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COMPETITION IN THE PHARMACEUTICAL MARKETPLACE: ANTITRUST IMPLICATIONS OF PATENT SETTLEMENTS

HEARING

BEFORE THE

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THURSDAY, MAY 24, 2001

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 2:07 p.m., in room SD–226, Dirksen Senate Office Building, Hon. Orrin G. Hatch, Chairman of the committee, presiding.

Present: Senators Hatch, Schumer, Cantwell, and Leahy.

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

Chairman HATCH. Good afternoon. I hate to tell you, but I have just gotten through arguing for Ted Olson over on the floor and I have to go back there, then to the tax conference, and I cannot imagine a more important hearing than this one. So, as you can imagine, I am under a lot of pressure, but good afternoon.

Today, we are examining the antitrust implications of recent settlements relating to pharmaceutical patents. As the co-author, along with Henry Waxman, of the Drug Price Competition and Patent Term Restoration Act of 1984, I have long been interested in the laws and competitive forces that underpin the American pharmaceutical industry. If there is interest in revisiting these laws, I am willing to play the same type of facilitator role that I did 17 years ago.

Indeed, there is a good deal at stake here. We want to make available today's medicines at the most competitive and affordable prices, but we also want to provide the necessary incentives to encourage the development of tomorrow's breakthrough drugs. Those are two very important goals and they sometimes seem conflicting.

My preference is to develop a comprehensive consensus legislative package that provides incentives for all segments of the industry to better produce their products that have so many benefits for the American public. We need to find ways to just grow the pie, not just to slice it, or perhaps reslice it would be a better word.

This is, of course, a very tall order that will demand a good deal of bipartisan spirit, hard work, and leadership. I commend Senator Leahy for his work in introducing legislation aimed at helping to promptly identify any possible anti-competitive pharmaceutical patent settlements. I believe there is great merit in his notification approach and would like to work with him on that legislation.

I must also commend our colleagues. Senator Schumer, who has taken a great interest in this area and with whom I enjoy working, has offered legislation with Senator McCain in some of the areas that I have just outlined. And while I would prefer to take a broader and more balanced approach than that reflected in their bill, I want to recognize them for their work. They are the catalysts in bringing this to everybody's attention.

Now, let me focus on the specific issue before the Committee today. The public deserves the effective and affordable drugs that competition can bring, not elaborate legal machinations that identify or create and then exploit anti-competitive loopholes. Some have already concluded that the 1984 law as implemented by the FDA regulation and interpreted by the courts presents a legal framework that invites improper anti-competitive settlements. The 1984 law provides incentives for generic drug applicants to challenge the validity of, or invent around the patents of pioneer drugs. Each time a patent is found to be deficient or can be legally circumnavigated, consumers can benefit from speedier access to generic products.

In order to encourage such pro-consumer activities, the 1984 law awarded 180 days of marketing exclusivity for the first generic firm to meet certain conditions. My friend, Bill Haddad, helped negotiate this provision on behalf of the generic industry. For many years, FDA practice provided that exclusivity be awarded only to the first applicant to file a substantially complete drug application, be sued by the pioneer firm under the special terms of the statute, and win the suit. However, due to the series of Federal court decisions, the successful defense requirement has been struck down.

As the Senate author of the 1984 law, I am afraid, to paraphrase the great philosopher Pogo, this may be a case of "We have met the enemy, and he is me. Mea culpa." Mea culpa, is all I can say. Many have observed that the blocking position that the statute grants to first filers creates perverse incentives for patent settlements. While as a general matter the law smiles upon patent settlements under the joint DOJ–FTC guidelines, not all such patent settlements will automatically survive antitrust scrutiny.

Several recent pharmaceutical patent settlements have triggered antitrust actions. The Committee needs to know if these cases represent a few outliers or a pattern. We will get more information about a major study that the FTC has recently initiated to gauge the frequency and the nature of these settlements. I am more interested in examining the pattern of cases and whether the law needs to be changed than I am in conducting a, "Who struck John?" analysis of the cases that have triggered governmental involvement. I would hope that my colleagues on the Committee will also step back and focus on the forest rather than any particular tree.

While no parties to these settlements are testifying today, in the interest of fairness, I will hold the record open until Friday to allow the Committee to receive their written testimony or the testimony of any other interested parties who may take interest in these proceedings.

In closing, I want to remark again upon the tremendous advances that we are making in scientific research and discovery. I wish each of you could experience the sheer excitement that Dr. Al

Rabson conveys to me when discussing the latest developments in cancer research. Dr. Rabson is one of America's unsung heroes. He has long served as the Deputy Director of the National Cancer Institute and we are fortunate to have had him in government for the past 46 years. Al Rabson tells me that cancers that have been virtually untreatable are now succumbing to medications like the recently announced leukemia drug STI–571, and that, in his 46 years, he has never been so excited.

We are literally at the doorstep of a revolution in biology that promises to benefit mankind in profound ways. With the stakes so high, it is imperative that our intellectual property laws provide the proper incentives to facilitate a new era in our understanding of human biology, health, and disease. At the same time, we must be sure that the pharmaceutical marketplace is highly competitive so that patients and their families can obtain their medicines at the most affordable prices.

These are the challenges before us today, challenges I hope we will be able to meet as the Congress continues consideration of these issues.

[The prepared statement of the Chairman follows:]

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

Good afternoon. I am pleased that the Committee is holding this hearing today on the antitrust implications of recent settlements relating to pharmaceutical patents.

Not only is this a matter squarely within the jurisdiction of the Judiciary Committee, but as a coauthor with Rep. Henry Waxman of the Drug Price Competition and Patent Term Restoration Act of 1984, I have long been interested in the laws and competitive forces that underpin the American pharmaceutical industry. And as I have stated on occasions, if there is interest in revisiting these laws, I am willing to play the same type of facilitator role that I did in 1984.

The American public has a great stake in achieving the twin ends of the 1984 law. These goals are:

- First, making available today's medicines at the most competitive and affordable prices; and,
- Second, encouraging the development of tomorrow's breakthrough cures.

We should all take pride in the fact that the United States is the world's leader in biomedical research. Through a public/private partnership that has grown steadily since World War II, it is our country that is on the cutting edge of medicine. Just this year alone, there has been a combined $50 billion investment in life science research. It is America's scientists and technology that have led the way for the mapping of the human genome. We stand poised to unravel the mysteries of the human genetic code and translate this knowledge to advance the health of public.

A1 Rabson is one of America's unsung heroes. Dr. Rabson has long served as the Deputy Director of the National Cancer Institute. He started his distinguished career at NIH 46 years ago. I wish all of you could experience first hand the sheer excitement that Dr. Rabson conveys to me when discussing the latest developments in cancer research. He tells me that cancers that have been virtually untreatable are now succumbing to medications like the recently announced leukemia drug, STI–571.

We are literally at the doorstep of a revolution in biology that promises to benefit mankind in profound ways. But this progress will not come easily; nor will it come cheaply. When factoring in the costs of false starts and blind alleys, it can take literally several hundred million dollars to bring an effective new drug to market. Some estimate that for every product that makes it through the complex scientific and regulatory screening systems, five thousand failures fall by the wayside—and do so with great expenditures of time, expense, and talent.

When we speak about competition, we must not forget that, in addition to critical price competition between pioneer and generic firms, it is the competition among pioneer firms for the next generation of diagnostic and therapeutic products where the future of medicine resides. But we must never lose sight of the hard fact of life that an unaffordable medication may be the same as no medication at all.

With the stakes so high, it is imperative that our intellectual property laws provide the proper incentives to facilitate a new era in our understanding of human biology, health, and disease. At the same time, we must be sure that the pharmaceutical marketplace is highly competitive so that patients and their families can obtain their medicines at the most affordable prices.

Congress is debating the question of developing a Medicare drug benefit for one simple but powerful reason: too many of our seniors have a hard time making ends meet when paying the out-of-pocket costs of prescription drugs. For those of us who also serve on the Finance Committee, the estimates of providing a Medicare drug benefit have skyrocketed over the last several months. CBO tells us that it may take at least $368 billion over ten years to pay for catastrophic drug coverage alone; and these estimates, in my opinion, will continue to go up.

I mention these staggering costs in part because of the growing therapeutic importance of biological products which can sometimes be very expensive. Therefore I think it is imperative, and frankly inevitable, for policymakers to examine whether there ought to be alternative regulatory pathways for biological products to enter the market once patents have expired.

I know there are formidable scientific questions regarding the wisdom of even beginning down the path of a fast track approval system for equivalent biologics. But, as was evidenced yet again in the mad dash to complete the mapping of the human genome, properly motivated scientists have away of overcoming scientific obstacles. I just raise the question of whether Congress can, or should, enact and sustain over time a Medicare drug benefit in parallel with a FDA regulatory system that acts like a secondary patent by barring bioequivalent biological products. At some point, the forces of economics will compel discussion of science and legal issues involved in the consideration of fast track biologicals.

Also at the intersection of science and law are questions pertaining to the patenting of human genes. We must also examine how much science has changed since 1984 and whether our patent laws facilitate both basic research and appropriate commercial development of genetic discoveries.

I am proud of the Drug Price Competition and Patent Term Restoration Act—CBO estimates that it contributes to consumer savings of $8 to $10 billion annually. We have had a substantial success on both fronts: we have helped stimulate the development of many new drugs all the while fostering an environment in which the generic segment of the market has about tripled and now comprises almost half of all new prescriptions in the United States. Some experts have projected that each additional percentage point of generic drug usage represents over $1 billion in consumer savings.

To those who would propose to change the 1984 legislation, I would urge you to consider that this is a carefully balanced bill and caution against making changes that tilts the balance. Yet no law is so perfect that it cannot stand improvement as it gets tested by the realities of a changing marketplace and society. There have been several unanticipated and unintended consequences of the 1984 Act and other changes in the landscape that need attention.

- In this regard, I believe this Committee should examine in detail the operation of the 30 month stay provision of the 1984 law. Over the last several months, there have been a number of controversial cases of late-issued patents that have been entered into the FDA Orange Book. There are powerful arguments that justify the 30 month statutory period to allow pioneer firms a fair chance to attempt to resolve the status of patents. Yet, there may be grounds to treat patents differently that suddenly appear in the Orange Book so late in the day that there are literally approved generic products on the loading docks that must be destroyed. As well, the 30 month stay provision has an effect on the nature of the patent settlements we explore today although we want to concentrate on the settlements themselves and the 180 day rule at today's hearing.
- Similarly, the Committee should explore the ramifications of the First Amendment and the U.S. Supreme Court's Noerr-Pennington Doctrine as they relate to suggestions to remedy the alleged abuses of the citizens' petition process with respect to challenges to generic drug applications. Sometimes, legitimate questions of science are raised by those who might directly benefit from FDA delay. Maybe the 10 year battle over premarin fits this model.
- There has also been concern that FDA's bioequivalence standards should be examined and that perhaps we should codify the FDA guidelines in this area. Certainly this issue should be fully examined.
- As well, on the R&D side of the industry, there are those who argue for day for day patent term restoration, harmonization of U.S. law with Euro-

pean marketing exclusivity rules, and for changes in the current limitations on the type of patents and products that may receive partial patent term restoration. Frankly, I think the Committee would be well advised to put these issues on the table and learn about their merits and down-sides. I believe it might be a worthwhile inquiry to examine the implications of the fact that the 1999 American Inventors Protection Act generally permits all patents to be restored up to 17 years of patent life if there is undue delay at the PTO but under the 1984 HatchWaxman law, patent term restoration in recognition of the lengthy FDA review of new drugs is capped at 14 years. Why should PTO review time be treated differently than FDA review time?

So there are many areas relating to pharmaceutical development that Congress should examine.

My preference is to see if we can develop a comprehensive consensus legislative package that addresses all of the issues I have just outlined. Such a bill would provide incentives for all segments of the industry to better produce their products that have so many benefits for the American public. We need to find ways to grow the pie, not just re-slice it.

This is, of course, a tall order. It will take a bipartisan spirit, hard work, and leadership to craft legislation that can help usher in the next generation of treatments and do so at more affordable prices.

I commend Senator Leahy for his work in introducing legislation aimed at helping to promptly identify any possibly anti-competitive pharmaceutical patent settlements. These settlements are the subject of our hearing today and I believe there is great merit in his notification approach and would like to work with him on this legislation.

I must also commend our colleague from New York, Sen. Schumer, who with my friend, Sen. McCain, has offered legislation on some of the areas that I just outlined. While I personally would prefer to take a broader and more balanced approach and have some reservations about how they resolve some of the issues, I want to recognize them for their work.

Having said that, I would like to focus in on the important matters before the Committee today. The 1984 provides incentives for generic drug applicants to challenge the validity of, or invent around, the patents of pioneer drugs. Each time a patent is found to be deficient or can be legally circumnavigated, consumers can benefit from speedier access to generic products.

In order to encourage such pro-consumer activities, the 1984 law awarded 180 days of marketing exclusivity for the first generic firm to meet certain conditions. For many years, FDA practice provided that this exclusivity be awarded only to that applicant first to file a substantially complete drug application, be sued by the pioneer firm under the special terms of the statute, and win the suit.

However, due to a series of federal court decisions, that FDA will further explain in its testimony, the successful defense requirement has been struck down. The courts in the Mova and Granutec decisions, strictly construing the language of the law, awarded the exclusivity to the first filer. As a drafter of the 1984 law, I am afraid that, to paraphrase the great philosopher Pogo, this may be a case of "We have met the enemy, and he is me. Mea Culpa. Mea Culpa."

Once the courts struck down the successful defense requirement there has been a potential mismatch of the first filer and the party who actually defeats the patent. Many have observed that the blocking position the statute grants to first filers creates perverse incentives for patent settlements.

As a general matter, the law smiles upon patent settlements. For example, the 1995 joint DOJ–FTC Antitrust Guidelines for the Licensing of Intellectual Property state:

"Settlements involving cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements."

Yet, according to these guidelines not all such patent settlements will automatically survive antitrust scrutiny:

"(w)hen such [settlement] involves horizontal competitors, [the government] will consider whether the effect of the settlement is to diminish competition among entities that would have been actual or likely potential competitors."

As the FTC will explain, several agreements in the last few years have triggered antitrust actions. The Committee needs to know if these cases represent a few outliers or a pattern. The Committee needs to know if the existing antitrust laws are sufficient to police this situation. We need to know if there are ways to improve Sen. Leahy's legislation that is designed to help solve the problem by assisting FTC and DOJ to respond more quickly and effectively in this area.

The FTC will tell us about a major study that they have recently initiated to gauge the frequency and nature of these settlements. This will help the Administration and Congress examine whether there is a pattern of behavior that requires a comprehensive legislative response rather than the current case by case approach.

The public deserves the effective and affordable drugs that competition can bring, not elaborate legal machinations that identify or create then exploit anti-competitive loopholes. Some have already concluded that the 1984 law, as implemented by FDA regulation, and interpreted by the courts, presents a legal framework that invites improper, anti-competitive settlements.

For example, as former FTC official, David Balto, has assessed the situation:

"The competitive concern is that the 180-day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws and the Hatch-Waxman Act by delaying generic entry for a substantial period of time."

In short, the questions we face at today's hearing are straightforward: Is the 180 day exclusivity law broken and, if it is, how should we fix it?

I am pleased that the FTC, DOJ, and FDA will help us start to think through these issues. I am also pleased that Attorney General Mark Shurtleff from my home state of Utah will explain how a group of states have responded to the current environment.

I am more interested in examining the underlying law, pattern of cases, and whether the law needs to be changed than I am in conducting a "Who Struck John" analysis of the cases that have triggered governmental involvement. I would hope that my colleagues on the Committee will also step back and focus on the forest rather than the trees.

While no parties to these settlements—either pioneer or generic firms—requested to testify today, I understand there may well be interest in how these agreements may be characterized. Without objection, I will hold the record open until next Friday to allow the Committee to receive comments from all parties interested in today's hearing.

I look forward to learning from the testimony we will receive today.

Chairman HATCH. Senator Leahy is not here. Would you care to represent the Democrats on the committee?

Senator SCHUMER. Thank you, Mr. Chairman.

Chairman HATCH. I need to say Democrats, not minority, anymore.

Senator SCHUMER. We still are, for the last few hours.

Chairman HATCH. Well, we wish you well when you take over.

Senator SCHUMER. Thank you. Thank you. And seriously, you have always been fair in the majority——

Chairman HATCH. Thank you.

Senator SCHUMER.—and we will try to be just as fair.

Chairman HATCH. Thank you.

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

Senator SCHUMER. This is not Senator Leahy's statement, this is my own. I have been very interested in this issue, but I do want to commend him for his leadership. He is on the floor right now dealing with another issue that has been before this committee, the nomination of three Justice Department appointees.

But Mr. Chairman, I want to first thank you for holding this hearing, and more importantly, for your longtime dedication to the important issue of pharmaceutical competition. Because of Senator Hatch's leadership, consumers have saved billions of dollars on pharmaceuticals in the two decades since the Hatch-Waxman Act was enacted, and you are, as I told you privately, Mr. Chairman, I think this is one of the most important pieces of legislation that this Congress has passed in the last 20 years and you should be awfully proud to have your name attached to it.

Chairman HATCH. Thank you.

Senator SCHUMER. Hatch-Waxman, as we know, reformed patent laws and created a blueprint that provided additional patent protection for research-based brand name drugs in conjunction with a timetable to allow less-expensive generic equivalents on the market. The law did two things. It preserved intellectual property rights for the pharmaceutical companies that have put lots of effort and produced wonder drugs that keep people alive, but at the same time, it created competition after that reward for the intellectual property was granted and it saved consumers billions of dollars, still allowing brand name companies to stay profitable and innovative. It was an exquisite balance that worked.

Unfortunately, the balance has been thrown out of whack in recent years. The large pharmaceutical companies basically have been playing by their own rules. As the stakes and profits have become higher, lawyers for that industry have picked the Hatch-Waxman law clean. Again, I believe in intellectual property, but we came up with a formulation, and to now extend patent after patent after patent when that was never envisioned in the Hatch-Waxman law for the reasons that they were is the reason that we are here today and is the reason that we need real reform once again.

The Drug Competition Act that Senator Leahy has introduced, and which I am proud to cosponsor, is an important first step in ensuring the full potential of the Hatch-Waxman Act. It would provide the very cornerstone to ensuring fair competition in the pharmaceutical marketplace. Too often, the agreements between pharmaceutical companies are brokered with an anti-competitive spirit. In requiring these agreements to be disclosed to the FTC and DOJ, the legislation ensures anti-competitive efforts on the part of these companies, both generic and brand name, are identified and resolved quickly so that consumers do not suffer unjustly. I find these agreements outrageous. I am even more angry at the generic companies that do them than the pharmaceutical companies because they are basically selling their birthright for a few silver coins and it is just awful.

But, Mr. Chairman, we have to do more than close just the loopholes which allow the pharmaceuticals to too easily enter into agreements that are not in the best interests of consumers. Dovetailing with Senator Leahy's efforts, Senator McCain and I reintroduced a bill last month called the GAAP Act, the Greater Access to Affordable Pharmaceutical Act. Our bill seeks to breathe new life into the Hatch-Waxman law, not by redrawing ideological battle lines—that is for a different day and time—but by restoring the intent of our patent laws. In doing so, it will save consumers $71 billion over the next 10 years on their drug costs.

Our intention is not to cut innovators off at the knees. We want to protect their rights. Our bill is not a freebie for the generic drug industry, either. It only makes the approval process fair and brings lower-cost alternatives to the market. The bill would eliminate the 30-month stay automatically handed to brand companies who file suit against a generic challenger, regardless of the merits of the case. Another 30 months, way out of line from what you, good sir, intended, simply by filing a case. What could be more abusive and

outrageous than that? Whether the case has merits should be determined in the courts before any 30-month extension is granted.

The GAAP Act also strengthens the citizen petition process, intended to allow average people to express concern over a drug, which has become a back door way for pharmaceutical companies, both brand name and generic, to delay a competitor's entry in the market. Today, the test to prove that a generic drug is truly bioequivalent to the original drug is a contest of exploiting loopholes in Hatch-Waxman to ensure that the generic never sees the light of day, a total 180-degree turn from what was intended in the law.

The GAAP Act reforms the so-called 180-day rule by closing the loophole that enables a brand name company to pay a generic manufacturer to stay off the market. We do not just ask for disclosure. We prohibit these nefarious type agreements. Closing the loophole would prevent problems like the cases we are discussing here today, the Hytrin case, where Abbott Laboratories paid Geneva Pharmaceuticals $4.5 million a month to keep their hypertension drug off the market, or the recent KDur 20 case, where Schering-Plough allegedly paid Upsher-Smith and American Home Products millions of dollars to delay launching a generic potassium chloride supplement. Again, these are outrageous.

Now, I know some of the brand name large pharmaceutical companies say, well, we have no choice, because sometimes there are injustices done at the other end. In other words, it takes too long for the drug to come on the market. I have no problem with correcting those abuses, but one abuse—those are really not abuses, but those injustices, if you want to elevate it to probably a higher level than I would, given the level of profitability of the industry, but these wrongs should be corrected. I am open to correcting them, but not in the ad hoc way that they are done in the way that people file petitions and things like that, and they do them for drugs whether they have been on the market 2 years, 4 years, 10 years, 8 years, 12 years. One has nothing to do with the other in the specific case of each drug.

So, Mr. Chairman, as Congress wrestles with the complexity of crafting and paying for a Medicare prescription drug benefit, we must not overlook a straightforward solution to escalating drug prices facing seniors, businesses, insurers, and consumers. If we can ensure fair competition in the pharmaceutical marketplace, a level playing field for both brand and generic companies, everyone will win. For the consumer, cheaper drugs. The generics can be out and the pharmaceuticals' attempts at price controls and other type of non-economic behavior will not have as much pointed weight.

So I thank you, Mr. Chairman, for holding this important hearing and look forward to working with you, Senator Leahy, and with the FDA and the FTC to encourage fair marketplace practices while preserving both safety and intellectual property rights to provide customers with affordable pharmaceutical alternatives.

Chairman HATCH. Thank you, Senator.

Let me introduce today's witnesses. First, we will hear from Mr. Gary Buehler, the Acting Director of FDA's Office of Generic Drugs. Mr. Buehler will describe some of the key statutory and regulatory provisions that have colored the patent settlements under discussion today.

Next, we will get the perspective of the Federal Trade Commission, the lead Federal agency in antitrust enforcement for the pharmaceutical industry. Ms. Molly Boast is the Director of the Bureau of Competition. We are surely glad to have both of you with us today. Ms. Boast will tell us about some recent pharmaceutical patent settlement cases and a major survey into the industry's practices.

To fill out the first panel, we have Mr. James Griffin, Deputy Assistant Attorney General for the Antitrust Division at the Department of Justice. He will explain how the Department of Justice and FTC divide the responsibility for antitrust enforcement and how the Department retains the sole authority for any criminal matters in the antitrust area.

Now, without objection, I think we can expedite today's hearing by collapsing the witnesses into one panel. We have only one witness on the second panel, Attorney General Mark Shurtleff from my home State of Utah. Attorney General Shurtleff will tell us what the States are doing in the area of pharmaceutical patent settlement. So if we could get you to take your seat there, as well, General Shurtleff.

If you could, please confine your oral testimony to 5 minutes. I know this is pretty complex stuff. If you need more time, I have always been courteous about that. You will be able to place your complete remarks in the record, but if you could try and keep it to 5 minutes, it will help us, and especially me today since I have so much pressure to do these other things. I have just been told I have to be at leadership meeting at four o'clock, as well.

Because of the interest in this hearing, I think we should hold the record open for 1 week so that interested parties will have a chance to provide their views, and although no company involved in these settlements asked to testify today and I do not plan to parse each paragraph of these settlements, they may have some useful perspectives on these issues. Certainly, consumer groups and purchasers of drugs will have views, too, so we are hopeful that we will hear from all of you.

We will turn to you first, Mr. Buehler, and take your testimony, and then we will just go across the table.

STATEMENT OF GARY BUEHLER, R.PH., ACTING DIRECTOR FOR GENERIC DRUGS, FOOD AND DRUG ADMINISTRATION, WASHINGTON, D.C.

Mr. BUEHLER. Thank you, Mr. Chairman. Mr. Chairman and members of the committee, my name is Gary Buehler. I am a registered pharmacist and Acting Director of the Office of Generic Drugs at FDA. I am here today to discuss FDA's implementation of the exclusivity provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, the Hatch-Waxman amendments, which govern the generic drug approval process.

These amendments are intended to balance two important public policy goals. First, drug manufacturers need meaningful market protection incentives to encourage the development of valuable new drugs. Second, once the statutory patent protection and market exclusivity for these new drugs has expired, the public benefits from

the rapid availability of lower-price generic versions of the innovator drug.

The FD&C Act requires that an ANDA contain a certification for each patent listed in the Orange Book for the innovator drug. The certification relevant to exclusivity is a Paragraph IV certification that states that such patent is invalid or will not be infringed by the generic drug for which approval is being sought. If the NDA sponsor or patent owner files a patent infringement suit against the ANDA applicant within 45 days of the receipt of notice, FDA may not give final approval to the ANDA for at least 30 months from the date of notice. This 30-month stay will apply unless the court reaches a decision earlier in the patent infringement case or otherwise orders a longer or shorter period for the stay.

The statute provides an incentive of 180 days of market exclusivity to the first generic applicant who challenges a listed patent by filing a Paragraph IV certification and running the risk of having to defend a patent infringement suit. The 180-day period of exclusivity will begin either from the date the generic applicant begins commercial marketing or from the date of a court decision finding the patent invalid, unenforceable, or not infringed, whichever is first. These two events, first commercial marketing and a court decision favorable to the generic, are often called triggering events, because under the statute, they can trigger the beginning of the 180-day exclusivity period.

Approval of an ANDA does not trigger exclusivity. Until an eligible ANDA applicant's 180-day exclusivity period has expired, FDA cannot approve subsequently submitted ANDAs for the same drug, even if the latter ANDAs are otherwise ready for approval and the sponsors are willing to immediately begin marketing. Therefore, an ANDA applicant who is eligible for exclusivity is often in the position to delay all generic competition for that innovator product.

The 180-day exclusivity provision has been the subject of considerable litigation and administrative review in recent years as the courts, industry, and the FDA have sought to interpret it in a way that is consistent both with the statutory text and with the legislative goals underlying the Hatch-Waxman amendments. In light of the court decisions finding certain FDA regulations inconsistent with the statute, the agency proposed new regulations in August 1999 to implement the 180-day exclusivity. Since then, many comments have been submitted and there have been additional court decisions further interpreting the statute and complicating the regulatory landscape.

The agency has not yet published a final rule on 180-day exclusivity. As described in the June 1998 guidance for industry, until new regulations are in place, FDA is addressing on a case-by-case basis those 180-day exclusivity issues not addressed by the existing regulations.

One of the most fundamental program changes is the determination by the courts that a district court decision favorable to the generic applicant will trigger the 180-day exclusivity period. This interpretation means that if 180-day exclusivity is triggered by a decision favorable to the ANDA applicant in the district court, the ANDA sponsor who wishes to market during that exclusivity period now may run the risk of treble damages if the district court deci-

sion is reversed on appeal to the Federal circuit. As a practical matter, it means that many generic applicants may choose not to market the generic and, thus, the 180-day exclusivity period could run during the pendency of an appeal.

FDA continues to implement the Hatch-Waxman amendments' exclusivity provisions in the best manner possible, given the text of the legislation, the history of the legislation, and the numerous court challenges. FDA has tried to balance innovation and drug development and expediting the approval of lower-cost generic drugs.

Thank you, Mr. Chairman. I would be pleased to answer any questions if I can.

Chairman HATCH. Thank you, Mr. Buehler.

[The prepared statement of Mr. Buehler follows:]

STATEMENT OF GARY BUEHLER, RPH, ACTING DIRECTOR, OFFICE OF GENERIC DRUGS, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Gary Buehler, RPh, Acting Director of the Office of Generic Drugs in the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA or Agency). I am here today to discuss FDA's implementation of provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (HatchWaxman Amendments) which govern the generic drug approval process. These provisions give 180 days of marketing exclusivity to certain generic drug applicants. The 180-day generic drug exclusivity provision is one component of the complex patent listing and certification process, which also provides for a 30-month stay on generic drug approvals while certain patent infringement issues are litigated.

The Hatch-Waxman amendments are intended to balance two important public policy goals. First, drug manufacturers need meaningful market protection incentives to encourage the development of valuable new drugs. Second, once the statutory patent protection and marketing exclusivity for these new drugs has expired, the public benefits from the rapid availability of lower priced generic versions of the innovator drug.

STATUTORY PROVISIONS

The Hatch-Waxman Amendments amended the Federal Food, Drug, and Cosmetic (FD&C) Act and created section 5050). Section 5050) established the abbreviated new drug application (ANDA) approval process, which permits generic versions of previously approved innovator drugs to be approved without submission of a full new drug application (NDA). An ANDA refers to a previously approved new drug application (the "listed drug") and relies upon the Agency's finding of safety and effectiveness for that drug product.

The timing of an ANDA approval depends in part on patent protections for the innovator drug. Innovator drug applicants must include in an NDA information about patents for the drug product that is the subject of the NDA. FDA publishes patent information on approved drug products in the Agency's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the. Orange Book) (described in more detail below). The FD&C Act requires that an ANDA contain a certification for each patent listed in the Orange Book for the innovator drug. This certification must state one of the following:

(I) that the required patent information relating to such patent has not been filed;
(II) that such patent has expired;
(III) that the patent will expire on a particular date; or
(IV) that such patent is invalid or will not be infringed by the drug, for which approval is being sought.

A certification under paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under paragraph III indicates that the ANDA may be approved on the patent expiration date.

A paragraph IV certification begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may

be answered by the courts prior to the expiration of the patent. The ANDA applicant who files a paragraph IV certification to a listed patent must notify the patent owner and the NDA holder for the listed drug that it has filed an ANDA containing a patent challenge. The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. The submission of an ANDA for a drug product claimed in a patent is an infringing act if the generic product is intended to be marketed before expiration of the patent, and therefore, the ANDA applicant who submits an application containing a paragraph IV certification may be sued for patent infringement. If the NDA sponsor or patent owner files a patent infringement suit against the ANDA applicant within 45 days of the receipt of notice, FDA may not give final approval to the ANDA for at least 30 months from the date of the notice. This 30-month stay will apply unless the court reaches a decision earlier in the patent infringement case or otherwise orders a longer or shorter period for the stay.

The statute provides an incentive of 180 days of market exclusivity to the "first" generic applicant who challenges a listed patent by filing a paragraph IV certification and running the risk of having to defend a patent infringement suit. The statute provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent invalid, unenforceable or not infringed, whichever is first. These two events—first commercial marketing and a court decision favorable to the generic—are often called "triggering" events, because under the statute they can trigger the beginning of the 180-day exclusivity period.

In some circumstances, an applicant who obtains 180-day exclusivity may be the sole marketer of a generic competitor to the innovator product for 180 days. But 180-day exclusivity can begin to run—with a court decision—even before an applicant has received approval for its ANDA. In that case, some, or all, of the 180-day period could expire without the ANDA applicant marketing its generic drug. Conversely, if there is no court decision and the first applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period. Approval of an ANDA has no effect on exclusivity, except if the sponsor begins to market the approved generic drug. Until an eligible ANDA applicant's 180-day exclusivity period has expired, FDA cannot approve subsequently submitted ANDAs for the same drug, even if the later ANDAs are otherwise ready for approval and the sponsors are willing to immediately begin marketing. Therefore, an ANDA applicant who is eligible for exclusivity is often in the position to delay all generic competition for the innovator product.

Only an application containing a paragraph IV certification may be eligible for exclusivity. If an applicant changes from a paragraph IV certification to a paragraph III certification, for example upon losing its patent infringement litigation, the ANDA will no longer be eligible for exclusivity.

COURT DECISIONS AND FDA ACTIONS

This 180-day exclusivity provision has been the subject of considerable litigation and administrative review in recent years, as the courts, industry, and FDA have sought to interpret it in a way that is consistent both with the statutory text and with the legislative goals underlying the Hatch-Waxman Amendments. A series of Federal court decisions beginning with the 1998 Mova [1] case describe acceptable interpretations of the 180-day exclusivity provision, identify potential problems in implementing the statute, and establish certain principles to be used by the Agency in interpreting the statute.

In light of the court decisions finding certain FDA regulations inconsistent with the statute, the Agency proposed new regulations in August 1999 to implement the 180-day exclusivity. Since then many comments have been submitted and there have been additional court decisions further interpreting the 180-day exclusivity provision and complicating the regulatory landscape. The Agency has not yet published a final rule on 180-day exclusivity. As described in a June 1998 guidance for industry, until new regulations are in place, FDA is addressing on a case-by-case basis those 180-day exclusivity issues not addressed by the existing regulations.

One of the most fundamental changes to the 180-day exclusivity program that has resulted from the legal challenges to FDA's regulations is the determination by the courts of the meaning of the phrase "court decision." The courts have determined

[1] *Mova Pharmaceutical Corp.* v. *Shalala*, 140 F.3d 1060, 1065 (D.C. Cir. 1998).

that the "court decision" that can begin the running of the 180-day exclusivity period may be the decision of the district court, if it finds that the patent at issue is invalid, unenforceable, or will not be infringed by the generic drug product. FDA had interpreted the "court decision" that could begin the running of 180-day exclusivity (and the approval of the ANDA) as the final decision of a court from which no appeal can be or has been taken—generally a decision of the Federal Circuit. FDA's interpretation had meant that an ANDA applicant could wait until the appeals court had finally resolved the patent infringement or validity question before beginning the marketing of the generic drug. FDA had taken this position so that the generic manufacturer would not have to run the risk of being subject to potential treble damages for marketing the drug, if the appeals court ruled in favor of the patent holder. The current interpretation means that if the 180-day exclusivity is triggered by a decision favorable to the ANDA applicant in the district court, the ANDA sponsor who wishes to market during that exclusivity period now may run the risk of treble damages if the district court decision is reversed on appeal to the Federal Circuit. As a practical matter, it means that many generic applicants may choose not to market the generic and thus the 180-day exclusivity period could run during the pendency of an appeal.

In one of the cases rejecting FDA's interpretation of the "court decision" language in the statute, the court determined that the applicant who relied in good faith on FDA's interpretation of the 180-day exclusivity provision should not be punished by losing its exclusivity. The court, therefore, refused to order FDA to begin the running of 180-day exclusivity upon the decision of the district court in the patent litigation at issue. FDA has taken a similar approach in implementing the courts' decisions: the new "court decision" definition will apply only for those drugs for which the first ANDA was submitted subsequent to March 30, 2000. In adopting this course, a primary concern for the Agency was to identify an approach that would minimize further disruption and provide regulated industry with reasonable guidance for making future business decisions.

To advise the public and industry of this position, FDA published a Guidance for Industry in March 2000. FDA intends to incorporate the courts' interpretation of the "court decision" trigger for 180-day exclusivity into the final rule implementing the changes in 180-day exclusivity.

ORANGE BOOK LISTINGS

There have been concerns expressed over FDA's role in the listing of patents in the Orange Book which can have an impact on generic drug approvals by delaying approval and 180-day exclusivity. Under the FD&C Act, pharmaceutical companies seeking to market innovator drugs must submit, as part of an NDA or supplement, information on any patent that 1) claims the pending or approved drug or a method of using the approved drug, and 2) for which a claim of patent infringement could reasonably be asserted against an unauthorized party. Patents that may be submitted are drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method of use patents. Process (or manufacturing) patents may not be submitted to FDA.

When an NDA applicant submits a patent covering the formulation, composition, or method of using an approved drug, the applicant must also submit a signed declaration stating that the patent covers the formulation, composition, or use of the approved product. The required text of the declaration is described in FDA's regulations. FDA publishes patent information on approved drug products in the Orange Book.

The process of patent certification, notice to the NDA holder and patent owner, a 45-day waiting period, possible patent infringement litigation and the statutory 30-month stay mean there is the possibility of a considerable delay in the approval of ANDAs as a result of new patent listings. Therefore, these listings are often closely scrutinized by ANDA applicants. FDA regulations provide that, in the event of a dispute as to the accuracy or relevance of patent information submitted to and subsequently listed by FDA, an ANDA applicant must provide written notification of the grounds for dispute to the Agency. FDA then requests the NDA holder to confirm the correctness of the patent information and listing. Unless the patent information is withdrawn or amended by the NDA holder, FDA will not change the patent information listed in the Orange Book. If a patent is listed in the Orange Book, an applicant seeking approval for an ANDA must submit a certification to the patent. Even an applicant whose ANDA is pending when additional patents are submitted by the sponsor must certify to the new patents, unless the additional patents are submitted by the patent holder more than 30 days after issuance by the U.S. Patent and Trademark Office.

FDA does not undertake an independent review of the patents submitted by the NDA sponsor. FDA does not assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug. FDA has implemented the statutory patent listing provisions by informing interested parties what patent information is to be submitted, who must submit the information, and when and where to submit the information. As the Agency has stated, since the implementation of the 1984 HatchWaxman Amendments began, FDA has no expertise or resources with which to resolve complex questions of patent coverage, and thus the Agency's role in the patent-listing process is ministerial. The statute requires FDA to publish patent information upon approval of the NDA. The Agency relies on the NDA holder or patent owner's signed declaration stating that the patent covers an approved drug product's formulation, composition or use. Generic and innovator firms may resolve any disputes concerning patents in private litigation. As noted above, if the generic applicant files a paragraph IV certification and is sued for patent infringement within 45 days, there is an automatic stay of 30 months, substantially delaying the approval of the generic drug and, thus, the availability of lower cost generic drug products.

CONCLUSION

FDA continues to implement the Hatch-Waxman Amendments exclusivity provisions in the best manner possible given the text of the legislation, the history of the legislation and the numerous court challenges. Again, as previously noted, FDA has tried to balance innovation in drug development and expediting the approval of lower-cost generic drugs.

Chairman HATCH. Ms. Boast, we will turn to you now.

STATEMENT OF MOLLY BOAST, DIRECTOR, BUREAU OF COMPETITION, FEDERAL TRADE COMMISSION, WASHINGTON, D.C.

Ms. BOAST. Thank you, Mr. Chairman and members of the committee. It is a true privilege for me to be able to participate in this hearing today on a topic that I think is fundamentally important, the ready availability of pharmaceutical products at competitive prices.

The Commission has been very active in the pharmaceutical area generally, and in particular in considering the relationship between pioneer and generic drug manufacturers as their relationship has evolved under the Hatch-Waxman Act. And, frankly, speaking for myself, since I am here as the Director of the Bureau of Competition, not as a spokesman for the Commission itself, I think this is among the Commission's most important work. We know that generic products, once they are introduced to the marketplace, tend to bring prices down in the range of 20 to 50 percent within a very few months. It is quite a dramatic change. I would estimate that over the last 2 years, approximately 25 percent of the resources of the Bureau of Competition have been devoted to the pharmaceutical industry. So you are able to see the high degree of importance we assign to this.

My comments here are going to highlight the three recent enforcement actions the Commission has taken challenging settlement agreements between branded and generic drug manufacturers.

Chairman HATCH. Did you say 25 percent of your time is spent on——

Ms. BOAST. Twenty-five percent of the Bureau of Competition's resources have gone——

Chairman HATCH. Is that right?

Ms. BOAST. This is an estimate, Mr. Chairman, to the pharmaceutical industry generally. That includes——

Chairman HATCH. The important thing, I am just showing how important this is, though.

Ms. BOAST. It is very important.

Chairman HATCH. Even I am amazed.

Ms. BOAST. It includes our merger enforcement work in this industry, as well.

Chairman HATCH. Sure. Sorry to interrupt you. I apologize.

Ms. BOAST. I am always happy when I capture someone's attention with that kind of information.

[Laughter.]

Chairman HATCH. I know I look tired, but I am not that tired.

[Laughter.]

Ms. BOAST. Let me briefly try to summarize what the Commission's recent enforcement actions challenging these settlement agreements between branded manufacturers and generic firms are about, and then talk very briefly about the Commission's Section 6(b) study.

The Commission's enforcement initiatives address settlement agreements reached between the branded and generic firms in the context of the patent litigation that is spurred by the Hatch-Waxman Act. Now, I agree with both Chairman Hatch and Senator Schumer's characterization of Hatch-Waxman. This was a remarkable creation, an effort to bridge our interest in encouraging innovation through protection of intellectual property rights and our interest in competition introduced through generic entry.

But as Mr. Buehler has described, Hatch-Waxman provides a mechanism pursuant to which the generic firm can certify to the branded manufacturer that its proposed product does not infringe the pioneer's patent or that the patent is invalid, and this often triggers patent litigation between the two firms.

Settlements have been reached in this context, and it is not the fact that settlements have taken place that is our concern. Rather, the Commission has become concerned that there are incentives created quite inadvertently under Hatch-Waxman that have led to settlements on anti-competitive terms. The agreements in question share two things in common.

First, the Commission has alleged in each of these three cases that payments have been made by the branded manufacturer who has a strong incentive to discourage generic entry to the generic firm to delay the date of entry, rather than letting litigation resolve the question of the patent validity, which would, if resolved favorably in the generic's favor, trigger the 180-day exclusivity and begin the process of generic entry, and rather than allowing the generic to come to market on the date at which it might absent the payment.

The second feature that links these cases is a provision, or variations of a provision, that preclude entry with non-infringing products, that is, products entirely outside the scope of the patent litigation in which the settlement takes place. In light of these provisions, in all three cases, the Commission has found reason to believe that the arrangements constitute unreasonable restraints of trade.

To give you a sense of the magnitude of the potential harm, we can take an example such as was involved in the Commission's case against Hoechst and Andrx. The product there was called Cardizem CD. This is a product that is used to treat angina and other heart-related disease. It is very widely prescribed. In 1998, Cardizem CD enjoyed sales of $700 million in 1 year alone, and over 12 million prescriptions were written. So you can see that if you allow generic entry and this substantial price decrease I described earlier, the benefits to consumers are quite substantial.

Let me turn quickly with my remaining time to the Commission's 6(b) study which is underway. This study was undertaken by the Commission in its unique role as an advisor to Congress and specifically at the request of Representative Waxman, who is interested in using the study vehicle to determine whether the problems we have identified in the Commission's recent cases are prevalent or just isolated and whether there are other features of the statutory and regulatory framework that need to be addressed.

The study will shed light on issues such as how pervasive are these agreements? How do the exclusivity provisions operate to affect the incentives of the generic firms? Is the Orange Book listing process being abused? Are the stay provisions of Hatch-Waxman being abused? And how frequently is the citizen petition process being used to delay entry? I hope it will make a substantial contribution to this committee's work and to the work of Congress in general.

I would be very happy to answer any questions, Mr. Chairman, and I look forward to the Commission's further work with you.

Chairman HATCH. Thank you, Ms. Boast. When do you project that your survey will be completed, the data analyzed and distributed to the Congress and the public?

Ms. BOAST. The responses are due from the firms next month and it is our hope that the report will be given to Congress by the end of the year, end of the calendar year.

Chairman HATCH. Can we have some advance things?

Ms. BOAST. I would need to confer with my colleagues about that, but——

Chairman HATCH. Some of us might want to know as much as we can in advance of the end of the year distribution.

Ms. BOAST. I am unaware of what legal constraints might exist——

Chairman HATCH. I understand.

Ms. BOAST.—but I certainly have no principled objection to some consultative process, if that is——

Chairman HATCH. If we could, I would like to be kept up to speed because we do need to do some things in this area and I would like to do them right.

Ms. BOAST. I completely agree.

Chairman HATCH. Thank you.

[The prepared statement of Ms. Boast follows:]

STATEMENT OF MOLLY BOAST, DIRECTOR, BUREAU OF COMPETITION, FEDERAL TRADE COMMISSION, WASHINGTON, DC

Mr. Chairman and Members of the Senate Judiciary Committee, I am Molly Boast, Director of the Federal Trade Commission's Bureau of Competition. I am pleased to appear before you to present the Federal Trade Commission's ("Commis-

sion" or "FTC") testimony on our activities involving the pharmaceutical industry in general and patent settlement cases in particular.[1] The benefits to consumers from generic competition are dramatic. A Congressional Budget Office ("CBO") report estimates that consumers saved $8 billion to $10 billion on prescription drugs at retail pharmacies in 1994 by purchasing generic drugs instead of brand name products.[2] The CBO also noted that the 1984 Hatch-Waxman Act had "greatly increased the number of drugs that experience generic competition and, thus, contributed to an increase in the supply of generic drugs."[3]

The surging cost of prescription drugs is a pressing national issue. Recent reports suggest expenditures for retail outpatient prescription drugs rose in the year 2000 to $131.9 billion, an 18.8% increase from the previous year.[4] This dramatic increase has helped focus attention on the need to ensure competition in pharmaceutical markets. The Commission is encouraged that Congress, and particularly the members of this Committee, have shown a strong interest in this issue, both in Chairman Hatch's decision to convene this hearing and in recent bills introduced by Senators Leahy, Schumer, Kohl, Durbin and McCain, among others.[5]

The Commission has gained substantial recent experience concerning competition in the pharmaceutical industry from its antitrust enforcement activities affecting both the branded and generic drug industries.[6] In 1999, the staff of the FTC's Bureau of Economics released a report on competition issues in the pharmaceutical industry.[7] In addition, the Commission's staff has submitted comments over the past two years in connection with the Food and Drug Administration's ("FDA") regulation of generic drugs,[8] and has recently filed a Citizen Petition with the FDA seeking clarification of certain issues relating to patent listings with the FDA.[9]

The Commission's recent activity includes three challenges to alleged anticompetitive agreements between pioneer pharmaceutical manufacturers and generic manufacturers. These actions address agreements reached in the context of the 1984 Hatch-Waxman Act. The Act was crafted to balance the legitimate but different interests of the pioneer and generic manufacturers. Recently, however, the Commission has observed conduct suggesting that some firms may be exploiting the statutory and regulatory scheme by reaching agreements to delay the introduction of ge-

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[1] The views expressed in this statement reflect the views of the Commission. My oral statement and responses to questions are my own and are not necessarily those of the Commission or any individual Commissioner.

[2] Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical lndustry (July 1998) <http://www.cbo.gov>.

[3] 3 Id

[4] See National Institute for Health Care Management Research and Educational Foundation, "Prescription Drug Expenditures in 2000: The Upward Trend Continues" at 2 (May 2001) (available at www.nihcm.org).

[5] See S. 754, "Drug Competition Act of 2001," introduced by Senators Leahy, Kohl, Schumer, and Durbin; S. 812, "Greater Access to Affordable Pharmaceuticals Act of 2001," introduced by Senators Schumer and McCain.

[6] E.g., *Federal Trade Commission* v. *Mylan Laboratories, Inc. et al.*, 1999–2 Trade Cas. (CCH) ¶72,573 (D.D.C. 1999); Roche Holding Ltd, C–3809 (February 25, 1998) (consent order); CibaGeigy, Ltd, 123 F.T.C. 842 (1997) (consent order); Hoechst AG, 120 F.T.C. 1010 (1995) (consent order). For a discussion of recent FTC pharmaceutical enforcement actions, see FTC Antitrust Actions Involving Pharmaceutical Services and Products, <http://www.ftc.gov/bc/rxupdate>; see also David A. Balto & James Mongoven, Antitrust Enforcement in Pharmaceutical Industry Mergers, 54 Food & Drug Law Journal 255 (1999).

[7] Staff of the Federal Trade Commission, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change" (March 1999) <http://www.ftc.gov/reports/phannaceutical/drugexsum.htm>. The report reviews significant informational, institutional, and structural changes that have influenced price and non-price competition strategies of brand-name pharmaceutical companies, particularly during the last 15 years. The study considers the possible antitrust implications of these changes by examining alternative anticompetitive and procompetitive explanations for the pricing, vertical contracting, and vertical and horizontal consolidation strategies that have emerged in this environment of change.

[8] Comment of the Federal Trade Commission Staff, In the Matter of Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action, Docket No. 99N–2497 (Mar. 2, 2000), <http://www.ftc.gov/be/vOO0005.pdf>; Comment of the Federal Trade Commission Star, In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, Docket No. 85N–0214 (Nov. 4, 1999), <http://www.ftc.gov/be/v990016.htm>.

[9] The Bureau of Competition and Policy Planning Staff of the Federal Trade Commission's Citizen Petition to the Commissioner of Food and Drugs pursuant to 21 C.F.R. §§ 10.25(a) and 10.30 concerning certain issues relating to patent listings in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") and requesting that the FDA clarify these issues via industry guidance or other means that the FDA considers appropriate (May 16, 2001).

neric drugs to the market. Pioneer firms have strong incentives to delay generic entry.

Delaying or preventing the generic entry that Hatch-Waxman seeks to promote could preserve millions of dollars of ongoing profits for pioneer drug companies. The typical steep price decline upon generic entry results in an enormous drop in market share and profits for the pioneer firm. The Commission has reason to believe the agreements it has challenged were designed to forestall that result.

The complexity of the strategies prompted by the operation of the Hatch-Waxman Act and the regulatory framework for introducing new drugs to the market cannot be fully comprehended through any particular enforcement action. Accordingly, the Commission is undertaking a study, pursuant to its authority under Section 6(b) of the FTC Act, of pharmaceutical industry practices relating to the Hatch-Waxman Act. The study will examine:

- the extent to which agreements between brand-name pharmaceutical manufacturers and generic drug firms may have delayed generic competition;
- the operation of provisions in the Hatch-Waxman Act that award a 180-day period of market exclusivity to a generic firm;
- the impact of provisions in the Act on the listing of patents by brand-name pharmaceutical companies in the FDA "Orange Book," and of provisions that trigger a stay on FDA approval of a proposed generic drug; and
- the use of the FDA's Citizen Petition process by brand-name drug companies to oppose potential generic entrants.

The Commission hopes that this study will provide valuable information to Congress as it considers possible reform of the Hatch-Waxman Act.

This testimony provides an overview of the significance of generic drugs in the pharmaceutical industry and a brief description of the statutory and regulatory schemes governing generic drugs, and then turns to a discussion of recent FTC enforcement actions challenging settlement agreements between certain branded pharmaceutical manufacturers and their generic competitors. The testimony also briefly describes the generic drug study currently underway at the agency.

I. BACKGROUND

A. SIGNIFICANCE OF GENERIC DRUGS

Generic drugs contain active ingredients that are the same as their branded counterparts, but typically are sold at substantial discounts from the branded price. Generic drugs account for approximately 40% of all prescriptions, but for only about 9% of total prescription drug expenditures.[10] The first generic manufacturer to enter a market typically charges 70% to 80% of the brand manufacturer's price. As additional generic versions of the same drug enter the market, the price continues to drop, sometimes decreasing to a level of 50% or less of the brand price.[11]

Within the next 5 years, patents on brand-name drugs with combined U.S. sales approaching $20 billion will expire.[12] This provides an enormous opportunity for the generic drug industry. Presumably the brand-name industry views the situation in quite the opposite way. The successful entry of generic versions of these drugs should affect dramatically the amount consumers pay for the drugs they need.

B. STATUTORY AND REGULATORY SCHEME

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, known as the HatchWaxman Act,[13] to accomplish a delicate balancing of two policy goals:[14] (1) to facilitate and encourage the introduction of generic drugs,

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[10] See National Institute for Health Care Management Research and Educational Foundation, "Prescription Drug Expenditures in 2000: The Upward Trend Continues" at 2 (May 2001).

[11] Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (July 1998), <http://www.cbo.gov>.

[12] 12 Id at 3. See also Amy Barrett, "Crunch Time in Pill Land," Business Week 52 (Nov. 22, 1999).

[13] Pub. L. No. 98–417, 98 Stat. 1585 (1984), codified at 21 U.S.C. 355, 360cc, and 35 U.S.C. 156, 271, 282.

[14] See *Tri-Bio Labs, Inc.* v. *United States*, 836 F.2d 135, 139 (3d Cir. 1987), cert. denied, 488 U.S. 818 (1988). See also Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 15 USPQ2d 1121 (1990); and *Bristol-Myers Squibb Company* v. *Royce Laboratories, Inc.*, 69 F.3d 1130, 1132, 1133–34, 36 USPQ2d 1641 (Fed. Cir. 1995).

and (2) to protect the incentives of brand-name drug companies to invest in new drug development.[15]

The Hatch-Waxman Act permits pharmaceutical manufacturers to seek FDA approval of generic versions of previously approved drug products[16] by submitting an "abbreviated new drug application" ("ANDA").[17] Under the abbreviated procedure, an ANDA applicant that demonstrates bioequivalency with a pioneer drug may rely upon FDA findings of safety and efficacy for the relevant drug.[18] The Food, Drug and Cosmetics Act ("FDCA")[19] requires the ANDA applicant to provide a certification showing one of the following for each patent that "claims the listed drug" or the method of the drug's use for which patent information is required to be filed:[20]

> (I) that the required patent information relating to such patent has not been filed;
> (II) that such patent has expired;
> (III) that the patent will expire on a particular date; or
> (IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

The Commission's recent enforcement actions involve agreements between pioneer manufacturers and ANDA applicants that filed a certification under paragraph IV of these provisions.[21] A certification under paragraph IV requires the ANDA applicant to give notice of the ANDA filing to the patent owner and the firm that obtained the new drug approval for the listed drug (typically the pioneer manufacturer). This notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid, is unenforceable, or will not be infringed.[22] An applicant whose ANDA is pending when additional patents are listed must certify to the new patents, unless the patent owner or NDA holder fails to submit the additional patents within 30 days after their issuance by the Patent and Trademark Office.[23] In addition, if the ANDA applicant does not seek approval for a use of the drug claimed in a listed patent, the FDCA allows the ANDA to include a statement (commonly referred to as a "Section viii Statement") that the ANDA does not seek approval for such a use.[24]

The filing of a paragraph IV certification triggers an important process that reflects the Hatch-Waxman Act's core purpose of encouraging generic competition while protecting pioneer companies' incentives to innovate. If an action for patent infringement is brought against the ANDA applicant within 45 days of the date the patent owner receives notice of the paragraph IV certification,[25] final approval of the ANDA cannot become effective until 30 months from the receipt of notice. That

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[15] See H.R. Rep. No. 98–857(1), at 14–15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647–48 (stating that the purposes of the Hatch-Waxman Act are "to make available more low cost generic drugs [and] to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket approval").

[16] 21 U.S.C. 3550).

[17] 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.

[18] 21 U.S.C. 3550)(2).

[19] 21 U.S.C. 355(a), (b).

[20] 21 U.S.C. 3550)(2)(A)(vii). By regulation, the FDA has defined the "listed drug" to mean the approved new "drug product." 21 C. F. R. 314.3(b).

[21] If a certification is made by the generic manufacturer under paragraph I or II indicating that patent information pertaining to the drug or its use has not been filed with FDA or the patent has expired—the ANDA may be approved immediately, and the generic drug may be marketed. 21 U.S.C. 355(j)(5)(B)(i). A certification under paragraph III indicates that the ANDA applicant does not intend to market the drug until after the applicable patent expires, and approval of the ANDA may be made effective on the expiration date. 21 U.S.C. 355(j)(5)(B)(ii).

[22] 21 U.S.C. 355(j)(2)(B); 21 C.F.R. 314.95(c)(6).

[23] 21 C.F.R. 314.94(a)(12)(vi).

[24] 21 U.S.C. 355(j)(2)(A)(viii); 21 CYR 314.94(a)(12)(iii). In the event of a dispute as to the accuracy or relevance of patent information submitted to the FDA and subsequently listed in the Orange Book, the FDA may request the NDA holder to confirm the correctness of the patent information and listing. Unless the patent information is withdrawn or amended by the NDA holder, however, the FDA will not change the patent information listed in the Orange Book. Id.

[25] 21 U.S.C. 355(j)(5)(B)(iii); 21 C.F.R. 314.107(f)(2). The statute also states that "[u]ntil the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28, for a declaratory judgment with respect to the patent." Id

timing cannot be changed unless a final court decision is reached earlier in the patent case or the patent court otherwise orders a longer or shorter period.[26]

The Hatch-Waxman Act also provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge allegedly invalid patents or design products they contend are non-infringing. The Act grants to the first ANDA filer a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. The 180-day exclusivity period begins running on the earlier of (1) the date the first ANDA filer begins commercial marketing of its generic drug, or (2) the date a court decides that the patent addressed by the paragraph IV certification is invalid or not infringed. No other generic manufacturer may obtain final FDA approval to market its version of the relevant product until the first filer's 180.-day exclusivity period has expired.[27]

II. FTC CASES CHALLENGING SETTLEMENTS

The FTC has taken a lead role in promoting competition in the pharmaceutical industry and has been significantly involved in antitrust cases arising in the context of the Hatch-Waxman regulatory framework. In three recent cases, the Commission challenged agreements between brand-name and generic drug companies that allegedly delayed or were intended to delay generic drug competition in order to maintain higher prices.[28] In each case the Commission alleged that as part of a settlement agreement, the branded firm made payments to the generic firm in exchange for delayed entry. The Commission further alleged in each case that the agreements in question also delayed or were intended to delay entry of generic manufacturers other than those to which payments were made.

A. AbbottlGeneva

In May 2000, the Commission issued a complaint and consent order against Abbott Laboratories and Geneva Pharmaceuticals, Inc.[29] The complaint charged that Abbott paid Geneva approximately $4.5 million per month to keep Geneva's generic version of Abbott's proprietary drug (Hytrin) off the U.S. market, potentially costing consumers hundreds of millions of dollars a year. Hytrin is used to treat hypertension and benign prostatic hyperplasia (BPH or enlarged prostate)—chronic conditions that affect millions of Americans each year. BPH alone afflicts at least 50% of men over 60. In 1998, Abbott's sales of Hytrin amounted to $542 million (over 8 million prescriptions) in the United States. Abbott projected that Geneva's entry with a generic version of Hytrin would eliminate over $185 million in Hytrin sales in just six months.[30]

According to the complaint, Geneva agreed not to enter the market with any generic version of Hytrin, even if it were non-infringing, until the earlier of (1) the final resolution of the patent infringement litigation involving Geneva's generic version of Hytrin tablets, including review through the U. S. Supreme Court; or (2) entry of another generic Hytrin product. Geneva also agreed not to transfer, assign, or relinquish its 180-day exclusivity right. These provisions ensured that no other company's generic version of Hytrin could obtain FDA approval and enter the market during the term of the agreement, because Geneva's agreement not to launch its product meant the 180-day exclusivity period would not begin to run.[31]

Under the terms of the Commission's consent order, Abbott and Geneva are barred from entering into agreements pursuant to which a first-filing generic company agrees with a manufacturer of a branded drug that the generic company will not (1) give up or transfer its exclusivity or (2) bring a non-infringing drug to market. In addition, agreements to which Abbott or Geneva is a party that involve payments to a generic company to stay off the market must be approved by the court when undertaken during the pendency of patent litigation (with prior notice to the Commission), and the companies are required to give the Commission 30 days' notice before entering into such agreements in other settings. In addition, Geneva was

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[26] 21 U.S.C. 355(j)(5)(B)(iii). A court may shorten or lengthen the period if either party to the action fails to reasonably cooperate in expediting the case. Id

[27] 21 U.S.C. 355(j)(5)(B)(iv).

[28] It is important to note that the first two cases discussed below, Abbott-Geneva and Hoechst-Andrx, were resolved by settlement, while the third, Schering-Upsher-ESI Lederle, is pending administrative trial. Thus, although the Commission found reason to believe that there was a violation of the antitrust laws in each case, there has been no admission or final determination of unlawfulness in any of these matters.

[29] Abbott Laboratories, C–3945 (May 26, 2000) (Analysis to Aid Public Comment), <http://www.ftc.gov/os/2000/03>.

[30] Id (complaint).

[31] Abbott Laboratories, C–3945 (May 26, 2000) (complaint).

required to waive its right to a 180-day exclusivity period for its generic version of Hytrin tablets, so other generic tablets could immediately enter the market.

B. Hoechst Marion Roussel'Andrx

In a second matter, the Commission charged that Hoechst Marion Roussel (now Aventis), the maker of Cardizem CD, a widely prescribed drug for treatment of hypertension and angina, paid Andrx Corporation over $80 million to refrain, during the pendency of patent litigation, from bringing to market any competing generic drug, without regard to whether it was allegedly infringing.[32] Hoechst's Cardizem sales in 1998 exceeded $700 million, and over 12 million prescriptions were sold. Hoechst forecasted internally that a generic version of Cardizem CD, sold at 70% of the brand price, would capture approximately 40% of Cardizem CD sales within the first year.

The complaint further alleged that Andrx's agreement not to market its product was intended to delay the entry of other generic drug competitors, thereby denying consumers access to lower priced generic drugs.[33] As in Abbott, the ability to preclude other generic competitors flows from the exclusive 180-day marketing right granted to the first generic to file an ANDA.[34] This case was settled before trial, and the Commission issued final consent orders on May 11, 2001. The orders entered against Hoechst and Andrx contain relief similar to that in the Abbott and Geneva orders.

C. Schering-Plough/Upsher-Smith/ESI Lederle

In its most recent case, the Commission issued an administrative complaint on March 30, 2001, against Schering-Plough Corporation and two generic pharmaceutical manufacturers Upsher-Smith Laboratories, the first ANDA filer, and ESI Lederle, Inc. (a division of American Home Products Corp.). The complaint charges the three companies with entering into agreements aimed at delaying the entry of generic versions of Schering's product—KDur 20, a widely prescribed potassium chloride supplement used to treat patients with insufficient levels of potassium, a condition that can lead to serious cardiac problems.[35] Schering's K–Dur products (in two different strengths) had 1998 sales of over $220 million. In 1997, Schering allegedly projected that the first year of low priced generic competition would reduce branded K–Dur 20's sales by over $30 million.[36]

The Commission alleged in its complaint that Schering and Upsher-Smith settled a patent infringement lawsuit by agreeing that Schering would pay Upsher-Smith not to enter the market. Upsher-Smith allegedly agreed not to sell either the product for which it had filed an ANDA, or any other generic version of Schering's K–Dur 20 (regardless of whether Schering had any basis to claim infringement), until September 2001.[37] In exchange, Schering paid Upsher-Smith $60 million. Upsher-Smith also licensed five of its products to Schering but, according to the complaint, the $60 million had little relation to the value of those products. It is alleged that Schering's agreement with Upsher-Smith created a bottleneck by preventing other potential generic competitors from entering the market because of the 180-day exclusivity granted to Upsher-Smith as the first generic company to file an ANDA.

The Commission complaint alleges that Schering entered into a second agreement with ESI Lederle to delay further the marketing of a generic version of K–Dur–20. Schering and ESI Lederle allegedly settled a patent infringement case with an agreement by which ESI Lederle, in exchange for payments from Schering, promised not to market any generic version of K–Dur 20 until January 2004, and thereafter to market only one generic version until September 2006 (when Schering's patent expires). In addition, ESI Lederle allegedly agreed that it would not help any other firm with studies in preparation for an ANDA for a generic version of K–Dur 20

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[32] Hoechst Marion Roussel, Inc., Docket 9293 (March 16, 2000) (complaint), <http://www.ftc.gov/os/2000/03>.

[33] 33 Id

[34] In each of the cases brought by the Commission—Abbott, Hoechst, and Schering—it is not the general principle of the 180-day exclusivity that is at issue; rather, the complaints alleged that the parties entered into agreements that delayed or prevented the triggering of the first ANDA filer's exclusivity period, thereby also blocking other generic firms from entering.

The Commission's cases challenging settlement agreements also do not mean that parties to patent litigation cannot settle their disputes. Indeed settlement of litigation can serve important public purposes. But the antitrust laws have long condemned settlements that unreasonably limit competition. See, e.g., United States v. Singer Mfg. Co., 374 U. S. 174 (1963).

[35] In the Matter of Schering-Plough Corporation, et al., Docket No. 9297 (Mar. 30, 2001).

[36] K–Dur 20 is the 20 mg version of the product and is the product version at issue in this matter. Schering also makes a 10 mg version.

[37] Upshur-Smith received final FDA approval in November 1998 to market a generic version of K–Dur 20.

until September 2006. The Commission complaint alleges that Schering agreed to pay $30 million in exchange for these agreements and for licenses to two ESI Lederle products that the complaint alleges were not as valuable as the $15 million designated for them.

The Commission complaint alleges that the Schering/Upsher and the Schering/ESI Lederle agreements are unreasonable restraints of trade and that the companies conspired to monopolize the market for potassium chloride supplements, in violation of Section 5 of the FTC Act. In addition, the complaint charges Schering with unlawful acts of monopolization. The case is now in a pretrial stage before an Administrative Law Judge.

III. OTHER COMMISSION ACTIONS

A. FTC v. Mylan

Although competition between manufacturers of branded and generic drugs is critical and a continuing focus of Commission resources, the Commission also is concerned about maintaining competition among generic firms. In *FTC* v. *Mylan Laboratories, Inc.*, the Commission, along with several states, sued Mylan Laboratories, one of the nation's largest generic pharmaceutical manufacturers, charging Mylan and other companies with monopolization, attempted monopolization, and conspiracy in connection with agreements to eliminate much of Mylan's competition by tying up supplies of the key active ingredients for two widely-prescribed drugs—lorazepam and clorazepate—used by millions of patients to treat anxiety.[38]

The FTC's complaint charged that Mylan's agreements allowed it to impose enormous price increases—over 25 times the initial price level for one drug, and more than 30 times for the other. For example, in January 1998, Mylan raised the wholesale price of clorazepate from $11.36 to approximately $377.00 per bottle of 500 tablets, and in March 1998, the wholesale price of lorazepam went from $7.30 for a bottle of 500 tablets to approximately $190.00. The price increases resulting from Mylan's agreements allegedly cost American consumers more than $120 million in excess charges.

The Commission filed this case in federal court under Section 13(b) of the FTC Act seeking injunctive and other equitable relief, including disgorgement of ill-gotten profits. In July 1999, the U. S. District Court for the District of Columbia upheld the FTC's authority to seek disgorgement and restitution for antitrust violations. In settlement of the Commission's case Mylan agreed to pay $100 million for disbursement to qualified purchasers of lorazepam and clorazepate.[39] On April 27, 2001, the federal court granted preliminary approval to a distribution plan for these funds.[40]

B. FTC Pharmaceutical Industry Study

In light of the serious questions raised by its various generic drug investigations, in October 2000 the Commission proposed a focused industry-wide study of generic drug competition. This study is designed to examine more closely the business relationships between brand-name and generic drug manufacturers in order to better understand the extent to which the process of bringing new low-cost generic alternatives to the marketplace—and into the hands of consumers—is being impeded in ways that are anticompetitive. The study will provide a more complete picture of how generic drug competition has developed under the Hatch-Waxman Act, including whether agreements between brand-name pharmaceutical manufacturers and generic drug firms of the type challenged by the FTC are isolated instances or are more typical of industry practices. In addition, the Commission will examine whether particular provisions of the Hatch-Waxman Act have operated as intended—to balance the legitimate interests of pharmaceutical companies in protecting their intellectual property and the legitimate interests of generic companies in providing competition—or whether some provisions unintentionally have enabled anticompetitive strategies that delay or deter the entry of generic drugs into the market.

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[38] CV–98–3115 (D.D.C., filed Dec. 22, 1998; amended complaint filed Feb. 8, 1999). Over 20 million prescriptions are written for these drugs each year.

[39] The Commission approved the settlement on November 29, 2000. *FTC* v. *Mylan Laboratories, Inc.*, FTC File No. X990015 (Nov. 29, 2000). The Commission vote to accept the proposed agreement was 4–1, with Commissioner Thomas Leary dissenting in part and concurring in part.

[40] *FTC* v. *Mylan, et al.*, CV 1:98CV03114(TFH), Order Preliminarily Approving Proposed Settlements (Apr. 27, 2001).

In April, the Commission received clearance from the Office of Management and Budget to conduct the study.[41] The Commission has since issued 75 special orders to brand-name pharmaceutical manufacturers and generic drug companies to provide the Commission with information about certain practices that were outlined in the Federal Register notices that preceded OMB clearance to pursue the study.[42] The Commission staff focused each special order on specific name-brand drug products that were the subject of paragraph IV certifications filed by potential generic competitors, and, for generic companies, on specific drug products for which they had filed an ANDA containing a paragraph IV certification. Responses from the companies are expected by June 25, 2001.

The Commission plans to compile the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions of the Hatch-Waxman Act have influenced the development of generic drug competition. For example, the Commission staff anticipates analyzing how often the 180-day marketing exclusivity provision has been used, how it has been triggered (by commercial marketing or court orders), the frequency with which innovator companies initiate patent litigation, and the frequency with which patent litigation has been settled or litigated to a final court decision. The Commission will use the agreements provided, along with underlying documents related to the reasons for executing the agreement, to examine whether it appears that agreements between innovator and generic companies (or between generic companies) may have operated to delay generic drug competition.[43]

In addition, the study will provide evidence about innovator companies' patent listings in the Orange Book, the timeliness of the listings, and how frequently challenges are made to those listings by generic companies. Some have raised concerns that manufacturers of pioneer drugs are listing additional patents shortly before the expiration of previously listed patents, thereby starting procedures through which branded manufacturers can sue ANDA applicants who have filed a paragraph IV certification and can thus invoke the automatic 30-month stay for generic approval under the Hatch-Waxman Act.[44]

The study also will provide information about innovator companies' use of Citizen Petitions in connection with generic versions of their brand-name drug products. In March 2000, FTC staff provided some preliminary input to FDA in connection with its proposed rule concerning Citizen Petitions. The proposed rules are aimed at improving the efficiency of FDA's Citizen Petition process and narrowing the types of actions that can be requested of FDA through the Citizen Petition process.[45] Concerns have been raised about the potential for abuse, for example, by companies filing petitions to keep a rival drug product or medical device off the market for as long as possible. The FTC is concerned about the potential for abusing the regulatory process, but recognizes that some of this activity may implicate First Amendment rights that may present a barrier to antitrust enforcement.[46] Thus, the staff

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[41] The Commission obtained OMB clearance because the number of Special Orders being sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S. C. Ch. 35, as amended.

[42] See 65 Fed. Reg. 61334 (Oct. 17, 2000); 66 Fed. Reg. 12512 (Feb. 27, 2001).

[43] Commission staff commented to the FDA on the 180-exclusivity issue in connection with a proposed rulemaking. See Comment of the Federal Trade Commission Staff, In the Matter of 180 Day Generic Drug Exclusivity for Abbreviated New Drug Applications, Docket No. 85N–0214 (Nov. 4, 1999), <http://www.ftc.gov/be/v990016.htm>.

[44] See, e.g., *Mylan* v. *Bristol-Myers Squibb*, Civ. Action OOCV2876 (D.D.C. Mar. 13, 2001) (case alleging last-minute Orange Book listing by Bristol-Myers Squibb ("BMS") of another patent in connection with BuSpar, a leading anti-anxiety drug produced by BMS, just as BMS's patent exclusivity for BuSpar was about to expire; the propriety of that listing and the issue of whether the potential generic competitor can challenge the listing are currently the subject of this litigation).

[45] In the Matter of Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action, Docket No. 99N–2497, 64 Fed. Reg. 66822 (Nov. 30, 1999).

[46] *Eastern Railroad Presidents Conference* v. *Noerr Motor Freight, Inc.*, 365 U. S. 127 (1961); *United Mine Workers* v. *Pennington*, 381 U. S. 657 (1965). The Noerr-Pennington doctrine shields private parties from antitrust liability when they engage in certain concerted and genuine efforts to influence governmental action, even though the conduct is undertaken with an anticompetitive intent and purpose. For a further discussion of the Noerr-Pennington doctrine, see James D. Hurwitz, "Abuse of Governmental Processes, the First Amendment, and the Boundaries of Noerr," 74 Geo. L.J. 601 (1985). There are some exceptions to the application of the Noerr-Pennington doctrine. The Supreme Court has made clear that where one uses "the governmental process—as opposed to the outcome of that process as an anticompetitive weapon," the protection of the Noerr doctrine may not apply. Indeed if litigation or regulatory intervention is "objectively baseless in the sense that no reasonable litigant could realistically expect

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supported the FDA's attempt to maintain the Citizen Petition process for legitimate purposes, while limiting the ability of firms to use the process solely to hinder competitors.[47]

Finally, the study will examine whether the size of a drug product's sales influences the use of strategies to delay generic competition. The Commission expects to complete the study by the end of 2001.

IV. CONCLUSION

The Commission appreciates the opportunity to share with the Committee its observations about the pharmaceutical industry. The Commission looks forward to working with the Committee to address problems that may arise in this important sector of the U.S. economy. Thank you.

Chairman HATCH. Mr. Griffin, we will go to you.

STATEMENT OF JAMES M. GRIFFIN, DEPUTY ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION, DEPARTMENT OF JUSTICE, WASHINGTON, D.C.

Mr. GRIFFIN. Thank you, Mr. Chairman. It is a pleasure to be here and I appreciate the opportunity to speak to you and the Committee today.

As a starting point, I thought it would be helpful if perhaps I simply describe in general terms the division of labor between the Antitrust Division and the Federal Trade Commission in the enforcement of the antitrust laws.

The Department of Justice and FTC, of course, share Federal responsibility for antitrust enforcement, but that shared enforcement is limited to civil enforcement, including merger cases. Section 1 of the Sherman Act prohibits contracts, combinations, and conspiracies in restraint of trade. Criminal prosecution under that section is vested exclusively in the Department of Justice and those criminal prosecutions under that section are generally confined to that class of agreements that have been found to be unambiguously harmful to consumers and are considered per se unlawful. Examples of those kinds of agreements are agreements among competitors to fix prices, rig bids, allocate markets, and such agreements are generally secret. Businesses and consumers are defrauded and misled because the conspirators continue to hold themselves out as competitors.

The Division places a very high priority on criminal enforcement of the antitrust laws, and in recent years, we have aggressively pursued price fixing, bid rigging, market allocation, and customer allocation conspiracies in both international and in domestic markets.

Let me just summarize briefly some of the things that we have done on the international side. The division has prosecuted international cartels operating in a broad spectrum of commerce, including products found in household goods, such as vitamins and food

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success on the merits," a party's behavior may not be immune from antitrust challenge. As an example, the Supreme Court identified as unprotected conduct "the filing of frivolous objections to the license application of a competitor," with no real expectation of achieving denial of the license, "in order to impose expense and delay." *See Professional Real Estate Investors, Inc.* v. *Columbia Pictures Indus. Inc.*, 508 U.S. 49, 61 (1993); *Columbia* v. *Omni Outdoor Advertising, Inc.*, 499 U. S. 365, 380 (1991) (quoting *California Motor Transport Co.* v. *Trucking Unlimited*, 404 U.S. 508 (1972)).

[47] See Comment of the Federal Trade Commission Staff, In the Matter of Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action, Docket No. 99N–2497 (Mar. 2, 2000), <http://www.ftc.gov/be/vOO0005.pdf>.

preservatives; also in products used in manufacturing, such as graphite electrodes, which are used in the manufacture of steel; products used in the agricultural sector, such as animal and livestock feed additives; as well as a variety of services ranging from auctioning fine art to marine transportation and construction. We estimate that these international cartels, those that we have prosecuted over the last few years, have affected over $10 billion in U.S. commerce, and perhaps more disturbingly, this cartel activity in these cases has cheated U.S. businesses and consumers of many hundreds of millions of dollars annually.

On the domestic side of our docket, the Division recently has prosecuted bid rigging cases, cartels affecting hundreds of millions of dollars in contracts to supply food to such institutions as schools, hospitals, and other public institutions, rigging of contracts to provide relief construction projects in disaster areas, real estate foreclosure auctions, and contracts for the construction of water treatment plants, as well as price fixing conspiracies involving metal, building insulation, and numerous anti-competitive schemes in the graphics display markets.

Now, not all Section 1 violations, of course, rise to the level of criminal conduct, but may be subject to civil antitrust enforcement. Because we share Federal antitrust enforcement responsibility with the FTC, we have developed a clearance protocol with the Commission to determine which agency will investigate a particular matter or a particular civil matter. That determination is based primarily on which agency has the greater expertise in the area, in the product market as a result of recent antitrust investigations.

The clearance protocol enables the two agencies to most effectively use our resources as well as to avoid duplicative investigatory requests on private parties. Under this clearance protocol, the FTC has handled the recent civil investigations involving patent disputes and the delay of generic competition in the pharmaceutical industry, and as Ms. Boast just mentioned, the FTC is currently undertaking a broad investigation into this activity and we are all looking forward to the results of that study.

However, because the Division has sole responsibility for criminal antitrust enforcement, if the FTC were to uncover evidence of potential criminal violations relating to the pharmaceutical industry, under our clearance procedure, the FTC would refer that matter to us for prosecution. Likewise, if at the very outset of an investigation it appeared that the violation likely would turn out to be criminal, the Division would investigate the matter regardless of which agency had the greater expertise.

In fact, in this very market, the pharmaceutical market, the Division recently prosecuted the largest criminal antitrust conspiracy ever uncovered, the international vitamin cartel. To date, we have prosecuted 11 companies, 13 individuals for cartel activity in ten separate vitamin markets. The companies prosecuted were headquartered in Switzerland, Germany, Canada, Japan, and the United States, and to date, we have obtained almost $1 billion in fines in this investigation, including the largest fine ever imposed in a Federal criminal prosecution in the United States, the $500 million fine against the Swiss company Hoffman-LaRoche. In addition, we have obtained the first jail sentences ever imposed against

European business executives for violating U.S. antitrust laws, and that investigation, Mr. Chairman, is continuing.

I hope this information will be helpful to the Committee and I look forward to answering any questions you may have.

Chairman HATCH. Thank you so much, Mr. Griffin.

[The prepared statement of Mr. Griffin follows:]

STATEMENT OF JAMES M. GRIFFIN, DEPUTY ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION, DEPARTMENT OF JUSTICE

Good afternoon, Mr. Chairman and members of the Committee. I appreciate being invited here to testify.

The issues raised by today's hearing on the antitrust implications of patent settlements in the pharmaceutical marketplace are currently the subject of investigations being conducted by the Federal Trade Commission ("FTC"). As a starting point I thought it would be helpful to the Committee if I were to describe in general the division of labor between the Antitrust Division and the FTC in the enforcement of the antitrust laws.

The Department of Justice and the FTC share federal responsibility for antitrust enforcement, but that shared responsibility is limited to civil antitrust enforcement, including merger enforcement. The Department of Justice has exclusive responsibility for criminal antitrust enforcement.

Because criminal investigations are highly sensitive, I cannot comment on any specific investigation. However, I can describe generally what distinguishes conduct subject to criminal prosecution from conduct subject to a civil enforcement action.

Section 1 of the Sherman Act prohibits contracts, combinations, and conspiracies in restraint of trade. Criminal prosecution is generally confined to a class of agreements that have been found to be unambiguously harmful and are considered per se unlawful. Examples of such conduct include naked agreements among competitors to fix prices, rig bids, or allocate customers, territories, or sales. Such agreements are generally secret, and businesses and consumers are defrauded and misled because the conspirators continue to hold themselves out as competitors.

I should note, however, that there are some situations in which criminal investigation or prosecution may not be considered appropriate, even though the conduct may appear to be a per se violation of law. Such situations may include cases in which (1) there is confusion in the law; (2) there are truly novel issues of law or fact presented; (3) confusion reasonably may have been caused by past prosecutorial decisions; or (4) there is clear evidence that the subjects of the investigation were not aware of, or did not appreciate, the consequences of their action. In these instances, as well as in other cases where the conduct does not rise to the level of a criminal violation of Section 1, the conduct may be subject to civil antitrust enforcement.

Individuals criminally convicted of violating the Sherman Act are subject to fines up to $350,000 and prison sentences up to three years, and corporations are subject to fines up to $10 million. Under the alternative sentencing provision found in 18 U.S.C. § 3571, a convicted defendant is subject to higher fines equaling twice the gain resulting from the violation, or twice the loss caused to the victims, whichever is higher.

The Antitrust Division places a high priority on criminal antitrust enforcement. In recent years, the Division has aggressively pursued price-fixing, bid-rigging, and market- and customer-allocation conspiracies in both international and domestic markets.

On the international side, the Division has prosecuted international cartels operating in a broad spectrum of commerce, including: products found in household goods, such as vitamins and food preservatives; products used in the manufacturing sector, such as graphite electrodes used in steel making; products used in the agricultural sector, such as animal and livestock feed additives; and a variety of services, ranging from auctioning fine art to marine transportation and construction. The Division estimates that the international cartels it has prosecuted over the last few years affected well over $10 billion in U.S. commerce. More importantly, the cartel activity in these cases cheated U.S. businesses and consumers of many hundreds of millions of dollars annually.

On the domestic side, the Division recently has prosecuted bid-rigging cartels affecting hundreds of millions of dollars in contracts to supply food to schools, hospitals, and other public institutions; typhoon relief projects; real estate foreclosure auctions; and contracts for the construction of water treatment plants, as well as

price-fixing conspiracies involving metal building insulation and numerous anti-competitive schemes in the graphics display industry.

Because we share federal antitrust enforcement responsibility for civil violations with the FTC, we have a clearance protocol with the FTC to determine which agency will investigate a particular civil matter. That determination is based primarily on which agency has the greater expertise in the product market as a result of recent antitrust investigations conducted by that agency. The clearance protocol enables the two agencies to make the most effective use of enforcement resources, as well as to avoid duplicative investigatory requests on private parties. Under this clearance protocol, the FTC has handled recent civil investigations involving patent disputes and the delay of generic competition in the pharmaceutical industry.

However, because the Division has sole responsibility for criminal antitrust enforcement, if the FTC were to uncover evidence of a potential criminal violation relating to the pharmaceutical industry, under our clearance protocol the FTC would be required to refer that evidence to us for criminal investigation. Likewise, if at the outset of an investigation, the evidence suggested a potential criminal violation, the Division would investigate the matter, regardless of which agency had greater expertise in the product market.

In fact, in the pharmaceutical market, the Division recently prosecuted the largest criminal antitrust conspiracy ever uncovered—the international vitamin cartel. To date, we have prosecuted eleven companies, headquartered in the United States, Switzerland, Germany, Canada, and Japan, and thirteen individuals for cartel activity in ten vitamin markets. We have obtained nearly $1 billion in fines, including the $500 million fine imposed against F. HoffmannLa Roche, the largest fine ever imposed in a U.S. criminal prosecution of any kind. In addition, we obtained the first jail sentences ever imposed against European business executives for violating U.S. antitrust laws. The investigation is continuing.

Mr. Chairman, I hope this information is helpful to the Committee. I would be happy to answer questions if I can.

Chairman HATCH. General Shurtleff, let us hear from you now.

STATEMENT OF MARK SHURTLEFF, ATTORNEY GENERAL, STATE OF UTAH, SALT LAKE CITY, UTAH

Mr. SHURTLEFF. Thank you very much, Mr. Chairman. It is truly an honor and a privilege to be here to testify today regarding competition in the pharmaceutical marketplace, and more specifically on the antitrust implications of settlements in patent litigation between brand name and generic drug manufacturers.

As you know, on May 14, 15 State Attorneys General filed a Federal antitrust lawsuit alleging that drug companies conspired to keep cheaper generic alternative to the high blood pressure drug Cardizem CD off the market. That case was filed in Federal district court in Michigan. Now, as the chief legal officers of our States, attorneys general have a sworn mandate to enforce the laws passed both by Congress and those of our respective State legislatures. The decision to pursue legal action against alleged unlawful conduct is made more difficult when different laws intended to protect and benefit the public apparently conflict.

There are those who believe that litigation is the desirable method of resolving those conflicts, and, in effect, using the courts to legislate. I do not share that belief. To the contrary, it is the most expensive and the least effective method of resolving apparent conflicts in the law and closing loopholes. But until the law is changed by the legislative branch and we, as representatives of the executive branch, have substantial evidence that existing laws have been violated to the injury of our States and our citizens, we must move to hold the offenders accountable.

Today, I am wearing a pin that the Attorney General of Delaware gave me. It represents the scales of justice. You know that

signifies balance and equity and fairness in both creating and administering the laws of the land. Today, I am here to address, and I apologize that some of it is repetitive, the balance between the two canons of law, which are intended in different ways to benefit and protect consumers, and I speak of patent laws on the one side of the scale and antitrust laws on the other side.

The purpose, of course, of the former, the patent law, is to benefit the consumer by encouraging innovators and risk takers to invest, to invent, develop, and create products that better our lives by granting these industrial, commercial, and medical pioneers temporary monopolies. The latter, the antitrust law, was passed on the other side to protect the consumer from those who unfairly act in restraint of trade or to monopolize the marketplace to their financial benefit at the expense of the consuming public.

I read the 1984 Hatch-Waxman amendments to the Federal Food and Drug and Cosmetic Act as an example of this balancing task between these two very important laws. On the one side of the scale, on the patent, Hatch-Waxman encourages innovation by confirming or extending that patent right, exclusive right to market protection to those pioneering name brand and generic drug companies. Millions of Americans have been blessed in the last 17 years by the tremendous advances in pharmaceuticals available to us. Lives have been saved. Lives have been enriched. So these innovators and pioneers, which also have been enriched substantially. The past decade has seen a huge increase, also, as you are very aware, in the cost of prescription drugs, which has a major impact primarily on our senior citizens, who most often need and are most benefited by those advances, but who again most often are on fixed incomes and can least afford these important medicines.

On the antitrust or consumer protection side of the scales of justice, Hatch-Waxman was intended to and has succeeded in getting more low-cost generic or bioequivalent drugs to consumers faster. Pioneer innovators have been protected and encouraged to develop and market better medicines by the 30-day prohibition on generics going to market after a patent infringement suit is filed. Cost saving generic innovators are protected and encouraged to get cheaper bioequivalence to the public by the 180-day exclusive marketing grant should a court rule against the brand name company in the patent infringement action.

So, in theory and for the most part in practice, Hatch-Waxman has balanced that scale. Consumers and producers are in harmony, and again, millions are the better for it.

However, as sometimes occurs with the best laid plans, something happens to upset that balance and tip the scales. Throughout history, unscrupulous businessmen or shopkeepers have at times been found to have put a thumb on one side of the scale or to otherwise manipulate the weights and measures with the intent to cheat their customers and make a few extra bucks. When accused, those shopkeepers often would—their first defense was to say, well, I did not have my thumb on there. The problem is in the scale. The scale must be malfunctioning. This is not a problem of their making, so they say, why should we be punished for taking advantage of that problem, that loophole, perhaps, without notifying the buyer? We are not talking about a few bucks here. We are talking

about millions and millions of dollars today in this pharmaceutical industry.

Hatch-Waxman is silent on the question of what happens in a patent infringement action if it is resolved by settlement as opposed to going to the judge. Some have called this a loophole in the law. They have rushed to take advantage of it, thereby tipping the scale against the consuming public.

FTC Chairman Robert Pitofsky has reportedly called this burgeoning "sue, then settle" practice "private treaties that rob consumers." The president of one drug company admitted in a press release that, "There are clear abuses that are occurring in the industry that are actually delaying generic products from reaching consumers." He also said that settlement agreements do not per se so delay and may, in fact, "get lower price product to them faster." However, if brand name and generic companies are, again in the words of Chairman Pitofsky, "gaming the rules to their financial benefit by delaying the availability of cheaper alternatives to the consuming public, then it is my responsibility to protect the public, right the scales, and hold the cheaters liable."

As stated before, some would argue that "sue, then settle" arrangements are unlawful per se. I do not believe so. I think the jury is out on that.

At this point in time, with the evidence currently available on a number of these deals, it appears as if some companies have acted unreasonably in the restraint of trade under a rule of reason approach. Unless and until Congress acts to close the loophole, State attorneys general will be required to continue to scrutinize and bring enforcement actions.

As I stated at the beginning, I would prefer that you, the Congress, act to balance the scale. I appreciate you have asked me here today as an executor of the law. I disagree with some of those who would suggest that the answer is tipping the scale over altogether and doing away with the protections that have been in place for so many years. I think a more reasoned approach is that the Department of Justice or if the FTC have noticed an approval of settlement agreements, and again, I thank you for the opportunity to address you, Senator Hatch, and your committee. I look forward to answering any questions you might have.

Chairman HATCH. Thank you, General. We appreciate it.

[The prepared statement of Mr. Shurtleff follows:]

STATEMENT OF MARK L. SHURTLEFF, UTAH ATTORNEY GENERAL

Mr. Chairman, Members of the Committee:

It is an honor and a privilege to testify to you today regarding competition in the pharmaceutical marketplace; and more specifically on the antitrust implications of settlements in patent litigation between brand name and generic drug manufacturers. As you know, on May 14th, fifteen state attorneys general filed a federal antitrust lawsuit alleging that drug companies conspired to keep a cheaper generic alternative to the blood-pressure drug Cardizem CD off the market.

As the chief legal officers of our states, attorneys general have a sworn mandate to enforce the laws passed by Congress and those of our respective state legislatures. The decision to pursue legal action against alleged unlawful conduct is made more difficult when different laws, intended to protect and benefit the public, apparently conflict. There are those who believe that litigation is the desirable method of resolving those conflicts and, in effect, using the courts to legislate. I do not share that belief. To the contrary, it is the most expensive and least effective method of resolving apparent conflicts in the law and closing loopholes. But until the law is

changed by the legislative branch, and we, as representatives of the executive branch have substantial evidence that existing laws have been violated to the injury of our states, and individual citizens thereof, we must move to hold the offenders accountable. Today I am wearing a lapel pin representing the "scales of justice," which as you know signifies balance, equity and fairness in both creating and administering the laws of the land. I am here today to address the balance between two cannons of law which are intended in different ways to benefit and protect consumers. I speak of Patent Law and Antitrust Law. The purpose of the former is to benefit the consumer by encouraging innovators and risk-takers to invent, develop and create products that better our lives, by granting these industrial, commercial and medical pioneers temporary monopolies. The latter was passed to protect the consumer from those who unfairly act in restraint of trade or to monopolize the marketplace to their financial benefit at the expense of the consuming public.

I read the 1984 Hatch-Waxman amendments to the Federal Food, Drug and Cosmetic Act as a classic example of the aforementioned balancing task. On one side of the scales, Hatch-Waxman encourages innovation by confirming or extending the patent law's "exclusive right to market protection" to pioneering name brand and generic drug companies. Millions of Americans have been blessed in the last 17 years by the tremendous advances in pharmaceuticals available to us. Lives have been saved. Lives have been enriched. The innovators and pioneers have also been enriched. The past decade has seen a huge increase in the cost of prescription drugs which has had a major impact primarily on our senior citizens who most often need and are benefitted by the advances, but who again most often are on fixed incomes and can least afford these medicines.

On the antitrust or consumer protection side of the scales of justice, Hatch-Waxman was intended to, and has succeeded in, getting more low-cost generic or bioequivelent drugs to consumers faster. Pioneer innovators have been protected and encouraged to develop and market better medicines by the thirty month FDA prohibition on generics going to market after a patent infringement suit is filed. Cost-saving generic innovators are protected and encouraged to get cheaper bioequivelents to the public by the 180 day exclusive marketing grant should a court rule against the brand name company in the patent infringement action.

In theory, and in most part in practice, Hatch-Waxman balanced the scale. Consumer and producer are in harmony and, again, millions are better for it. However, as sometimes occurs with the "best laid plans," something happens to upset the balance and tip the scales.

Unscrupulous businessmen or "shopkeepers" have, throughout time, been found to have rested a thumb on one side of the scale, or otherwise to have manipulated the weights and measures with the intent to cheat their customers and make a few extra bucks. When accused, often their first defense was to claim there must be a malfunction in the scale itself. A problem not of their making, so why should they be punished for taking advantage of it without notifying the buyer?

Hatch-Waxman is silent on the question of what happens when a patent infringement action is resolved by settlement rather than judicial ruling. Some have called this a "loophole" in the law and have rushed to take advantage of it, thereby tipping the scale against the consuming public. FTC Chairman Robert Pitofsky has called this burgeoning sue-then-settle practice: "private treaties that rob consumers." The president of one drug company admitted that "there are clear abuses that are occuring in the industry that are actually delaying generic products from reaching consumers." He also said that settlement agreements do not per se so delay, and may in fact "get lower priced product to them faster." However, if brand name and generic companies are, again in the words of Chairman Pitofsky, "gaming the rules," to their financial benefit by delaying the availability of cheaper alternatives to the consuming public, then it is my responsibility to protect the public, right the scales and hold the cheaters liable.

As stated, some would argue that sue-then-settle arrangements are unlawful per se. I believe the jury is, literally, still out on that argument. At this point in time, with evidence currently available on a number of these deals, it appears as if some companies have acted unreasonably in restraint of trade under a Rule of Reason approach. Unless and until Congress acts to resolve or close this "loophole," state attorneys general will be required to continue to scrutinize and bring enforcement actions. As I stated at the beginning of my remarks, I would prefer that you act to balance the scale. I appreciate that you have asked me here today as part of an analysis of that possibility. As an "executor" of the law, I disagree with those who would suggest the answer lies in tipping the scale over completely. That will benefit no one. I think a much more reasoned approach of requiring notice and/or DOJ or FTC approval of settlement agreements, along the lines proposed in S. 754, is worthy of close consideration.

Thank you again for the opportunity to address you on this issue of extreme importance to the states and our good citizens. I would be happy to respond to any questions.

Chairman HATCH. Let me just go right to the belly of the beast of the 1984 law. Section 505(j)(2)(v), paragraph four, on this chart. As we've heard, applications for equivalent products who certify that a pioneer patent is invalid or infringed may, if successful, trigger a 180-day period of marketing exclusivity. Now, my first question is fact oriented and will, for a moment, leave aside the important question of which generic applicant, the first filer or the first to successfully defend the pioneer's lawsuit, should obtain such a potentially valuable exclusivity. The question is this, and any of you can answer if it you would like. Do any of your agencies have the precise fix on the number of times Paragraph IV certifications have been made, how many times the pioneer firms have elected to bring or not to bring suit, and the ultimate disposition of such suits and applications? I am particularly interested in the breakdown between the number of times patents have been held valid or invalid versus the number of times the contest has centered on non-infringement. If you do not have this information today, I would like to know in particular if the FTC would yield such data, and if it cannot, if it will not, can you help us get these facts so that we know where we are going and what we are talking about?

Mr. BUEHLER. I do not have that information right now, Mr. Chairman. I believe we have provided some similar information to FTC, though.

Ms. BOAST. Mr. Chairman, this is precisely the kind of information that the Commission's study pursuant to Section 6(b) of the FTC Act is designed to procure. You are exactly on point with the kinds of information that would be relevant to figuring out how severe a problem we have here and what are the points at which the severity is most obvious and, therefore, where we should direct our energy. We do not have that information in a systematic form today, to my knowledge, and as I said, subject to legal constraints that might exist on the confidentiality of the collection process, I do not see any reason why a consultation with members who are interested in this area would not be appropriate, but there may be legal constraints.

Chairman HATCH. My second question is more policy oriented. Let us deconstruct Paragraph IV. If we look at the language of Paragraph IV, we see two very different concepts lumped together, patent invalidity and non-infringement. The former suggests a frontal assault on the patent while the latter suggests a careful navigation around protected intellectual property. The 1984 law wishes to encourage generic drug manufacturers to challenge weak patent claims and to invent around valid patents so that consumers can reap the benefits of generic competition as quickly as possible. But should these very different routes be treated to the identical 180-day marketing exclusivity benefit?

That is a question I have. I am very concerned about that. Presumably, there may be cases where a non-infringer has some sort of trade secret or even patent technology not available to subsequent applicants so that the exclusivity can operationally extend beyond the 180 days. Conversely, if a second or third ANDA appli-

cant comes up with a different non-infringing technology from the first applicant, why should these applicants and consumers be denied the benefits of more competition in the marketplace for the balance of the 180 days?

Let me just say further, this invalidity, non-infringement distinction seems to be a proper topic for debate. One of the most brilliant lawyers I have ever come across is Al Engelberg, who played a key role in the compromises of 1984 and who has made out very well challenging patents. Here is what Al said on this issue, and I quote, "In cases involving an assertion of non-infringement, an adjudication in favor of one challenger is of no immediate benefit to any other challenger and does not lead to multi-source competition. Each case involving non-infringement is decided on the specific facts related to that challenger's product and provides no direct benefit to any other challenger. In contrast, a judgment of patent invalidity or enforceability creates an estoppel against any subsequent attempt to force the patent against any party. The drafters of the 180-day exclusivity provision failed to consider this important distinction," very critical of me but very accurate.

So here is your——

Senator LEAHY. How dare he be critical.

Chairman HATCH. I have wondered that myself, so here is your chance to take a shot at one of the drafters of the law, I think. I want to ask the witnesses from DOJ and FTC or from the FDA, if you want to join in, to comment upon the effects of equating invalidity and non-infringement in Paragraph IV. Now, this is a tough question. I realize you are in no position to render a final administration view today, but I ask you to help me reanalyze the impact of this law. So please help us think through the question of whether consumers might be better off and the marketplace more competitive if non-infringement was treated differently than claims of invalidity.

I turn it over to you. That was a long question, but it is pretty hard to put out there without giving you that much information. Do you want to start, Mr. Buehler?

Mr. BUEHLER. Mr. Chairman, you are correct. There is presently no distinction between the two, and obviously that is the way we regulate the statute, is there is no distinction between the two. Whether there should be or that should be changed, I am afraid that the Administration does not have a position on that particular issue at the present time, as you stated.

Chairman HATCH. OK.

Ms. BOAST. Mr. Chairman, it was not only a long question but a very good question and a very difficult question. I certainly cannot speak for the Commission on this. I will say that I think the Commission in its enforcement actions has not focused on that distinction. Rather, the concern has been that once an agreement has been reached to delay entry by the first filer, that exclusivity provision time is not running and, therefore, no one else can enter. And, indeed, it is one of the reasons that I focused in my structural description of what links these three cases on the provisions of the settlement agreements that preclude entry with non-infringing products. That is fairly offensive, I think.

I think you raise a very, very legitimate issue and it is something that, again, without the Commission having a position or having studied it directly, we clearly ought to be considering as we move forward in this area.

Chairman HATCH. Will you make that recommendation and get that done for us?

Ms. BOAST. I certainly will.

Chairman HATCH. I think it is pretty important.

Ms. BOAST. I certainly will, Mr. Chairman.

Chairman HATCH. Let me just ask a final question. At last December's Food and Drug Law Institute conference on Hatch-Waxman, Liz Dickinson, and I am told by my staff that she is one of the most able, dedicated, and respected members of the FDA General Counsel's Office, raised a fundamental question to us. Let me emphasize that Liz was participating in the FDLI Educational Conference and made clear she was not speaking in a way that would bind the agency or the Administration.

As a good attorney and expert policy analyst, she should be applauded for raising some tough questions that bear further consideration by all of us in this matter. In fact, I encourage everyone interested in Hatch-Waxman reform to get a copy of and study Liz's remarks, along with the complete record of the December conference. I think it is important.

As Liz said in December, "I suggest we look at whether 180-day exclusivity is even necessary, and I know that there is this idea that it is an incentive to take the risk. I say the facts speak otherwise. If you have a second, third, fourth, fifth generic in line for the same blockbuster drug filing at Paragraph IV certification, undertaking the risk of litigation without the hope of exclusivity, is that exclusivity even necessary?"

Then she goes on. She said, "We have got a provision that is supposed to encourage competition by delaying competition. It has got a built-in contradiction, and that contradiction, I think, is bringing down part of this statute."

So my question for the panel is the one raised by Liz, among others. Is it necessary or advisable to retain the 180-day exclusivity period given the enormous financial incentives to challenge patents on blockbuster drugs?

Ms. BOAST. Mr. Chairman, again, speaking only for myself, I believe that the balance that was struck by Congress in the original Hatch-Waxman Act contemplated encouraging generic entry by giving them this 100-day [sic] exclusivity provision. What the Commission staff has said is in support of an FDA proposal to create a sort of use or lose regime, in which if the first filer did not take advantage of exclusivity within a certain amount of time, other firms would be able to enter, and that is one way of addressing the concern about exclusivity being misused by this, to say you have got to take advantage of it or you cannot have it.

Chairman HATCH. OK. Anybody else?

Mr. BUEHLER. Mr. Chairman, as Liz stated at the meeting, we often have the second, third, fourth, fifth challengers to the same patent, oftentimes when the challengers actually realize that they are not first and there is no hope for them to get the 180-day exclusivity. So with that in mind, I would agree with Liz's statement

that generic firms will continue to challenge patents. Whether the 180-day exclusivity is a necessary reward for that challenge is unknown, but it does not appear that it is.

Chairman HATCH. I would like answers to this. Right now, I personally favor the 180-day provision, but I would like to have the best expertise I can possibly get on this and you both have been very helpful here. In fact, all four of you have, but I seem to have had the two of you on the hot spot for most of these questions today. Mr. Griffin, I am not trying to ignore you.

Let me just ask one more question and then I will turn to our Democratic leader on the committee. Please explain what, in your view, are the pros and cons of Congress adopting any of the following 180-day exclusivity regimes. First, a legislative override of Mova and a statutory reversion back to the old rule of first to file, first to be sued and win. Second, the type of ruling exclusivity embraced in the Schumer-McCain legislation. And third, the 180-day triggering period provision contained in the 1999 FDA proposed rule whereby if the first filer did not or could not start the use of the exclusivity within 180 days, all other filers could march in.

Mr. BUEHLER. Mr. Chairman, all of these are somewhat related to pending legislation, and at this point——

Chairman HATCH. I do not want any weasel excuses here. I do not want you weaseling out——

[Laughter.]

Mr. BUEHLER. OK. Let me just try to address the first part, the Mova part. Prior to Mova, prior to the Mova decision, from 1984 through 1997, three generic firms were granted 180-day exclusivity. Post-Mova, 31 generic firms were granted 180-day exclusivity. Post-Mova, we have been barraged by lawsuits and various litigation.

Chairman HATCH. You mean legislation that I write leads to lawsuits and litigation?

[Laughter.]

Chairman HATCH. Go ahead. I am sorry. The second one was the type of rolling exclusivity embraced in the Schumer-McCain legislation.

Mr. BUEHLER. Well, again, pending legislation, the Administration does not have a position on that particular pending legislation.

Chairman HATCH. How about you? What is your opinion?

Mr. BUEHLER. I am the agency today.

Chairman HATCH. Well, you can speak for yourself here. We will not hold the agency responsible.

Senator LEAHY. They will never notice what you say.

[Laughter.]

Mr. BUEHLER. I am also Acting Director, Mr. Chairman.

Chairman HATCH. I have to say, a lot of them will not understand what you say, either.

[Laughter.]

Chairman HATCH. Go ahead. Just give us to the best of your ability. If it is too uncomfortable, that is OK with me.

Mr. BUEHLER. Our preamble to our proposed rule for the 180-day revision notes the number of lawsuits that we have had to defend and had to become involved in post-Mova in trying to sort out the,

I guess, legislative difficulties right now with the Hatch-Waxman amendments.

Chairman HATCH. So your concern is that the Schumer-McCain legislation might even lead to more litigation?

Mr. BUEHLER. I did not say that.

[Laughter.]

Chairman HATCH. "Might" may be too small a word, is that right?

Mr. BUEHLER. Can I go to rolling exclusivity?

Chairman HATCH. Yes, go ahead.

Mr. BUEHLER. Our present system does not provide for rolling exclusivity. We believe that rolling exclusivity would actually be an impediment to generic competition in that the exclusivity would continue to bounce from the first to the second to the third if, somehow or other, the first was disqualified. Right now, when the first is disqualified, there is no exclusivity. Everyone can come on the market and let the competition begin.

Chairman HATCH. OK. Does anybody else care to comment?

Ms. BOAST. Mr. Chairman, I would simply reiterate what I had said before, and that is that at the staff level, at least, we have supported the use or lose approach to this. I would observe that, again, the Commission's study is the vehicle it proposes to use to try to help sort out some of these issues and to provide better advice to Congress on this. My other observation is that there seems to be in these three different approaches clear recognition that something needs to be done with exclusivity.

Chairman HATCH. I have other questions I will submit in writing. I have one in particular for you, General Shurtleff, but I will submit it in writing. We would like the best analysis that you can give us.

This has been very, very interesting to me, as you can imagine, and you have been particularly interesting witnesses. I want to commend you and compliment, all four of you, for what you have been able to say. This is a very important subject and it is very important that we refine this bill to make it even more effective than it has been, and everybody admits it has been pretty effective—almost everybody, I should say. I guess I had better not be universal in any statement.

But to make a long story short, we would like all the help we could get on it because I would like it to work better. I would like more competition. I would like more innovation. I would like to see the two sides balanced and we need your help in order to know what is best to do in this particular area.

I am going to head back over to the floor, so I am going to turn this hearing over to our soon-to-be Chairman who has a complementary bill and who, of course, is very interested in this issue, as well. If you could finish this hearing, I sure would appreciate it, and if you will forgive me for running off. I have about four conflicts right now and I apologize to you. He says he is going to praise me, so I had better stay for just a few minutes. This is such a rare occasion.

[Laughter.]

Senator LEAHY. Now, now, now.

Chairman HATCH. No, he has been pretty good for a Vermonter, is all I can say.

[Laughter.]

Chairman HATCH. I am just kidding. I am just kidding. Jim is a great——

Senator LEAHY. We Vermonters are the best thing that ever happened to the U.S. Senate.

Chairman HATCH. There might be some dispute there, but I am willing to accept that.

Senator LEAHY. This could go on too far and get us both in trouble. But Mr. Chairman, you and I have always worked well together on patent, copyright, broadcast, and the other high-technology issues, and I appreciate that. It is a mark of our legislative friendship on these issues, but also, I think, reflects our personal friendship, which goes back a quarter of a century.

It was not long ago, Mr. Chairman, when you and I and the Committee hit a high-tech home run. We had passage of three major bills of enormous importance to consumers. In one fell swoop, we provided consumers with local-into-local satellite television, protected important patent rights and terms, and enhanced electronic commerce and trademark protection.

Chairman HATCH. How does that equal a home run? There are only three hits there? A couple of them were doubles?

Senator LEAHY. The bases were loaded.

Chairman HATCH. OK.

[Laughter.]

Senator LEAHY. On the first one. They were all three home runs.

Chairman HATCH. That is right. OK.

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

Senator LEAHY. [Presiding.] In light of the testimony we are going to hear today, I hope we can work together and quickly report out a bill which I introduced last Congress and reintroduced this year, S. 754, the Drug Competition Act. This bill, which has Senators Kohl, Schumer, Durbin, and Feingold on it, would put a stop to secret agreements made between drug companies which hurt our senior citizens and American families, that cheat health care providers and inflate Medicaid and Medicare reports.

I am pleased that Attorney General Shurtleff is here to talk about this harm to families in his and other States. I appreciate the legal action you took with 14 other States, including Vermont. I know the high regard that Attorney General Sorrell has for you. It is just another example that Vermont and Utah work closely together and so on.

But in General Shurtleff's prepared testimony, he says that, "I think a much more reasoned approach requiring notice along the line proposed in S. 754 is worthy of close consideration." I want to thank you, General, and I also want to thank the Federal Trade Commission. They deserve a lot of credit for exposing this problem.

What I want to do, and the reason for my bill is to say there will be no more secret deals to keep generic drugs off the market. If you want to boil it down to the basics, no more secret deals keeping generic drugs off the market. Any agreements have to be immediately

provided to the law enforcers, in that case, the FTC and the Justice Department. So if you are going to notify the deals immediately, I think it is going to be a heck of a deterrent to making these kinds of illegal deals in the first place, and any such deal would be subject to immediate investigation and action by the Federal Trade Commission or the Justice Department. If you have something like that, people are going to think twice before they do a secret deal, an illegal deal, and it would solve the most difficult problem, that is, just finding out about the improper deals in the first place.

It does not change the Hatch-Waxman Act. It does not amend FDA law. It does not slow down the drug approval process. It allows existing antitrust laws to be enforced because the enforcement agencies have the information they need.

A New York Times editorial published last July, "Driving Up Drug Prices," mentioned that the FTC is taking aggressive action to curb the practice. It needs help from Congress to close loopholes in Federal law. Well, my bill provides that help. It would slam the door shut on would-be violators. How? By exposing the deals to our enforcement agencies. So I think Congress should make sure the FTC and Justice look at every single deal that could lead to abuse, and only the deals that are consistent with the intent of the law will be allowed to stand. I will insert the rest of this for the record before I have to go to one of the same things that Senator Hatch had to.

Ms. Boast, let me ask you, first, I want to thank the FTC for the outstanding job you do in helping protect both consumers and also to promote competition, which helps us all. I think the legal actions you have filed show a lot of very, very careful work. I can only imagine the amount of effort that went into crafting them. As a lawyer, I am in awe. But I am going to be very direct and ask you a few questions about the Drug Competition Act, my bill.

The bill simply requires that agreements between branded drug manufacturers and potential generic competitors be provided to the FTC and the DOJ within 10 days after the agreements are signed. You would then confidentially—they would not be filed publicly, but you would confidentially review these documents and you would take any actions you deem necessary. So my first question is this. If the Drug Competition Act were enacted, would the FTC obtain additional documents, obtain them more quickly than under the current system, and if that is so, would that help you enforce the law?

Ms. BOAST. Senator Leahy—I hope I have the title right as of the moment——

Senator LEAHY. We are all struggling with titles, so Senator Leahy is great. Being a Senator from Vermont is something that gives me pride.

Ms. BOAST. First of all, let me thank you for your compliments for our work. These are, you are quite correct, very resource-intensive cases. They involve very difficult legal issues and intellectual property issues, and anything that could be done to help us be more effective in enforcing the law in this area would be helpful.

I believe that a legal regime that gave us notice of agreement so that we did not have to find out about them by accident could be quite helpful in the enforcement mission, with due regard to the

burdens on business that it might impose, which I am sure you have taken account of in your drafting.

Senator LEAHY. Do you think it is safe to say that it would deter branded name pharmaceutical companies from entering into written agreement with potential generic competitors that might violate our antitrust laws?

Ms. BOAST. Senator, I think it would be very likely to have that kind of effect. It might deter the agreements outright, but it also certainly would force the firms who were contemplating those agreements to give them much more careful scrutiny for potentially offensive provisions.

Senator LEAHY. You are doing a study, I understand, a very important study of the pharmaceutical practices relating to the Hatch-Waxman Act. If my bill became law, would the FTC have access to otherwise secret agreements between branded name companies and potential generic competitors? And if you had access to that, would that help you carry out the study you are doing regarding Hatch-Waxman?

Ms. BOAST. Senator, it certainly could enhance our work on the study that the Commission has underway, but I would like to note that the virtue of your approach is that it goes beyond the relatively time-bound request that is present in the study that is underway. Your proposal would create an ongoing obligation that would far exceed the scope of the study.

Senator LEAHY. Am I right in assuming these agreements are not routinely provided to the FTC now?

Ms. BOAST. You are quite right that they are not routinely provided.

Senator LEAHY. So how would you get access to these agreements?

Ms. BOAST. Senator, it is not that easy. I mean, detecting illegal conduct is part of what we are about. We sometimes hear about it from people in the industry. We have had a very, very close and cordial working relationship at the staff level with FDA, who I think has been interested in, let us say, our efforts in this area. But we have not had, short answer, a systematic tool such as you propose.

Senator LEAHY. You do not get them 10 days after the agreement is signed, I take it.

Ms. BOAST. That is exactly right, Senator.

Senator LEAHY. I am going to submit the other questions for the record so I can go back to this other matter. I will leave the record open until the close of business tomorrow—for a week, I have just been told. You see, Senators are merely constitutional impediments to the staff. The staff really knows what is going on around here.

[Laughter.]

Senator LEAHY. We will leave it open for a week if anybody wants to submit questions, and I will include a statement from Senator Brownback in the record at this point.

[The prepared statement of Senator Brownback follows:]

STATEMENT OF HON. SAM BROWNBACK, A U.S. SENATOR FROM THE STATE OF KANSAS

Recently, there has been a great deal of publicity concerning possible antitrust violations in settlements of patent disputes between innovator and generic pharmaceutical companies. It's been alleged that these settlements have resulted in higher

prescription drug prices to consumers. Companies have defended these agreements as procompetitive, arguing in part that they enable generic manufacturers to challenge patents of branded companies without incurring the risks of draconian liabilities or loss of the incentive to promote the development of generic drugs for which the Hatch-Waxman Act was intended. Be that as it may, there are efforts this year here in Congress to re-open the Hatch-Waxman Act, which was passed in 1984, and controls the entry of generic drugs into the market.

During the past 17 years, the Hatch-Waxman Act has been extraordinarily successful in achieving its dual objectives—encouraging research by innovator companies, and facilitating the entry of lower cost generic drugs into the market. I want to insure its continued success.

- The Act has created a strong generic drug industry whose share of the prescription drug market has risen from 19% in 1983 to nearly 50% today. Likewise, spending on research by innovator companies is many times higher now than it was prior to Hatch-Waxman, and important new therapies continue to be introduced.
- Much of the concern over alleged abuses relates to a provision of the law that provides 180 days of exclusivity to certain generic applicants who challenge innovator patents. That provision was added to the Act in 1984 to provide a reward for generic manufacturers who challenge a patent on the innovator drug it wishes to copy. It has been alleged, however, that in some cases a generic manufacturer and the patent holder have settled cases in a way that uses the 180-day exclusivity provision to delay the approval of generic products of manufacturers that were not party to the settlement . Those allegations are being disputed.
- The purpose of our hearing is to review the situation and elicit the facts. After 17 years, any statute, no matter how successful, should be reviewed to see how it is working and whether flaws have developed that need to be corrected. Therefore, I look forward to today's witnesses and testimony.
- However, I must say that this statute should not be changed lightly, even if we decide that there have been occasional abuses. The statute has generally worked exceedingly well, and it is highly complex. If we do change it, we seriously risk triggering the law of unintended consequences, which could, unless we are very careful, result in less research or fewer generic drugs.
- It may be that after our hearings we will decided that changes are essential. But at this point, it seems to me quite possible that adequate remedies already exist in the law to deal with any abuses which may exist. I note that the Federal Trade Commission has brought actions involving some of the settlements, which have resulted in consent decrees. There is also private litigation involving some settlements. Further, I understand that the FTC is undertaking an extensive investigation stemming from patent dispute settlements and related issues, and plans to issue a report later this year.
- In the case of the 180-day provision and its possible abuse, the FDA issued a proposed rule in August 1999 to address the issue. It would require the applicant with the 180 days of exclusivity to begin marketing within 180 days after approval of a second generic application. FDA's proposal is intended to limit delays resulting from patent dispute settlements.
- Before Congress acts to change this important and complex law by amending the 180-day provision, we should see whether the FDA can resolve any problems through a revision of its rules after due consideration of public comments on its proposal. In addition, we should not pre-empt the FTC's investigation by hurried Congressional action and should wait for the results of that investigation.
- After the FTC has issued its report and FDA has issued its regulations, I think it will be completely appropriate to hold further hearings on this matter to see if legislative change is necessary.

Senator LEAHY. General Shurtleff, you came the furthest here today and I appreciate you doing that. As I said, Bill Sorrell says very nice things about you.

Mr. SHURTLEFF. Thank you. I look to returning to your State in a couple of weeks. The National Association of Attorneys General is meeting in Vermont next month, so I look forward to that.

Senator LEAHY. I understand that Bill passed out pictures of people in snowshoes for that time of year, but trust me, it has been gorgeous. We have had probably the warmest spring we have had since I was a child, and I hope you have a good time. I know where

you are going. I know the area you are going to be in. I just hope the weather cooperates. I think you will enjoy it, just as I have always enjoyed the hospitality any time I have been in your State.

Mr. SHURTLEFF. Thank you, Senator.

Senator LEAHY. Mr. Griffin, Ms. Boast, Mr. Buehler, thank you very much for being here.

Mr. BUEHLER. Thank you, Senator.

Ms. BOAST. Thank you, Senator.

Mr. GRIFFIN. Thank you.

Senator LEAHY. The Committee is adjourned.

[Whereupon, at 3:18 p.m., the Committee was adjourned.]

[Submissions for the record follow:]

SUBMISSIONS FOR THE RECORD

Statement of Aventis Pharmaceuticals Inc., Bridgewater, New Jersey

These comments are submitted by Aventis Pharmaceuticals Inc. to be included in the formal record of the hearing of the Committee on the Judiciary of the United States Senate concerning "Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements" which was conducted on May 24, 2001. Aventis Pharmaceuticals Inc. conducts the U.S. business of Aventis Pharma AG, the pharmaceutical company of Aventis S.A. With headquarters in Bridgewater, N.J., Aventis Pharmaceuticals focuses its activities on important therapeutic areas such as cardiology, oncology, anti-infectives, arthritis, allergy and respiratory, diabetes, and the central nervous system. Last year, Aventis Pharma spent approximately $2 billion dollars in research to develop new and innovative pharmaceutical products to help Americans live better, live longer and have happier and more productive lives.

THE IMPORTANCE OF PHARMACEUTICAL PATENT SETTLEMENTS

PHARMACEUTICAL PATENTS BENEFIT CONSUMERS

At the outset, we endorse the views expressed by Senator Hatch and others acknowledging the critical role that pharmaceutical patents play in bringing new and innovative health care solutions to the market. Often lost in this debate is the fact pharmaceutical patents benefit consumers because they provide a necessary and irreplaceable incentive for research companies to develop new and innovative drug therapies to prolong and improve the quality of life. To bring a new pharmaceutical product to the market requires an investment of hundreds ofmillions of dollars [1] and hundreds of person-years in testing, research, and product evaluation. A pharmaceutical patent provides the research company and its shareholders with a fair opportunity to recoup that investment. Without the patent system, innovation in the pharmaceutical industry and all other areas of science would suffer.

The importance of pharmaceutical patents for promoting innovation and rewarding innovators also requires that the rights of pharmaceutical patent holders to enforce their patents and exclude infringing products be protected and sustained. Yet too often, the legitimate efforts of pharmaceutical patent holders to enforce their patents against infringing goods are characterized as anticompetitive or illegal. When a patent holder files and prosecutes a patent infringement action, the presumption should not be that the company is engaged in some sort of suspect activity. Rather, absent clear and convincing evidence to the contrary, a patent holder's efforts to exclude an alleged infringer from the market should receive the same presumption of validity and regularity that the law extends to all patents. Pharmaceutical patents should not be treated differently.

PUBLIC POLICY FAVORS PATENT SETTLEMENTS

We also note that public policy favors the settlement of disputes without litigation. There is no special contrary rule for patent litigation. When a generic manufacturer decides to settle a case for less than an immediate right to market the allegedly infringing product, that decision reflects the generic company's subjective as-

[1] In 2000, the aggregate investment in new pharmaceutical product by the nation's research pharmaceutical companies totaled more than $36 billion.

sessment of the value of its case and its likelihood of prevailing on the merits. Similarly, a decision by the patent holder to license its technology to the generic company at some future point within the patent term reflects the patent holder's uncertainty as to its ability to achieve a positive outcome from litigating the patent action. Thus, in reaching settlements, the parties make these internal risk assessments and then reach a compromise that maximizes the benefit and minimizes the risk that each otherwise would have to accept. In this regard, settlements of patent litigation also are generally "win/win" outcomes from the consumer's point of view.

PATENT SETTLEMENTS OFTEN CONTAIN EXCLUSIONARY TERMS

Because patents exist to protect the patent holder from infringing products in the market, settlements of many patent cases, particularly those in which the patent holder is perceived to have a strong case, necessarily will include some limitation on the alleged infringer's post-settlement right to enter the market with its product. The right to settle a patent dispute by providing for a limited exclusion of an allegedly infringing good is a subset of the patent holder's statutory right to completely exclude infringing goods. Therefore, limitations on market entry are legitimate points of compromise in a patent infringement case. The federal and state antitrust agencies nevertheless seem too ready to presume that any post-settlement limitation on the right of the alleged infringer to enter the market is the product of anticompetitive motivation rather than a good faith compromise between both parties' assessments of the strength of the patent infringement claim.

For similar reasons, we believe that interim settlements can be as procompetitive as final settlements. The prosecution of a motion for a preliminary injunction is not inconsequential; it can significantly delay the ultimate resolution of the merits of the patent case and dramatically increase the costs and burden of litigation for the parties and the courts alike.

Interim settlements that manage the short-term risks posed to the parties by the unresolved patent litigation generally should be favored, as long as they do not discourage the parties from diligently prosecuting the case and seeking its ultimate resolution. Of course, where an interim settlement has the effect of significantly reducing the significance of the Court's ultimate ruling, that settlement is more akin to a final settlement and should be analyzed as such.

THE HMR/ANDRX STIPULATION AND THE FTC

As the Committee is aware, Aventis Pharmaceuticals Inc. recently resolved its dispute with the Federal Trade Commission which related to an interim Stipulation and Agreement that an Aventis predecessor, Hoechst Marion Roussel Inc. ("HMR") had entered into with Andrx Pharmaceuticals Inc. as part of their patent litigation over Andrx's generic version of HMR's Cardizem® CD product. Without admitting any wrongdoing, Aventis agreed, as part of this settlement, to notify the Commission in advance before entering into certain agreements in the future. Because the Committee may have drawn certain incorrect assumptions from the Prepared Statement that was submitted by the Commission and the oral comments of Ms. Boast, Aventis would like to take this opportunity to amend the record.

THE HMR/ANDRX STIPULATION AND AGREEMENT CAUSED NO CONSUMER HARM

The Commission's prepared statement accurately recounts that the Commission's Administrative Complaint, filed on March 16, 2000, alleged that HMR paid Andrx to refrain from bringing to market any generic version of Cardizem® CD, "without regard" to whether such product infringed HMR's patents. Prepared Statement of the *Federal Trade Commission, Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Before the Comm. on the Judiciary United States Senate*, at 12 (May 24, 2001) ("FTC Statement"), *In the Matter of Hoechst Marion Roussel, Inc., et al*, FTC Docket No. 9293 (March 16, 2000) ("FTC Complaint") at ¶32. The Administrative Complaint also alleged that the purpose and intended effect of the Stipulation and Agreement was to "delay the entry of other generic drug competitors" and "den[y] consumers access to lower priced generic drugs." FTC Statement at 12; FTC Complaint at ¶33.

Regrettably, the Prepared Statement presented only half the story. Following the filing of the administrative complaint, the Commission's staff engaged in substantial discovery and conducted depositions that significantly enhanced the Commission's understanding of the case. As the completion of discovery neared, the Commission and respondents reached agreement on the Draft Consent Order that ultimately resolved the case. As to the potential for consumer harm, the Commission stated, in the Analysis in Aid of Public Comment that was released along with the Draft Consent Order on April 4, 2001, that:

> Based on the FTC's investigation, 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 issued delayed consumer access to a generic version of Cardizem CD.

Analysis in Aid of Public Comment, FTC Docket No. 9293 at 4 (April 2, 2001) ("FTC Analysis").

While prepared remarks must necessarily distill a great deal of information into a brief and succinct statement, we respectfully submit that the Commission's assessment of the Stipulation and Agreement at the close of the Commission's investigation is at least as important as the allegations that were charged when the case was originally brought. By separate letter, we have provided the Committee with a copy of the Commission's Analysis in Aid of Public Comment and have asked that it be placed in the formal record of this Committee as well.

THE HMR/ANDRX STIPULATION AND AGREEMENT DID NOT BLOCK THE SALE OF ANY NON-INFRINGING GENERIC VERSION OF CARDIZEM® CD

The Commission's prepared statement also noted that the original Administrative Complaint charged that the HMR/Andrx Stipulation and Agreement had the effect of preventing Andrx from bringing to market "any competing generic drug, without regard to whether it was allegedly infringing." FTC Statement at 12. Again, we respectfully observe that the Analysis in Aid of Public Comment reveals a quite different result:

> The agreement terminated in June 1999. It was at that time that Andrx received FDA approval to market, and commenced marketing, a reformulated generic version of Cardizem CD that HMR stipulated did not infringe any HMR patent.

FTC Analysis at 4.

Thus, the Commission's own statement acknowledges that the Stipulation and Agreement did not prevent Andrx from bringing a "competing generic drug" to market. Instead, it recognizes that when Andrx perfected a reformulated product that HMR determined not to sue for patent infringement, and secured prompt FDA approval, Andrx entered the market with its reformulated product without interference from HMR or the Stipulation and Agreement. By recognizing Andrx's substantial efforts to "work around" HMR's patents, the statement in the Commission's analysis also tacitly acknowledges the reasonableness of HMR's initial patent infringement claims. Companies like Andrx do not spend millions of dollars and years of effort in the laboratories working around patent claims that are either clearly invalid or not potentially infringed.

The fact that Andrx expended millions of dollars and years of research in an effort to invent around HMR's patent claims while the patent litigation was underway underscores the fact that no intelligent analysis of the potential competitive impact of these settlements can be undertaken without due consideration of the strength of the underlying patent claims. By definition, a patent confers upon the patent holder the power to completely exclude infringing goods from the market. It follows therefore that some patent settlements will necessarily include some limitations on the right of the alleged infringer to enter the market. We respectfully submit that if HMR had the right to permanently exclude Andrx's originally infringing formulation from the market, it should also have the right to try to prevent the sale of that same product until its patent rights are vindicated without running afoul of the antitrust laws.

THE HMR/ANDRX STIPULATION AND AGREEMENT WAS NOT INTENDED TO DELAY THE ENTRY OF OTHER GENERIC DRUG COMPETITORS.

The Commission's prepared statement recounts that the Commission's original complaint alleged that the intent of the Stipulation and Agreement was "to delay the entry of other generic drug competitors, thereby denying consumers to lower priced generic drugs." The Commission's original allegation was premised on the assumption that by delaying market entry by Andrx, the ANDA first-filer, Aventis could take advantage of the first filer's 180-day market exclusivity rights under Hatch-Waxman to block the entry of second and third generic applicants.

The problem with the Commission's theory is that it depends upon a judicial interpretation of the 180-day market exclusivity rights that had not been decided at the time that the HMR/Andrx Stipulation and Agreement was executed.

As Senator Hatch noted in his opening remarks, until the D.C. Circuit decided the matter in *Mova Pharmaceuticals Corp.* v. *Shalala*, 140 F.3d 1060 (D.C. Cir.

1998), the generally accepted FDA position was that the first generic filer was entitled to the 180-day exclusivity period only if it had successfully defended its position in the patent litigation before the second or third generics received final FDA approval. Under this pre-*Mova* interpretation of the statute, no agreement between the pioneer company and first-filer generic company prior to the conclusion of the patent litigation between them could have precluded the second or third generic filers from entering the market upon receiving final FDA approval for their products. (There are other reasons why such foreclosure could not have taken place in this case which are case- specific and therefore not pertinent to this Committee's concern).

In charging that an intended effect of the HMR/Andrx Stipulation and Agreement was to block the second and third generic applicants, the Commission overlooked the fact that the Stipulation and Agreement was executed more than six months prior to the D.C. Circuit's decision in *Mova* and eight months before the FDA acquiesced in the *Mova* decision and agreed to apply it to companies like Andrx. As a result, the Commission's case essentially sought to charge the parties with anticompetitive intent premised upon the holding of a court decision that was rendered six months later and which overturned the FDA's long-standing interpretation of its own statute. We respectfully submit that this charge is and was unfair and, in fact, the Commission itself acknowledged this change of law had occurred in its final Analysis.[2]

We also believe that the Commission's attempt to employ *ex post facto* legal precedent to charge the respondents with anticompetitive intent underscores the need for absolute clarity should this Committee consider making any significant revisions of existing law. It took fourteen years for *Mova* to arise from the seemingly clear and uncomplicated language of HatchWaxman. It would be a shame if, in attempting to clarify and simply Hatch-Waxman at this date, this Congress were to include language that might serve as a trap from the unwary in the future.

AVENTIS PROVIDED TIMELY NOTICE OF THE HMR/ANDRX STIPULATION AND AGREEMENT TO THE PUBLIC AND TO THE FEDERAL TRADE COMMISSION.

During her oral remarks, Molly Boast, Director of the FTC's Bureau of Competition suggested in several different ways that it was difficult for the Commission to learn of settlements arising in pharmaceutical patent cases and that legislation was needed to address this problem. While Ms. Boast did not specifically suggest that Aventis or Andrx had been remiss in terms of providing timely public notice or not cooperating with the Commission, we feel it appropriate to note for the record Aventis' predecessor provided both the public and the Commission with timely notice of the HMR/Andrx Stipulation and Agreement.

Regarding public disclosure, HMR issued a press release within hours of the execution of the Stipulation and Agreement on September 24, 1997, generally describing the agreement. While the press release did not contain the competitively sensitive details of the agreement, it did recite the fact that Andrx had agreed to refrain from marketing its generic product during the pendency of litigation, that HMR had agreed to make substantial "lost profits" payments to Andrx in the event that it lost the patent case, and that non-refundable interim payments were also part of the transaction.

Within days of the document's execution, the Commission received a copy of the Stipulation and Agreement. It is worth noting that the Commission had the Stipulation and Agreement in its possession for nearly ten months before the agreement became effective on July 9, 1998. Neither the Commission nor its staff registered and indeed, it was not until after the parties to the stipulation had resolved their litigation, some nineteen months later, that the Commission staff first shared its preliminary concerns about the transaction with the parties.

As a matter of corporate policy, Aventis adheres to the view that information concerning potentially significant events affecting the company should be promptly shared with its stockholders and the public and that reasonable requests for documents from federal regulatory agencies should receive an affirmative and timely response, providing, of course that appropriate safeguards are in place to protect the confidential and competitively sensitive terms of such transactions. To the extent that the Congress believes that some generally applicable codification of this policy

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[2] "Under current FDA regulations, the Act grants the first company to file an ANDA with a paragraph IV certification a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired. *At the time the Respondents entered into the challenged agreement in 1997, the governing FDA regulations required that an ANDA applicant successfully defend the patent holder's patent suit in order to be entitled to this exclusivity*." FTC Analysis at 2 (Emphasis added).

might be in order, Aventis would not object, provided that such a notification system would not impose additional burdens on parties seeking to resolve patent litigation and that it contained a workable system to protect competitively sensitive materials from disclosure under F01A or other federal disclosure statutes.

PHARMACEUTICAL PATENT SETTLEMENTS—LOOKING TOWARDS THE FUTURE

Looking forward, we believe it unlikely that Congress or the federal agencies will see transactions in the future like those that have captured so many headlines over the past several years. Responsible pharmaceutical companies focus their attention on what is transpiring in the laboratory and in the marketplace. Right or wrong, pharmaceutical companies would prefer to avoid the time, expense, and distractions occasioned by a Commission investigation. For that reason, the Commission's docket remains focused on a group of transactions that arose before the preclusive effect of the first-filer's 180-day exclusivity rights were established by the D.C. Circuit in *Mova* in the spring of 1998.

On a going forward basis, we believe that companies will consciously steer clear of the kinds of transactions that might provoke the Commission's interest. Doubtlessly, this caution likely will mean that some cases that should have been settled will not be settled and that consumer access to certain generic pharmaceuticals will be delayed as patent litigation grinds on. These are the unavoidable consequences of the enforcement decisions that have been made by federal and state agencies.

We believe that the Commission's Pharmaceutical Industry Study likely will produce some information useful to Congress, the federal agencies, and the regulated community in understanding how changes in the legal and regulatory environment have affected the manner in which research pharmaceutical companies secure and defend their intellectual property rights. But while gathering this information is worthwhile, it is not enough. We believe that it is also important to review and reconsider some of the legal and economic assumptions that have heretofore driven much of this debate.

For example, in the current version of the "*Antitrust Guidelines for the Licensing of Intellectual Property Rights," U.S. Department of Justice/Federal Trade Commission* (April 6, 1995)("IP Guidelines"), the relationship between a patent holder and a party not possessing patent rights is deemed to be vertical with respect to the patented technology, even though the patent holder and the party seeking to acquire rights to that patent are horizontal competitors in the market for their finished goods. See EP Guidelines, Section 3.3, especially Example 5. By correctly describing this relationship as vertical, the EP Guidelines expressly permit the patent holder to license his patented technology to his erstwhile competitor without running the risk of being accused of engaging in prohibited conduct with a horizontal competitor.

Most often, a competitor will recognize his need to obtain a license from the patent holder only after patent infringement litigation has been threatened or initiated. In our view, the logic set forth in the IP Guidelines is as applicable to defining the relationship between a patent holder and a potentially infringing party when those parties are engaged in litigation as it is when they are not. By regarding litigants in a good-faith patent dispute as being vertically related, the IP Guidelines permit the parties to settle their dispute without being charged with engaging in illegal horizontal activity.

However, at least one FTC staffer has publicly voiced his view that good-faith disputants in pharmaceutical patent cases must necessarily be viewed as horizontal competitors or at least potential horizontal competitors in assessing patent settlements. While we doubt very seriously whether this view is shared at the Commission level, this sort of statement leaves companies vulnerable to charges in private litigation that their good faith patent settlement represents nothing more than a market allocation agreement between horizontal competitors—a per se violation of the antitrust laws. Intended or not, this sort of half-baked policy statement creates a minefield for those who might otherwise be disposed to settle a pharmaceutical patent case. By increasing the potential costs and risks of settlement, policy statements like these make it more likely that marginal cases will remain in litigation—a result that serves no one's interests.

Comparable challenges are presented on the economic front. For example, one widely-quoted former FTC staffer recently suggested in a paper on pharmaceutical patent settlements that:

> A payment flowing from the innovator to the challenging generic . . . may indicate whether the generic firm has the incentive or ability to enter the market or to pursue fully the litigation. In essence, the generic firm may have chosen the "quiet life," at least temporarily, of an amicable settlement, rather than the hard life of competition. This situation would be trouble-

some particularly, where, as FDA observed, "the economic gains to the innovator from delaying generic competition exceed the potential economic gains to the generic applicant from 180 days of market exclusivity."

David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L.J. 321, 355 (2000) (quoting FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,882–3) .

The problem with this statement is that in the real world, the economic value of a patent to the innovator will always exceed the potential economic gains that a generic company might enjoy were it able to enter the market with a non-infringing product. Where a generic sells at a price point 60% and 70% of the price of the branded product, the loss of revenue to the innovator is always much greater than the revenue gained by the generic company, regardless of whether the generic enjoys 180 days of market exclusivity or not. So the "particularly troublesome" economic factor that causes this commentator particular concern is present in every patent infringement dispute involving a patent holder and a first-filer generic.[3]

In our view, these examples are good illustrations of the fact that many of the legal and economic assumptions informing the public debate and employed in reviewing these cases are inadequate and incomplete. We respectfully submit that working through these legal and economic issues in a reasoned and objective manner is as important to this process as the information gathering of the Commission's Pharmaceutical Industry Study. We hope that the Commission's study will be only the beginning of a more substantial effort on the part of the federal regulatory and law enforcement authorities to develop better tools to enforce the law, provide guidance to industry, and inform this important debate before the Congress.

Statement of Hon. Maria Cantwell, a U.S. Senator from the State of Washington

Thank you, Mr. Chairman. Today's hearing is one of the most important—and most fascinating—consumer interest hearings before the Committee this year.

Americans are becoming ever more reliant on more effective—and more complicated—drug therapies. Total health care spending in the United States totaled more than $1.2 trillion in 1999, an increase of 5.6 percent from the previous year, according to a March report released by the Health Care Financing Administration. And prescription drug expenditures are the fastest growing segment of the health care market—with spending for drug therapies rising nearly 17 percent that year alone. Drug expenditures in the United States rose from about $5.5 billion in 1970 to $100 billion in 1999, and the report predicts that prescription drug expenditures will continue to increase faster than any other category of health care spending throughout the next ten years. Those two factors—great dependency on drug therapies and skyrocketing drug prices—put us on a collision course in our efforts to provide affordable health care.

There is no doubt in my mind that the patent rights and privileges enjoyed by the pharmaceutical companies fuel the drive for research and development in this area. And one day soon I hope to see a cure for Alzheimer's, cancer, or cystic fibrosis. Furthermore, this debate is not about pitting research and development against consumer protections because these issues should go hand-in-hand.

This is why, almost 20 years ago, Chairman Hatch worked to create a balanced law to encourage innovation in the pharmaceutical industry while facilitating the speedy introduction of lower-cost generic drugs. But frankly, the reports that name-brand companies have exploited the law and allegedly paid-off their generic opponents, distress me.

Congress is trying to take a reasoned and rational approach to drug price competition, and I am very concerned that companies may be taking the law Congress wrote for the benefit of both business and consumers for their advantage alone. It

[3] To address the problem of generic companies preferring the "quiet life" of settlement to the "hard life of competition," we believe that a proper focus for the antitrust agencies would include an examination of whether the generic company's receipts in settlement exceed what it could enjoy were it to enter the market with a non-infringing good. If the generic company's settlement receipts approach what it might expect to receive in the market place, then some additional scrutiny may be warranted. On the other hand, if the receipts in settlement are but a fraction of what it would likely earn in the market, then the opposite presumption—that the generic company is concerned about the merits of the underlying patent case and that the settlement is not objectionable—should be drawn.

is outrageous that buying off generic settlements could be a calculated business expense in the pharmaceutical marketplace.

Generic medicines account for 42 percent of all prescriptions dispensed in America and on average are put on the market at 75 percent of the cost of their name-brand rivals. Two hundred drug patents are set to expire over the next five years—representing a loss of approximately $28 billion to name-brand pharmaceutical companies. This is a key time for this Committee to examine actions by the pharmaceutical industry intended to prevent generics from becoming available at lower costs to consumers. We are beginning to see indications that the practice of using secret, and possibly illegal, deals is much more common within the industry than previously known.

Despite the fact that "Hatch-Waxman" is truly landmark legislation, as with a lot of legislation, industry officials have learned over time how to get around the letter, if not the spirit, of the law. By extending FDA and FTC authority to investigate how wide-spread this practice is, Senator Leahy's bill is certainly a step toward ending these collusive practices.

Interject these facts into the political debate surrounding the need to provide Medicare coverage of prescription drugs for our elderly and disabled, and we have a debate to be rivaled by few others. Only thirty percent of Medicare beneficiaries have prescription drug coverage and the average senior spends $1,100 a month on prescriptions.

Thank you, Mr. Chairman for convening this hearing so that we may learn more about this problem. I am hopeful we can work together to find a solution.

Statement of Hon. Russell D. Feingold, a U.S. Senator from the State of Wisconsin

Mr. Chairman, thank you very much for holding this hearing. This is a very important issue for consumers of prescription drugs in this country. It goes to the integrity of our antitrust laws and the Hatch-Waxman Act, which I know you feel very strongly about.

There is mounting evidence that drug companies are attempting to deprive consumers of the option of less expensive generic drugs by paying those companies to delay development or sales of competing drugs. The beauty of Sen. Leahy's bill, which I am proud to cosponsor, is that it doesn't change the substantive law in any way. It doesn't modify the Hatch-Waxman Act, or the antitrust laws, or reach any judgment about whether a particular agreement violates those statutes. It simply requires that agreements between brand name manufacturers and potential generic competitors that could limit the research, development, manufacture or marketing of a competing generic drug be provided to the Federal Trade Commission or the Department of Justice within 10 days of signing. It is my understanding that the agreements will remain confidential so there is no argument that companies will be forced to release trade secrets.

I believe this simple step of throwing some sunshine on these agreements will be a significant deterrent to anti-competitive agreements. It will allow the FTC and DOJ to determine whether the agreements violate the antitrust laws or the Hatch-Waxman Act. And it will ultimately lead to lower prices for consumers.

I hope today's testimony will shed some light on the kinds of agreements that might be exposed by this bill, and how this bill will assist the antitrust enforcement agencies to protect the public. And I hope that after the hearing, the Committee will move expeditiously to mark the bill up and send it to the Senate floor. This is a rare instance where the Congress can save consumers potentially hundreds of millions of dollars through simple, commonsense, legislation that poses no possibility of financial harm to law abiding drug companies.

Again, I thank you, Mr. Chairman, for holding this hearing and beginning the process of enacting this legislation. And I congratulate Sen. Leahy and Sen. Kohl for this bill. I am proud to support it.

Statement of the Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers Of America (PhRMA) is pleased to provide a statement of its views in connection with the Committee's hearing on the antitrust implications of patent settlements. PhRMA represents the country's

leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. Investing over $30 billion this year in discovering and developing new medicines, PhRMA companies are literally leading the way in the search for cures, just as hoped for by Congress when Hatch-Waxman was passed in 1984.

THE HATCH-WAXMAN ACT

The Hatch-Waxman Act had the dual objectives of encouraging pharmaceutical innovation and easing the entry of generic drugs into the market. In PhRMA's view, HatchWaxman has been successful in achieving its objectives. Spending on research by PhRMA members is now many times higher than it was before passage of the Act, and important new therapies continue to be introduced. At the same time, a generic drug industry has been created and is now thriving. The generics' share of the prescription drug market (by countable units) has grown from 18 percent in 1984 to over 47 percent by 1999. Moreover, it must be underscored that the "$71 billion" in savings for consumers that some advocates of legislative change to Hatch-Waxman have touted (see press release of May 1, 2001 from the offices of Senators Schumer and McCain) were calculated based on coming patent expirations and generic applications provided for under the current provisions of Hatch-WaxTnan.

In his opening statement for this hearing, Chairman Hatch acknowledged that tine twin goals of the HatchWaxman Act have been achieved. Although the Chairman listed a number of issues that have been raised about the Act, and suggested that they need attention, he cautioned that the legislation was carefully balanced and that changes that tilt the balance should not be made. PhRMA concurs with that assessment.

Of course, after 17 years, any statute, no matter how successful, should be reviewed to see how it is working and whether—flaws have developed that need correction. But many of the asserted flaws in the Hatch-Waxman Act can be addressed under existing law without amending Hatch-Waxmmi in ways that may lead to unintended and undesirable consequences. A prime example of an alleged defect that can be remedied without new legislation is the specific topic of this hearing—patent dispute settlements.

PATENT DISPUTE SETTLEMENTS

Recently, there has been publicity concerning possible antitrust violations in settlements of patent disputes between generic and innovator pharmaceutical companies. It has been alleged that these settlements have resulted in higher prescription drug prices to consumers. As a result, there are efforts this yeas in Congress to reopen Hatch-Waxman.

Much of the concern over alleged abuses centers on a provision in Hatch-Waxman related to generic drug exclusivity. That provision provides 180 days of exclusivity to certain generic applicants who challenge innovator patents. It has been alleged that, in some cases, a generic manufacturer and the patent holder have settled cases by using the 180-day provision in a way that delays the approval of generic products of manufacturers who are not parties to the settlement.

PhRMA has no view on whether the particular cases that have been cited do or do not violate antitrust laws. That is a question best left to the agencies and the courts. But fhRMA does believe that the highly successful and highly complex Hatch-Waxman Act should not be changed lightly on the basis of a very small number of allegedly problematic cases. If Congress changes the statute because of the current clamor, it seriously risks triggering the law of unintended consequences, which could, unless great care is taken, result in less research or fewer generic drugs.

Since 1984, there have been 8,259 generic applications submitted to the Food and Drug Administration (FDA). According to FDA, more than 94 percent of these (some 7,781) involved no patent issues; less than 6 percent involved a 'paragraph IV" certification. To place the subject of the May 24 hearing in perspective, only 3 innovator-generic agreements (involving less than 0.1 percent of generic applications) are reportedly alleged by the Federal Trade Commission (FTC) to be involved iii inappropriate patent dispute settlements—matters which the FTC has itself settled with consent decrees. There is also private litigation involving some settlements. Further, the FTC is undertaking an extensive investigation in this area, with a report due later this year. If there is a problem, there is reason to believe it is small and the iudicial and regulatory systems are dealine with it.

Also, in August 1999, the FDA issued a proposed rule to address problems it perceived in the 180-day exclusivity rule. The proposal would require an applicant with the right to 180 days of exclusivity to begin marketing within 180 days of approval

of a second generic or lose its exclusivity. FDA's proposal is designed to limit delays resulting from patent dispute settlements, among other purposes. To help resolve the issue of patent dispute settlements, FDA should finalize that rule in the near future after any appropriate changes based on the public comments.

PhRMA urges the Committee to take great care when dealing with the Hatch-Waxman Act. Congress should not hurriedly act to change this important and complex law by amending the 180-day exclusivity rule or other provisions. The number of alleged abuses is very small, and the system seems to be dealing with the alleged abuses adequately. PhRMA encourages the Committee, and the Congress as a whole, to let the FDA and FTC actions take their course, and not rush to judgment.

THE FTC STUDY

Although PhRMA believes that Congress should await the FTC study before reaching mzy conclusions about the need for new legislation, we are concerned whether the design of the study, as outlined in the testimony in this hearing, will provide the kind of objective analysis that would assist Congress. Although Hatch-Waxman was designed to balance the public interest in both innovative research and lower drug prices—and the FTC testimony pays lip service to those objectives—the study seems slanted toward finding obstacles to the introduction of generic drugs.

Thus, in examining the 30-month stay provision in Hatch-Waxman, which is the provision allowing innovator companies to protect their patent rights, the only stated objective of the FTC study is to determine whether the stprovision has influenced the development of generic drums competition. Obviously it has, since a statutory provision delayiiiFDA approval of generic drugs nendina patent litigation has that effect as its intended result. The value ofthe 30month stav and its related procedure for patent litigation riot to FDA approval ofalle fnfringiL7g products cannot properly be analyzed solely by reference to their effect on generic drug competition; they must also be analvred by reference to the need to protect, patent holders until the courts have spoken. The procedure for patent litigation, including the 30-month stay, was included to prevent judgment-proof generic drug companies from incurring huge damages and destroying the innovator's market through sale of an infringing product.

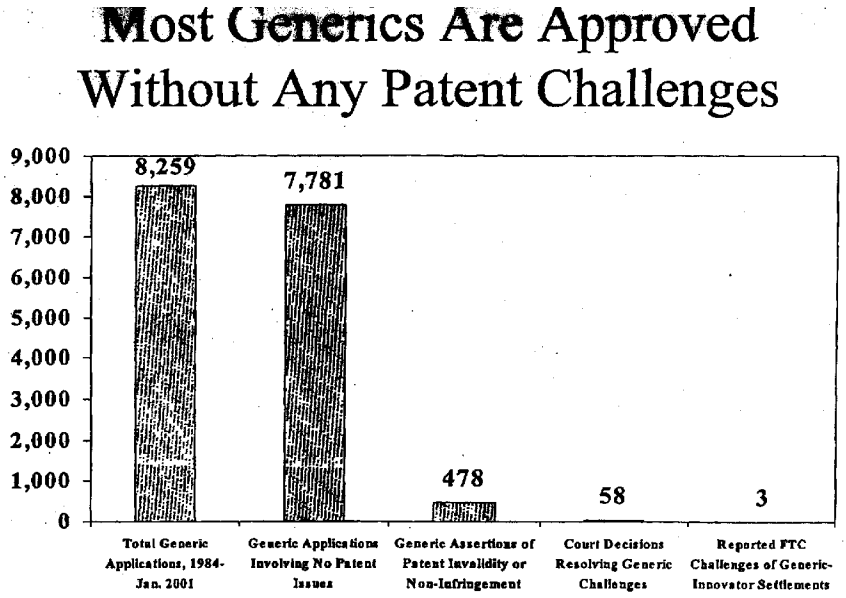
Similarly, the FTC testimony questions the filing of citizen petitions at the FDA related to generic drugs. Although the FTC acknowledges that First Amendment rights are implicated, it endorses FDA's pending proposed regulation to restrict the use of citizen petitions. Under the proposal, citizen petitions could be filed only if they proposed general policies and not if they raised scientific or other pertinent issues regarding specific products, such as proposed generic drugs. The FTC testimony characterizes FDA's inappropriately restrictive proposal as limiting the citizen petition process to "legitimate purposes" and as "limiting the ability of firms to use the process solely to hinder competitors." The FTC's conclusion, prior to completing its study, that the filing of a citizen petition addressing scientific issues raised by a particular product necessarily and invariably represents an illegitimate attempt to hinder competitors does not inspire confidence that the study will be an objective analysis. In our view, FDA should welcome, rather than reject, valid scientific data submitted via the petition process.

The FTC testimony also announced that it had itself filed a citizen petition with FDA in connection with its study. The petition, in the form of a May 16 letter, seeks FDA's detailed interpretations of the regulations governing which patents are eligible for listing in FDA's Orange Book. This petition is also of concern. The FTC petition does not seek pre-existing interpretations from FDA—since there are few if any such interpretations in existence—but asks FDA to issue new interpretations consistent with the FTC's reading of the rules. If there are ambiguities in the regulations that have not been clarified by FDA, one would think that an objective FTC study would point to those ambiguities and suggest clarification if they have created problems. Instead, it appears that the study's authors want to develop a case, based on after-the-fact pronouncements from FDA, that certain patents were improperly submitted to FDA for publication in the Orange Book. This approach would not seem to be consistent with an objective review of the HatchWaxman procedures.

CONCLUSION

PhRMA welcomes analysis of the Hatch-Waxmnan Act and its implementation. The possible problems that have been identified should be carefully anal objectively studied before any legislative solution is undertaken. Many of the problems can and are being addressed through existing mechanisms without the need for amending

Hatch-Waxman. It is extremely important that the balance in this important legislation not be upset by ill-considered amendments.



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