations on the right to settle reduce incentives to innovate and invent? By definition, it would make pharmaceutical patents less valuable. How much? There is no direct evidence, but recall that pharmaceuticals is the one industry where even patent skeptics agree innovation is spurred by the value of patents.[65] The per se ban of

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[62] If that case had settled, it would provide an obvious example where the length of the license is not affected by the fact of the payment. The two license periods proposed were as close together as the parties expectations would allow. The payment did not lengthen the license that would have been granted in its absence because no license would have been granted in its absence. The payment just bridged an otherwise unbridgeable gap in the parties' positions created by the difference in the way they value license length. *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1060-67 (2004).

[63] *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391, 400-01 (Summer 2003) ("We know that joint profits are higher under the agreement than under litigation, . . . so in the absence of any fixed fees, the incumbent captures all of the gains from trade. If we think in terms of Nash bargaining, . . . we would expect the incumbent and entrant to split these gains from trade, which would imply a fixed payment running from the incumbent to the entrant.").

[64] *Gregory Glass, Why Settle?, Update, Sept./Oct. 2005, at 17-19*, (finding that patent holders prevailed in 53 % of all cases decided or settled, while generics prevailed in 47 %).

[65] *See supra* page 11 & n.26.

H.R. 1902 should not be enacted without some assessment of its effect on investments in new drug research.

Will limitations on settlements reduce generic challenges? Quite probably. As noted above, many (including generic companies) believe it will. To maximize these incentives, a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it.[66]

What will be the effect of H.R. 1902's changes to Hatch-Waxman's 180-day exclusivity rights? In my view, allowing forfeiture to start from dismissal of any Declaratory Judgment for lack of jurisdiction, as does Section 4, encourages frivolous Declaratory Judgment actions. The subsequent filer is actually better off if the Declaratory Judgment court dismisses the case than if it allows jurisdiction and the second filer has to litigate. This provision would seem to lessen the value of being a first-filer. It would take very little time for a frivolous Declaratory Judgment to be dismissed, and the first-filer may still be litigating. Thus its 180 days would be lost while it was still pursuing litigation. The FTC is currently studying how critical the exclusivity is to first-filer incentives to file challenges, and whether the threat of authorized generics lower those incentives. It would be surpassingly odd for Congress to pass a statute that may harm those incentives far more without awaiting the results of that study.

Finally, if Congress believes that Section 4 of H.R. 1902 eliminates the "bottleneck" issue, what is the need for the rest of the statute? Free entry to a market usually removes any potential for competitive harm. The danger of creating a bottleneck by settling with the first-filer will be over.

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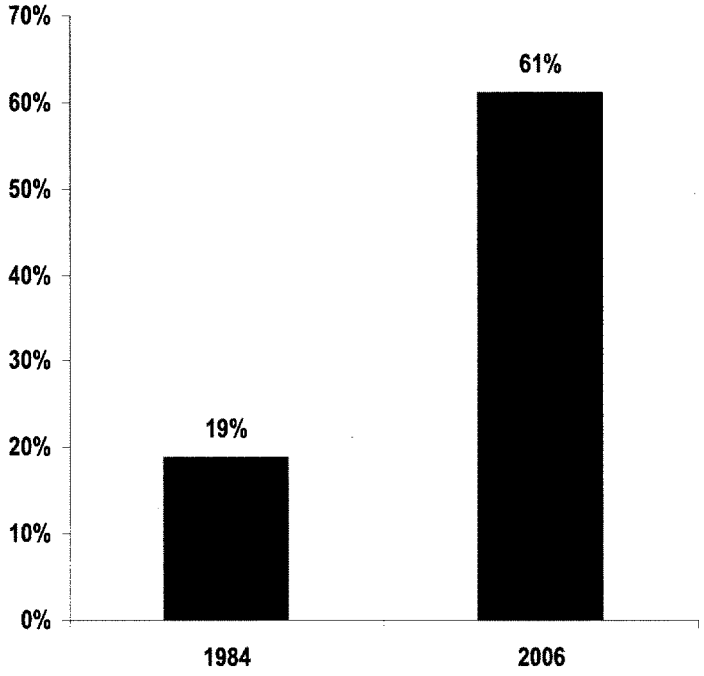
[66] *See, e.g.*, *Cipro*, 261 F. Supp. 2d at 256; *see also supra* pp. 9-11.

V. CONCLUSION

I thank the Chairman and Members of the Committee for inviting me to testify and submit this written statement. I believe that the American public is well served by the Committee's attention to these issues so important to the health and welfare of our Country.

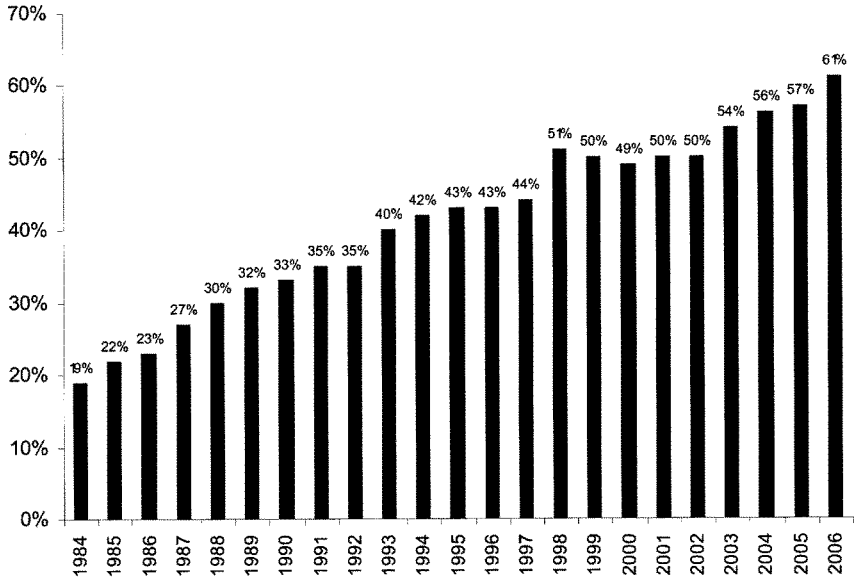
Balancing the twin goals of innovation and invention championed by our system of patents with lower-cost drugs through increased competition due to generic entry is not easy. Congress, through the passage of Hatch-Waxman, and the FTC, through its enforcement efforts, have brought about a dramatic increase in the availability of generic drugs to the American public. While there always will be differences of opinion regarding specific cases, overall Congress' balance between the patent laws and the antitrust laws is working. With the FTC as a vigilant prosecutor, there is no need to create a unique industry specific carve-out from the antitrust laws. Moreover, such a carve-out for specific conduct in a specific industry is contrary to the almost 117 years of reasoned jurisprudence that has and continues to be our antitrust laws.

APPENDIX A



Sources: Deutsche Bank report; 2005: Denske Equities; 2006: Credit

APPENDIX B



Sources: Deutsche Bank report; 2005: Denske Equities; 2006: Credit Suisse

Mr. RUSH. Thank you.

Mr. RUSH. Our next witness would be Mr. Wroblewski.

Mr. Wroblewski, you are recognized for 5 minutes.

STATEMENT OF MICHAEL WROBLEWSKI, PROJECT DIRECTOR, CONSUMER EDUCATION AND OUTREACH, CONSUMERS UNION

Mr. WROBLEWSKI. Thank you, Mr. Chairman, members of the subcommittee. Thank you for the invitation to testify this afternoon.

Consumers Union is the independent nonprofit publisher of Consumer Reports. We investigate and report extensively on issues surrounding the cost, safety and effectiveness of prescription drugs so that we can provide our 7.3 million subscribers with expert advice on how to manage their health.

Consumers Union's publications carry no advertising and receive no commercial support.

Consumers Union strongly supports H.R. 1902, the Protecting Consumer Access to Generic Drug Act of 2007. This legislation ends the use of patent settlements in which the generic applicant receives anything of value in exchange for agreeing not to research, develop, manufacture, market or sell its generic product. These settlements can deny consumer 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 general inflation, in part due to the high costs and rate of inflation of brand name drugs. Generic drugs can dampen health inflation because they cost up to 70 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 drugs available. We currently provide information for 17 different classes of medicine and will expand to more classes in the near future. Consumers can use this information to check to see if there is a safe, effective and low-cost alternative to any medicine they are taking.

We encourage consumers to talk to their doctors about this information. Access to these low-cost generic drugs saves consumer substantial sums.

The second reason we support legislation is to counter the incentives that brand name and generic companies have to enter lucrative settlement agreements. It is an economic fact that the brand companies' total profits from sales of its brand drug prior to generic entry exceed the combined profits of the brand name and generic company after generic entry occurs. In Commissioner Leibowitz's testimony he referred to that as the sweet spot.

The upshot is that the brand name company has powerful incentives to pay the generic applicant to delay in entry. This payment is still less than the amount it would lose if the generic entered the market. The generic applicant, on the other hand, also gains by earning more from the settlement than it would otherwise compet-

ing in the market. Indeed, legal sanctions of these agreements have the potential to encourage generic companies to challenge otherwise strong patents with the hope of obtaining at least some payment.

These transfers from brand to generic companies to not serve any public interest. These economic incentives are inadvertently exacerbated by the 180-day marketing exclusivity provision of the Hatch-Waxman Act. Any settlement with the first filer that delays entry blocks any subsequent generic from entering the market. So the brand company can forestall generic competition for years by settling with just the first filed generic. And the generic who is first in line also has powerful incentives to ask for payment because not only will it get the payment, but it retains the 180 days of marketing exclusivity.

The irony, of course, is that the intent behind the act was to speed generic drug entry, not provide the generic a windfall to delay its market entry.

The third reason we support legislation is because we believe it is a legislative question as to how to balance the competing consumer interests of speeding generic entry with providing incentives for continued pharmaceutical innovation. We believe that the use of these exclusionary payments has upset the finely crafted balance that Congress struck in 1984 and reaffirmed in 2003 in the Medicare Modernization Act between these two objectives.

We believe the courts won't fix this problem in a timely manner. Two recent appellate court decisions have taken a lenient view of these patent settlements. These courts have ignored the specific statutory incentives in the act that encourage generic applicants to challenge weak patents and to obtain court rulings on these suits. 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.

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.

[The prepared statement of Mr. Wroblewski follows:]

United States House of Representatives,
Subcommittee on Commerce, Trade, and Consumer Protection Hearing on
H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007

May 2, 2007

Statement of Michael Wroblewski
Project Director, Consumer Education and Outreach
Consumers Union, the Independent, 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]

Consumers Union strongly supports H.R. 1902, the "Protecting Consumer Access to Generic Drugs Act of 2007." This legislation ends the use of patent settlements in which the generic applicant receives anything of value in exchange for agreeing not to research, develop, manufacture, market, or sell its generic product.[2] These settlements

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[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.

[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.

with exclusionary payments 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 competitive prices. In light of the recent increased use of these agreements with exclusionary payments,[3] 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 and innovation. The Hatch-Waxman Act (the Act),[4] which governs the approval of generic drugs, inadvertently exacerbates these incentives. Moreover, continued reliance on the courts to provide consumers with timely relief is misplaced.

The testimony also describes Consumers Union's support of the other main provision of H.R. 1902 that updates the regulatory structure governing approval of subsequently-filed generic applications. The provision breaks the bottleneck on FDA approval which can occur when generic applicants cannot obtain decisions on the merits concerning patent infringement.

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[3] *See* Prepared Statement of the Federal Trade Commission before the Committee on Judiciary of the United States Senate, "Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution," (Jan. 17, 2007) at 17, ("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" in fiscal year 2006.), ("FTC Senate Judiciary Committee Statement") *available at* http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

[4] 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)).

Finally, the testimony describes Consumers Union's support of several other legislative changes to speed generic entry, including: (a) clarifying the law to provide for the development of generic versions of complex molecular biologic medicines, (b) clearing the backlog of generic applications at the FDA, and (c) 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.[5] 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.[6]

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 assuming all brand prescriptions were filled with the generic version.[7] This year and in 2008, several brand-drugs are expected to go

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[5] *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).

[6] David Reiffen and Michael Ward, "Generic Drug Industry Dynamic," 87 *Review of Econ. & Stat.* 37 (2005).

[7] 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.

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).[8] 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.[9] 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 17 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.

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[8] FDA, Approved Drug Products with Therapeutic Equivalence Evaluations (Electronic Orange Book) - *via on-line resources* FDC Reports, *The Pink Sheet (*2004-2005).

[9] *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*[sm] 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.[10] 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

[10] *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.[11] 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 the amount of money 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. Indeed, the ability to obtain a cash payment and defer market entry could encourage generic companies to challenge strong patents that it would otherwise not challenge, to the detriment of consumer's interest in continued pharmaceutical innovation. 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 Inadvertently 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 low-cost generic drugs, while at the same time restoring patent life lost due to the length of FDA brand-name drug approval process.[12] This balance recognized two important consumer needs – the need for competitively priced pharmaceutical products and the need for strong patent rights to encourage development of life-saving medicines. Congress created a number of industry-specific incentives to

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[11] *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.

[12] H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984).

accomplish these goals. 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.

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.[13] 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

[13] 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.

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.

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 can exacerbate 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 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."[14] 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."[15]

[14] S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

[15] *See* Statement of Sen. Orrin Hatch, Senate Floor Debates on S. 812, *Cong. Rec.* at S7567 (July 30, 2002).

C. Experience Shows that Brand-Name Companies and Generic Applicants Do Not Need to Use Exclusionary 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.[16] Two observations can be made from this fact. First, public knowledge of the FTC's investigations into these types of settlement arrangements in 1999 effectively ended the use of agreements with these terms. Second, brand-name and generic companies continued to settle patent disputes during this period (roughly from 1999 to 2005). The parties settled their differences on terms that did not include an exclusionary payment. Rather, they settled presumably on the basis of the relative strength of their cases. If they could not settle their differences, a court decided the patent issues. Any contention that exclusionary payments are necessary to settle patent litigation is undermined by these two facts.

Consumers Union believes that in light of the consumer harm that can occur from settlements with exclusionary payments, the public interest is served when a court either upholds the brand company's patent rights or resolves the patent issues so that generic entry can proceed expeditiously.

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 the use of exclusionary payments has upset the delicate balance initially struck within the Hatch-Waxman framework. Moreover, it is unlikely the federal courts will provide consumers relief in a timely manner. Two recent appellate court

[16] 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 Senate Judiciary Committee Statement at 17.

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.[17] 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.[18]

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.[19]

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

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[17] *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).

[18] *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.

[19] *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).

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.[20]

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.[21] 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.

IV. Break the Bottleneck on Generic Entry

Consumers Union also supports the provision in H.R. 1902 that updates the regulatory structure governing FDA approval of subsequently-filed generic applications. Under current law, there is no way to trigger a forfeiture of the first-filer's 180-day period if a subsequent applicant is not sued, although the FDA may be ready to approve the subsequently filed application. The provision in H.R. 1902 merely updates the regulatory conditions under which the FDA can approve the subsequently-filed generic product.

V. Other Legislative Suggestions to Help Speed Generic Entry.

Congress also may wish to consider three specific actions so that consumers have access to safe and effective generic medicines in a timely manner. First, there is no clear

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[20] 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.

[21] 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.

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.[22] Existing FDA law should be clarified to allow the U.S. to do what the Europeans are doing: bringing some relief to consumers.[23] To this end, Consumers Union supports Chairman Waxman's legislation, the "Access to Life-Saving Medicine Act."

We note, however, the possibility of patent settlement agreements that restrict generic entry, which are the subject of today's hearing, are also likely to occur with biogeneric drugs. As a result, we support using the same approach in H.R. 1902 to define these types of agreements as "unfair methods of competition." We also support requiring brand and generic biologic manufacturers to file their patent settlement agreements with the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice, similar to the way in which brand and generic pharmaceutical manufacturers file their agreements under the MMA.

Second, we urge Congress to provide the FDA with sufficient resources to eliminate the backlog in the approval of generics.[24] In a memo to Consumers Union last autumn, the FDA reported that an unduplicated count of pending generic applications

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[22] Tsao, Amy. "Seeking a Prescription for Biogenerics." Business Week. October 24, 2003.

[23] *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.

[24] *Id.* at 19.

showed a backlog of 394 drugs pending more than 180 days—drugs which could help lower costs to consumers if they were approved.

Third, we urge Congress to stop the use of phony citizen's 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.[25] We recommend Congress end this abuse.

Respectfully Submitted,

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[25] *Consumer Reports* (Nov. 2006) at 5.

Mr. RUSH. Thank you.

Mr. RUSH. Final witness is Mr. Whitehouse.

Mr. Whitehouse, you are recognized for 5 minutes.

STATEMENT OF THEODORE C. WHITEHOUSE, PARTNER, WILLKIE FARR & GALLAGHER LLP, WASHINGTON, DC

Mr. WHITEHOUSE. Thank you, Chairman Rush, members of the subcommittee, and good afternoon. Teva and I appreciate the opportunity to be heard on the important issues that you are considering today.

As I think you all know, Teva has been an active participant in the process leading up to this hearing. Representatives of Teva have had numerous meetings with Chairman Rush's staff and staff of other sponsors of this bill, as well as meetings with Members and staff on the Senate side. We have also had what we believe have been very constructive discussions with some of the Commissioners of the Federal Trade Commission as well as several members of the Federal Trade Commission's staff.

We hope that it has been apparent to everyone that Teva is very concerned about this and similar legislative proposals, but also very willing to work constructively with Congress and the FTC in an effort to ensure that the concerns being raised here are addressed without doing harm to the vital incentives at the heart of the Hatch-Waxman process.

The basic principle in health care since ancient times has been first do no harm. That sums up the message Teva wants to convey today. Teva believes that the intricately crafted Hatch-Waxman process that Congress put in place more than 20 years ago has worked and is working very well. Teva's basic position is that no new legislation is needed. Teva is therefore opposed to H.R. 1902.

As we had some advocacy this morning on the bright line, we can say the bright line may be quick and simple, as Commissioner Leibowitz said, but that doesn't make it right. Teva believes that the ability to reach reasonable, timely and proconsumer settlements in Hatch-Waxman in Paragraph IV litigation is absolutely essential to Teva's ability to bring low-cost generic drugs to market as soon as possible. That is Teva's fundamental business, to work to bring products to market as soon as possible.

One of the things that a company like Teva has to consider in deciding what its options may be when it takes an action that has the probability of starting an expensive lawsuit is what options it may have to settle if circumstances change or it turns out the case was not as good as it initially appeared to be.

It is important to keep in mind that Teva has to make that decision not just as to one case in isolation, but as a balancing of resources among many simultaneous cases. That is an important point that seems to be missing in some of the academic analysis, such as that Dr. Hemphill has presented.

Today Teva knows it has the option to settle a case on proconsumer terms and to redirect its resources to other products if circumstances warrant doing that. All of that is to the benefit of consumers. The proposed legislation would change that by making settlements much more difficult to accomplish. It would do that by prohibiting Teva and others from using procompetitive provisions

that have proved necessary to getting settlements done and that have resulted in settlements that were good for consumers.

Teva does not contend that all Hatch-Waxman settlements are necessarily good for consumers, but takes strong issue with legislation that would have prevented Teva from engaging in any of the 10 settlements that Teva has reached since 1999 that produced real benefits for consumers. Those 10 settlements have taken approximately 83½ years off the lives of the patents at issue and will end up saving consumers more than $67 billion.

Teva believes that more serious consideration should be given to legislative alternatives that have been discussed, such as mandatory review by the courts, or more formal FTC preeffectiveness review process. If this subcommittee determines to proceed with the approach embodied in H.R. 1902, Teva strongly urges that the exceptions or carve-outs in the bill be broadened to make clear that at least the kinds of terms that Teva has successfully employed in the past to reach settlements that produced real benefits for consumers remain permissible.

Those provisions include early generic entry on other products, a full release for damages in the covenant not to sue going forward on all patents on all generic products involved in the settlement, limited exclusive license during the exclusivity period, and case-by-case authority for the FTC to address individual settlements without rulemaking formality and delay.

Most of H.R. 1902 is directed to patent settlements; however, section 4 addresses a different set of issues not tied or limited to patent settlements. Essentially section 4 would broaden the circumstances under which the first generic company to challenge the brand company's patents could lose or forfeit the 180 days of marketing exclusivity provided to first filers under Hatch-Waxman.

As you have heard today, there are people in the industry who don't like the 180-day exclusivity provisions, but it is important to be very clear that those provisions have been in Hatch-Waxman from the start and are absolutely central to the incentive structure that has brought this country to the vibrantly competitive and publicly beneficial generic drug industry which we have today, and which benefits consumers, third-party payers, and the Federal and State governments.

I respectfully invite your attention to my written statement for full explanation of Teva's concerns regarding section 4.

Very briefly, Teva believes that proposed subsection CC addresses an obsolete issue, and that proposed subsection DD is unclear and potentially severely overbroad.

Those observations bring me back to where I started. On all of these issues Teva hopes to continue an active and constructive dialogue with Members of Congress and their staffs and with FTC Commissioners and the FTC staff all with a view to trying to address any legitimate concerns while carefully preserving all that is good and necessary about the existing and highly successful Hatch-Waxman process.

Thank you very much. I will look forward to answering your questions.

Mr. RUSH. Thank you very much.

[The prepared statement of Mr. Whitehouse follows:]

Testimony of

THEODORE C. WHITEHOUSE

of
Willkie Farr & Gallagher LLP

on behalf of
TEVA PHARMACEUTICALS USA, INC.

Concerning

H.R. 1902,

"Protecting Consumer Access to
Generic Drugs Act of 2007"

Before the

Subcommittee on Commerce, Trade, and Consumer Protection
of the
Committee on Energy and Commerce
of the
United States House of Representatives

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2 May 2007

SUMMARY

- This testimony is submitted on behalf of Teva Pharmaceuticals USA, Inc., the largest *generic* pharmaceutical company in the US with probably the most experience with Hatch-Waxman Paragraph IV patent challenges.

- Based on its considerable experience with Hatch-Waxman litigation, Teva strongly believes that settlements of those cases are an absolutely necessary part of the Hatch-Waxman process and that it is essential to have an adequate range of terms over which to bargain to reach necessary and pro-consumer settlements like those in which Teva has engaged.

- Teva's settlements have brought major benefits to consumers by making possible the present and future launch of products an aggregate of 83.4 years before the expiration of relevant patents, thereby saving consumers more than $67 billion. H.R. 1902 as currently drafted would ban settlement terms that have enabled Teva to bring generic drugs to market years before they might otherwise have become available to consumers.

- Teva does not believe that legislation like that embodied in H.R. 1902 is necessary or desirable. However, recognizing the concerns raised by the FTC and in Congress with respect to perceived anticompetitive abuses in particular settlements, Teva has worked and will continue to work with members and staff in both houses of Congress to develop and refine legislative options that do not severely restrict the kinds of settlements that help to bring products to market for the benefit of consumers.

- The outcome of pharmaceutical patent litigation may be more uncertain today than it has been in the past and the need for the flexibility to settle when circumstances warrant is more important than ever.

- Alternative forms of legislation providing for review of settlements before they become effective, either by the court handling the patent litigation or by the FTC through a process similar to current Hart-Scott-Rodino merger review procedures, would be less potentially disruptive to the Hatch-Waxman process than a ban on particular kinds of settlement terms.

- H.R. 1902 imposes too stringent a limitation on settlements. At a minimum, it needs to be revised to allow for the kinds of settlements by which Teva has brought great benefits to consumers.

- The provisions of H.R. 1902 relating to forfeiture of the 180-day exclusivity for first filers are at least unnecessary and potentially very damaging to the core incentives underlying the Hatch-Waxman process.

Chairman Rush, Ranking Member Stearns, and members of the Subcommittee, good afternoon. My name is Ted Whitehouse and I am a partner in the law firm of Willkie Farr & Gallagher LLP, where I specialize in antitrust law and litigation. I have had the privilege of serving for several years as an antitrust lawyer for Teva Pharmaceuticals USA, Inc. ("Teva"), a leading pharmaceutical company that participates in both the generic and the branded sides of the industry. Teva appreciates the opportunity to appear and be heard on the important issues being considered here today.

Teva is in the business of bringing low-cost generic drugs to market as soon as possible. Teva believes that the ability to reach reasonable and pro-consumer settlements in Hatch-Waxman patent litigation is absolutely essential to Teva's efforts to bring low-cost generic drugs to market as soon as possible. From a consumer welfare standpoint, settlements that result in bringing products to market sooner and with more certainty than might otherwise have been the case are a good thing. As a practical matter, settlement is more likely to be achieved if the parties have the ability to bargain over a variety of terms than would be the case if the parties are forced to bargain over only one issue. Because H.R. 1902 would, in Teva's view, unduly restrict the terms over which parties to Hatch-Waxman litigation may bargain to reach a settlement, Teva does not support H.R. 1902 as currently drafted.

In the testimony that follows, I propose to elaborate on these points and focus on specific concerns with the proposed legislation. I will begin by noting that Teva believes that legislation providing for prior review of patent

settlements by a court or the Federal Trade Commission ("FTC") would be preferable to legislation categorically banning certain kinds of settlements. I will then explain how H.R. 1902 in its current form would unnecessarily ban some of the kinds of provisions that Teva has found to be necessary and useful in reaching pro-consumer settlements in the past. Finally, I will address briefly the provisions of H.R. 1902 that would amend the Food, Drug, and Cosmetics Act ("FDCA") so as to impose additional restrictions on the availability of the 180-day period of marketing exclusivity that is a crucial component of the incentive structure on which the entire Hatch-Waxman process depends.

I. TEVA AND ITS POSITION ON THESE ISSUES

Teva and its affiliates together constitute the largest *generic* pharmaceutical company in the world and the largest pharmaceutical company of any kind in the United States in terms of number of prescriptions filled. One result of that status is that Teva is the most active initiator of Paragraph IV Hatch-Waxman patent challenges and therefore has a lot of experience with litigating and settling the patent infringement cases that may result from challenging the patents on branded drugs. Based on that experience, Teva strongly believes that settlements of such cases are an absolutely necessary part of the Hatch-Waxman process. Teva's experience confirms that it is essential to have an adequate range of terms over which to bargain in order to reach necessary and pro-consumer settlements. Given that the parties are likely to disagree about the relative strengths of their respective cases, a negotiation for settlement limited to only one variable is highly likely to fail

because the parties will not be able to reach the agreement about the relative strength of their cases that is necessary to reach agreement on that one variable. The ability to negotiate over multiple variables increases the likelihood that the parties' differences can be bridged.

Teva believes that the Hatch-Waxman process is today working very well under the existing law as interpreted by the courts. The process is producing the savings to consumers, third-party payers, and the government that it was supposed to produce. Teva does not believe that legislation of the sort reflected in H.R. 1902 is necessary or desirable and is, therefore, opposed to H.R. 1902. However, Teva is very aware that there is strong sentiment in Congress and elsewhere that some action by Congress is needed to address perceived anticompetitive abuses in particular settlements. Teva has therefore been working and plans to continue to work constructively with members and staff of both houses of Congress in an effort to ensure that legislation motivated by a desire to ban what are perceived as bad settlements does not also ban good, necessary, and publicly beneficial settlements.

II. THE HATCH-WAXMAN PROCESS

The Hatch-Waxman amendments to the FDCA were intended to promote the introduction of low-cost generic drugs for the benefit of consumers. A central feature of those amendments is a process that enables generic drug companies to challenge the patents claimed to protect brand-name drugs. That process is designed to encourage generic companies to incur the expense and risk of designing around patents or facing patent litigation by

certifying to a belief that the branded drug company's patents are not a legitimate obstacle to generic competition, either because the generic company's proposed product does not infringe or because the patents are invalid or unenforceable. That is called a Paragraph IV certification. The Hatch-Waxman amendments offer the first generic company to make a Paragraph IV certification a 180-day period of marketing exclusivity as an inducement to identify opportunities to enter into the market before the expiration of the brand company's patents listed in the Food and Drug Administration ("FDA") Orange Book.

Under the Hatch-Waxman amendments, the making of a Paragraph IV certification often results in a patent infringement lawsuit being brought by the branded company against the generic company. Because patent litigation is expensive and can consume a large amount of the time of key company personnel -- and the resources of generic companies are, of course, finite -- generic companies must have the flexibility to reevaluate their position in Paragraph IV litigations as those cases proceed. Such reevaluation may lead reasonably to the conclusion that the prospects for success, when balanced against the costs of litigation and the other potential products to which the resources being consumed by the litigation might more productively be directed, are such that the case should be settled.

III. TEVA'S EXPERIENCE WITH HATCH-WAXMAN LITIGATION

Teva has probably been involved in more Hatch-Waxman Paragraph IV litigation than any other generic company and therefore has

substantial experience with litigating and settling such cases. Teva has litigated many cases but Teva believes that it is essential that it be able to settle these cases where appropriate. Taking away the ability to settle and redirect efforts to other, more promising alternatives will make certain generic companies less willing to commit to Paragraph IV patent challenges with respect to some products. That result would be detrimental to consumers' interests in timely availability of generic drugs.

Teva's experience makes clear that it is not easy to settle Paragraph IV cases. An artificial and unnecessarily restrictive limit on the terms available to be negotiated in such settlements will increase the likelihood that cases will be litigated rather than being settled on terms that are more favorable to consumers than a loss by the generic company.

Since 1999, Teva has either launched its generic product without waiting for a final court decision (what is known in the industry as launching "at-risk") or launched pursuant to a settlement 29 products on which it was the first generic firm to challenge the branded company's patent. In 19 of those cases, Teva launched at risk and, in the remaining 10 cases, Teva launched its product on the basis of a settlement. In the 19 at-risk launches, Teva brought products to market an aggregate of 200 years before patent expiration and saved consumers approximately $161 billion. In the 10 cases involving settlements, all of which provided for entry earlier than the expiration of the patents, Teva's settlements have made possible the past and future launches of products an aggregate of 83.4 years before patent expiration and brought and

will bring over $67 billion in savings to consumers. In five of its ten settlements, Teva brought its product to market in the same year as the settlements were reached. In four of its settlements, Teva secured the additional consumer benefit of early market entry on a product not at issue in the litigation being settled.

A settlement of the Paragraph IV litigation can often be the most pro-consumer outcome available to a generic company. Any settlement that produces some form of early entry is going to be preferable from a consumer perspective to a loss of the litigation by the generic company and the consequent delay of entry until the patent expires. As noted above, some of Teva's settlements have produced results that could not have been obtained from litigating the case to judgment, such as (1) early entry on products in addition to the one in suit, (2) protection for consumers in the event that the brand company undertakes to convert the market to another product, and (3) obtaining a comprehensive release and covenant not to sue covering all patents on the product at issue, not just the patent in suit, thereby assuring entry without further litigation.

One argument that has sometimes been advanced in the recent discussions about patent settlements is that generic companies are so likely to win Paragraph IV challenges that they have no good reason to settle. That argument is typically based on statistics showing that, in the early years of Hatch-Waxman litigation, generic companies won over 70 percent of such cases. If that statistic was ever true, it is certainly not so today.

Paragraph IV cases today involve more difficult issues than they typically did a few years ago and may be more difficult for generic companies to win. Paragraph IV litigation used to be primarily focused on issues of infringement but, in recent years, the predominant issues involve validity of the patents. In 1999, only 18 percent of Teva's Paragraph IV litigations were primarily focused on invalidity issues and 82 percent of those cases were focused primarily on issues of noninfringement. By contrast, in 2005, those percentages literally flipped, with invalidity cases accounting for 86 percent of the total and noninfringement cases accounting for 14 percent. That is very significant because, in general, invalidity cases are more difficult to win than are noninfringement cases. Also, an increasing proportion of the cases being litigated involve challenges to the basic compound patent rather than intrinsically easier issues involving more peripheral patents. During this same period, Teva believes that brand companies have become more sophisticated in their patenting and patent litigation strategies. What this means is that there is greater uncertainty about the outcome when Paragraph IV litigation is initiated than there used to be and a greater need to be able to reassess and move on to other more promising opportunities when events in the litigation make that advisable.

IV. POTENTIAL LEGISLATIVE ALTERNATIVES REGARDING PATENT SETTLEMENTS

As Teva understands the situation, the introduction of H.R. 1902 and the convening of this hearing today reflect a concern that some settlements of Paragraph IV Hatch-Waxman litigation have not been procompetitive or in

consumers' best interests. To the extent that there is a problem that requires legislative attention, Teva is aware of at least two broad categories of solutions that have been advanced to address it. The first category of solutions would involve establishing formal procedures to ensure that some responsible public official or agency has an opportunity and an obligation to evaluate the competitive effects of a proposed settlement before it becomes effective. The second category of solutions -- exemplified by H.R. 1902 -- would categorically ban certain kinds of settlements.

A. Formal Court or Agency Review Procedures

The first category of potential measures to address the perceived problem of bad patent settlements -- and the one that seems least likely to disrupt the existing and successful Hatch-Waxman process -- involves mechanisms to ensure that settlements are reviewed by a court or administrative agency to ensure that they conform to the standards already established in the antitrust, patent, and Food and Drug laws. One approach that has been suggested would be for the court before which the litigation being settled is pending to have an explicit mandate to review the settlement to ensure that it is lawful. The court before which the case is pending is particularly likely to be in a good position to know the relative strength of the parties' respective cases and to assess whether the settlement reasonably reflects that and other relevant factors.

An alternative or supplement to court review would involve more formal review processes before the FTC. Already, as a result of the 2003 MMA

amendments,[1] all settlements of Paragraph IV Hatch-Waxman litigation are now required to be filed with the FTC and the Antitrust Division of the Department of Justice. In Teva's experience, all such agreements are carefully reviewed by lawyers and economists at the FTC. A potential legislative approach that has been suggested would be for the FTC to have a more formal and structured review process for patent settlements, perhaps involving procedures similar to the Hart-Scott-Rodino procedures that have long governed large corporate mergers.[2] Under that kind of process, parties to a settlement of a Paragraph IV litigation would have to file their settlement agreement and it would not become effective for a reasonable period of time so as to let the FTC review it before it was actually carried out by the parties.

Teva believes that, if Congress concludes that legislation is needed to address bad settlements of Paragraph IV litigation, serious consideration ought first to be given to establishing mechanisms to ensure that all settlements are given timely review by the courts or the FTC. Teva believes that such mechanisms could adequately and non-disruptively address any perceived problems with bad patent settlements. Teva and others have previously suggested draft legislative language that would establish such mechanisms.

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[1] Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[2] 15 U.S.C. § 18a (2007); 16 C.F.R. §§ 801-803 (2007).

B. Comments and Suggestions on H.R. 1902

H.R. 1902, like similar legislation pending in the Senate,[3] would broadly prohibit certain kinds of patent settlements (so-called "reverse-payment" settlements), subject to limited exceptions. The legislation would broadly ban any settlement in which any form of benefit flows to or through the generic company with only limited exceptions. Among other things, this means that all ten of the pro-consumer Teva settlements that I described earlier as having brought 83.4 years of time off the relevant patents and over $67 billion in savings to consumers would probably have been prohibited had H.R. 1902 been the law.

The legislative approach reflected in H.R. 1902 implicitly assumes that the parties to Paragraph IV litigation can reach pro-consumer settlements with only a very limited number of terms over which to bargain -- essentially, limited only to an agreement to entry on some date prior to the expiration of the patent in issue and waiver of damages for launches at risk that precede an unfavorable judgment in the patent litigation. Teva's experience is that restricting the terms of a potential settlement too narrowly will reduce the likelihood that any settlement will be reached and will thus create an undesirable risk that entry will not occur at all before patent expiration. Teva strongly urges that any legislation in this area at least allow for the sorts of pro-consumer settlements to which Teva has been a party.

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[3] S. 316, 110th Cong. (1st Sess. 2007)

As currently drafted, H.R. 1902 would allow a settlement to be based on early entry only with respect to the patent and product in suit. That limitation is likely to be a significant problem for at least two reasons.

First, as a litigator I can tell you that it is typical for the parties on opposite sides of litigation to have very different views of the strength of each of their cases. In those circumstances, a negotiation for settlement limited to only one variable has a high likelihood of failure because the parties will not be able to reach the consensus about the strength of their respective cases necessary to agree on that one variable. The ability to work with more variables increases the likelihood that the parties' differences can be bridged.

Second, branded drug companies often have strategic reasons that have nothing to do with the merits of the pending patent infringement lawsuit for refusing absolutely to negotiate entry as to the product in suit earlier than a date that is too late for fully competitive entry as to that product. Under those circumstances, a settlement based only on the entry date prescribed by the brand company for the product in suit would make little sense but a settlement providing also for early entry on some other product might make for a commercially sensible settlement that is in the best interests of consumers.

H.R. 1902 desirably provides for settlements to include a waiver of damages for prior marketing of the ANDA drug. We understand this provision to be intended to address, for example, the situation in which a generic company launches at risk on the basis of a favorable lower court decision and then finds it necessary to settle following an unfavorable ruling on appeal.

Teva has had actual experience with such a situation and strongly supports making provision for it in any legislation on this issue. However, Teva's experience suggests that broader language is necessary to make clear that settlements may permissibly include a complete release and covenant not to sue as to all patents on the product in suit so as to eliminate the risk that the branded company will settle and then later brandish other patents not asserted in the initial suit as a means to forestall generic entry. Also, consistently with the point as to other drug products in the time-off-the-patent provision, above, Teva believes that the release provision should clearly allow a full release and covenant not to sue as to such other products.

As many of those present are well aware, branded drug companies have recently adopted a strategy of releasing so-called "authorized generics" during the 180-day period of market exclusivity provided by the Hatch-Waxman law to the first filer of a Paragraph IV ANDA. The purpose and effect of such product releases by the branded companies are to diminish the value of the 180-day first-filer exclusivity to generic companies with the obvious goal of discouraging generic companies from pursuing the patent challenges that the Hatch-Waxman amendments were designed to encourage. To mitigate the effects of this undesirable practice, Teva believes that any legislation on these issues should specifically allow the parties to a settlement of a Paragraph IV litigation to agree through the means of an exclusive license for a limited duration that the branded company will not engage in this undesirable practice. Such a license is, of course, permissible under the current law.

Section 3 of H.R. 1902 contemplates FTC rulemaking to establish other potential carve-outs from the general prohibition. Teva supports that idea but also believes that it would be desirable to give the FTC specific authority to approve settlements on a case-by-case basis, notwithstanding the general prohibition, to avoid undue delay and to ensure that pro-competitive settlements are not blocked.

V. PROVISIONS OF H.R. 1902 RELATING TO FORFEITURE OF EXCLUSIVITY

In addition to the provisions directed to settlements of Paragraph IV Hatch-Waxman litigation, Section 4 of H.R. 1902 contains proposed amendments to core provisions of Hatch-Waxman amendments codified in the FDCA. Those proposed amendments to Hatch-Waxman are not limited to -- or necessarily related to -- settlements, and Teva believes that they could have substantial negative effects on the carefully balanced incentive structures that are at the very heart of the Hatch-Waxman process.

As noted previously in this testimony, the Hatch-Waxman amendments to the FDCA provide that a generic company that is the first to challenge a brand company's patent on a drug is entitled to 180 days of market exclusivity when it brings the generic product to market. The particular provisions of the FDCA that are proposed to be amended[4] are very complex and deal with the circumstances under which a generic company entitled to 180 days of first-to-file exclusivity may lose, or forfeit, that exclusivity. It is important to note at

[4] 21 U.S.C. § 355(j)(5)(D)(i) (2007).

the outset that the law as it exists today already addresses the situation in which a settlement agreement is held to be unlawfully anticompetitive: Under that circumstance, exclusivity is already required to be forfeited.[5]

Teva understands that the first proposed amendment -- proposed new subsection CC -- is intended to address a problem that no longer requires attention. That problem arose from case law in the United States Court of Appeals for the Federal Circuit that did not allow district courts to entertain certain declaratory judgment actions in cases in which generic companies filed Paragraph IV challenges to brand company patents and the brand companies refused either to sue or to promise not to sue over those patents. In the 2003 Medicare Modernization Act, Congress tried to make clear that declaratory judgment relief should be available to the generic company in that circumstance,[6] but the Federal Circuit held that declaratory judgment relief was not available due to constitutional limits on the jurisdiction of the federal courts. In technical terms, the Federal Circuit ruled that the courts did not have subject matter jurisdiction over such claims.[7] In January of this year, the United States Supreme Court ruled that the Federal Circuit's "reasonable apprehension of imminent suit" standard for subject matter jurisdiction in

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[5] 21 U.S.C. § 355(j)(5)(D) (2007).

[6] Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[7] *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 405 F.3d 990 (Fed. Cir. 2005).

declaratory judgment cases was not consistent with the Constitution,[8] and the Federal Circuit has acknowledged that the courts may no longer refuse to hear declaratory judgment cases relating to patents listed in the Orange Book.[9] Thus, the concern to which this provision is directed is no longer a live concern. Given the potential for unintended consequences and unpredictable mischief that seems to inhere in all provisions of this complicated law, Teva strongly recommends that Congress not adopt this unnecessary provision.

The second proposed amendment to the forfeiture provisions of the FDCA -- captioned subsection DD -- seems to contemplate stripping the first filer of an ANDA of the exclusivity it has earned if some other applicant for authority to make the same generic drug purchases or otherwise obtains from the branded company and files with the FDA a covenant not to sue. The circumstances under which that would be a fair and appropriate result are not apparent to Teva.

CONCLUSION

Teva appreciates the opportunity to be heard today and welcomes the opportunity to maintain a continuing and constructive dialogue on these important issues with Members and their staffs.

Thank you.

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[8] *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 772-774 (2007).

[9] *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, No. 06-1181, 2007 WL 942201, at *11 (Fed. Cir. 30 Mar. 2007); *cf. Sandisk Corp. v. STMicroelectronics, Inc.*, No. 05-1300, 2007 WL 881008, at *7 (Fed. Cir. 26 Mar. 2007).

Mr. RUSH. The Chair recognizes himself for 5 minutes.

My first question is directed to Mr. Hemphill. Mr. Hemphill, the FTC's deterrent impact has been greatly diluted as shown by the increased number of reverse payment settlements, particularly since the Eleventh Circuit ruled in Schering, which, by the way, was a 7-year battle. So isn't that why this legislation that we are considering today is essential and necessary?

Mr. HEMPHILL. Mr. Chairman, that is correct. As was earlier mentioned, there is a division of opinion among the courts of appeals in the Sixth Circuit. There is a rule per se, a legality on the rather special facts of that case. But as you have noted, the Second Circuit and the Eleventh Circuit have come out quite sharply against the illegality of these settlements. That makes it an uphill battle for a private plaintiff or for the FTC to win litigation in the courts.

And as a matter of resetting the system in a way, if you will, a bill like this is quite important.

Mr. RUSH. Mr. Whitehouse, in your testimony, you assert that brand name and generic drug companies will be hard pressed to settle their patent disputes if we would ban exclusion payments. Why is it that all other commercial sectors are able to settle patents without exclusion payments, and what makes the drug companies so unique and so special?

Mr. WHITEHOUSE. Mr. Chairman, I think we need to first recognize that when we say exclusion payments, that has become a term that may cover a lot or a little. And if it is talking about something like what is at issue in the Cardizem case in the Sixth Circuit, which is found to be per se unlawful, that is one end of the spectrum.

We think there are other things that are being unfairly disparaged as exclusion payments that are, in fact, legitimate and necessary terms of settlements in patent cases that wind up producing very substantial benefits for consumers. And our fundamental point is that you can't lump all of these mechanisms into one basket.

Mr. RUSH. Professor Hemphill, in Mr. Whitehouse's written testimony, he states, and I quote, "given that the parties are likely to disagree about their relative strengths of their respective cases, a negotiation for settlement limited to only one variable is highly likely to fail", end of the quote.

Mr. Whitehouse is referring to traditional patent settlements in which the two parties agree on an early entry date, and only on an early entry date, without any other payments.

Now, referring to your testimony, you take almost the exact opposite stance from Mr. Whitehouse and assert that this is precisely the way that brand name and generics ought to settle. Can you explain your position, please?

Mr. HEMPHILL. I would say that Teva and other generic firms remain free to reach procompetitive settlements as we saw during the period prior to the adverse decisions in tamoxifen and in Schering, and that they ought to be able to do so without conferring payment from the innovator to the generic firm.

There is, I think, a related confusion, though, that bears mentioning here, which is that I think perhaps Teva, perhaps other ge-

neric firms, have taken the view, an erroneous view, I think, that the gambles that they make in engaging in ANDA-based litigation ought to always have a payoff, that in each and every case they ought to be able to receive some kind of compensation to justify their expenditure on the litigation.

But the nature of a gamble is that that is just not so. Sometimes when you drill, you find a dry hole. And it is just not the case that the inability to even receive compensation in a particular case ought to be something that necessarily troubles us.

Mr. RUSH. Thank you.

In my last few minutes I want to ask Mr. Proger. Mr. Proger, you characterize the bill I have introduced with Mr. Waxman as adopting a, quote, "blunt instrument", end of quote. Yet I see our bill as a scalpel that goes after a very specific practice that is totally and completely unique to the drug industry.

Can you explain how is that being blunt, and especially since we create flexibility by authorizing the FTC to promulgate further exceptions to the rule? And I want to also ask Mr. Wroblewski and Mr. Hemphill to give me their comments.

Mr. PROGER. Mr. Chairman, I characterized the bill as being blunt because it doesn't go on a case-by-case basis, and the bill prohibits the generic challenger from receiving anything of physical value. We continue to talk in this session about payments as if payments are only cash. You can attain the exact same solution by licensing, by other forms of entry, and still have the same economic consequences. And as I read your legislation, absent action by the Federal Trade Commission, all of those would be prohibited. Some of those particular practices have been endorsed by proponents of Hatch-Waxman and proponents of your legislation. And so that is where my concern is.

And I think one other thing, if I may, sir, we keep hearing Schering and tamoxifen as if those decisions somehow went against the American public and ruled that you can do whatever you want. That is not the case. The Second Circuit and Eleventh Circuit found that those settlements were not anticompetitive because the settlements were within the scope of the patent. We have to remember that there is a patent here.

Mr. RUSH. My time has ended.

Mr. Hemphill or Mr. Wroblewski, if you all care to respond, please do so.

Mr. WROBLEWSKI. I think the approach is a reasonable approach given that Congress's intent in doing Hatch-Waxman in the first place was to provide an incentive to challenge patents.

And so in response to Mrs. Blackburn, your question, in terms of was there any other industry in which there has been—the Federal Government is kind of dictating what the terms or not the terms could be of a particular settlement, I can't think of any. And I agree with Mr. Proger. I don't know if there are any, but I don't know of any other industry in which Congress has specifically incentivized generic companies to challenge patents and to get resolution of those patent issues, which I believe is just as important in terms of the public interest.

And regardless of which way the resolution turns out, if the brand company wins, then that is good for innovation because

strong—as we have known, pharmaceutical innovation depends on strong patents. So that is good. And on the other hand, if the generic wins, well, that is good for consumers because they will get a competitively priced generic drug.

Mr. RUSH. Thank you.

Mr. Hemphill, I am going to ask the other Members for their questions. We will come back to you a little later.

The Chair recognizes now the ranking member.

Mr. STEARNS. Thank you, Mr. Chairman.

Mr. Sherman, I understand that your company and Bristol-Myers Squibb negotiated a settlement related to Bristol-Myers' drug Plavix, a deal which was subsequently rejected by the FTC.

Now, once this deal was rejected, your generic version entered the market despite what seemed to be a blatant patent infringement. Indeed, after 3 weeks you were forced to pull the drug from the market. Did the consumer benefit more from 3 weeks of availability in 2006, or would he or she have benefited more from the 6 months in 2011 as the settlement had called for? Does that make sense?

Mr. SHERMAN. Well, you have to keep in mind the litigation is not over yet, and we think that there is a very high probability that we will win the litigation either in the first instance or on appeal.

So, it was—and certainly also the—we did launch the product. We sold very large quantities for which the consumer certainly benefited very highly. And I think the benefit from our launching now is equal to what it would have been from a launch many years from now.

But on top of that, as I said, there is a strong probability that we will yet be back in the market and save many billions of dollars for consumers by litigating and winning.

Mr. STEARNS. Is it possible that litigation will last longer than the patent time?

Mr. SHERMAN. No. No. No. The decision in the district court will come within months, and then a decision on appeal will come probably a year later.

Mr. STEARNS. Isn't it true that a settlement can provide a certainty of early generic market entry before patent expiry, particularly in a difficult challenge?

Mr. SHERMAN. Well, it depends on your frame of reference. If you assume that all patents are valid and would be infringed, then any settlement that gives any early entry beyond patent expiry is pro consumer. But large numbers of patents are invalid or would not be infringed. The very purpose of the Hatch-Waxman provisions was to put that to the test, as Mr. Wroblewski, I think, articulated very well.

The incentive is you get a reward. You are supposed to get a reward from taking on the risk of litigating it. That is what you are supposed to do. And it is fundamentally wrong for a company to be able to be the first to file, take the reward and not litigate, and agree not only not to launch the product for years and not to litigate, but in so doing block everybody else from doing so.

Mr. STEARNS. Mr. Proger, this question is for you.

If many of these settlements are pacts, end quote, to keep generics off the market early, as proponents of the bill have said, then in your view why have courts not adjudicated them as collusive behavior?

Mr. PROGER. Ranking Member Stearns, we have to start with the proposition that there is a patent that is presumed to be valid and enforceable. If the patent is valid and enforceable, and the settlement is within the scope and time of the patent, there is nothing wrong under our law today with the patent holder sharing that. We have to remember someone invented this wonder drug in the first place, and it is the patent holder, and we have given them certain rights.

I am an antitrust lawyer. I am a past chair of the section of antitrust law of the American Bar Association. I believe in the antitrust laws; have been my whole life. But there are other equal dignities in our society, and the patent laws are one.

Mr. STEARNS. Mr. Wroblewski, your goal is to get cheaper generic drugs to market sooner; is that correct?

Mr. WROBLEWSKI. Actually consumers have two interests. I would say one would be for competitively priced generic drugs, but also continued pharmaceutical innovation.

Mr. STEARNS. If generic companies choose to stop challenging patents, delaying market entry, wouldn't that cost consumers millions of dollars?

Mr. WROBLEWSKI. But there is an incentive to challenge.

Mr. STEARNS. What is the incentive for generic companies to challenge a patent currently? If that incentive disappears, do you expect the same number of patent challenges that you see today?

Mr. WROBLEWSKI. I don't anticipate it disappearing.

Mr. STEARNS. Isn't it true products brought to markets through patent settlements have saved consumers a significant amount of money? I would think, ostensibly, yes.

Mr. WROBLEWSKI. I am not sure. Do you have an example in mind?

Mr. STEARNS. No, I am asking you the question.

Mr. WROBLEWSKI. Are there settlements in which there has been——

Mr. STEARNS. Isn't Prozac a good example, 2.5 billion?

Mr. WROBLEWSKI. Prozac was—they invalidated the patent. So they came in via the incentive, and it worked the way it should work.

Mr. STEARNS. Have any of the settlements that involved a reverse compensation component aided consumers, in your view?

Mr. WROBLEWSKI. Not that I am aware of.

Mr. STEARNS. Thank you, Mr. Chairman.

Mr. RUSH. The committee now recognizes Ms. Hooley from Oregon for 5 minutes.

Ms. HOOLEY. Thank you, Mr. Chairman; and I thank our panel for your presentation.

I have a few questions. Mr. Hemphill, we will start with you. Are these pay-for-delay settlements found in patent disputes outside the Hatch-Waxman framework? And, if not, why not?

Mr. HEMPHILL. The situation in pharmaceuticals is quite special because of the fairly unique incentives that have been created by

the scheme that Commissioner Leibowitz and others have said. So I would say they are highly special, which is why we see positive payments from the innovator to the generic firm in this industry but not in others and also why, when we pay attention to the interaction, as Mr. Proger mentioned, the equal dignity in antitrust and in patent law, we also have to think of the Hatch-Waxman Act, the sector-specific regulation that is in play here, which created this big push in the direction of litigation and in the direction of competition, which is being undermined by these settlements.

Ms. HOOLEY. OK. Thank you.

Why do you think—and I am going to stay with you, Mr. Hemphill, for another question. Why do you think it is preferable to enact legislation such as H.R. 1902, rather than have the FTC challenge these deals on a case-by-case basis?

Mr. HEMPHILL. Well, if we were writing on a clean slate where there wasn't already a set of judicial opinions that have come out, to my view, the wrong way, perhaps the status quo would be fine. But in light of the fact that we have repeated cases that have failed to recognize and remedy the anti-competitive harm, under those circumstances I think stronger medicine is justified.

Ms. HOOLEY. Mr. Sherman, as a generic manufacturer, you are testifying in support of this bill?

Mr. SHERMAN. Yes, with qualifications.

Ms. HOOLEY. With qualifications. While Teva, another generic manufacturer, does not support it as currently drafted, that is my understanding, why does your generic company seem to take a different position than another generic company on the bill?

Mr. SHERMAN. Well, I think that it is fair to say that each person tries to serve the interest of his own company. In the case of most of our generic competitors, they see an enormous upside to be made through being first to file and settling litigation as opposed to litigating. But our view is that our proper role is to fight to bring the products to market as early as possible, and we have made a corporate decision to pursue that objective, and we have let our customers know. We hope that our customers will appreciate what we are doing in fighting to bring products to market and in opposing anti-competitive settlements that delay market entry.

Ms. HOOLEY. OK. Thank you.

Mr. Whitehouse, your testimony cites a need for flexibility to settle these cases, but doesn't this bill afford flexibility in section 3 where it authorizes the FTC to promulgate rules that permit settlement terms that are not anti-consumer or anti-competitive?

Mr. WHITEHOUSE. Well, the answer in short is no, because the rulemaking process is a particularly protracted and long-running process, and we are advocating that we need to have, at a minimum, a process whereby the FTC could, on a case-by-case basis, provide for exceptions where provisions seem obviously pro-competitive.

Furthermore, in the interest of simple business planning and business certainty, it is important to know there are certain things you can do. So we also advocate there be specific carve-outs for other kinds of provisions beyond simply time off the patent that is now provided for in the introduced legislation that would enable business people to know there are certain kinds of things that have

been demonstrably pro-competitive that should be permitted, and we have articulated those in our testimony.

Ms. HOOLEY. OK. Thank you.

Mr. Wroblewski, can the Consumers Union provide any figures on the loss to consumers because of these exclusionary payment settlements? Do you know how much of this loss is borne by the taxpayer through payments for prescription drugs under Medicare or Medicaid? And can we assume that any lack of available lower cost generic drugs increase the cost to the American industry through higher costs for employer health benefits or health plans?

Mr. WROBLEWSKI. It is difficult to put a number on what could have been, because the settlement agreements aren't made public. So we don't know what the terms of the settlements are. I know when we released our most recent best buy drug recommendations on cholesterol-reducing drugs we calculated that a consumer who takes the best buy drug, which in that particular case would have been a generic version, could have saved about $1,800 a year, which is substantial amounts of money, you know, for a particular consumer.

Ms. HOOLEY. Thank you.

Mr. Whitehouse, I know you have a note in your hand. Go ahead.

Mr. WHITEHOUSE. If I may, a couple of things. There was an important question left pending by Congressman Stearns that is relevant to the questions you are asking, which is are there savings from these settlements; and, of course, as I said in my oral statement and my written statement, there are. Settlements we think have taken about 83½ years off the patent life of the drugs where we have made settlements and have saved consumers about $67 billion, which is about the same as that annual amount which Mr. Leibowitz referred to for Medicare Part D. That is a lot of money. So there have been, we think, very real, substantial savings.

The second thing is one needs to remember that a lot of these answers presume that we would have won the case, and of course that is exactly what is wrong here. There is a very high probability and a growing probability that you can't make that assumption. So you are faced with the need, again, if you are a substantial generic manufacturer, to decide among numerous cases and decide among those numerous cases which are the ones most likely to produce an imminent consumer benefit through litigating, which ones look weaker, we would be in a better position to settle, get something at least for the benefit of consumers, some time off the patent, and get an outcome that is still preferable to losing the case. And you have to be able to make those decisions.

A one-dimensional negotiation with a brand company is not going to enable you to implement those decisions to the benefit of consumers with any confidence or predictability.

Ms. HOOLEY. Thank you.

Mr. RUSH. The gentle lady's time is up.

The Chair recognizes the gentle lady from Tennessee, Mrs. Blackburn.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

I just wish I could take everybody's time and ask a lot of questions. I have lots of questions for all of them.

Mr. Wroblewski, I, just listening to you, appreciate you and appreciate your magazine. But I am going have to tell you, sir, I just feel like you are kind of the cheerleader of the crowd. You want everybody to get it all and to get it all at a good price, but somebody has got to pay the price at some point, and that R&D has to be paid.

I appreciate your position, as I said. I have been a long-term reader of your magazine. But I think we do have to realize these innovators and patent holders have to recoup their cost at some point.

Mr. Proger, reading your background, your resume, you have worked with clinics, hospitals, a lot of the business process mergers. Antitrust you said was your kind of law. The settlements on first filers, is this something that innovators now look at just as the cost of doing business? Do they anticipate they are going to have to pay this? And is that adding to the overall cost of drugs?

Mr. PROGER. Well, certainly the innovator, the inventor of the drug, has to now consider the incentives of Hatch-Waxman, recognize that they may be challenged and there will be additional costs.

Mrs. BLACKBURN. Did they set aside for that? As you are making your pro forma, do you say, well, and we are probably going to need *X* amount? Do you just write this in and consider it a cost of doing business, just a yes or no?

Mr. PROGER. I am not aware of whether they do so up front.

Mrs. BLACKBURN. Would you advise people to?

Mr. PROGER. Yes.

Mrs. BLACKBURN. You would?

Mr. PROGER. It is a very practical concern.

Mrs. BLACKBURN. It would be a best practice action?

Mr. PROGER. It is certainly going to happen.

Mrs. BLACKBURN. All right. So it would increase the cost of doing business.

You know, sometimes I feel like we sit here, and it is easy for us to pick winners and losers, and it is unfortunate that many times that we do that. That is why I think, Mr. Hemphill, your statement about resetting the system and us doing that legislatively rather than the market doing that, that is of concern to me. That is kind of a red flag for me.

We all think our kids are special, we think different things are special, and for you to say, you know, this is special, this is unique, it is still the process of innovation and doing business.

And, let's see, I have 2 minutes left, so I am going to have to be quick. Mr. Sherman, very briefly, going back to the situation that you have been dealing with, I have got an article here, an August 9, 2006, article where, as you are talking about the regulatory review and the situation you have been in, you said you viewed efforts by brand name companies to extend monopolies through settlement negotiations as outrageous. Our focus was to get the concession that would enable us to launch when the FTC turned us down. That was your statement.

OK, so let's say that is the case. So if that is the case, why don't we just get out of the way and let the private sector do its work? Very quickly.

Mr. SHERMAN. Get out of the way in what sense, by repealing the Hatch-Waxman provisions?

Mrs. BLACKBURN. I am asking you. Your best answer.

Mr. SHERMAN. Well, my best answer would be that repealing the Hatch-Waxman provisions entirely would be better than a system in which the first to file can take the exclusivity and keep it while not moving to market and using it to keep others off the market.

Mrs. BLACKBURN. OK. We have 1½ minutes left, and I want a yes or no from everybody down the line. Do you believe that it is going beyond our traditional jurisdiction or at least that it would be inappropriate for Congress to insert itself into the private legal negotiations between two parties and preventing them an avenue to redress their concerns? Yes or no?

Mr. WHITEHOUSE. Let me start at this end of the table. The answer is to the extent such a regulation sensors, the antitrust law is already provided as they presently stand.

Mr. WROBLEWSKI. No, because you already set up a structure to specifically encourage these types of patent challenges.

Mr. SHERMAN. Yes.

Mr. PROGER. No, because Congress has already.

Mr. HEMPHILL. I think Congress has to intervene, because it set up the Hatch-Waxman provisions, which provide a unique set of circumstances.

Mrs. BLACKBURN. Very good. My time is gone. Thank you all very much.

Mr. RUSH. Mr. Burgess, you are recognized for 5 minutes for questioning.

Mr. BURGESS. Thank you, Mr. Chairman.

Being a doctor, it has been kind of a life-long fantasy of mine to tell a lawyer answer the question yes or no, but I am going to resist doing that.

Dr. Sherman, I just got to tell you, we hear all the time that Canada is a place where drugs are so cheap that they are literally jumping off the shelves into consumers' hands and that nobody ever has to worry about drug prices in Canada and we should do the same thing here in this country. So I was a little bit surprised to learn that you are even concerned about a generic and would spend all that money on a lawsuit. Are generics valuable to Canada as well?

Mr. SHERMAN. Well, the situation is very similar in Canada to that in the United States. There is a brand market and a generic market, and we fight to bring products to the Canadian market as generics, just as we do in the United States.

Mr. BURGESS. But I thought you regulated prices in Canada.

Mr. SHERMAN. The prices of brand name products are regulated, patented products.

Mr. BURGESS. So the patent price is regulated?

Mr. SHERMAN. Patented products are regulated.

Mr. BURGESS. When the patent goes away, it would be the generic that could be competing with the brand name, is that not correct?

Mr. SHERMAN. Yes. And there are usually several generics and the prices are much lower than the brands because prices are determined by competition.

Mr. BURGESS. Again, that was just for my general information. I thought Canada was completely different from where we live.

Mr. SHERMAN. No.

Mr. BURGESS. Well, the bottleneck issue, though, for me keeps coming up; and I am concerned about the story that you told and the concept of forfeiting exclusivity. Do you think we go far enough in the bill that is before us? Has it addressed the problem sufficiently?

Mr. SHERMAN. No, it hasn't addressed the problem.

Mr. BURGESS. It hasn't addressed it at all, has it?

Mr. SHERMAN. No. I think what is important is not what the terms are of a settlement between a brand and a generic company. They should be free to settle as they wish. What is fundamentally wrong is that the generic in settling is blocking, continues to block all others from making a deal that is better for the consumer or from litigating and winning by retaining the exclusivity that it hasn't earned by not litigating.

Mr. BURGESS. This is such an important subject, and we have got such limited time.

Mr. Proger, if I could ask you, if there were going to be one thing we were going to improve this legislation as it goes through, what approach should we take? What should we do?

Mr. PROGER. Obviously, Congressman, I have been pretty clear that I think the antitrust laws on a case-by-case basis would be far preferable to a broad ban on settlements. Many of the settlements contain pro-competitive aspects, and unless you know whether or not the patent is valid and enforceable you don't know whether there is a restraint in the first place.

We keep presuming that the patent holder's patent is not valid. In many of these cases, it is. And because of Hatch-Waxman, which I would point out to the committee expressly says doesn't change the laws of patents, because of Hatch-Waxman, someone who may have a very valid, enforceable patent may still settle because they have so much at risk.

Now, Hatch-Waxman has done a lot of good. It has brought generics to the market, and it cured a problem. The problem was that you could not even begin to start the generic process at FDA until after the patent expired; and the evidence was that—and Congressman Waxman pointed this out at the time of the legislation—that it was taking 3 more additional years to get the products to market. Now they come within 2 or 3 months.

But in balancing the interest Hatch-Waxman also balanced the interest of getting someone to innovate and invent. We don't have these drugs in the first place if someone didn't invent them.

Mr. BURGESS. Mr. Whitehouse, would you have a thought if we were looking to improve this situation that we have in front of us going forward, do you have a suggestion for the committee?

Mr. WHITEHOUSE. Yes, Mr. Burgess. We have, in fact, proposed several suggestions that we would like to see changed. They include broadening the carve-outs, basically.

If you are going to proceed down this path of having a prohibition with carve-outs, which we suggest may not be the best way to proceed, but if you are going to go down this path, that you ought to make sure that we can have arrangements for early entry on ge-

neric products other than the one that is the one in suit. That obviously is to the consumer's benefit when you can bring that about. That you be able to negotiate a full release for damages in a covenant not to sue going forward on all the patents on generic products that might be involved in the litigation or in the settlement; that you have a limited exclusive license during the exclusivity period when you come to market, again to preserve the incentives that Hatch-Waxman creates for generic companies; and, as we discussed earlier, that the FTC have case-by-case authority not just rulemaking authority—to exempt settlement provisions other than those specifically provided for in the carve-outs.

Mr. BURGESS. So more flexibility at the level of the FTC?

Mr. WHITEHOUSE. Yes, sir.

Mr. BURGESS. Let me ask you a question. The world is a little bit different place than in 1984 when Hatch-Waxman was first passed. Has it kept pace with the times?

Mr. WHITEHOUSE. Hatch-Waxman, generally, Mr. Burgess, has worked very, very well, we think. It has produced enormous benefits for consumers. It is intricate and complex in the interaction of its parts; and that is exactly why, as I think Mrs. Blackburn also recognized, there is an important need to be careful and not to make changes that have unintended consequences and upset an equilibrium that right now we think is working very, very well to the benefit of consumers, of the Government, of third-party payors and preserving the health of the pharmaceutical companies which are essential to making all those other things happen.

Mr. RUSH. The gentleman's time is up.

Mr. BURGESS. I thank the chairman.

Mr. RUSH. This concludes the testimony of our——

Mr. WHITEHOUSE. Mr. Chairman, may I have your indulgence to make two short points that I will try to take less than a minute to do? I would be grateful if you would. I am sorry for intruding on the committee's time.

I would like to point out that the 70 percent success statistic Mr. Wroblewski referred to refers to a time period between 1992 and 2000, a time period in which patent challenges were very different from those, as my testimony makes clear in some length, had different characteristics and had different probabilities of success for the parties involved. And it is materially harder to win these cases now than it was then.

And, second, it is very important to remember that generic pharmaceutical companies, their stock price isn't going to be helped by taking cash settlement payments in patent cases. They are going to benefit only in the marketplace, from bringing products to market as effectively and as quickly as they can. So their incentives are not to take cash or any other form of consideration in lieu of coming to market. So there is a fundamental assumption we made here that there is some nefarious or unwholesome incentive on the part of these companies and the very nature of these companies makes that improbable.

Thank you very much.

Mr. RUSH. Thank you.

Mr. Wroblewski, did you want to respond for 1 minute?

Mr. WROBLEWSKI. In terms of the 70 percent rate, that is the only statistic that is really out there that shows over a broad, you know, an 8-year period that looked at every case that was out there.

And I think we get somewhat sidetracked when we concentrate on the actual number. As I tried to make the point earlier, and maybe I was unsuccessful, but the number, the success rate isn't really that important. Because if the generic wins, that is good for consumers because it allows a generic to come into the market at competitively priced. If the brand company wins, it validates their investment, which encourages additional innovation; and so that is good, too.

So I think if it were 30 percent, it is neither here nor there. It is the fact that you have put an incentive in there to try to clear out the patents that are invalid. And if they are unsuccessful, then that is fine. You want to validate the brand company's patent rights.

Thank you.

Mr. RUSH. Thank you very much. This concludes the testimony.

I have in my hand an article from the Wall Street Journal dated May 1, 2007, under the title "Patent Holder's Power is Curtailed". I would enter this article into the record with unanimous consent.

I also want to announce that there will be a period of 30 days that the record will be open for parties to insert statements into the record. The witnesses, I will ask that you be prepared to receive written follow-up questions from members of this committee and to respond within the 30-day period of time. Thank you very much.

I want to thank the witnesses for coming and for participating. You certainly have helped this committee tremendously, and thank you so very much for your sacrifices of your time. Thank you so very much.

The subcommittee stands adjourned.

[Whereupon, at 5:20 p.m., the subcommittee was adjourned.]

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